PERMANENTE JOURNAL
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Circulation: 25,000 print readers per quarter, 6000-7000 online readers, and in 2014, TPI content had 1 million page views—760,000 of those on TPI articles on PubMed. Viewers visited from 167 countries/territories.

ORIGINAL RESEARCH & CONTRIBUTIONS

29 Patient Satisfaction after Thoracoscopic Sympathectomy for Palmar Hyperhidrosis: Do Method and Level Matter? Amy Cheng, MD, Hugo Johnson, MD, Michael Y Chang, MD

Although surgery is widely recognized as the local treatment for palmar hyperhidrosis (PH), the technique is based on surgeon preference. In a retrospective medical chart review, 168 patients underwent bilateral thoracoscopic procedures for PH between 1995 and 2010, and 210 (33%) responded to the questionnaires. Sixteen surgeons performed 150 sympathectomies, 83 sympathotomies, and 19 ligations with thoraclips. Mean follow-up was 5.5 years. Most patients reported relief of their PH and were satisfied with surgical intervention, regardless of method used.

33 An Education Program for Patient Self-Management of Varicose Veins. Kathryn T Jinnett, PharmD, BCPS, CACCP, Rachel Simmons, PharmD, BCPS, CACP; Thomas Delate, PhD; Nathan P Clark, PharmD, FCP; BCP, Dina Kurz; Daniel M Witt, PharmD, FCP, BCP

Developing and administering a varicose Patient Self-Management (PSM) education program for those with arterial occlusion was feasible. It was introduced in PSM training (34.9% to 95.3%) and high levels of self-reported comfort (100% prepared to self-manage vascular and 98% comfortable changing doses on their own).

50 Study of the Use of Lipid Panels as a Marker of Insulin Resistance to Determine Cardiovascular Risk. Beth Ann Bolich, MD, PhD, FACGP; Maqdooda A Merchant, MSc, MA

High-density lipoprotein cholesterol, which is inversely correlated with insulin resistance, is an advantageous measure of cardiovascular disease risk. Our study identified the use of insulin resistance markers in the selection of high-risk patients for intervention and the use of lipid panel markers as a tool for insulin resistance detection.

51 Right-Side Colon Ischemia: Clinical Features, Large Visceral Artery Occlusions, and Long-Term Follow-Up. George F Longstreth, MD, FAGA, FACG; Robert J Hye, MD, FACS

Large visceral artery occlusion (LVAO) can underlie right-side colon ischemia (RSCI) but is little known. In a retrospective observational study in an integrated health care system, 18 of 49 patients underwent surgery—6 of 6 developed RSCI in hospital following surgical procedures and 14 of 43 had RSCI before hospitalization. Among 44 survivors (median follow-up of 3.9 years), including 3 of 10 operated cases, had symptoms LVAO and underwent angioplasty and stent placement. Patients with RSCI may have symptomatic LVAO, therefore, we advise they undergo careful inquiry for symptoms of abdominal angina and right visceral artery imaging.

92 Effect of Structured Touch and Guided Imagery for Pain and Anxiety in Elective Joint Replacement Patients—A Randomized Controlled Trial. Maqdooda A Merchant, MSc, MA; John Brent Forward, MD, FACP, ABIHM; Nancy Elizabeth Greuter, RN, LMT; Robert J Hye, MD, FACS

We compared structured touch, guided imagery, or usual care intervention. The largest predicted difference in narcotic pain medication between groups. There was no significant decreases in both pain and anxiety care. M showed the largest predicted difference in touch, guided imagery, or usual care intervention.

96 Scarlet Macaws at a Mineral Lick, Crowder, MD, FACOG; Jeff M Slezak

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The Permanente Journal/ Fall 2015/ Volume 19 No. 4

BOOKS PUBLISHED BY PERMANENTE AUTHORS:

Case-Based Simulation and Review for the USMLE Step 2 CS
Thaddeus X O’Connell, MD
Timothy J Mortaz, MD
ISBN-10: 1416054742
Papercback: 524 pages
$50.00

The Permanente Journal
Fall 2015/ Volume 19 No. 4
46 Incentive-Based Primary Care: Cost and Utilization Analysis.
Marcus J Hollander, MA, MSc, PhD; Helena Kadlec, MA, PhD

This study used Canadian Ministry of Health administrative data for Fiscal Year 2010-2011. After controlling for patients’ age, sex, service-needs level, and continuity of care (ie, attachment to a general practice), the incentives reduced the net annual health care costs for patients with hypertension, chronic obstructive pulmonary disease, and congestive heart failure, but not for diabetes. The incentives were also associated with fewer hospital days, fewer admissions and readmissions, and shorter lengths of hospital stays for all 4 groups.

58 Anxiety’s Impact on Length of Stay Following Lumbar Spinal Surgery.
Hollis Floyd; Mazen Sanoufa, MD; Joe Sam Robinson, MD

The authors retrospectively reviewed the medical records of 307 patients who consecutively underwent elective lumbar decompression and fusion surgery from October 1, 2010 through September 30, 2013. This study suggests that those with a diagnosis of anxiety who are medicated for the condition have a longer length of stay than those with no diagnosis of anxiety, and who are not medicated for the condition. This could be because when these patients are required to be nil per os for 12 hours before surgery it leaves them vulnerable to states of anxiety.

Special Report
61 Navigating the Next Accreditation System: A Dashboard for the Milestones.
Samir Johna, MD; Brandon Woodward, MD

In July 2014, all residency programs accredited by the Accreditation Council for Graduate Medical Education were enrolled in the new Next Accreditation System. The authors used existing electronic goals and objectives for each rotation coupled with appropriate end-of-rotation evaluations reflecting the specialty-specific milestones. A resident’s final, overall performance was visually represented on a plot graph. The novel dashboard proved simple to use and reduced the time for each resident evaluation to 5 to 10 minutes.

Special Report
65 SQUIRE 2.0 (Standards for QUality Improvement Reporting Excellence): Revised Publication Guidelines from a Detailed Consensus Process.
Greg Ogrinc, MD, MS; Louise Davies, MD, MS; Daisy Goodman, DNP, MPH; Paul Batalden, MD; Frank Davidoff, MD; David Stevens, MD

Since the publication of Standards for QUality Improvement Reporting Excellence (SQUIRE 1.0) guidelines in 2008, the science of the field has advanced considerably. SQUIRE 2.0 is intended for reporting the range of methods used to improve health care, recognizing that they can be complex and multidimensional. It provides common ground to share these discoveries in the scholarly literature (www.squire-statement.org). This is a simultaneous publication with BMJ Quality and Safety.

REVIEW ARTICLES
71 Primary Epithelial Neuroendocrine Tumors of the Retropertitoneum.
Ahmed Dehal, MD; Sean Kim, MD; Aamna Ali, MD; Thomas Walbolt, DO

Neuroendocrine tumors are either epithelial or neural in origin. Neuroendocrine tumors of the retropertitoneum are mostly metastatic. Primary epithelial neuroendocrine tumors of the retropertitoneum are exceedingly rare. The authors describe the case of a retropertoneal tumor that was discovered incidentally during exploratory laparotomy for small-bowel obstruction. The literature is reviewed and discussed. To date, this is only the fifth reported case.

CASE REPORTS
76 High-Dose Viscum album Extract Treatment in the Prevention of Recurrence of Bladder Cancer: A Retrospective Case Series.
Tido von Schoen-Angerer, MD, MPH; Johannes Wilkers, MD; Gunver S Kienle, MD; Helmut Kienle, MD; Jan Vagedes, MD, MA

Viscum album extract (European mistletoe), containing immune-active compounds with dose-dependent cytotoxic activity, is being used as an adjuvant cancer treatment in Europe. Few studies have been done with high-dose, fever-inducing Viscum album treatment. The authors retrospectively analyzed the case notes of patients with resectable bladder cancer who underwent initiation of high-dose Viscum album treatment at their clinic between January 2006 to December 2012. High-dose Viscum album showed a possible beneficial effect in 5 of 8 patients. No tumor progression was observed. Treatment was generally well tolerated and no patient stopped treatment because of side effects.

COMMENTARY
84 Strategies to Increase Physical Activity.
Phillip Tuso, MD, FACP, FASN

One key intervention to prevent preventable diseases and to make health care more affordable is to increase the percentage of Americans who are physically active. No single intervention will increase activity rates, but a group of interventions working together in synergy may be the stimulus needed to get Americans moving.

89 Research Letter: Sensor-Based Systems and the Objective Measure of Physical Activity.
Phillip Tuso, MD, FACP, FASN

Similar to medication adherence, objective measures of physical activity may allow physicians to improve activity rates among individual patients and patient populations, which should improve health care outcomes. Sensor-based systems may become a best practice for objective measurement of physical activity and the management of physical activity programs. Given the ease of tracking with these new devices and the ability to upload information automatically, a sensor-based system has the potential to prevent preventable diseases and lower health care costs.

NARRATIVE MEDICINE
90 Primary Health Care and Narrative Medicine.
John W Murphy, PhD

Key to the strategy to improve health care outlined at the Alma Ata conference in 1978 is citizen participation in every phase of service delivery. But a new epistemology, compatible with narrative medicine, is necessary so that local knowledge is elevated in importance and incorporated into the planning, implementation, and evaluation of health programs. In this way, relevant, sustainable, and affordable care can be provided. The aim of this article is to discuss how primary health care might be improved through the introduction of narrative medicine into planning primary health care delivery.

BOOK REVIEW
95 The Lost Art of Retinal Drawing.
Review by Mark Cohen, MD
Erratum:

In the article 2014 Hypertension Guideline: Recommendation for a Change in Goal Systolic Blood Pressure by Joel Handler, MD, which appeared in the Summer 2015 issue, the sentence “Therefore, the evidence favoring a goal systolic pressure lower than 150 mmHg in hypertensive individuals aged 60 years and older with a personal history of stroke is speculative” is missing the words “other than” and should be: “Therefore, the evidence favoring a goal systolic pressure other than lower than 150 mmHg in hypertensive individuals aged 60 years and older with a personal history of stroke is speculative.”

In the section “Endorsements of the Evidence-Based Guideline,” American Association of Family Practitioners should have been American Academy of Family Physicians. The new sentence should read: The American Academy of Family Physicians representing more than 100,000 primary care physicians, has endorsed the Evidence-Based Guideline.

The text has been corrected on our Web site. We apologize for this error.
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Study of the Use of Lipid Panels as a Marker of Insulin Resistance to Determine Cardiovascular Risk

Ruth Ann Bertsch, MD, PhD, FACP; Maqdooda A Merchant, MSc, MA

ABSTRACT

Context: When assessing the lipid panel, practical physicians tend to focus on the low-density lipoprotein cholesterol (LDL-c). However, an elevated triglyceride/high-density lipoprotein cholesterol (HDL-c) ratio, suggesting insulin resistance, also effectively predicts cardiovascular outcomes but requires different treatments than an elevated LDL-c. We tested whether high triglyceride/HDL-c ratios are associated with more risk than high LDL-c concentrations or other lipid markers of atherogenicity.

Methods: We followed 103,646 members aged 50 to 75 years without cardiovascular disease or diabetes in a community health plan. Subjects were categorized as insulin sensitive or insulin resistant on the basis of triglyceride and HDL-c in the index year. The primary outcome was ischemic heart disease. The percentage of subjects with a primary outcome after 8 years was stratified by insulin category, lipid measures, and blood pressure. Hazard ratios (HR) for insulin resistance, LDL-c, age, sex, and the presence of hypertension were determined in a multivariate analysis.

Results: Subjects with insulin resistance but lipid measures healthier than the median had worse outcomes than those who were insulin sensitive but had unhealthier lipid measures such as non-HDL-c and the ratios of total cholesterol/HDL-c and LDL-c/HDL-c. The HR for a 60 mg/dL increase in LDL-c was 1.14 (95% confidence interval [CI], 1.10-1.18); the HR for an LDL-c greater than 160 mg/dL was 1.19 (95% CI, 1.12-1.28). In contrast, the hazard ratio for having an insulin-resistant triglyceride/HDL-c ratio was 1.68 (95% CI, 1.57-1.80), compared with an insulin-sensitive ratio. There was no difference in outcomes between insulin-resistant but normotensive patients and insulin-sensitive but hypertensive patients.

Conclusion: Insulin resistance, as manifested by a high triglyceride/HDL-c ratio, was associated with adverse cardiovascular outcomes more than other lipid metrics, including LDL-c, which had little concordance. Physicians and patients should not overlook the triglyceride/HDL-c ratio.

INTRODUCTION

Predicting patients’ risk for cardiovascular disease (CVD) is an important function of medicine. The risks of high concentrations of low-density lipoprotein cholesterol (LDL-c) are well recognized. Treatment of LDL-c with 3-hydroxy-3-methylglutaryl-coenzyme A reductase inhibitors (statins) reduces the incidence of myocardial infarctions.1 Both the number of LDL-c measurements in high-risk patients and the percentage of those whose LDL-c is below 100 mg/dL were used until 2015 as quality metrics for health care facilities.24 Until the latest 2013 cholesterol guidelines advocated that we dose statins according to overall CVD risk, we were encouraged to dose statins according to the absolute LDL-c concentration.3 So, until recently, busy, practicing physicians were encouraged to focus on the LDL-c.

Other components of the lipid panel provide information for assessing CVD risk, although these risk factors are not well understood by many physicians. For example, the ratio of triglycerides to high-density lipoprotein cholesterol (HDL-c) reflects the presence of insulin resistance. A ratio greater than 3.0 has been measured as 64% sensitive and 68% specific for insulin resistance compared with the gold standard insulin suppression test.4 The extreme manifestation of insulin resistance is better known as the metabolic syndrome.5 Insulin resistance develops in the presence of both a genetic predisposition and excess adiposity—usually frank obesity.5,7 The resulting insulin resistance is associated with much hypertension, diabetes, atherosclerosis and its complications, and even many cancers.5 In addition to being a good measure of insulin resistance, the ratio of triglycerides to HDL-c is a powerful predictor of CVD.10-13 Yet insulin resistance, even when manifested by the metabolic syndrome, is often unrecognized in clinical practice.14-16 The only American study that showed good recognition of the metabolic syndrome was based on a survey with only a 30% response rate.17 Furthermore, the best treatment for insulin resistance is weight loss and exercise, yet neither the Joint Commission nor the principal evaluator of the quality of American hospitals (Healthcare Effectiveness Data and Information Set) mentions exercise. The measures of the Healthcare Effectiveness Data and Information Set only recently started requiring that body mass index be documented for a fraction of adults.18 Many physicians do not even discuss obesity with their obese patients.19-20

When reviewing the lipid panel, physicians often address the LDL-c but neglect the triglyceride and HDL-c ratio. Yet, multiple small and moderately sized studies suggest that the triglyceride to HDL-c ratio is more predictive of cardiovascular events than the LDL-c,
Study of the Use of Lipid Panels as a Marker of Insulin Resistance to Determine Cardiovascular Risk

We undertook a large, retrospective study to assess which metric better predicts the risk of ischemic heart disease among members of an American community Health Plan, Kaiser Permanente Northern California (KPNC).

METHODS

Patient Selection

We conducted a retrospective cohort study among members of KPNC, a non-profit, prepaid Health Plan that serves more than 3 million people. The Kaiser Foundation Research Institute’s institutional review board approved this study and waived informed consent.

Inclusion criteria were adults age 50 to 75 years, the presence of a fasting lipid panel in the year 2000, a minimum of 12 months’ continuous membership in the year before the index lipid panel, and at least 10 months of membership in each of the 3 years preceding the year before the index lipid panel. Exclusion criteria were members who had triglycerides greater than 400 mg/dL, who were prescribed at least a 180-day supply of a statin in the year before the lipid panel, who had diabetes before the index lipid panel, or who had evidence of significant atherosclerosis (Figure 1). Refer to Table 1 (available online at: www.thepermanentejournal.org/files/Fall2015/ICD9.pdf) for the International Statistical Classification of Diseases, Ninth Revision, codes describing the inclusion, exclusion, and censorship criteria.

Definitions of Outcomes and Risk Factors

The primary outcome was any ischemic heart disease (International Statistical Classification of Diseases, Ninth Revision, codes 410 through 414), including death caused by any of those codes after the index lipid panel.

The patient was deemed insulin resistant if the triglyceride level was in the highest tertile of the cohort and the HDL-c was in the lowest tertile of the cohort. The patient was deemed insulin sensitive if the triglyceride level was in the lowest tertile of the cohort and the HDL-c level was in the highest tertile.

Patients not meeting criteria for insulin resistance or insulin sensitivity were put in a single intermediate category.

The diagnosis of hypertension required that a primary care clinician had included hypertension as a diagnosis for at least two visits in the two years before the lipid panel or one visit in the previous two years coupled with one of the following: 1) one or more inpatient hypertension diagnoses in the past two years; 2) a filled prescription for hypertension medication in the previous six months; or 3) a history of diabetes, CVD, heart failure, or stroke.

Statistical Analysis

For the bivariate analysis, we excluded patients with a gap of more than 4 months in membership. Thus, we included only patients who had died of ischemic heart disease during the 8 years after the first lipid panel in 2000 or patients who had 8 years of complete follow-up from the time of the first lipid panel in 2000 (n = 80,328). We used $\chi^2$ analysis to look for differences in the primary outcome of ischemic heart disease among the 3 insulin groups, stratified by various parameters of the lipid panel or hypertension. The lipid

![Flow diagram of patient selection and inclusion criteria.](https://www.thepermanentejournal.org/files/Fall2015/ICD9.pdf)
parameters were dichotomized at the median values of the cohort. The Fisher exact test was used to compare the incidence of ischemic heart disease between the 2 main groups of interest: those with insulin resistance but lipid or blood pressure measures below the median, and those with insulin sensitivity but lipid or blood pressure measures above the median. The results were adjusted for multiple comparisons using the permutation method; p values < 0.05 indicated a significant difference.

The Cox proportional hazard model was used for the multivariate analysis. Our outcome variable was again diagnosis of ischemic heart disease or death therefrom subsequent to the first lipid panel in 2000. The main predictors were insulin resistance and LDL-c; covariates included sex, age (per year), and being hypertensive. The full cohort of 103,646 people was included in the analysis with follow-up ending at death; organ transplant; diagnosis of end-stage renal disease; diagnosis of or death resulting from CVD; a gap of more than 4 months of membership; or December 31, 2008, whichever came first. We tested the proportional hazard assumptions for our main predictors, insulin resistance and LDL-c, using Schoenfeld residuals because our large sample size was not conducive to using the computing-intensive Martingale residuals. Neither variable violated the proportional hazard assumption.

RESULTS

Table 2 describes the final cohort of 103,646 patients: 16.7% were insulin resistant and 17.8% were insulin sensitive. The cutoff lipid values of the insulin resistant group turned out to be ≥ 176 mg/dL for the triglycerides and ≤ 60 mg/dL for the HDL-c. For the insulin sensitive group, the cutoffs were ≤ 112 mg/dL triglycerides and ≥ 60 mg/dL HDL-c. The distribution of insulin responsiveness varied significantly by age, sex, self-identified race, blood pressure, and various lipid values. Men were more insulin resistant than women. Insulin resistance was associated with high blood pressure, as expected.26,27

For the population with at least 8 years of follow-up (n = 80,328), the incidence of ischemic heart disease was significantly higher in insulin-resistant patients with lower LDL-c (17.7%) than in insulin-sensitive patients with higher LDL-c (10.0%) (p < 0.001; Figure 2). Similarly, insulin-resistant patients with a lower LDL-c/HDL-c ratio had a significantly higher incidence of ischemic heart disease (16.2%) than insulin-sensitive patients with a higher LDL-c/HDL-c ratio (9.96%) (p < 0.001; Figure 3). A similar pattern emerged with total cholesterol/HDL-c and non-HDL-c (Table 3). Thus, being insulin resistant carried a significantly

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Insulin sensitive (n = 18,418)</th>
<th>Indeterminate insulin sensitivity (n = 67,878)</th>
<th>Insulin resistant (n = 17,350)</th>
<th>Total population (N = 103,646)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean years (SD)</td>
<td>60.3 (7.1)</td>
<td>60.5 (7.1)</td>
<td>59.8 (7.0)</td>
<td>60.3 (7.1)</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>Sex, %</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Male</td>
<td>26.2</td>
<td>43.7</td>
<td>67.8</td>
<td>44.6</td>
<td>&lt; 0.001*</td>
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<tr>
<td>Female</td>
<td>73.8</td>
<td>56.3</td>
<td>32.3</td>
<td>55.4</td>
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<tr>
<td>Race, %</td>
<td></td>
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</tr>
<tr>
<td>White</td>
<td>66.8</td>
<td>65.2</td>
<td>66.1</td>
<td>65.7</td>
<td>&lt; 0.001*</td>
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<td>Asian</td>
<td>10.2</td>
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<td>11.0</td>
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<td>Black</td>
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<td>3.4</td>
<td>6.2</td>
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<td>9.9</td>
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<td>Other/unknown</td>
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<td>8.9</td>
<td>9.6</td>
<td>8.9</td>
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<td>Blood pressure, %</td>
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<td></td>
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<td>Normotensive</td>
<td>74.7</td>
<td>65.0</td>
<td>58.3</td>
<td>66.6</td>
<td>&lt; 0.001*</td>
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<td>Hypertensive</td>
<td>25.3</td>
<td>35.0</td>
<td>41.7</td>
<td>34.4</td>
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<tr>
<td>Lipid values, mean (SD)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LDL-c, mg/dL</td>
<td>134 (34)</td>
<td>146 (35)</td>
<td>140 (37)</td>
<td>143 (36)</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>Triglycerides/HDL-c</td>
<td>1.1 (0.3)</td>
<td>2.9 (1.2)</td>
<td>6.7 (2.0)</td>
<td>3.2 (2.1)</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>Total cholesterol, mg/dL*</td>
<td>225 (36)</td>
<td>231 (41)</td>
<td>230 (38)</td>
<td>230 (40)</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>Triglycerides, mg/dL*</td>
<td>80 (19)</td>
<td>152 (61)</td>
<td>255 (60)</td>
<td>157 (76)</td>
<td>&lt; 0.001*</td>
</tr>
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<td>HDL-c, mg/dL</td>
<td>75 (13)</td>
<td>54 (12)</td>
<td>39 (4)</td>
<td>55 (16)</td>
<td>&lt; 0.001*</td>
</tr>
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<td>Total cholesterol/HDL-c</td>
<td>3.1 (0.6)</td>
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<td>6.0 (1.1)</td>
<td>4.4 (1.3)</td>
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<td>Non-HDL cholesterol, mg/dL</td>
<td>150 (35)</td>
<td>176 (39)</td>
<td>191 (37)</td>
<td>174 (40)</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>LDL-c/HDL-c</td>
<td>1.8 (0.6)</td>
<td>2.8 (0.9)</td>
<td>3.6 (1.0)</td>
<td>2.8 (1.0)</td>
<td>&lt; 0.001*</td>
</tr>
</tbody>
</table>

* p values were calculated using the y2 test.
* p values were calculated using the General Linear Model.
* SI conversion factors: To convert cholesterol values to millimoles per liter, multiply by 0.02586. To convert triglycerides to millimoles per liter, multiply by 0.01129.
HDL-c = high-density lipoprotein cholesterol; LDL-c = low-density lipoprotein cholesterol; SD = standard deviation.
Higher risk of ischemic heart disease than having an LDL-c, LDL-c/HDL-c, total cholesterol/HDL-c, or non-HDL-c cholesterol higher than the median values of 142 mg/dL, 2.69, 4.30, and 173 mg/dL, respectively. However, there was no difference in the incidence of ischemic heart disease between insulin-resistant but normotensive patients and insulin-sensitive but hypertensive patients (Table 3).

For the full cohort of 103,646 patients, the mean follow-up was 7 years (median, 8.3 years). We ran 2 models; in the first we used LDL-c as a categorical variable using LDL-c ≤ 100 mg/dL as the reference and compared this with both the LDL-c between 101 mg/dL and 160 mg/dL and the LDL-c ≥ 161 mg/dL. In the second model we used LDL-c as a continuous variable and calculated the hazard ratio on the basis of increases in increments of 60 mg/dL. Both models give identical results for male sex, hypertension, age, and insulin resistance. All conferred 60% to 72% greater risk of ischemic heart disease than female sex, having normal blood pressure, and being insulin sensitive, respectively (Table 4). In contrast, LDL-c > 160 mg/dL conferred a 19% risk. In the second model a 60-mg/dL increase in LDL-c conferred a 14% greater risk of developing ischemic heart disease. The 68% risk of ischemic heart disease for insulin-resistant patients is much higher than the LDL-c in both models. For every 1 year of increased age, a person was 5.9% more likely to develop ischemic heart disease, assuming all other measured variables did not change. This does not scale linearly with additional years (because the hazard ratio is the exponent of beta [the point estimate] for age in the model).

**DISCUSSION**

In this large-scale analysis of members of a Health Plan, we found that insulin resistance, as defined by high triglycerides and low HDL-c, was more predictive of ischemic heart disease than LDL-c among 50 to 75 year olds who had not had a major cardiovascular event or acquired diabetes. Also, the people in the worst tertile of triglycerides and HDL-c had worse ischemic heart disease than those with elevated non-HDL-c, total cholesterol/HDL-c ratios, or LDL-c/HDL-c ratios.

Our population provides several advantages. First, it is a community cohort, not a study group, which may enable the results to apply more generally. Second, the cohort is ethnically heterogeneous. Third, it is a large population; more than 100,000 individuals were included in this study. Finally, a large study in an American population may have greater potential to affect the behavior of Americans, who underestimate the danger of insulin resistance and often overestimate the effect of total cholesterol or LDL-c on their cardiovascular health. In one study, a group of New Englanders thought that cholesterol levels (ie, total cholesterol or LDL-c) were more important to cardiovascular health than blood pressure, smoking, or exercise. In another study, more people in underserved, rural Pennsylvania identified high cholesterol as a risk factor than identified smoking or diabetes.

Our results showed that being insulin resistant (as suggested by a high triglyceride/HDL-c ratio) and having LDL-c ≤ 142 mg/dL conferred a higher risk of CVD than being insulin sensitive and having an elevated LDL-c.
... the treatment of a high LDL-c/HDL-c ratio depends on its exact problem—whether the LDL-c is too high or the HDL-c is too low. In contrast, the triglyceride/HDL-c ratio is relatively specific to insulin resistance.

The same was true for being insulin resistant and having an LDL-c/HDL-c ratio ≤ 2.69, a total cholesterol/HDL-c ratio ≤ 4.30, or a non-HDL-c concentration ≤ 173 mg/dL. These results suggest that LDL-c is not a dominant predictor of cardiovascular outcomes in this study. Consistent with these results, the Cox proportional hazard model identified insulin resistance, hypertension, and male sex as the risk factors most important in predicting cardiovascular outcomes in our cohort. An increase in LDL-c of 60 mg/dL conferred only 14% more risk of ischemic heart disease.

Similar to our study, the Copenhagen Male Study sorted approximately 3000 Danish men into 3 groups based on triglycerides and HDL-c levels and found that high triglycerides and low HDL-c were more predictive of subsequent ischemic heart disease than LDL-c. However, the results of our χ² analyses were even stronger than those from the Copenhagen Male Study, likely because our population was more diverse than those from the Copenhagen Male Study, the study by Bampi et al., and the study by the Women’s Ischemia Syndrome Evaluation, the Boston Area Health Study, the Physicians’ Health Study, and the Women’s Ischemia Syndrome Evaluation.

Data from larger trials are also consistent with our findings. The Helsinki Heart Study showed that LDL-c was a poor predictor of myocardial infarction, but that triglycerides and HDL-c were good predictors. Using the Framingham risk algorithm to evaluate people with the metabolic syndrome, Wong et al. calculated the percentage of CVD that would be prevented if the LDL-c or the HDL-c could be optimized. They found that HDL-c was a more powerful risk factor among patients with the metabolic syndrome than LDL-c and that an optimal HDL-c would prevent more events than an optimal LDL-c. The Physicians’ Health Study found that both HDL-c and the total cholesterol/HDL-c ratio were effective predictors of myocardial infarction but that a potential surrogate for LDL-c, apolipoprotein B-100, was not. Data from the Framingham Study and the Coronary Primary Prevention Trial showed that the ratios of cholesterols (total/HDL-c and LDL-c/HDL-c) were superior to LDL-c for prediction, but the study did not test the predictiveness of the triglycerides or HDL-c alone. In the Prospective Study of Pravastatin in the Elderly at Risk trial, LDL-c was not predictive of CVD and stroke, but HDL-c, LDL-c/HDL-c, and total cholesterol/HDL-c were.

Other smaller studies also partially support our findings. A study evaluated the first 100 nondiabetic patients who presented for coronary angiography at the time of their first heart attack and who had never received treatment that might have affected the evolution of coronary artery disease. The HDL-c was significantly predictive of coronary artery disease, whereas the LDL-c, triglycerides, and total cholesterol were not. A case-control study of 180 Taiwanese hospitalized patients showed the HDL-c was more associated with coronary artery stenosis than the LDL-c. A study of 900 diabetic patients in a Japanese clinic that used ultrasound of the carotid artery to assess atherosclerosis showed that LDL-c, total cholesterol, and triglycerides were not significantly predictive; however, HDL-c, LDL-c/HDL-c, total

Table 3. Incidence of ischemic heart disease within 8 years of the index lipid panel stratified by insulin resistance and by various components of the lipid panel or hypertension

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Insulin sensitive (n = 14,411), %</th>
<th>Indeterminate insulin sensitivity (n = 52,515), %</th>
<th>Insulin resistant (n = 13,402), %</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total cholesterol/HDL-c</td>
<td></td>
<td></td>
<td></td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>≤ 4.30</td>
<td>9.0</td>
<td>11.7</td>
<td>20.6</td>
<td></td>
</tr>
<tr>
<td>&gt; 4.30</td>
<td>9.3</td>
<td>15.8</td>
<td>18.4</td>
<td></td>
</tr>
<tr>
<td>Non-HDL-c</td>
<td></td>
<td></td>
<td></td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>≤ 173 mg/dL²</td>
<td>8.6</td>
<td>13.1</td>
<td>16.7</td>
<td></td>
</tr>
<tr>
<td>&gt; 173 mg/dL²</td>
<td>10.3</td>
<td>14.5</td>
<td>19.3</td>
<td></td>
</tr>
<tr>
<td>Blood pressure</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normotensive</td>
<td>7.1</td>
<td>11.1</td>
<td>15.2</td>
<td>0.52²</td>
</tr>
<tr>
<td>Hypertensive</td>
<td>14.7</td>
<td>18.8</td>
<td>22.9</td>
<td></td>
</tr>
</tbody>
</table>

* Fisher exact test p value compares 9.3 with 20.6.  
¹ Fisher exact test p value compares 10.3 with 16.7.  
² Fisher exact test p value compares 14.7 with 15.2.  
HDL-c = high-density lipoprotein cholesterol.

Table 4. Hazard ratios for risk factors predicting ischemic heart disease at 8 years after the index lipid panel

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Hazard ratio</th>
<th>95% CI</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin resistance (compared with insulin sensitivity)</td>
<td>1.69</td>
<td>1.57-1.80</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>LDL-c (≥ 160 mg/dL, compared with ≤ 100 mg/dL)</td>
<td>1.19</td>
<td>1.12-1.28</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Age, years</td>
<td>1.06</td>
<td>1.06-1.06</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Male sex</td>
<td>1.72</td>
<td>1.65-1.79</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Hypertension</td>
<td>1.60</td>
<td>1.54-1.66</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

* To convert milligrams of cholesterol per deciliter to SI units, multiply by 0.02586.  
CI = confidence interval; LDL-c = low-density lipoprotein cholesterol.
Our findings might contradict the prevailing wisdom that LDL-c is a powerful risk factor for ischemic heart disease. There are several possible explanations for these data. First, LDL-c >142 mg/dL may not be dangerous enough to statistically demonstrate excessive ischemic disease. The Copenhagen Male Study used a cutoff for high LDL-c of 170 mg/dL; in contrast, 66% of the KPNC population with “high” LDL-c had LDL-c values < 171 mg/dL. Nonetheless, the Copenhagen Male Study found that the triglycerides/HDL-c ratio was more predictive than even these higher levels of LDL-c.

Second, the index lipid panel in this study was acquired in the absence of statin use. However, our results could be explained if most people in the cohort started using statins immediately after the index measurement. This would have mitigated the deleterious effects of elevated LDL-c, thereby nullifying the negative predictive value of the initially untreated LDL-c. These results would support the continued clinical evaluation of LDL-c to assess whether a statin should be administered. However, the results would then suggest that clinicians should also focus on insulin resistance because it remains a powerful risk factor even after treatment of high LDL-c.

Alternatively, KPNC may have waited until after approximately the early 2000s (until after the majority of the big statin trials were released) before ramping up statin prescriptions for primary prevention. Thus, this cohort may not have been on statins long enough for the drugs to reduce ischemic outcomes substantially. Approximately half the diagnoses of ischemic heart disease occurred within the first year after the index lipid panel. If KPNC did not start aggressively treating LDL with statins until late in the decade, then approximately half the events would have occurred in the absence of statin treatment. If so, our results would indicate that an untreated LDL-c is not as dangerous as insulin resistance. In fact, Yeh et al have already published the rate of statin use in the KPNC members more than 30 years of age who developed their first myocardial infarction between 1999 and 2008. Statin use was starting to ramp up in 2000 but did not reach peak penetration until 2005. More investigations are currently in progress to determine the role of statins in this cohort.

By better understanding the risks conferred by the various components of the lipid panel, physicians and patients can do more to mitigate those risks. In addition to the triglyceride/HDL-c ratio, the LDL-c/HDL-c and the total cholesterol/HDL-c ratio are very predictive of CVD risk. Many clinicians like the LDL-c/HDL-c ratio because the results generally range from 2 to 10, numbers that are easy to remember. However, the treatment of a high LDL-c/HDL-c ratio depends on its exact problem—whether the LDL-c is too high or the HDL-c is too low. In contrast, the triglyceride/HDL-c ratio is relatively specific to insulin resistance. This study would have confirmed that a high triglyceride/HDL-c ratio is a good surrogate for insulin resistance if other metrics of insulin resistance had been measured also. Hypertension was measured and was virtually as strong a risk factor for CVD outcomes as the high triglyceride/HDL-c ratio. Body mass index, weight, actual blood pressures, blood sugars, and hemoglobin A1c would also have been relevant to this study. Unfortunately, the accuracy of the body mass index and weight data in 2000 needs clarification. The other metrics were beyond the scope of this study.

CONCLUSION

Physician counseling can change patients’ behaviors if effective techniques are used. If more physicians understood that insulin resistance is a huge risk factor for ischemic heart disease, we could potentially do more to motivate our patients. More than two-thirds of Americans are overweight or obese, and a large fraction of these have insulin resistance. Currently, we may be missing opportunities, because a sizable fraction of patients don’t recall hearing their physicians address their obesity. Focusing on LDL-c levels is not sufficient; triglycerides and HDL-c should also be routinely monitored and problematic values addressed to decrease the associated risks. 

Disclosure Statement

The author(s) have no potential conflicts to disclose.

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Acknowledgments

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Mary Corrado, ELS, provided editorial assistance.

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Right-Side Colon Ischemia: Clinical Features, Large Visceral Artery Occlusion, and Long-Term Follow-Up

George F Longstreth, MD, FAGA, FACP; Robert J Hye, MD, FACS

ABSTRACT

Objective: To assess patients with RSCI through long-term follow-up, including features and management of LVAO.

Main Outcome Measures: Mesenteric ischemia and mortality.

Design: Retrospective observational study in an integrated health care system.

Results: Of 49 patients (30 women [61.2%]; mean [standard deviation] age, 69.4 [11.9] years), 19 (38.8%) underwent surgery—that is, 5 (83.3%) of 6 who developed RSCI in hospital following surgical procedures and 14 (32.6%) of 43 who had RSCI before hospitalization (p value = 0.03); overall, 5 (10.2%) died. Among 44 survivors with a median (range) follow-up of 5.19 (0.03-14.26) years, 5 (11.4%), including 3 (20.0%) of 15 operated cases, had symptomatic LVAO and underwent angioplasty and stent placement: 2 for abdominal angina that preceded RSCI, 1 for acute mesenteric ischemia 1 week after resection of RSCI, 1 for RSCI 6 weeks after resection of left-side ischemia, and 1 for abdominal angina that began 3 years after spontaneous recovery from RSCI. None had further mesenteric ischemia until death from nonintestinal disease or the end of follow-up (1.6 to 10.2 years later). Kaplan-Meier survival estimates for all 44 survivors at 1, 3, 5, and 10 years were 88.6%, 72.3%, 57.6%, and 25.9%, respectively. Thirty-one patients (70.4%) died during follow-up, 19 (61.3%) of a known cause; the 39 patients not treated for LVAO lacked mesenteric ischemia.

Conclusion: Patients with RSCI may have symptomatic LVAO; therefore, we advise they undergo careful query for symptoms of abdominal angina and routine visceral artery imaging.

INTRODUCTION

Colon ischemia (ischemic colitis) varies in extent from mucosal and submucosal ischemia to transmural infarction and in severity from reversible to fatal disease. In left-side colon ischemia, the most common type, the ischemic segments typically correspond to the “watershed” areas of potentially limited collateral flow between the superior mesenteric artery (SMA) and inferior mesenteric artery (IMA) circulations or between the superior hemorrhoidal artery and IMA circulations, affecting the descending colon and sigmoid colon. Vascular imaging is rarely helpful. In contrast, rates of surgery and mortality are much greater after rightside colon ischemia (RSCI), suggesting a different pathophysiology in some cases, including large artery disease. A committee comprised of three gastroenterologists and one surgeon that recently developed practice guidelines for colon ischemia cited anecdotal evidence that RSCI can herald acute mesenteric ischemia caused by large artery occlusion. Therefore, they advised routine computed tomographic (CT) angiography for patients with RSCI, but they found no published supporting data. There is also little information on other aspects of the long-term outcome of survivors of RSCI, including recurrent mesenteric ischemia, other morbidities, and rates of death and its causes.

The importance of diagnosing and treating large visceral artery disease is emphasized by the severe nature of acute mesenteric ischemia and the effectiveness of therapy. We assessed the clinical characteristics and treatment of patients hospitalized for RSCI and their long-term outcome, including the features of large visceral artery occlusion diagnosed from the index episode of RSCI until follow-up ended, as well as morbidity and mortality during follow-up.

MATERIALS AND METHODS

The patients were members of Kaiser Foundation Hospitals and Health Plan in San Diego, CA, a prepaid, integrated health care system serving more than 500,000 people. Most patients were treated at the Kaiser Permanente (KP) hospital, and the records included reports on cases treated at a contract hospital or other facility. The studied cases were included in a report of 417 consecutive episodes of acute colon ischemia of various large bowel segments in 401 patients: left side, 363 (87.1%); right side, 39 (9.4%); bilateral (extension of ischemia distally to at least the splenic flexure), 10 (2.4%); and transverse only, 5 (1.2%). Because there is no unique International Classification of Diseases, Ninth Clinical Modification (ICD-9-CM) code for colon ischemia, the primary author reviewed inpatient records of all patients with ICD-9-CM...
code 557.0 (acute vascular insufficiency of intestine), 557.1 (chronic vascular insufficiency of intestine), or 557.9 (unspecified vascular insufficiency of intestine) from January 1, 2000, through December 31, 2006. Patients without colon ischemia or with mechanical obstruction, pseudo-obstruction, or small bowel ischemia were excluded and assigned levels of diagnostic evidence according to clinical and testing criteria. Epidemiologic and other data from patients with ischemia of any part of the large bowel were combined for most analyses.11

In the present study conducted in 2014 on the 49 patients who had 1 episode of RSCI (including 10 with bilateral ischemia), the primary author reviewed prehospitalization outpatient records and posthospitalization outpatient and inpatient records and entered data into a spreadsheet application (Excel v14; Microsoft, Redmond, WA). The final follow-up date was the date of records review for current KP members, disenrollment from KP, or death, using the earlier of the latter 2 dates. Disenrollment dates were recorded in an institutional electronic database, and death dates were obtained from KP records, the State of California Department of Health and Human Services, and the Social Security Administration (available through 2012 from the latter 2 sources). For patients who had died while KP members, causes of mortality were determined from medical records, including death certificates. The KP institutional review board approved the study.

We summarized normally distributed continuous data as mean (standard deviation [SD]) and data not normally distributed as median (range). Statistical analysis comprised the Wilcoxon 2-sample test for continuous variables and Fisher exact test for categorical variables, accepting statistical significance as 0.05 by 2-tailed testing. Survival after discharge was analyzed using the Kaplan-Meier method.

RESULTS
The 49 patients who had RSCI ischemia included 30 women (61.2%) who were 69.4 (SD 11.9) years of age. Presenting clinical features began fewer than 10 days before hospitalization and included abdominal pain, 46 (93.9%); diarrhea, 26 (53.1%); rectal bleeding, 24 (49.0%); and vomiting, 14 (28.6%). Thirty-three patients (67.3%) had prompt abdominal/pelvic CT, in most cases with oral and intravenous contrast media but not timed for optimal arterial visualization; all scans revealed abnormalities typical of colon ischemia,12 but only 1 report mentioned the status of visceral arteries. Diagnostic evidence comprised colonoscopic13,14 and biopsy or surgical pathology findings typical of colon ischemia15 in 40 patients (81.6%); CT and colonoscopic findings typical of colon ischemia without biopsies performed in 7 (14.3%); and CT findings typical of colon ischemia in 2 (4.1%). Comorbid hypertension, hyperlipidemia, nonvisceral vascular disease (cerebral, peripheral, or peripheral), diabetes, heart disease, and dialysis dependency were common (Table 1). Twenty-one patients (42.9%) had vascular disease in at least 1 nonvisceral bed. Ten patients (20.4%) were smokers. One patient each had concurrent acute myocardial infarction or bleeding gastric ulcer. RSCI occurred in 43 patients (87.8%) before hospitalization and in 6 (12.2%) during hospitalization after noncolonic surgery: 1 patient each had undergone repair of ruptured abdominal aortic aneurysm, coronary artery bypass grafting, bariatric surgery, lung malignancy resection, subdural hematoma evacuation, or peripheral vascular surgery.

Figure 1 summarizes the treatment and outcome of the 49 patients from the index episode of RSCI to the end of follow-up. Ischemic right colon was

Table 1. Chronic comorbidities in 49 patients with right-side colon ischemia

<table>
<thead>
<tr>
<th>Disease</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension</td>
<td>36 (73.5)</td>
</tr>
<tr>
<td>Hyperlipidemia (drug-treated)</td>
<td>18 (36.7)</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>13 (26.5)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>13 (26.5)</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>9 (18.4)</td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>8 (16.3)</td>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td>7 (14.3)</td>
</tr>
<tr>
<td>Depression (drug-treated)</td>
<td>7 (14.3)</td>
</tr>
<tr>
<td>Peripheral vascular disease</td>
<td>7 (14.3)</td>
</tr>
<tr>
<td>Chronic renal disease (dialysis-dependent)</td>
<td>5 (10.2)</td>
</tr>
<tr>
<td>Chronic obstructive pulmonary disease</td>
<td>5 (10.2)</td>
</tr>
<tr>
<td>Dementia</td>
<td>3 (6.1)</td>
</tr>
<tr>
<td>Miscellaneousa</td>
<td>11 (22.4)</td>
</tr>
</tbody>
</table>

*D The total exceeds 49 because of patients with multiple comorbidities.

**a**Valvular heart disease in 2 patients (4.1%); 1 patient (2.0%) each with celiac disease, cocaine ingestion, chronic myelogenous leukemia, metastatic prostate cancer, myelodysplasia, pulmonary sarcoidosis, progressive systemic sclerosis lung disease, sleep apnea, or thrombotic thrombocytopenic purpura.
resected in 19 patients (38.8%)—that is, 5 of 6 patients (83.3%) who developed RSCI while receiving postoperative hospital care and 14 of 43 patients (32.6%) who developed RSCI before hospitalization (p value = 0.03). The 19 operated patients comprised 14 of 39 patients (35.9%) with RSCI and 5 of 10 patients (50%) with bilateral ischemia. The procedures were subtotal colectomy in 17 patients, 9 of whom underwent ileostomy, and 1 each who underwent proctocolectomy or total colectomy with ileostomy. All pathologic examinations on resected tissue showed ischemia, but none revealed arteriosclerosis. Four of 19 operated patients (21.1%) died during the index hospitalization, 3 of 5 patients (60.0%) whose RSCI began during postoperative care versus 1 of 14 patients (7.1%) whose RSCI began before hospitalization (p value = 0.04). One nonoperated patient died during the index hospitalization, yielding an overall mortality rate of 10.2%.

We followed the 44 survivors for 5.19 (0.03 - 14.26) years. Nineteen survivors (43.2%) had 1 or more asymptomatic vascular disease in a nonvisceral vascular bed before the index episode of RSCI, and 5 of 25 patients (20.0%) who initially had no other vascular disease had the onset of symptomatic or follow-up ended (after ≥ 10 years). The age and proportions that were women or had nonvisceral vascular disease of these 5 patients versus the 39 other survivors were statistically similar: age, 69.6 (SD = 7.5) versus 69.0 (SD = 12.5) years (p value = 0.91); women, 2 (40.0%) versus 26 (66.7%) (p value = 0.34); and nonvisceral vascular disease, 4 (80.0%) versus 15 (38.5%) (p value = 0.15).

Of the 44 survivors of RSCI, 31 (70.5%) died during follow-up or after disenrollment from KP (Figure 1). Twenty-seven (87.1%) died while KP members owing to the following: pneumonia (5); malignant tumor (3); acute myocardial infarction (2); sepsis (2); and 1 each for dementia, pulmonary fibrosis, postcardiac surgery complications, progressive systemic sclerosis, stroke, renal failure, and retroperitoneal abscess; and unknown cause (8). Four patients (12.9%) died after disenrollment; hence, their cause of death was unknown. Therefore, of the 31 patients who died, the cause of death was known for 19 (61.3%); none of them died of mesenteric ischemia. Figure 2 shows the Kaplan-Meier survival curve for the 44 patients who survived the index episode. Estimated survival at 1, 3, 5, and 10 years was 88.6%, 72.3%, 57.6%, and 25.9%, respectively.

**DISCUSSION**

In this retrospective study, we describe a consecutive series of patients hospitalized with RSCI, including long-term follow-up. Segmental colon ischemia was initially recognized over 50 years ago, and it results from numerous heterogeneous factors. More recent studies revealed important distinguishing features of RSCI compared with colon ischemia involving other sites, including the predominance of pain over bleeding, and higher rates of comorbidities, including coronary artery disease, atrial fibrillation, and dialysis dependency…

... distinguishing features of RSCI compared with colon ischemia involving other sites, including the predominance of pain over bleeding, and higher rates of comorbidities, including coronary artery disease, atrial fibrillation, and dialysis dependency…

…female predominance…
of RSCI to the left side (bilateral or total colon ischemia) also have higher rates of surgery and mortality.\textsuperscript{5,14} The female predominance, vascular and nonvascular comorbidities, and rates of surgery and mortality in our series are similar to the findings in these reports. Notably, rates of surgery and surgical mortality were significantly higher among patients with RSCI that began while they were receiving postoperative hospital care than among those whose RSCI started before hospitalization. As previously reported, right-side or bilateral distribution among various patient characteristics yielded the highest adjusted odds ratio for severe colon ischemia, defined as surgery and/or death.\textsuperscript{11} In this series, the 38.8% surgical rate and overall mortality of 10.2% are much higher than rates of 3.3% and 2.7%, respectively, in 368 episodes of non-RSCI treated at the same institution during the same period.\textsuperscript{11} Therefore, a role of large artery occlusion in RSCI is plausible compared with the predominant nonocclusive hypoperfusion in patients with ischemia in other locations of the large bowel.\textsuperscript{1}

Our most important finding is that 5 patients (11.4%), including 20% of operated cases, had symptomatic large visceral artery occlusion that caused a clinical spectrum comprising abdominal angina preceding RSCI but not diagnosed until after surgical resection (2 cases), midgut ischemia 1 week after resection of RSCI (1 case), RSCI 6 weeks after resection of severe left-side colon ischemia (1 case), and abdominal angina beginning more than 3 years after spontaneous recovery from RSCI (1 case). All were treated with angioplasty.

### Table 2. Clinical features, therapy, and follow-up of 5 survivors of right-side colon ischemia who had additional mesenteric ischemia because of large visceral artery occlusion

<table>
<thead>
<tr>
<th>Case</th>
<th>Age, sex</th>
<th>Clinical features and therapy</th>
<th>Chronic comorbidities</th>
<th>Follow-up events</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>73, Female</td>
<td>Postprandial abdominal pain and nausea for 1 year, 7-kg loss RSCI; right hemicolecotomy, ileo-colic anastomosis 16 months later abdominal pain persisted, 9-kg loss; abdominal angina identified Catheter angiography: 100% stenosis CA and IMA. 90% stenosis SMA Therapy: SMA ABES</td>
<td>COPD 50 pack/year smoker</td>
<td>Pain stopped, 12-kg gain No mesenteric ischemia in 10.2 years to Kaiser Permanente disenrollment</td>
</tr>
<tr>
<td>2</td>
<td>70, Male</td>
<td>Postprandial abdominal pain for 2 years RSCI; right hemicolecotomy, ileostomy, colon mucus fistula 5 weeks later abdominal pain persisted; abdominal angina identified Catheter angiography: 100% stenoses SMA; tight stenosis CA and IMA Therapy: CA and IMA ABES</td>
<td>COPD Hypertension Peripheral vascular disease 100 pack/year smoker</td>
<td>Pain stopped, 10-kg gain Femoral endarterectomy, femoral-antior tibial bypass No mesenteric ischemia until death from glioblastoma in 1.6 years</td>
</tr>
<tr>
<td>3</td>
<td>80, Male</td>
<td>RSCI; right hemicolecotomy, ileostomy, colon mucus fistula 1 week later altered mental status, leukocyte count 24,800/mm\textsuperscript{3}, creatinine 4.5 mg/dL, dusky ileal stoma; mesenteric ischemia suspected Catheter angiography: tight SMA stenosis Therapy: SMA ABES</td>
<td>Type 1 diabetes Hyperlipidemia Coronary artery disease Cerebrovascular disease Atrial fibrillation Congestive heart failure COPD</td>
<td>No mesenteric ischemia until death from COPD in 3.3 years</td>
</tr>
<tr>
<td>4</td>
<td>64, Male</td>
<td>LSCI with shock; left hemicolecotomy on vasopressors, colostomy stapled Next day “second-look” laparotomy, colostomy matured 6 weeks later RSCI, recovery without surgery Catheter angiography: tight stenoses IMA and SMA Therapy: SMA ABES</td>
<td>Type 2 diabetes Hypertension Hyperlipidemia Coronary artery disease</td>
<td>No mesenteric ischemia until death from myocardial infarction in 7.7 years</td>
</tr>
<tr>
<td>5</td>
<td>61, Female</td>
<td>RSCI, recovery without surgery 3.5 years later, onset of postprandial abdominal pain, vomiting, 8-kg loss; abdominal angina identified Catheter angiography: tight stenoses CA, IMA, and SMA Therapy: SMA ABES</td>
<td>Type 1 diabetes Hypertension Hyperlipidemia Coronary artery disease Peripheral vascular disease 50 pack/year smoker</td>
<td>Pain stopped, 9-kg gain No mesenteric ischemia in 10.0 years of Kaiser Permanente follow-up</td>
</tr>
</tbody>
</table>

*Age in years at index episode of right-side colon ischemia.
ABES = angioplasty and balloon-expandable stent placement; CA = celiac artery; COPD = chronic obstructive pulmonary disease; IMA = inferior mesenteric artery; LSCI = left-side colon ischemia; RSCI = right-side colon ischemia; SMA = superior mesenteric artery.
and balloon expandable stent placement and had no recurrent mesenteric ischemia until death from nonintestinal disease or at least 10 years of follow-up. Nonvisceral vascular disease was common among all patients with RSCI; 25% of survivors who initially did not have such disease developed it later and there was a trend toward more nonvisceral vascular disease in the 5 patients treated for large visceral artery occlusion than in other patients. Serious cardiac rhythm disturbances and malignant tumors also occurred frequently during follow-up. Overall survival fell progressively for 10 years; 70.4% had died at final follow-up or after disenrollment from KP. Mesenteric ischemia was not diagnosed during follow-up of the other 39 patients or listed as a cause of death in the 61.3% of patients for whom a cause was recorded.

Because the SMA supplies most of the small bowel and the proximal and transverse colon, SMA hypoperfusion with inadequate collateral circulation can cause extensive acute mesenteric ischemia. Poor development of collaterals commonly occurs in the mesentery of the right colon compared with the left side.2 A pathogenic role of large artery hypoperfusion is manifested when colon ischemia occurs after the IMA is sacrificed during surgery for abdominal aortic aneurysm15,16 or colon resection,21 as in case 4 (Table 2), eliminating a critical source of collateral supply to the distribution of a diseased SMA. Therapy of visceral artery occlusion is effective. Patency rates for open revascularization are superior 5 years after treatment; however, postprocedural morbidity and mortality are lower and survival is similar after endovascular treatment.18

Our experience expands knowledge on the association between RSCI and large artery occlusion, which is not well described in the literature. In the past, authorities ascribed little role to angiography in colon ischemia,2 and use of angiography was not reported in more recent descriptions of RSCI.37 Chronic mesenteric ischemia preceding RSCI could have been overlooked because patients with RSCI typically present to Emergency Departments where physicians may focus on their acute symptoms and not recognize previous abdominal angina. A case report describes a 64-year-old American woman who had initial colon ischemia of unstated distribution, subsequent left-side colon ischemia, and previous chronic abdominal pain who underwent stenting of celiac artery and IMA stenoses. She was pain-free 12 weeks later.22 Another report comments on 2 patients who died of recurrent colon ischemia after arterial stenting for chronic mesenteric ischemia, but clinical, angiographic, and other details are lacking.23 Some authors now suggest angiography may be useful when acute mesenteric ischemia is also considered in association with colon ischemia or in some cases of RSCI.24,25 To our knowledge, this is the first detailed report on symptomatic large visceral artery occlusion and its treatment in survivors of RSCI.

The duration of postdischarge follow-up of published series of patients with RSCI was unstated,3,6,7 or comprised only 30-day1 or 120-day1 mortality, limiting identification of subsequent mesenteric ischemia and other events. A recent report on the long-term survival of patients who had undergone surgical resection for colon ischemia at various locations did not assess comorbidities, including mesenteric ischemia, or causes of death.26 We are unaware of any other detailed long-term outcome studies on RSCI. A limitation of this study is that we could not assess the usefulness of routine visceral arterial imaging in this study because most of the CT examinations were not properly timed for arterial visualization. Therefore, we have no information on the vascular status of patients who did not undergo angiography. Routine CT angiography could have increased the detection of severe occlusive disease in asymptomatic patients; however, none had mesenteric ischemia diagnosed during long-term observation. Nevertheless, it is possible that the frequency of large-vessel arterial occlusive disease is underestimated in our study. Another limitation is the lack of information on the cause of death in 38.7% of patients, whom we cannot exclude from dying of mesenteric ischemia. Strengths of this study include comprehensive review of outpatient and inpatient records before and after RSCI and prolonged outcome assessment in an integrated health care system.

CONCLUSION

Our experience indicates that physicians should ask patients with RSCI about prior symptoms of abdominal angina (postprandial pain, fear of eating, and weight loss) and that chronic abdominal pain in survivors of RSCI, even beginning years later, should prompt consideration of chronic mesenteric ischemia. Occlusive visceral artery disease should be especially considered in patients who have had surgical sacrifice of the IMA. We support visceral artery imaging by CT angiography routinely during hospitalization for RSCI. The 50% to 100% mortality of acute mesenteric ischemia8,9 implies that our 5 patients with symptomatic large artery occlusion would have been at high risk if physicians had not identified and treated their disease. CT angiography is accurate,10 noninvasive, and also useful in initial diagnostic imaging of patients suspected of having RSCI. Visceral duplex scanning22 and 3-dimensional gadolinium-enhanced magnetic resonance angiography29 are potential options, depending on local expertise. Catheter angiography confirms disease reported from noninvasive procedures and can be followed by angioplasty and stent placement. Prospective studies are called for to expand knowledge of large-artery visceral disease in RSCI. 

Disclosure Statement

The author(s) have no conflicts of interest to disclose.

Acknowledgments

The authors thank Qiaowu Li, MS, for statistical consultation. Mary Corrado, ELS, provided editorial assistance.

References

Tuning the Harp

The office of medicine is but to tune this curious harp of man's body and to reduce it to harmony.

— Sir Francis Bacon, 1561-1626, English philosopher, statesman, scientist, lawyer, jurist, and author
This photograph was taken in 2014 in an outdoor market in Burma. The lively patterns and vibrant colors on these umbrellas are distinctive traits of crafts from this region. Officially known as the Republic of the Union of Myanmar, or simply Myanmar, Burma has a long, rich history, much of it tinged by political and religious conflict.

Dr. Hahn retired from The Permanente Medical Group in 2010. He has been seriously exploring photography since 2000 and has an interest in both wildlife and landscape photography. For further information about his artwork, Dr. Hahn can be contacted at: hahnsk@sbcglobal.net.
ABSTRACT

Context: Postoperative management of pain after total joint arthroplasty remains a challenge despite advancements in analgesics. Evidence shows that complementary modalities with mind-body and tactile-based approaches are valid and effective adjuncts to reduce pain and anxiety postoperatively.

Objective: To investigate the effectiveness of the “M” Technique (M), a registered method of structured touch using a set sequence and number of strokes, and a consistent level of pressure on hands and feet, compared with guided imagery and usual care, for the reduction of pain and anxiety in patients undergoing elective total knee or hip replacement surgery.

Methods: Randomized controlled trial: M-TIJRP (Mighty Junior P). At a community hospital, 225 male and female patients, aged 38 to 90 years, undergoing elective total hip or knee replacement were randomly assigned to 1 of 3 groups (75 patients in each): M, guided imagery, or usual care. They were blinded to their assignment until the intervention.

Main Outcome Measures: Reduction of pain and anxiety postoperatively. Secondary outcomes measured use of pain medication and patient satisfaction.

Results: This study yielded positive findings for the management of pain and anxiety in patients undergoing elective joint replacement using M and guided imagery for 18 to 20 minutes compared with usual care. M showed the largest predicted decrease in both pain and anxiety between groups. There was no significant difference in narcotic pain medication use between groups. Patient satisfaction survey ratings were highest for M, followed by guided imagery.

Conclusion: The benefit of M may be because of the specifically structured sequence of touch by competent caring, trained providers.

INTRODUCTION

Knee and hip arthroplasty causes patients to experience physical and emotional discomfort, most notably pain and anxiety. Joint arthroplasty is associated with substantial postoperative acute pain which, if uncontrolled, decreases early rehabilitation and long-term joint function.¹

Patients facing surgery experience a disarray of emotion and a lack of feeling of control. The anxiety and pain experienced is associated with multi-system dysfunction, including altered cardiovascular-, neurosympathetic-, and endocrine-based responses. The anxiety experienced by patients affects respiration, pulse, and systolic blood pressure during the perioperative process, which may have a negative impact on recovery. Anxiety can slow the recovery process and has been found to be the only significant predictor of pain among patients undergoing total joint arthroplasty.²

Dalury et al³ wrote, “Failure to adequately control pain following total knee replacement induces pathophysiologic responses, which increase postoperative morbidity, hinder physiotherapy, increase anxiety, disrupt sleep patterns, and in general, decrease patient satisfaction and recovery.” According to the Joint Commission, pain is considered to be the “fifth vital sign” and adequate pain control is a “right” for all patients.⁴

Pellino and colleagues⁵ found that the postoperative use of nonpharmacologic measures resulted in the use of less opioid medication on postoperative Days 1 and 2, and patients showed a tendency for less anxiety compared with the usual care group. As perioperative analgesia shifts to integrate the use of complementary therapies into conventional practices, more physicians and nurses are becoming acquainted with various integrative approaches to preemptive analgesia, which have a positive effect in easing the recovery process.

The “M” Technique (M) is a registered method of structured touch created by Jane Buckle, PhD,⁶,⁷ who describes it as a series of gentle, slow, stroking movements done in a set sequence that causes the person being touched (receiver) to experience a greater sense of relaxation. The focus on repetitive sequences signals select areas of the brain, resulting in anxiety reduction and induction of prolonged relaxation.⁸ This gentle touch technique was developed for critically ill, fragile, or dying individuals, making it...
a valuable intervention in hospital and hospice settings. The level of pressure was confirmed by patients as a 3, with 10 being the deepest pressure.

In contrast to M, traditional massage, including light and rhythmic massage, provides no definition of pressure and aims to enhance blood and lymph flow. The anthropomorphic approach, including but not limited to rhythmic massage, complements the innate healing of the body using different hand techniques for different parts of the body to achieve different outcomes—without a clearly defined universal approach. M distinguishes itself from other massage techniques by using structured touch performed in a set pattern, sequence, and speed that never changes while involving the receiver in determining a consistent level of pressure.

Guided imagery describes any of various mind-focused techniques ranging from visualization and direct imagery-based suggestion through metaphor and storytelling. It affects almost all major physiologic control systems of the body, including respiration, heart rate, and blood pressure. Guided imagery has been shown to be an effective intervention for the reduction of anxiety and pain in surgical patients, also resulting in the decreased use of narcotic medications, which in one study was a decrease of nearly 50%. Antall and Kresevic note that guided imagery creates feelings of empowerment and relaxation, decreases anxiety and pain, increases endorphins, decreases blood loss, and decreases the use of pain medications in patients undergoing coronary artery bypass graft. A positive influence was also noted on recovery outcomes, pain, psychological well-being and patient satisfaction, distress, and length of stay. A study performed in patients undergoing total joint arthroplasty found guided imagery decreased levels of anxiety and pain at each time; however, the findings did not achieve overall significance between the groups.

Guided imagery affects the autonomic balance of the body by refocusing the mind, resulting in physiologic relaxation by lowering sympathetic and increasing parasympathetic nervous system response through neurochemical and peptide changes. This intervention through a created vision of healing and relaxation is personalized, having an influence on emotions and effects on the limbic system and neuroendocrine axis. According to Gonzales and colleagues, “These connections between emotions and the modulation of pain support the theory that higher anxiety may affect an individual’s perception and coping with the pain experience.”

The authors of this study present the results of the “M” Technique, Guided Imagery, or Usual Care on Anxiety and Pain Pre- & Post-operatively in Elective Joint Replacement Patients” (M-TIJRP) study (ClinicalTrials.gov Identifier NCT01874379). On the basis of a literature review and the needs of patients undergoing elective hip and knee replacement surgery, the authors investigated the following hypotheses as primary and secondary outcome measures:

1. M and guided imagery would have an impact on the anxiety and pain of patients undergoing elective knee and hip replacements. Specifically at least half of the patients in each treatment group would experience at least a 50% decrease in anxiety and a 25% decrease in pain.

2. Both interventions would result in reduced use of pain medication and improvement of patient satisfaction scores.

**METHODS**

The study sample consisted of 225 patients scheduled for initial or subsequent elective hip or knee replacement surgery at Saint Clare’s Health System in Denville, NJ. Eligibility criteria included adults older than age 18 years undergoing elective knee or hip replacement who agreed to participate in the study regardless of medications or existing medical conditions. Hospital demographic analysis has shown a population consisting of 81% white, 9% Asian, 3% black, 1% American Indian, and 6% other race or ethnicity. Patients were excluded from the study if they presented with an active infection or open wound in the extremities, were unable to perceive touch in the hands and feet (eg, peripheral neuropathy), had an aversion to touch (expressed desire not to be touched or did not want to be touched), were not primarily English speaking, or did not have the ability to adequately understand a normal spoken voice (as defined by the Saint Clare’s Health System Audiology Department). During established “Patient Education for Total Hip or Total Knee Replacement” classes, patients were presented with the study plan. Patients who volunteered to be part of this study and met the criteria signed an informed consent form at the end of class.

Western institutional review board approval was obtained. The staff was introduced to the study design, interventions, and administration of the anxiety and pain scales. Care was taken that patients did not feel rushed when completing the survey.

The effect of specific interventions of M and guided imagery on anxiety and pain was studied using a controlled randomization method for all intervention groups through use of blinded envelopes containing the group letter A, B, or C, which were mixed and then drawn randomly. After administration of the initial Numeric Visual Anxiety Scale (NVAS), Pain Numeric Rating Scale (PNRS), and Hamilton Anxiety Scale, the assigned intervention groups were revealed.

M was performed on the hands and the feet for 18 to 20 minutes, with touch equally distributed among available extremities, paralleling the length of the guided imagery audio program and the duration of massage shown to be most effective at anxiety and pain reduction in previously reported studies. The level of pressure rendered in M is always 3 on a scale in which the maximum pressure is 10 as perceived by the recipient.

The eight state-licensed massage therapists who participated in this study were trained in the consistent administration of Jane Buckle’s “M” Technique of the Hand and Foot and the use of the guided imagery equipment, and were familiar with patient intervention scripts. Each practitioner “settled” into the intent of the intervention, setting a relaxed tone and ensuring the patient’s comfort and centeredness to honor the mind and energy of the recipient.

The guided imagery program selected was Guided Meditation for Procedures or
Surgery, created by Diane Tusek, RN, BSN. This selection was based on multiple opinions of reviewers noting it to be the most soothing and versatile, with less clinical and affirmation-focused dialogue.

This study was designed to integrate and evaluate M and guided imagery interventions in addition to usual care at 4 specific times during the hospital stay using the NVAS for anxiety and the PNRS for pain, administered before and after interventions. The Hamilton Anxiety Scale was administered at the same time as the NVAS before the first intervention and after the last intervention to validate findings with the NVAS. The 8 data points for collection were before and after the 4 intervention times: preoperative Day 0; postoperative Day 0, postoperative Day 1; and postoperative Day 2. A patient satisfaction questionnaire was completed at the time of discharge.

The potential for interruptions during the therapeutic intervention was explained to the patient beforehand. In addition, the massage therapist stated, “We may experience an interruption during this intervention, as this is being performed in a real-life scenario.”

Study Design

Figure 1 shows the study design.

**Preoperative Day 0**

After the same-day surgery nurse prepared the patient for surgery, permission and consent was secured from the patient. The massage therapist administered the NVAS and PNRS, followed by the Hamilton Anxiety Scale for all 3 groups. For Group A (M group), M was then administered to the patient’s hands and feet for 18 to 20 minutes, with touch equally divided between extremities according to availability. Any hand or foot accessed by intravenous lines was avoided. For Group B (guided imagery group), the therapist then instructed the patient on the guided imagery protocol and provided the patient with headphones and an MP3 player using 2 tracks for preoperative guided imagery. The massage therapist monitored proper placement of headphones on the study patient, started the audio recording, and ensured that the volume was comfortable.

After interventions for Groups A and B, the NVAS and PNRS were administered after a pause of 30 to 60 seconds. For Group C (usual care group), the NVAS and PNRS were administered after an 18- to 20-minute wait. All documentation for interventions was recorded on individualized worksheets.

**Postoperative Day 0**

Once the patients were settled back into their rooms immediately after surgery and had been seen by the physical therapist for the first time, the massage therapist returned to administer the assigned intervention and the anxiety and pain scales before and after the intervention, consistent with the methods on preoperative Day 0.

**Postoperative Days 1 and 2**

Assigned interventions were performed after the first physical therapy session of the day. The Hamilton Anxiety Scale was administered to all groups on postoperative Day 2 after the final intervention, along with the NVAS and the patient satisfaction survey.

The primary objectives of this study were to determine if the M and guided imagery groups experienced a larger decrease in anxiety and pain than the usual care group, and to compare the two interventions. The usual care group was not anticipated to achieve the same extent of pain and anxiety decreases. These objectives were focused on intervention times 1 through 4 as previously described, and the assessment points for anxiety and pain.
were labeled as 1 through 8 surrounding intervention times.

The secondary objectives of this study were as follows: 1) to examine the trends of use of pain medication in all 3 groups and 2) to determine group patient satisfaction with their hospital experience as measured through a hospital preapproved patient satisfaction survey.

STATISTICAL ANALYSES

A sensitivity analysis assessment was done to determine the minimal detectable effect size with a sample size of 225, a power of 0.80, and an α level of 0.05. The model that was investigated is an analysis of covariance (ANCOVA) model with a main effect of treatment (ie, the effect of interest) with 3 covariates (eg, preintervention score on the outcome of interest, surgery type, and the type of medication used). As the ANCOVAs differed only by the outcome variable and the intervention point, only 1 sensitivity analysis was necessary to determine the minimal detectable effect. The result of this sensitivity analysis, performed by a free statistical power analysis software (G*Power 3; Heinrich Heine Universität; Düsseldorf, Germany), was that given the study design, an \( \eta^2 = 0.04 \) could be detected with 0.80 power. An \( \eta^2 \) is calculated as the sum of squares treatment divided by the sum of squares total.

A separate ANCOVA was performed for each of the pre- and postintervention measurements using difference scores for pain and anxiety, resulting in 8 analyses. In addition, analysis was also performed to compare the initial preoperative Day 0 measurement with the final postoperative Day 2 measurement for both pain and anxiety. This was performed to determine whether the amount of pain and anxiety decreased over the duration of the study and to assess variation according to the patient’s treatment group. This resulted in 10 separate ANCOVA analyses.

The predictors included in each of these analyses were the preintervention score on the outcome of interest, group, surgery type, and amount of medication used. These predictors were retained in the ANCOVA model regardless of their statistical significance, with significant predictors being presented and interpreted. (Full analysis of variance [ANOVA] tables are available from the authors on request.) All p values were corrected using the Bonferroni stepdown adjustment, accounting for all the p values involving group pairwise comparisons. This resulted in 30 comparisons: 3 for each of the 10 analyses. The 3 comparisons were M vs guided imagery, M vs usual care, and guided imagery vs usual care. The full list of adjusted and unadjusted p values is provided in Table 1. The covariates were excluded in the multiplicity control because they were not included in the family of tests. The family of tests is concerned only with all possible pairwise comparisons of the 3 groups; thus, the familywise error rate is controlled by employing the Bonferroni stepdown procedure. Descriptive statistics for all 8 of the pain and anxiety measurements are presented in Tables 2 and 3, and in graph form in Figures 2 and 3. For demonstration of the convergent validity of the NVAS with the Hamilton Anxiety Scale, the Hamilton Scale was also investigated using the ANCOVA.

### Table 1. Adjusted and unadjusted p values for pairwise comparisons

<table>
<thead>
<tr>
<th>Mean comparison</th>
<th>Outcome</th>
<th>Unadjusted</th>
<th>Bonferroni stepdown adjustment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pain</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group A-B</td>
<td>Preoperative Day 0 pre- vs postintervention</td>
<td>&lt; 0.0001</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Group A-C</td>
<td>Preoperative Day 0 pre- vs postintervention</td>
<td>&lt; 0.0001</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Group B-C</td>
<td>Preoperative Day 0 pre- vs postintervention</td>
<td>0.001</td>
<td>0.0188</td>
</tr>
<tr>
<td>Group A-B</td>
<td>Postoperative Day 0 pre- vs postintervention</td>
<td>0.0041</td>
<td>0.0648</td>
</tr>
<tr>
<td>Group A-C</td>
<td>Postoperative Day 0 pre- vs postintervention</td>
<td>&lt; 0.0001</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Group B-C</td>
<td>Postoperative Day 0 pre- vs postintervention</td>
<td>0.0075</td>
<td>0.1056</td>
</tr>
<tr>
<td>Group A-B</td>
<td>Postoperative Day 1 pre- vs postintervention</td>
<td>0.0537</td>
<td>0.5369</td>
</tr>
<tr>
<td>Group A-C</td>
<td>Postoperative Day 1 pre- vs postintervention</td>
<td>&lt; 0.0001</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Group B-C</td>
<td>Postoperative Day 1 pre- vs postintervention</td>
<td>0.0007</td>
<td>0.0135</td>
</tr>
<tr>
<td>Group A-B</td>
<td>Postoperative Day 2 pre- vs postintervention</td>
<td>0.0844</td>
<td>0.7599</td>
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<tr>
<td>Group A-C</td>
<td>Postoperative Day 2 pre- vs postintervention</td>
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<td>&lt; 0.0001</td>
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<tr>
<td>Group B-C</td>
<td>Postoperative Day 2 pre- vs postintervention</td>
<td>0.0115</td>
<td>0.1498</td>
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<tr>
<td>Group A-B</td>
<td>Postoperative Day 0 vs postoperative Day 2</td>
<td>0.434</td>
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<tr>
<td>Group A-C</td>
<td>Postoperative Day 0 vs postoperative Day 2</td>
<td>0.2885</td>
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<tr>
<td>Group B-C</td>
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<td>0.7841</td>
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<td><strong>Anxiety</strong></td>
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<td>Group A-B</td>
<td>Preoperative Day 0 pre- vs postintervention</td>
<td>0.0059</td>
<td>0.0884</td>
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<tr>
<td>Group A-C</td>
<td>Preoperative Day 0 pre- vs postintervention</td>
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<td>&lt; 0.0001</td>
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<tr>
<td>Group B-C</td>
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<td>&lt; 0.0001</td>
<td>&lt; 0.0001</td>
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<td>&lt; 0.0001</td>
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<td>Group B-C</td>
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<td>0.0227</td>
<td>0.273</td>
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<td>Group A-B</td>
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<td>Group A-C</td>
<td>Postoperative Day 1 pre- vs postintervention</td>
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<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Group B-C</td>
<td>Postoperative Day 1 pre- vs postintervention</td>
<td>&lt; 0.0001</td>
<td>&lt; 0.0001</td>
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<tr>
<td>Group A-B</td>
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<td>0.4169</td>
<td>1</td>
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<tr>
<td>Group A-C</td>
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<td>&lt; 0.0001</td>
<td>&lt; 0.0016</td>
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<td>Group B-C</td>
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<td>0.0016</td>
<td>0.0276</td>
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<tr>
<td>Group A-B</td>
<td>Postoperative Day 0 vs postoperative Day 2</td>
<td>0.5122</td>
<td>1</td>
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<td>Group A-C</td>
<td>Postoperative Day 0 vs postoperative Day 2</td>
<td>0.0401</td>
<td>0.4406</td>
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<tr>
<td>Group B-C</td>
<td>Postoperative Day 0 vs postoperative Day 2</td>
<td>0.1605</td>
<td>1</td>
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</tbody>
</table>

* These p values reflect application of the opioid equianalgesic conversion table. 

* Group A = “M” Technique; Group B = guided imagery; and Group C = usual care.
The secondary outcome of pain narcotic use was analyzed using ANOVA. An ANOVA was run with the main effects of group and medication. There was no need to define the medication type as a predictor because all medication dosages were calculated using an opioids-equianalgesic dosage conversion table. The ANOVA analysis was performed to determine if there were mean differences on patient satisfaction between the groups. All analyses were performed using SAS 9.2 software (SAS Institute Inc, Cary, NC).

RESULTS
A total of 225 patients were enrolled between November 2012 and June 2014. There were 75 participants randomly assigned to each intervention group. The study sample was 33.9% men (n = 76) and 66.1% women (n = 148). Of this sample, 31.3% (n = 70) underwent hip replacement, and 68.7% (n = 154) had knee replacement. Of the 4 intervention times for the 3 groups, there were 32 missed intervention times (14 for each of the intervention groups and 4 for the usual care group) because of various circumstances (eg, received late from recovery, patient refusal, adverse weather conditions, patient transfer requiring a higher level of care). This number reflects only 2% of the total number of points measured and thus is considered inconsequential.  

All participants assigned to a group were used in the analysis except one in the usual care group. Only three patients who took nonnarcotic medication were not included in the analyses. Otherwise, there was no attrition throughout the study, and there was no harm or unintended effects in any group.

Anxiety
The preintervention measure of anxiety and the group were significant predictors for the anxiety difference scores on the 4 measurement occasions (preoperative Day 0, postoperative Day 0, postoperative Day 1, and postoperative Day 2). The general trends for the group were also the same although the pattern of statistical significance varied across the measurement occasions. The M group experienced the largest anxiety decreases, followed by guided imagery, which was followed by usual care. The initial levels of anxiety and group were significant predictors of the difference score on preoperative Day 0. Larger baseline anxiety resulted in larger predicted anxiety decreases, B = -0.375, p < 0.0001, and partial η² (η²p) = 0.296. With use of the Bonferroni stepdown corrected p values, the M and guided imagery groups were predicted to experience significantly greater decreases in anxiety than the usual care group (p < 0.0001 and p < 0.0001, respectively; Table 1). Overall, the model explained 50.4% (adjusted R² = 0.504) of the difference score variance, F(3,202) = 43.078, p < 0.0001.

On postoperative Day 0, larger preintervention anxiety scores also resulted in larger predicted anxiety decreases, B = -0.375, p < 0.0001, and partial η² (η²p) = 0.296. With use of the Bonferroni stepdown corrected p values, the M and guided imagery groups were predicted to experience significantly greater decreases in anxiety than the usual care group (p < 0.0001 and p < 0.0001, respectively; Table 1). Overall, the model explained 50.4% (adjusted R² = 0.504) of the difference score variance, F(3,202) = 43.078, p < 0.0001.

There were no explicit expectations regarding the beginning and end of the study, but the corresponding proportion of patients had a percentage change larger than 50%.

### Table 2. Proportion of participants in each treatment group who experienced 25% pain decrease

<table>
<thead>
<tr>
<th>Mean difference</th>
<th>No.</th>
<th>Proportion who met the criterion</th>
<th>Average change, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guided imagery</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Pain 2-Pain 1</td>
<td>51</td>
<td>0.235</td>
<td>-26.6</td>
</tr>
<tr>
<td>Pain 4-Pain 3</td>
<td>55</td>
<td>0.200</td>
<td>-12.9</td>
</tr>
<tr>
<td>Pain 6-Pain 5</td>
<td>63</td>
<td>0.222</td>
<td>-25.3</td>
</tr>
<tr>
<td>Pain 8-Pain 7</td>
<td>55</td>
<td>0.309</td>
<td>-34.5</td>
</tr>
<tr>
<td>Pain 8-Pain 1</td>
<td>50</td>
<td>0.620†</td>
<td>-31.1</td>
</tr>
<tr>
<td>“M” Technique</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain 2-Pain 1</td>
<td>59</td>
<td>0.542</td>
<td>-53.0</td>
</tr>
<tr>
<td>Pain 4-Pain 3</td>
<td>63</td>
<td>0.349</td>
<td>-30.9</td>
</tr>
<tr>
<td>Pain 6-Pain 5</td>
<td>64</td>
<td>0.313</td>
<td>-36.1</td>
</tr>
<tr>
<td>Pain 8-Pain 7</td>
<td>63</td>
<td>0.587</td>
<td>-50.2</td>
</tr>
<tr>
<td>Pain 8-Pain 1</td>
<td>58</td>
<td>0.724‡</td>
<td>-50.3</td>
</tr>
<tr>
<td>Usual care</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain 2-Pain 1</td>
<td>52</td>
<td>0.019</td>
<td>2.2</td>
</tr>
<tr>
<td>Pain 4-Pain 3</td>
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<td>0.020</td>
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</tr>
<tr>
<td>Pain 6-Pain 5</td>
<td>64</td>
<td>0.078</td>
<td>-4.1</td>
</tr>
<tr>
<td>Pain 8-Pain 7</td>
<td>54</td>
<td>0.037</td>
<td>-7.0</td>
</tr>
<tr>
<td>Pain 8-Pain 1</td>
<td>53</td>
<td>0.679</td>
<td>-20.1</td>
</tr>
</tbody>
</table>

* Pain 2-Pain 1 surrounds preoperative Day 0, Pain 4-Pain 3 surrounds postoperative Day 0, etc.
* Negative numbers indicate a decrease while positive numbers indicate an increase in pain.
* There were no explicit expectations regarding the beginning and end of the study, but the corresponding proportion of patients had a percentage change larger than 25%.

### Table 3. Proportion of participants in each treatment group who experienced 50% anxiety decrease

<table>
<thead>
<tr>
<th>Mean difference</th>
<th>No.</th>
<th>Proportion who met the criterion</th>
<th>Average change, %</th>
</tr>
</thead>
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<tr>
<td>Guided imagery</td>
<td></td>
<td></td>
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<tr>
<td>Anxiety 2-Anxiety 1</td>
<td>65</td>
<td>0.431</td>
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<tr>
<td>Anxiety 4-Anxiety 3</td>
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<td>38</td>
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<td>Anxiety 8-Anxiety 7</td>
<td>45</td>
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<td>-51.9</td>
</tr>
<tr>
<td>Anxiety 8-Anxiety 1</td>
<td>64</td>
<td>0.906‡</td>
<td>-78.7</td>
</tr>
<tr>
<td>“M” Technique</td>
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<td></td>
<td></td>
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<tr>
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<td>67</td>
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<tr>
<td>Anxiety 8-Anxiety 1</td>
<td>66</td>
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<td>-85.0</td>
</tr>
<tr>
<td>Usual care</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Anxiety 2-Anxiety 1</td>
<td>62</td>
<td>0.016</td>
<td>5.4</td>
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<td>Anxiety 4-Anxiety 3</td>
<td>37</td>
<td>0.000</td>
<td>4.3</td>
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<td>Anxiety 6-Anxiety 5</td>
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<td>0.121</td>
<td>-0.7</td>
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<tr>
<td>Anxiety 8-Anxiety 7</td>
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</tr>
<tr>
<td>Anxiety 8-Anxiety 1</td>
<td>62</td>
<td>0.655‡</td>
<td>-76.3</td>
</tr>
</tbody>
</table>

* Anxiety 2-Anxiety 1 surrounds preoperative Day 0, Anxiety 4-Anxiety 3 surrounds postoperative Day 0, etc.
* Negative numbers indicate a decrease while positive numbers indicate an increase in anxiety.
* There were no explicit expectations regarding the beginning and end of the study, but the corresponding proportion of patients had a percentage change greater than 50%.
The improvement over the entire span of the study (baseline to postoperative Day 2 after intervention) did not follow a similar pattern of results. The only significant predictor was the level of preoperative Day 0 anxiety. Larger anxiety scores on preoperative Day 0 were associated with more improvement throughout the study. Although there was significant improvement during the course of the study, the group was not a significant predictor of the amount of improvement during the study period. This model explained 52.9% of the variance in the postoperative Day 2 difference scores, $F_{5,205} = 76.573, p < 0.0001$.

### Pain

The preintervention measure of pain and the group were significant predictors for the pain difference scores on the 4 measurement occasions (preoperative Day 0, postoperative Day 0, postoperative Day 1, and postoperative Day 2). The predictors also showed the same trend for each of the measurement occasions; larger amounts of pain at the initial measurement on a particular day resulted in larger predicted pain decreases. The general trends for the group were also the same, although the pattern of statistical significance varied across the measurement occasions. The M group experienced the largest pain decreases, followed by guided imagery, which was followed by usual care. The statistics for each measurement occasion are presented in detail here.

Significant predictors of pain difference score on preoperative Day 0 were the initial levels of pain as well as the group. Specifically, larger baseline pain resulted in larger predicted pain decreases, $B = -0.169 p < 0.0001$, and $\eta^2_p = 0.136$. With use of the Bonferroni stepdown corrected $p$ values, the M group was found to experience significantly greater decreases in pain than the guided imagery or usual care group ($p < 0.0001$ and $p < 0.0001$, respectively; Table 1). Overall, the model explained $36.70\%$ (adjusted $R^2 = 0.3670$) of the difference score variance, $F_{5,202} = 25.034, p < 0.0001$.

On postoperative Day 0, larger preintervention pain scores also resulted in larger predicted pain decreases, $B = -0.091, p = 0.0014$, and $\eta^2_p = 0.050$. On this occasion, the M group experienced significantly larger
decreases in pain than did the usual care group (p < 0.0001). The overall model explained 18.8% of the variance in the difference scores, $F_{5,197} = 10.345, p < 0.00001$. Postoperative Day 1 had the same pattern of results; for each additional unit increase in the preintervention pain measurement on postoperative Day 1, the amount of improvement increased by 0.141, $B = -0.141, p < 0.0001$, and $\eta^2_p = 0.087$. Both the M and guided imagery groups had significantly larger improvements than did the usual care group (p < 0.0001 and 0.00135, respectively) but were not significantly different from one another. This model explained 18.9% of the variance in the postoperative Day 1 difference scores, $F_{5,207} = 10.884, p < 0.0001$. The postoperative Day 2 results followed a similar pattern, with larger preintervention pain scores predicting larger decreases in pain, $B = -0.303, p < 0.0001$, and $\eta^2_p = 0.237$. The only group differences in this situation were that the M group improved significantly more than the usual care group did. This model explained 30.6% of the variance in the postoperative Day 2 difference scores, $F_{5,205} = 19.561, p < 0.0001$. The improvement during the entire span of the study (baseline to postoperative Day 2 after intervention) did not follow a similar pattern of results. Significant predictors were the type of surgery (knee vs hip; knees improved less, $B = 0.818, p = 0.0192$, $\eta^2_p = 0.039$), amount of medication used ($B = 0.021, p = 0.0051$, $\eta^2_p = 0.039$), and the baseline pain score ($B = -0.811, p < 0.0001$, $\eta^2_p = 0.550$). Specifically, the more medication taken resulted in less improvement, and those who had higher initial pain values were predicted to improve more. Although there was significant improvement over the course of the study, group was not a significant predictor of the amount of improvement over the study duration. This model explained 58.0% of the variance in the postoperative Day 2 difference scores, $F_{5,200} = 57.573, p < 0.0001$.

Secondary Analyses
With use of the Hamilton Anxiety Scale-derived difference scores as the outcome, the only significant predictor of the difference scores was the Hamilton scale's initial score ($B = -0.595, p < 0.0001$). The amount of medicine taken, type of surgery, and group were not related to the Hamilton Anxiety Scale's difference scores. This model explained 40.4% of the variance of these difference scores, $F_{5,204} = 29.360, p < 0.0001$. These results were very similar to the beginning vs the end-of-the-study results for the NVAS. The only significant predictor of the anxiety change from the beginning to the end of the study was the initial anxiety level ($B = -0.772, p < 0.0001$).

The amount of medicine taken, type of surgery, and group were not significant predictors of the NVAS. This model explained 64.8% of the variance in the NVAS difference scores. Statistically significant correlations between the Hamilton Anxiety Scale and NVAS measures at the beginning and end of the study also provided evidence for convergent validity of the 2 measures ($r = 0.592$ and 0.484, $p < 0.0001$, at the beginning and end of the study, respectively).

After using the opioid-equianalgesic dosages conversion table, there was not a significant difference in the amount of opioid medication taken between groups, $F_{2,216} = 1.56, p = 0.213$.

Figure 3. Anxiety means for each of four measurement occasions separated by group.

GI = guided imagery; M = “M” Technique; pre = preintervention; post = postintervention; UC = usual care.
A 1-way ANOVA was performed for patient satisfaction, and findings revealed that there were significant differences between the groups, $F_{2,214} = 30.75, p < 0.05$. Specifically, the M group had higher satisfaction scores than the guided imagery or usual care group ($p < 0.0001$), and the guided imagery group had higher satisfaction scores than the usual care group ($p = 0.0003$). This p value was corrected using the Bonferroni stepdown adjustment. The mean satisfaction scores were as follows: 4.784, 4.250, and 3.781 for the M, guided imagery, and usual care groups, respectively. This model explained 21.6% of the variance in the satisfaction outcome.

**DISCUSSION**

The findings in this study demonstrate that M was effective during usual care for significant reduction of both anxiety and pain at nearly all intervention points when incorporated during routine perioperative conditions in patients undergoing elective knee and hip replacement. Accounting for 32 missed interventions did not result in a statistically significant impact on findings. The application of both mind-body (guided imagery) and touch interventions (M) demonstrated significant decreases in anxiety when looking at preoperative-to-discharge comparisons over usual care. M showed significant improvement over both guided imagery and usual care for decreased pain scores at intervention times 1 and 2 and had the largest predicted decreases in anxiety and pain at all intervention points. The only point that an intervention was unsuccessful at decreasing anxiety over usual care was guided imagery at intervention Point 2. This is speculated to have occurred because this intervention point added a variable of persistent effects of anesthesia, which has been linked to greater postoperative pain.

According to Tusek, “… pain is a primary concern of patients, second only to the fear of death…” The beneficial effect of M and guided imagery on pain in our study met expected outcomes and was found to be successful in decreasing pain scores at all intervention points exceeding the usual care group, largely correlating with our findings on anxiety. Other studies have also shown that fear and anxiety are proportionately linked to pain severity in perioperative patients.12,24

We found the use of narcotic pain medication did not vary among groups. These findings are in contrast with those of a study done using guided imagery in patients undergoing major colorectal surgery.11 Additionally, a prospective randomized trial involving 130 patients at the Cleveland Clinic Foundation found that requirements for analgesics were significantly reduced in guided imagery recipients undergoing elective abdominal surgeries.11 Surprisingly, M had no influence on the amount of pain medication used despite showing a greater reduction by global average percentage change and postintervention assessments.

The M group had higher satisfaction scores than both the guided imagery and usual care groups, and the guided imagery group had higher satisfaction scores than the usual care group on discharge. This finding coincides with the results of our primary outcome measures, which demonstrated that M produced the largest predicted decreases in anxiety and pain.

A major strength of this study is the success of applying integrative interventions under routine conditions. This unique aspect using guided imagery and M demonstrates the ability for widespread use of integrative therapies for patients in a variety of health care settings, even those viewed as being associated with high stress. Originally, M was intended for and studied for use in frail, elderly, end-of-life patients. This is, to our knowledge, the first study demonstrating the value of M as a therapeutic measure for the reduction of anxiety and pain in orthopedic patients undergoing elective joint replacement.

In this study, M focused on two of the most sensitive and connected areas of the body: the hands and feet. Stimulation of mechanoreceptors in the hands and the feet may result in pain inhibition by stimulating nonpainful nerve fibers. Noteworthy is that there is a recently discovered type of nerve fiber in the skin, the mechanoreceptive tactile C afferent, which carries signals via afferent pathways to the brain when the skin is stroked gently.22 Further elucidation of these receptors and the conditions under which they are stimulated could help to explain the differences in response to different types of light touch being used. Kinesthetic afferent pathways are also stimulated by skin stretch receptors in addition to normal muscle spindles for limb positioning and movement. It may be important to point out that kinesthetic pathways for the upper limbs ascend to the brain via the posterior columns without relaying in the spinal cord, whereas the lower limb pathways ascend via the Clarke column and the dorsal spinocerebellar tract and require crossover in the spinal cord.23 This information could potentially influence the therapeutic and perceived effect of different pressure levels from varying touch modalities used on the hands, feet, or both. Novel interoceptive receptors, which are 40% responsive to light touch, may play an integral role in patient response.24

Referring to the needs of the older population, the anthropologist Montagu comments, “The most important and neglected of these needs is the need for tactile stimulation.” He also stated that the elderly often have impaired hearing and vision as well as decreased mobility and vitality, which leaves them feeling helpless and vulnerable. However, through the emotional involvement of touch, Montagu25 asserted, we can reach through the isolation and communicate love, trust, affection, and warmth. Touch releases endorphins, peptides, and other neuropeptides that play a role in enhancing relaxation at a deep level via multiple mechanisms. A commonly understood mechanism about the action of endorphins is that they are neuropeptides that have an opioid effect via blocking the release of Substance P, a neurotransmitter known to play a major role in the sensation of pain.
Another explanation for the positive effects that massage or touch therapy has on pain is called the gate-control theory. This theory suggests that the pain signal takes longer to reach the brain than a pressure signal that is stimulated by touch and will “close the gate” to the pain stimulus. A meta-analysis by Moyer et al on massage therapy research suggested that the gate-control theory’s explanation for pain reduction was not supported by the data because of a “... failure to find a significant effect for the immediate assessment of pain ...”. They note that improvement in anxiety and depression resulting from massage therapy may be caused by its influences on body chemistry and the psychological benefit of the therapist-client alliance.

The pain reduction benefit of M seems clearly related to a decrease in anxiety through many potential vehicles, including competent caring, physical comfort, and connectiveness through gentle repetitive motions, a calming touch on emotions, and likely by reasoning an energetic transfer through intention. In our study the benefits of M for anxiety closely parallels the effectiveness rate of traditional psychotherapy. The body’s sensory network connects the physical to the emotional and mental through a complex interplay of nerves and chemicals relayed through the brain as the central feedback filter, implying a multidirectional influence based on the intervention being used and the patient’s individual experience. Evidence that massage therapy reduces pain and anxiety via one or a complex interplay of multiple psychophysiologic factors would reflect on the magnificence of the human construction and imply that there can be multiple approaches taken to obtain similar positive outcomes.

Acknowledging our incomplete understanding of the true nature of mind-body-spirit integration, this study demonstrates that M, a touch-based intervention, does reach multiple levels of a patient’s being and is an effective treatment option for the significant reduction of pain and anxiety in elective knee and hip replacement surgeries. Guided imagery, a mind-based intervention, showed positive outcomes on anxiety and pain reductions most likely by influencing the mind on a deeper or subconscious level.

Many efforts have been made by hospital personnel to ease a patient’s transition through the surgical process. However, these efforts have primarily focused on time management and efficiency on the part of the staff and have not necessarily taken into account the patient’s psychological comfort nor considered the effect this could have on his/her recovery. Patients are often at their most vulnerable just before surgery, with anticipation, elevated stress, and fear, and also immediately afterward when their energy is lower and their bodies are trying to accommodate after an invasive procedure. Concern, fear, and anxiety experienced by family members and friends who are present or even not present also can contribute to the patient’s anxiety. This stress, anxiety, and pain associated with surgery and recovery can increase complication rates and slow recovery times, resulting in longer hospital stays. In the last several years, substantial strides have been made in researching the effects of various integrative and complementary medicine techniques and their positive influence on patient health, including in the operative setting.

Vital signs were not included in this study as a data point because the usual hospital protocol for elective joint replacement is already replete with interruption during the entire recovery phase, resulting in potential stress, anxiety, and frustration. Favorable changes in blood pressure after massage and in systolic blood pressure and heart rate after the use of guided imagery have previously been noted.

Interruptions interfere with the relaxation and healing cycle. Previous studies largely segregated interventions so there were minimal or no interruptions and were less than realistic to the actual situation. Integrative therapies that can be routinely incorporated as part of the normal work flow of perioperative protocols ultimately result in substantial patient benefit using inexpensive, easily learned, and effective tools.

Armstrong et al showed that the combination of massage and guided imagery demonstrated a more pronounced effect on anxiety reduction compared with the massage-only group in a pilot study involving 55 patients undergoing cardiac catheterization. Studies of the importance of choice of integrative intervention could be based on patient response and preference, to either having a single intervention or having both administered in tandem or simultaneously. Future studies could be designed in which these 2 integrative modalities are combined, to determine the potential for synergistic effect. M could be initiated before guided imagery with the intention of engaging the patient through touch into the competent caring process. This would enhance the sense of connection and healing, increase patient comfort, decrease anxiety, and facilitate patient receptiveness to the input of a guided imagery program. A more intriguing possibility would be simultaneous administration of M and guided imagery initiated by brief touch to heighten integration of all the senses. Furthermore, patient selection from various guided imagery audio programs for connectedness with script, voice, and background sounds would likely be shown to be beneficial. Additionally, the use of guided imagery with consistent, uninterrupted administration of the audio program may have enhanced the predicted outcomes of this intervention to the already positive effect that we found in this study. Further investigations between the uses of guided imagery scripting using direct vs open (integrated) suggestion and the difference made by patient involvement in this choice will likely enhance the effects and benefits of this intervention. Guided imagery may possibly have had a better outcome if preparation began several days before the procedure, allowing for stronger brain entrainment. The initiation of integrative adjunctive therapy with M in the immediate preoperative period may also subvert the necessity for advance preparation with the guided imagery program.

Inevitably, data showing increases in patient satisfaction, as seen in this investigation, would improve the reputation of the hospital in the community.
be looked on favorably by insurers, improve staff and patient morale, and solidify the spiritualistic principles underlying humanistic care. Physicians, nurses, and staff who learn these modalities can also use them for themselves for their own health and wellness.

This study did not control for three concepts: intention, belief, and subtle energies. There is a healing intentionality associated with the practitioners who administered M beyond its unique form of structured touch, which is an unwritten part of their protocol. Practitioners “settle” into their routine at the start of the intervention, setting a relaxed tone, ensuring the patient’s comfort and centeredness, which influences the mind and energy of the recipient beyond touch alone. The consistent patient contact and touch alone of M would seem more resonant to the recipient than guided imagery on multiple levels. When a caregiver touches a patient, there is an inherent belief by the recipient that the caregiver “cares” as the recipient perceives the patient-centered competent caring being administered. Competent caring provided during interventions is integral to managing a patient’s anxiety and pain. Competence implies knowledge, skill, and intelligence, whereas caring provides the humanitarian aspect with positive intention and effect. Competent caring provided during interventions is a useful component and contributes to the reduction of anxiety, pain, and fears and the promotion of wellness.32 Extending this intentionality to all members of the health care team could create a more optimum healing environment.

Belief is a powerful factor in one’s perception and effect in response to an intervention. The observation of expressed disappointment by a small number of recipients in the study regarding their own health and wellness.

A potential limitation of the study was that therapists were directly involved in administration of the scales before and after interventions. In this regard, a proactive measure was taken to train all facilitators to a scripted discussion regarding the administration of scales, data collection, and patient satisfaction questionnaire completion. Limited funding also influenced this decision.

The study design did not control for environmental light or noise in Group C patients, as they were intended to represent the standard of care. Likewise, inherent interruptions remained routine for all groups and were not controlled for other than posting a sign indicating the study was in process.

Other limitations included lack of uniformity of the availability of all 4 extremities for M, not accounting for the timing of administration of pain medication in relation to initiation of the interventions, lack of documentation of patient touch sensation in feet postoperatively on Day 0, and expressed disappointment by clients in the randomized group (implying preconceived patient expectations and/or preferences for intervention type).

Data assessment for the comparative group distribution of comorbidities was not included. Because the scope of the study was limited to two days postoperatively, the identification of complications and final outcomes beyond discharge to home or a rehabilitation facility was not captured. Another limitation of the study was the lack of separation of subjects into distinct comparative groups between knee and hip surgery, which was not intended for this investigation.

Future Applications

Replication of this study would probably benefit patient care and obtain similar results. Recommendations for changes in the design include improved demographics of groups investigated, documentation of comorbid conditions, detailed analysis of pain medication use and timing relative to interventions, and additional personnel, not directly involved in interventions, for scale administration. Additionally, this study can be replicated in a community environment (eg, home and clinics), where the technique is taught to caregivers for those in need of adjunctive pain and anxiety relief. Future studies can also include combining touch/energy with mind-body interventions for potential augmentation of positive outcomes.
CONCLUSION

This study is the first we are aware of that demonstrates reduced anxiety and pain using M and guided imagery in patients undergoing elective joint replacement performed under routine conditions. We conclude that the underlying reason for the impressive benefit of M is the use of a specifically structured sequence of touch by the hands of competent caring, trained providers during the intervention process. Touch is an essential part of the competent caring process during an intervention because it is a vehicle for skillful interaction with intention, and it promotes wellness and healing. The creation of a healing, loving environment with intention on the part of all caregivers will help provide optimal patient outcomes and satisfaction.

Disclosure Statement

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References


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Patient Satisfaction after Thoracoscopic Sympathectomy for Palmar Hyperhidrosis: Do Method and Level Matter?

Amy Cheng, MD; Hege Johnsen, MD; Michael Y Chang, MD

ABSTRACT

Context: Although surgery is widely recognized as the best treatment for palmar hyperhidrosis (PH), the decision to perform a sympathectomy, sympathectomy, or clipping of the thoracic sympathetic chain is based on surgeon preference.

Objective: We investigated the outcomes of patients who underwent surgical intervention for PH with regard to method used and level of sympathetic chain interrupted.

Design: This was a retrospective medical chart review. Patients who underwent thoracoscopic intervention for PH were mailed questionnaires regarding their presenting and postoperative symptoms and satisfaction 6 months to 15 years after their procedure. Analyses were performed to investigate whether the surgical method applied affected these outcomes.

Results: A total of 635 patients underwent bilateral thoracoscopic procedures for PH between April 1995 and February 2010, and 210 (33%) responded to the questionnaires. Sixteen surgeons performed 108 sympathectomies, 83 sympathicotomies, and 19 ligations with titanium clips for PH. Mean follow-up was 5.5 years. Overall palmar success was 85.4% and was not affected by the surgical method. The rate of compensatory hyperhidrosis was significantly lower if the operative level did not include the R2 ganglion (66.7% vs 80.6%, p = 0.028). Nevertheless, 76.2% of patients were satisfied with the results, and 85.7% would repeat the procedure if given the option to do it again.

Conclusion: Most patients reported relief of their PH and were satisfied with surgical intervention, regardless of method used. Although postoperative compensatory hyperhidrosis was common, this did not appear to affect overall patient satisfaction.

INTRODUCTION

Primary hyperhidrosis is characterized by idiopathic sweating in excess of that needed for normal thermoregulation. Although not life-threatening, it is often a cause for anxiety during everyday activities such as holding a pen, shaking hands, playing sports, and driving. Primary hyperhidrosis affects between 1% and 3% of the population and occurs equally in men and women. It can present at any age, although it tends to affect predominantly adolescents and young adults. Primary hyperhidrosis can involve sweating of the face, palms, soles, or axillae. Although the pathophysiology remains unclear, it appears to be associated with environmental and emotional triggers. The glands tend to be histologically normal and are innervated by the sympathetic nervous system with acetylcholine as the primary neurotransmitter.

Surgery is generally reserved for those for whom less invasive interventions have failed. The interruption of the thoracic sympathetic chain is widely accepted as the standard surgical treatment for primary palmar hyperhidrosis (PH), and endoscopic thoracic sympathectomy has been widely practiced since Kux introduced the procedure in 1978. Nevertheless, there is no consensus for the optimal technique (sympathectomy, sympathectomy, or clipping), and there is no consensus as to the level of sympathetic chain interruption even among patients with PH alone. The objective of this study was to investigate the outcomes of patients who underwent surgical intervention for PH with regard to method used and level of sympathetic chain interrupted, with particular attention to patient satisfaction and compensatory hyperhidrosis.

METHODS

The study was approved by the institutional review board of our institution (protocol number 5887). A retrospective review was conducted to identify all patients who underwent bilateral thoracoscopic procedures for PH between April 1995 and February 2010. All operations were performed by 16 surgeons whose catchment area included 3.6 million patients within a 12-hospital managed care organization, all of whom are linked by a single electronic health care record and central database registry.

Patients who had thoracoscopic procedures performed for PH during this 15-year period were mailed detailed questionnaires regarding their presenting and postoperative symptoms and satisfaction after their procedure. The questionnaire inquired about the location of the patient's hyperhidrosis both preoperatively and postoperatively and asked the patient to subjectively rate from 1 to 5 the...
degree of sweating preoperatively and postoperatively; the quality of life in regard to writing, holding objects, handshaking, playing sports, wearing sandals, driving, worrying, and ability to tolerate hot or enclosed spaces preoperatively and postoperatively; the overall satisfaction with the procedure; and finally, whether the patient would still undergo the procedure knowing the outcomes. This questionnaire has not undergone formal validation. Of those who responded, the outpatient and inpatient electronic medical records were reviewed, and the abstracted data included patient demographic characteristics, comorbidities, and operative details, including technique and level of interruption of the sympathetic chain. Successful therapy was defined as the reported absence of hyperhidrosis after the surgical procedure in patients who had reported the presence of hyperhidrosis in that area preoperatively.

Operative techniques included sympathectomies (complete division of the sympathetic chain with cautery), sympathectomies (resection of a portion of the sympathetic chain), and ligation with titanium clips. All operations were bilateral procedures performed thorascopically under a single session of general anesthesia. The nomenclature used in this study is rib-based, per the recent recommendations of the Society of Thoracic Surgeons, unless otherwise specified.

The results for the variables are reported as frequency distribution percentage. Statistical analysis was performed using the Fisher exact test (www.graphpad.com). A p value < 0.05 was considered to be statistically significant.

RESULTS

Six hundred thirty-five questionnaires were sent out via US Postal Service, and 210 responses were received. Response rate was 33%. Of those who responded, 71% were women and 29% were men. Mean (standard deviation [SD]) age was 34.5 (12.7) years. Mean (SD) body mass index (calculated as weight in kilograms divided by height in meters squared) was 25.4 (4.96), and 116 (55.2%) identified themselves as white. Only a minority had comorbidities, including hypertension (13 [6.2%]) and diabetes mellitus (5 [2.4%]). Thirty-four respondents (16.2%) had a history of tobacco use. Mean follow-up was 5.5 years.

The operative reports of respondents were reviewed. Sixteen surgeons performed 108 sympathectomies, 83 sympathectomies, and 19 ligations with titanium clips for primary hyperhidrosis. The operative level(s) interrupted were not standardized and ranged from R1 to R8, and this is listed in Table 1. The diagnosis was documented as subjective reporting by the patients.

Of the 210 patients who responded to the survey, 185 reported the presence of PH. Overall palmar success, defined as the resolution of sweating at the palms after the operation, was 85.4% (158 of 185). This was not affected by the surgical method, with 87.6% success (85 of 97) noted after sympathectomies, 81.9% (59 of 72) after sympathectomies, and 87.5% (14 of 16) after ligation with surgical clips (p > 0.05). Nor was this significantly affected by the level interrupted. Success rates ranged from 50% (1 of 2) of surgical procedures that included levels R3 to R5 to 100% (17 of 17) of procedures that included R2 to R4. For those who reported axillary (123 [58.6%]) and/or plantar (138 [65.7%]) hyperhidrosis, the overall success rates were 48.0% (59 of 123) and 18.1% (25 of 138), respectively.

Of the 210 who responded, 155 (73.8%) reported some degree of compensatory hyperhidrosis (CH). The degree of CH was not rated. The presence of CH was not affected by method used (72.2% [78 of 108] after sympathectomies, 77.1% [64 of 83] after sympathectomies, 68.4% [13 of 19] after ligation with clips; p > 0.05). However, the rate of CH was significantly lower if the operative level did not include R2 ganglion interruption (80.6% [87 of 108] vs 66.7% [68 of 102], p < 0.05). This is summarized in Table 2.

Two patients (1%) reported symptoms of Horner syndrome postoperatively. One was a sympathectomy, and the other was a sympathectomy. Both involved the interruption of the R2 ganglion only for the treatment of PH.

Nevertheless, 160 (76.2%) of the 210 patients were satisfied with the results of their surgeries, with ratings of 4 to 5 on the questionnaires. This was not affected by method used, with 75.0% (81 of 108) satisfied after sympathectomies, 74.7% (62 of 83) after sympathectomies, and 89.5% (17 of 19) after ligation with clips (p > 0.05). Of the 210 patients, 180 (85.7%) would repeat the procedure if offered to do it again.

DISCUSSION

Although it is well documented that surgical treatment of primary PH is generally effective and well-tolerated, and studies exists that compare one method to another, few studies sought to look at the outcomes comparing all three commonly used methods of sympathectomy, sympathectomy, or ligation with surgical clips. Our study found no difference in palmar success rates when stratified according to surgical method employed. Furthermore, the surgical method did not affect

### Table 1. Operation details from survey responses

<table>
<thead>
<tr>
<th>Type of operation</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sympathectomy</td>
<td>108 (51.4)</td>
</tr>
<tr>
<td>Sympathectomy</td>
<td>83 (39.5)</td>
</tr>
<tr>
<td>Ligation with clips</td>
<td>19 (9.0)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Rib Levels (R) of interruption</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1-R3</td>
<td>2 (1.0)</td>
</tr>
<tr>
<td>R2 only</td>
<td>36 (17.1)</td>
</tr>
<tr>
<td>R2-R3</td>
<td>28 (13.3)</td>
</tr>
<tr>
<td>R2-R4</td>
<td>17 (8.1)</td>
</tr>
<tr>
<td>R2-R5</td>
<td>25 (11.9)</td>
</tr>
<tr>
<td>R3 only</td>
<td>42 (20.0)</td>
</tr>
<tr>
<td>R3-R4</td>
<td>43 (20.5)</td>
</tr>
<tr>
<td>R3-R5</td>
<td>2 (1.0)</td>
</tr>
<tr>
<td>R3-R8</td>
<td>1 (0.5)</td>
</tr>
<tr>
<td>R4 only</td>
<td>14 (6.7)</td>
</tr>
</tbody>
</table>

*p < 0.05*
CH is the most common side effect after surgical intervention for primary hyperhidrosis, with rates ranging from 3% to 98% in the literature. The most common risk factor cited in the literature for CH appears to be interruption of higher ganglion levels, and in particular R2 ganglion interruption (between R2 and R3). This was also noted in our study, where the rate of CH was significantly higher in operations that included the R2 ganglion (81%) compared with those that did not (67%). Interestingly, the level and the number of levels interrupted did not appear to affect this outcome, although few went higher than the R2 ganglion in their dissection. The method of the interruption did not appear to affect the prevalence of CH, either.

Aoki et al examined the association between the extent of sympathectomy and postoperative CH, PH, and patient satisfaction. In their study of 53 patients, the degree of postoperative PH was not correlated with patient satisfaction. Instead, the severity of CH inversely correlated with the degree of patient satisfaction. It stands to reason that although CH is extremely common and affects almost three-quarters of those who responded to our questionnaires, the severity is likely not severe because most patients (76%) were satisfied with the results of the operation and would repeat the operation if they had to do it all over again (86%).

Our study had some limitations. It was retrospective in design, and therefore randomization was not possible. The response rate was low at 33%. There may be some selection bias although the impact of nonresponse bias has historically been difficult to gauge. All diagnoses were made via patient subjective reporting, thus tending toward recall bias, and it is difficult to quantify and characterize the degree of hyperhidrosis both preoperatively and postoperatively. There was no validated or standardized questionnaire at the time of this study. However, it must be pointed out that since this survey was conducted, there has been the development of the Hyperhidrosis Quality of Life Index (HidroQOL). Finally, there was no standardized technique even within the methods subgroups, and both methods and levels interrupted were determined by the variable practice pattern of each surgeon. However, despite these limitations, our study aimed to include all patients who underwent a thoracoscopic procedure for this subjective disease process and captured the variable practices seen in the community.

CONCLUSION

Most patients reported successful relief of their primary PH with surgical intervention, regardless of method used. Although CH was significant, this did not appear to affect overall patient satisfaction. The inclusion of the R2 ganglion resulted in a significantly increased incidence of CH.
Picturesque Île d’Orléans lies in the middle of La Fleuve Saint-Lawrent (the St Lawrence River), near Quebec City in Quebec, Canada. The entirety of this bountiful island is a designated historic district. The island specializes in agritourism and produces many internationally renowned agricultural and horticultural products.

Dr Levy is a Rheumatologist at the Downey Medical Center in CA.
An Education Program for Patient Self-Management of Warfarin

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ABSTRACT

Introduction: Although improved anticoagulation therapy outcomes have been demonstrated in clinical trials evaluating warfarin patient self-management (PSM) programs, these studies did not provide detailed information regarding PSM program development and patient training.

Objective: To evaluate the feasibility of and methods for developing and administering an education program to support a novel pilot warfarin PSM program.

Methods: Patients receiving warfarin for atrial fibrillation were recruited to participate in a prospective, intervention-only, open-label pilot PSM program that released venipuncture international normalized ratio results to patients via a secure, online Web site. To support the pilot, a warfarin PSM education program with a dosing algorithm was developed and delivered to patients during a two-hour classroom session.

Main Outcome Measure: A comparison of participants’ PSM competency test scores before and after attending the PSM program.

Results: Forty-four patients attended the education program. The mean age of patients was 71 years and 50% were women. Patients declining study participation were older (p = 0.003) and had a greater burden of chronic disease (p = 0.005) than participants. Following PSM training, the mean competency score improved from 55.8% to 88.8% (p < 0.001), and the proportion achieving a passing score increased from 34.9% to 95.3% (p < 0.001). In the poststudy survey, 100% of responders perceived that PSM training prepared them to self-manage warfarin, and 92.9% of responders were comfortable changing warfarin doses on their own.

Conclusion: Developing and administering a warfarin PSM education program for patients with atrial fibrillation was feasible. Improvement in PSM competency and high levels of self-reported comfort with warfarin PSM were identified.
The Clinical Pharmacy Anticoagulation and Anemia Service (CPAAS) at Kaiser Permanente Colorado (KPCO) provides comprehensive anticoagulation management services for approximately 9000 members. Blood for INR measurement is obtained by venipuncture at any of the 27 KPCO medical office laboratories without appointment. The results of INR testing are then reported to the ordering CPAAS practitioner through an electronic medical record and are simultaneously viewable by patients via a secure online messaging system. Traditional anticoagulation management by CPAAS in this model has demonstrated improved INR control and a reduction in the rate of anticoagulation therapy-related adverse events. Several small studies have demonstrated that PSM of warfarin results in INR control that is equivalent to that of specialized anticoagulation clinics, which indicates that this model could potentially be used in a large specialized anticoagulation service such as CPAAS. Although intensive intervention will always be required for complex and nonadherent patients, other models of anticoagulation management for relatively stable patients may benefit both patients and anticoagulation management staff.

The purpose of this study was to evaluate the feasibility and methods of developing and administering an education program to support a novel pilot warfarin PSM program whereby patients manage their own warfarin therapy using INRs measured from blood drawn by venipuncture at a medical office laboratory.

**METHODS**

**Study Design and Setting**

This was a descriptive study examining the feasibility and methods of developing and administering training for a warfarin PSM education program. The PSM pilot study occurred in two phases. The focus of this report is on the first phase, which consisted of developing the education program and recruiting and educating patients regarding warfarin PSM. The recruitment and training of patients occurred between January 2011 and February 2011. The second phase evaluating warfarin PSM outcomes is described in a separate report. Approval from the KPCO institutional review board was obtained for all study phases.

At KPCO, venipuncture-acquired INR results are routed electronically to the managing CPAAS pharmacist for assessment and clinical decision making. The patient is then informed of the INR result, the dose of warfarin to take, and the next INR assessment date via letter, telephone, or a secure online Web site (My Health Manager). My Health Manager allows patients to have access to health information, such as laboratory results, and to communicate via secure electronic mail with health care practitioners.

**Study Participants**

Eligible patients were 1) at least age 18 years; 2) receiving warfarin therapy for atrial fibrillation with 5 mg tablets, a goal INR range of 2.0 to 3.0, and at least 6 months of treatment before study recruitment; 3) willing to provide written informed consent; and 4) able to access My Health Manager. Patients were excluded if they 1) had a planned surgery/invasive procedure during the 3-month study period; 2) missed more than one ordered INR test within the 6 months before enrollment; 3) resided in a skilled nursing, assisted living, or long-term care facility; 4) had planned time away from the KPCO service area for more than 7 consecutive days during the 3-month study period; 5) had a gap in Health Plan membership exceeding 30 days in the 6 months before enrollment; 6) were non-English speaking; or 7) were deemed inappropriate for study participation by CPAAS program (eg, memory impairment, difficulty following instructions). To simplify development of a warfarin dosing algorithm, patients were also excluded if their warfarin dose was < 17.5 mg or > 70 mg per week.

**Study Outcomes**

The primary outcome was the education and competency assessment components of the program could be used to successfully train consenting participants in warfarin PSM. Training was deemed successful if the proportion...
An Education Program for Patient Self-Management of Warfarin

of patients demonstrating PSM competency increased after the PSM education phase. Secondary outcomes included the assessment of participants’ perceptions of education program quality and ease of use of the warfarin dosing algorithm after completion of the 3-month PSM pilot phase. Characteristics of patients who agreed or declined to participate in the pilot were also compared.

Patient Self-Management Training Development Process

A warfarin PSM dosing algorithm consisting of three paper-based visual aids was developed. These aids consisted of a Dosage Management Card (Figure 1), a Dosage Adjustment Card (Figure 2), and a Weekly Schedule Card (Figure 3). These dosing aids were incorporated into a step-by-step PSM process as follows: 1) determining the total weekly warfarin dose in milligrams; 2) using the Dosage Management Card and current INR to determine how much to adjust the dose (0% to 20%) and when to obtain the next INR; 3) using the Dosage Adjustment Card to determine new weekly dose in milligrams; 4) using the Weekly Schedule Card to determine daily doses; and 5) relaying therapeutic plans to CPAAS pharmacists via a secure electronic message using My Health Manager. During the PSM training, patients learned how to use worksheets detailing the step-by-step process as an aid in dosing management decisions (Figure 4).

A warfarin PSM competency assessment was developed and consisted of multiple-choice and short-answer questions. Four multiple-choice questions assessed knowledge of 1) the effect of vitamin K on INR, 2) recognizing and managing warfarin drug interactions, 3) distinguishing between serious and common bleeding complications, and 4) managing missed warfarin doses. Six short-answer questions assessed the following competencies: 1) adjusting warfarin doses on the basis of a low, slightly elevated, and significantly elevated INR; and 2) determining when to obtain a follow-up INR for each of these scenarios.

After providing informed consent, participants attended a 2-hour live training session before commencement of PSM. The competency test was administered to assess baseline knowledge before receiving education. During training, a slide presentation facilitated education regarding 1) warfarin; 2) obtaining INR results through My Health Manager; 3) adjusting warfarin doses using the 5-step process described above; 4) managing warfarin drug and dietary interactions; 5) managing missed warfarin doses; 6) responding to symptoms of bleeding and stroke; and 7) relaying therapeutic plans to CPAAS pharmacists using My Health Manager. Participants applied these principles to case-based problems, adjusting warfarin doses for various INRs, and making decisions on the basis of missed doses or drug/food interactions. At the end of the training session, the competency test was readministered with those participants achieving a score of at least 70% eligible to continue on to the PSM phase of the study.

Data Collection

Data regarding baseline patient characteristics for participants and nonparticipants were obtained via administrative data queries and included age, sex, risk factors for stroke and bleeding, time in therapeutic range during the 90-day pre-invitation phase, and length of time since enrollment in CPAAS. Information regarding household annual income and college education was collected administratively. A Chronic Disease Score, a measure of chronic illness burden, was calculated for all participants using administrative data from their pharmacy purchases in the six months before study enrollment.17,38

A postpilot survey aimed at assessing participant perceptions of the adequacy of the PSM training program was administered at the end of the PSM phase of the study using an online survey tool. This survey consisted of open-ended questions and 6 questions using a 5-point Likert-type scale with 1 being “Do Not Agree At All” and 5 being “Agree Completely.” A response of 4 or 5 was considered to be in agreement with the statement in question. The questions assessed the participants’ perceptions on 1) the quality of the

![Figure 3. Weekly schedule card](image)

INR = international normalized ratio; tab = tablet.

![Figure 4. Warfarin self-management worksheet/checklist](image)
An Education Program for Patient Self-Management of Warfarin

training class and dosing cards and worksheets; 2) whether they were prepared for adjusting warfarin doses and managing drug interactions; 3) whether they understood more about warfarin after attending the class; and 4) class size.

**Data Analysis**

Descriptive statistics were used to summarize baseline characteristics. Pre- and posteducation session mean test scores and the proportion of participants who achieved a passing test score were compared using a paired \( t \) test and McNemar’s test, respectively. Differences in baseline patient demographic characteristics between participants and nonparticipants were compared using the \( \chi^2 \) test of association or Fisher exact test and Wilcoxon rank sum test, as appropriate. Alpha was set at 0.05. SAS, version 9.1.3 (SAS Institute, Cary, NC), statistical software was used for analyses.

**RESULTS**

Of 506 patients screened for enrollment, 167 were eligible to participate and 44 (26.3%) consented to enroll in the study.

**Table 1. Patient characteristics by participation status**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Participant (n = 44)</th>
<th>Nonparticipant (n = 123)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (median, SD)*</td>
<td>70.6 (71, 6.9)</td>
<td>74.6 (75, 8.1)</td>
<td>0.003</td>
</tr>
<tr>
<td>Female sex, n (%)</td>
<td>22 (50)</td>
<td>52 (42)</td>
<td>0.424</td>
</tr>
<tr>
<td>Risk factors, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prior thromboembolism</td>
<td>1 (2)</td>
<td>3 (2)</td>
<td>0.951</td>
</tr>
<tr>
<td>Prior stroke</td>
<td>1 (2)</td>
<td>5 (4)</td>
<td>0.584</td>
</tr>
<tr>
<td>Prior bleed</td>
<td>3 (7)</td>
<td>15 (12)</td>
<td>0.324</td>
</tr>
<tr>
<td>Cancer</td>
<td>1 (2)</td>
<td>3 (2)</td>
<td>0.951</td>
</tr>
<tr>
<td>Diabetes</td>
<td>6 (14)</td>
<td>24 (20)</td>
<td>0.384</td>
</tr>
<tr>
<td>Heart failure</td>
<td>4 (9)</td>
<td>21 (17)</td>
<td>0.203</td>
</tr>
<tr>
<td>Hypertension</td>
<td>18 (41)</td>
<td>66 (54)</td>
<td>0.147</td>
</tr>
<tr>
<td>Mean family income in $ for the patient’s Census Block (median $, SD)^c</td>
<td>68,126 (63,634; 24,450)</td>
<td>66,559 (63,917; 23,871)</td>
<td>0.810</td>
</tr>
<tr>
<td>Mean percentage of persons in the patient’s Census Block with at least some college education (median %, SD)^d</td>
<td>25 (26, 5)</td>
<td>24 (24, 6)</td>
<td>0.839</td>
</tr>
<tr>
<td>Mean percentage of INRs in therapeutic range (median %, SD)^d</td>
<td>79 (78, 20)</td>
<td>80 (80, 18)</td>
<td>0.572</td>
</tr>
<tr>
<td>Mean length of time in days since enrollment in CPAAS (median days, SD)^e</td>
<td>1760 (1379, 1408)</td>
<td>1663 (1481, 1181)</td>
<td>0.981</td>
</tr>
<tr>
<td>Mean Chronic Disease Score (median, SD)</td>
<td>6.7 (6, 2.5)</td>
<td>8.0 (8, 2.6)</td>
<td>0.005</td>
</tr>
</tbody>
</table>

*As of January 19, 2011.
*Diagnosed in a medical office from July 1, 2010, through January 19, 2011.
*Based on 2010 census data.
*From laboratory results drawn in the 90 days before January 19, 2010.

CPAAS = Clinical Pharmacy Anticoagulation and Anemia Service; INR = international normalized ratio; SD = standard deviation.
(Figure 5). Participants in the PSM training were younger (70.6 vs 74.6 years, \( p = 0.003 \)) and had lower mean Chronic Disease Score (6.7 vs 8.0, \( p = 0.005 \)) but were otherwise similar to nonparticipants (Table 1).

A total of 13 two-hour training sessions were conducted to train the 44 participants. Class sizes ranged from 1 to 8 participants with 1 to 3 study team members present at each session. The mean pretest score was 55.8% (±19.5%) with only 15 participants (34.9%) achieving a passing score. One participant voluntarily withdrew from the study before taking the posteducation competency test and two participants voluntarily withdrew consent after successfully completing the posteducation competency test but before beginning the PSM phase of the study. After attendance at the PSM training program the absolute improvement in competency test scores and participants achieving a passing score were 33.0% and 60.4%, respectively (\( p < 0.01 \) for both) (Table 2).

Twenty-eight of 39 (71.8%) participants completed the anonymous online survey assessing their perceptions of the training program and/or materials (Table 3). The majority of participants expressed favorable impressions of the training program. Preference for group vs one-on-one training sessions was mixed with a slight majority favoring group sessions.

**DISCUSSION**

We developed and implemented a program to train patients in warfarin PSM and successfully enrolled and trained 26.3% of eligible patients. Our program differed from other warfarin PSM programs in that INR results were acquired via venipuncture instead of POC devices and results were conveyed to participants using a secure online messaging system. Only one other small PSM pilot study utilizing venipuncture-based INR testing has been published to date.\(^4\) In that study INR results were relayed to patients via mail or in person.\(^4\) Such methods delay receipt of INR results compared with our study, where INR results from our secure online messaging system were released in real time.

Notably, the rate of eligible patients who enrolled in our study was similar to prior POC-based studies, suggesting that using venipuncture-based INR testing did not substantially increase acceptability of warfarin PSM.\(^19\) However, our findings do indicate that PSM using venipuncture INRs conveyed to patients via a secure online messaging system can be a viable method of warfarin therapy management for carefully selected patients provided these patients receive thorough PSM training.

For our pilot, study participation was limited by relatively strict inclusion and exclusion criteria. We studied only one indication for warfarin therapy using a single warfarin tablet strength to simplify development of the training material and dosing visual aids. Patients also were required to be active users of the secure online KPCO messaging system, further limiting our pool of eligible study participants. However, this criterion provided our pilot with patients who had access to their INR results the same day the test was performed, thus providing rapid INR results analogous to POC INR testing.

In addition, because the most common reason for exclusion from our pilot was having missed more than one INR test in the previous six months, eligible patients were generally adherent to the demands of warfarin therapy monitoring.

We noted differences between patients who agreed to participate in the study and those declining participation. Participants were slightly younger and had lower burden of chronic disease than those who did not participate. We are unaware of any other PSM studies that compared patients agreeing and declining to participate; however, one study found that patients who completed PSM training were younger and more educated than patients who did not complete training.\(^20\) Patients responded positively to the training program; however, on the basis of the post-PSM survey, the portion of the PSM training focusing on management of drug interactions could be improved.

A potential barrier to widespread use of PSM is the initial time investment in training patients. Fifty-two study-staff hours were required to train 44 patients in PSM using our training method (including obtaining informed consent). Although current guidelines suggest classes with 3 to 6 participants,\(^9,10\) we found success with class sizes ranging up to 8 participants. Compared with PSM studies using POC machines, our program appeared to require less training.
time, probably in part because training patients to use POC devices for INR measurement was not required. In the future, to reduce the time commitment involved in PSM training, technology could be leveraged to create a Web-based PSM training program that patients could easily access from home. This would remove the need for patient travel and trainer travel and might decrease the time required to train patients in PSM. Providing opportunities for patients to ask questions in a Web-based training program might be challenging but could be achieved by using a live Webinar format. Although limited data exist for using Webinars for patient education, available data suggest that it may be a viable option. 11

There were several limitations to our study. Because this was a pilot, the sample size was small and a control group was not employed. The external validity of our results may be influenced by the study setting and the requirement for access and ability to use a computer with Internet access. However, secure online messaging systems are becoming more common in integrated health care models, and according to 2013 US Census data, 74.4% of households have Internet access with this number steadily increasing over time. 22 To this end, only 49 patients screened for our study did not meet inclusion criteria because they were not active on My Health Manager.

CONCLUSION

Developing and administering a focused education program and dosing algorithm for warfarin PSM using venipuncture INR results released through a secure Web site is feasible. The results of this pilot study may be used to inform the design of a randomized, controlled trial of this intervention compared with usual care practices.

Disclosure Statement

The authors of this article have no conflicts of interest to disclose. This study was funded by the Kaiser Permanente Colorado Pharmacy Department.

Acknowledgment

Mary Corrado, ELS, provided editorial assistance.

References

11. Simmons BJ, Jenner KM, Delate T, Clark NP, Kurz D, Witt DM. Pilot study of a
Safely Increase the Minimally Invasive Hysterectomy Rate: A Novel Three-Tiered Preoperative Categorization System Can Predict the Difficulty for Benign Disease

Esteban Andryjowicz, BScPhm, MD, FACOG; Teresa B Wray, MD, FACOG; V Reinaldo Ruiz, MD, FACOG; James Rudolf, MD, FACOG; Sara Noroozkhani, MD, FACOG; Sandra Crowder, MD, FACOG; Jeff M Slezak

ABSTRACT

Context: A nonlaparotomic route is recommended for hysterectomy for benign indications.

Objective: 1) Predict the difficulty of hysterectomy to treat benign disease as measured by operative time and risk of laparotomy, 2) confirm the safety and quality of increasing our minimally invasive hysterectomy (MIH) rate, and 3) determine whether the assistant’s experience affected the likelihood of an MIH being performed in equally difficult hysterectomies.

Design: All hysterectomies for benign disease performed at the Kaiser Permanente Fontana Medical Center in Fontana, CA, in 2012 were reviewed for length of surgery, length of stay, complications, and readmissions. A three-tiered category system was developed from four preoperative parameters (body mass index, number of vaginal deliveries, clinical uterine size, and history of major abdominal surgery) to anticipate length and difficulty of surgery.

Main Outcome Measures: Rates of MIH, complications, and readmissions as well as length of surgery and length of stay for similarly difficult hysterectomies. These outcomes were compared with surgeons’ and assistants’ experience.

Results: Of 576 hysterectomies performed for benign disease, 89% were MIH with a 3% complication rate and 4% readmission rate. An increase in the hysterectomy category was statistically significantly associated with longer surgery times and a higher percentage of laparotomy. With the most experienced assistants, the MIH rate was 98%.

Conclusions: Using 4 preoperative parameters, the average operating time for hysterectomy for benign disease can be predicted. A higher hysterectomy category predicts a more difficult surgery. Our center has increased its MIH rate to 89% while maintaining safety.

INTRODUCTION

Approximately 600,000 hysterectomies are performed annually in the US.¹ In 1998, approximately 65% of hysterectomies were performed via laparotomy, and in 2010, this rate went down to 54.2%.² Both the American College of Obstetricians and Gynecologists³ and Advancing Minimally Invasive Gynecology Worldwide⁴ have recommended a minimally invasive route (nonlaparotomic) for hysterectomy for benign disease. Andryjowicz and Wray⁵ demonstrated how the Southern California Permanente Medical Group reached a 78% rate of minimally invasive hysterectomy (MIH), across 13 Medical Centers involving more than 350 general gynecologists performing 4000 hysterectomies yearly for benign indications. This was achieved with education and expert mentoring. With a continued increase in MIH at our Medical Center, we wanted to ensure that safety and quality were maintained. It is more important than ever to be excellent stewards of our health care resources in this time of emphasis on value in health care.

The ability to determine how difficult a hysterectomy will be and to estimate the time required to perform it would enable a gynecologic practice to enhance surgeon and assistant pairing and operating room (OR) utilization as well as recognize the increased skills needed for the more difficult surgeries. Time in the OR is an expensive commodity, estimated to be more than $30 a minute at our Medical Center. Underbooking or overbooking cases is costly to the system in both dollars and stress on staffing. It also inconveniences patients waiting longer for elective surgeries if ORs are underutilized.

From a review of surgical case times at our Medical Center, across multiple specialties, we believed we could reduce the time between the closing incision at the end of one case to the start of the next case incision to 65 minutes for hysterectomies for benign disease. We chose this metric over the well-known “out of room to into room” because it better describes what the surgeon sees as the total nonoperating time in an OR. In our all-day surgical block, the first case was to be on the OR table by 7:15 am with a time for the surgeon’s incision by 7:55 am, and the last case was expected to be closed by 5 pm. This allowed 545 minutes of total OR time for the day, which would include the nonoperating close to incision time of 65 minutes between cases.
Several factors have been shown individually to affect the difficulty of performing a hysterectomy for benign disease. We combined four of these factors to preoperatively predict the length and difficulty of surgery.

A lack of history of vaginal delivery has been shown to increase the length of the surgical procedure, although it may or may not increase the complication rate, and it does not change the length of stay (LOS) or the readmission rates. An increasing uterine size also has been shown to increase the operative time, complication rates, and surgical conversions from MIH to laparotomy. With increasing body mass index (BMI), there is an increase in length of surgery, but no major increased risk of conversion from an MIH to laparotomy or of LOS, complications, or readmissions. A history of laparotomies increases the risk of conversion from vaginal hysterectomy to laparotomy, which can increase the length of surgery and the number of complications. Surgeon experience and volume of surgery can affect operating time, complication rates, risk of conversion from MIH to laparotomy, LOS, costs, and surgical approach taken for hysterectomy for benign disease.

The more experienced gynecologists at our Medical Center are able to predict the difficulty, and therefore the length of time required to perform a hysterectomy for benign disease, although this skill is not universal. They frequently arrange for an experienced assistant when difficult surgery is anticipated, again not universally. We sought to develop a method to help our gynecologists identify the more challenging cases so that they could both book longer OR time and arrange a more experienced assistant to improve their MIH rates while maintaining safety. Additionally, if all the cases for the day were anticipated to be of shorter duration, an extra case could be booked to improve efficiency.

The aims of this study were:
1. to predict the difficulty of hysterectomy for benign disease, measured by operative time and risk of laparotomy
2. to confirm the safety and quality of increasing the MIH rate by comparing complication and readmission rates with the literature
3. to determine if the assistant’s experience affected the likelihood of an MIH.

METHODS

This study was approved by the Kaiser Permanente Southern California (KPSC) institutional review board and was carried out at Kaiser Permanente Fontana Medical Center in Fontana, CA, 1 of 14 KPSC Medical Centers. In 2012, Fontana Medical Center provided services to approximately 430,000 patients. There were 39 general obstetrician-gynecologists performing hysterectomies for benign disease. We arbitrarily labeled the 19 clinicians having less than 3 years of consultant experience as junior. The 2 clinicians with extensive MIH experience were labeled senior, and the 18 clinicians with experience between these 2 levels were labeled midlevel. In 55 cases a resident physician from Loma Linda University was the primary assistant.

For type of hysterectomy performed, standard definition was used for total abdominal hysterectomy. Hysterectomy included the following:
- Laparoscopic-assisted vaginal hysterectomy: most cases included uterine artery coagulation via laparoscopy
- Vaginal hysterectomy
- Total laparoscopic hysterectomy: most removed vaginally
- Minilaparotomy: a 4- to 5-cm or smaller incision for removal of the specimen
- No robotic-assisted hysterectomies were carried out during the study period.

Minilaparotomy was classified as an MIH-type procedure. It has been shown that minilaparotomy for hysterectomy is better than laparotomy but not as good as the laparoscopic approach as related to morbidity and LOS. In our 21 cases with minilaparotomy for removal of the specimen, 19 patients went home by morning, and the highest pain score during their stay was less than 5 of 10 on a visual analog scale, with morbidity similar to any other MIH procedure.

All hysterectomies for benign disease performed in 2012 were identified from discharge codes (International Classification of Diseases, Ninth Revision): 68.41, 68.49, 68.51, and 68.59. These electronic medical records were then individually reviewed by the authors (each author reviewed about 120 charts) to remove all oncology cases, as well as any cases with add-on procedures planned other than cystoscopy. Outcome measures reviewed included length of surgery in minutes (incision to close), LOS in hours (out of room to out of hospital), complications, and readmissions before the 4-week postoperative visit. Other parameters reviewed included surgeon-assistant pairing as well as the patient’s BMI, medical history, surgical history, obstetric history, estimated uterine size, and actual uterine weight. Operative notes, discharge summaries, and notes from the first postoperative office visit were reviewed as well as the notes section in the electronic medical record to look for any other admission and discharge summaries after the initial surgical date. Follow-up was from 3 to 14 months postoperatively at the time of data collection.

We categorized hysterectomy for benign disease into Category 1, 2, or 3 depending on 4 preoperative parameters:
1) clinical uterine size (equivalence by weeks of gestation, a common gynecologic descriptive to indicate the size of a nonpregnant uterus), 2) BMI, 3) number and type of previous major abdominal surgeries (defined as cesarean delivery; hernia repair; appendectomy; myomectomy; bariatric; bowel; or endometriosis surgery), and 4) number of vaginal deliveries.

Table 1 demonstrates how the categories were defined and how many hysterectomies were in each category. Category 1 included a uterine size equivalent to or less than 12 weeks’ gestation, a BMI less than 30 kg/m², up to 1 previous laparotomy, and at least 1 vaginal delivery. Category 2 included 1 or 2 of the following factors: clinical uterine size of greater than 12 weeks but less than 18 weeks, a BMI of 30 to 40 kg/m², 2 or 3 prior major abdominal surgeries, and no prior vaginal deliveries. If there were 3 Category 2 items, the patient moved up to Category 3. Category 3 also included those with any one of the
following: a clinical uterine size 18 weeks or greater, BMI greater than 40 kg/m\(^2\), or 4 or more prior major abdominal surgeries.

All surgeons were encouraged to categorize their hysterectomies preoperatively and to be proactive in obtaining an assistant with the appropriate level of experience. The OR schedulers were also encouraged to use categorization and their knowledge of the surgeons and assistants to notify the Chief of the Department (TBW) when there seemed to be a mismatch between difficulty of surgery and surgeon-assistant pairing. When a mismatch was identified, a gynecologist more experienced in MIH was moved in to assist. However, this did not occur in all cases because of scheduling conflicts or simple oversight. The entire group was aware of the availability of the senior clinicians for the most difficult cases. In our center, the surgeon and assistant each tend to perform about half of the surgery (ie, their side of the hysterectomy). Educational rounds and expert mentoring were the primary methods used to improve our MIH rates safely.

Patient characteristics were described using percentages or the mean and standard deviation (SD). Statistical analysis to assess differences among patient characteristics and surgical measures between procedure types or categories was performed using the Kruskal-Wallis test for continuous measures and the \(\chi^2\) test for categorical factors. The number and percentage of MIH surgeries by combination of surgeon and assistant were tabulated. Multivariate linear regression was used to assess the association of preoperative factors with length of surgery. Logistic regression was used to assess the likelihood of MIH by surgeon and assistant. As senior surgeons performed only MIH in 2012, they were excluded from the model. Logistic regression was also used to assess the likelihood of MIH by surgeon and assistant when adjusting for surgical category and in the subset of Category 3 surgeries. Statistical analysis was performed using SAS 9.2 (SAS, Cary, NC). All tests were 2-sided, and \(p\) values of less than 0.05 were taken to indicate statistical significance.

**RESULTS**

There were 576 hysterectomies for benign disease carried out at the Fontana Medical Center in 2012, with an overall 89% MIH rate. Table 2 shows the number of each type of MIH.

Figure 1 shows the association of category with type of hysterectomy performed. As the category increased, the percentage of MIH decreased from 98% in Category 1 to 91% in Category 2 to 77% in Category 3. The odds ratio to perform MIH for Category 2 vs 1 was 0.21 (confidence interval = 0.06-0.70) and for Category 3 vs 1 was 0.06 (confidence interval = 0.02-0.20), both significantly reduced.

Table 3 reviews the type, number, and percentages of complications and readmissions, with a total rate of 4% complications and 3% readmissions. One ureteric injury was identified 1 week postoperatively and was repaired 2 months later, with no long-term sequelae.

Table 2 compares the various types of hysterectomy performed. It demonstrates that there were significant differences between the type of hysterectomy performed and uterine weight, previous major abdominal surgery and vaginal delivery, with no significant difference related to BMI. There

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**Table 1. Patient characteristics of the categories of hysterectomy (N = 576)**

<table>
<thead>
<tr>
<th>Category</th>
<th>Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category 1: All of below items (n = 140)</td>
<td></td>
</tr>
<tr>
<td>BMI, kg/m(^2)</td>
<td>&lt; 30</td>
</tr>
<tr>
<td>Major abdominal surgery, no.</td>
<td>≤ 1</td>
</tr>
<tr>
<td>Clinical uterine size, weeks</td>
<td>≤ 12</td>
</tr>
<tr>
<td>Vaginal delivery, no.</td>
<td>≥ 1</td>
</tr>
<tr>
<td>Category 2: 1 or 2 of below items (n = 279)</td>
<td></td>
</tr>
<tr>
<td>BMI, kg/m(^2)</td>
<td>30-40</td>
</tr>
<tr>
<td>Major abdominal surgery, no.</td>
<td>2-3</td>
</tr>
<tr>
<td>Clinical uterine size, weeks</td>
<td>&gt;12 - &lt;18</td>
</tr>
<tr>
<td>Vaginal delivery, no.</td>
<td>0</td>
</tr>
<tr>
<td>Category 3: Any of below items (n = 157)</td>
<td></td>
</tr>
<tr>
<td>BMI, kg/m(^2)</td>
<td>&gt; 40</td>
</tr>
<tr>
<td>Major abdominal surgery, no.</td>
<td>&gt; 3</td>
</tr>
<tr>
<td>Clinical uterine size, weeks</td>
<td>≥ 18</td>
</tr>
<tr>
<td>Total Category 2 items</td>
<td>3 or 4</td>
</tr>
</tbody>
</table>

BMI = body mass index; n = number of hysterectomies performed in each category.

---

**Table 2. Comparison factor by type of hysterectomy (N = 576)**

<table>
<thead>
<tr>
<th>Factor</th>
<th>LAVH (n = 409)</th>
<th>VH (n = 68)</th>
<th>TLH (n = 14)</th>
<th>Minilaparotomy (n = 21)</th>
<th>TAH (n = 44)</th>
<th>TAH from conversion (n = 20)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean BMI, kg/m(^2) (SD)</td>
<td>31 (7)</td>
<td>30 (7)</td>
<td>32 (8)</td>
<td>32 (8)</td>
<td>32 (7)</td>
<td>33 (6)</td>
<td>0.51</td>
</tr>
<tr>
<td>Mean uterine weight, g (SD)</td>
<td>241 (203)</td>
<td>157 (89)</td>
<td>220 (158)</td>
<td>1112 (620)</td>
<td>755 (916)</td>
<td>843 (1421)</td>
<td>&lt;0.0001*</td>
</tr>
<tr>
<td>Previous major abdominal surgery, no. (%)</td>
<td>202 (49)</td>
<td>13 (19)</td>
<td>10 (71)</td>
<td>9 (43)</td>
<td>23 (52)</td>
<td>13 (61)</td>
<td>&lt;0.0002*</td>
</tr>
<tr>
<td>Vaginal delivery, no. (%)</td>
<td>294 (72)</td>
<td>67 (98)</td>
<td>5 (36)</td>
<td>6 (29)</td>
<td>19 (43)</td>
<td>9 (39)</td>
<td>&lt;0.0001*</td>
</tr>
<tr>
<td>Mean incision-close, minutes (SD)</td>
<td>121 (48)</td>
<td>70 (25)</td>
<td>156 (62)</td>
<td>229 (63)</td>
<td>121 (40)</td>
<td>192 (75)</td>
<td>&lt;0.0001*</td>
</tr>
<tr>
<td>Mean length of stay, hours (SD)</td>
<td>19 (12)</td>
<td>24 (10)</td>
<td>27 (20)</td>
<td>24 (10)</td>
<td>67 (27)</td>
<td>64 (38)</td>
<td>&lt;0.0001*</td>
</tr>
<tr>
<td>Complication, no. (%)</td>
<td>11 (2)</td>
<td>3 (4)</td>
<td>1 (7)</td>
<td>0 (0)</td>
<td>2 (4)</td>
<td>7 (35)</td>
<td>&lt;0.0001*</td>
</tr>
<tr>
<td>Readmission, no. (%)</td>
<td>11 (2)</td>
<td>3 (4)</td>
<td>0 (0)</td>
<td>1 (5)</td>
<td>2 (4)</td>
<td>0 (0)</td>
<td>0.999</td>
</tr>
</tbody>
</table>

* Statistically significant at \(p < 0.05\).

BMI = body mass index; LAVH = laparoscopic-assisted vaginal hysterectomy; SD = standard deviation; TAH = total abdominal hysterectomy; TLH = total laparoscopic hysterectomy; VH = vaginal hysterectomy.
The highest and for laparotomy was 52 kg/m^2. The combination of surgeon and assistant is shown in Table 6. The effect of midlevel assistants. The likelihood of MIH based on the completeness of previous laparotomies for a patient undergoing MIH was 6, and for laparotomy it was 4. Of the 20 conversions to laparotomy, 18 originated as laparoscopic-assisted vaginal hysterectomy (4.4% of all laparoscopic-assisted vaginal hysterectomies performed) and 2 originated as vaginal hysterectomy (2.9% of all vaginal hysterectomies).

Table 4 compares the categories of hysterectomy. As expected from the criteria used to categorize, Category 1 had the smallest uteri, lightest patients, lowest percentage of previous major abdominal surgeries, and the highest percentage of previous vaginal deliveries. Category 3 was at the other end of the spectrum, and Category 2 was in-between. All these were statistically significant differences (Table 4). There were also statistically significant differences found in length of surgery and LOS, but not in complication or readmission rates.

Category 1 hysterectomies lasted approximately 1.5 hours; Category 2, approximately 2 hours; and Category 3, approximately 2.5 hours. The mean LOS increased from 20 (SD = 19) hours for Category 1 to 23 (SD = 18) hours for Category 2 and to 32 (SD = 25) hours for Category 3 (p < 0.0001). However, if one looks at the MIH procedures only, the increase in LOS was much smaller, from 18 (SD = 10) hours for Category 1 to 19 (SD = 12) hours for Category 2 and 23 (SD = 14) hours for Category 3, and did not reach statistical significance (p = 0.088). Category 3 simply had a larger percentage of open cases (23%) with their expected longer LOS.

Senior surgeons performed only MIH during the year (meaning no planned laparotomies or surgical conversions in 2012), whereas for midlevel and junior surgeons, 88% of the hysterectomies they performed were MIH. Table 5 reviews the rates of MIH depending on surgeon and assistant experience. For both junior and midlevel surgeons, their rates of MIH were below 85% when paired with a junior assistant and above 95% when paired with a senior assistant, with rates in-between for midlevel assistants. The likelihood of MIH based on the combination of surgeon and assistant is shown in Table 6. The effect of the surgeon’s experience between junior and midlevel was not significant. Also, there was no difference when a junior or resident was assisting. However, both junior and midlevel surgeons were somewhat more likely to perform MIH if paired with a midlevel assistant and greatly more likely to perform MIH if paired with a senior assistant, compared with a junior assistant.

Table 7 shows the impact of surgeon-assistant pairing on likelihood of MIH accounting for the difficulty (difficulty) of the surgery. Although higher categories were associated with a significantly lower odds of MIH, more experienced assistants were still associated with a significantly greater likelihood of MIH. In the Category 3 hysterectomies (most complex and least likely to be performed in a minimally invasive fashion), only the surgeries with senior assistants were significantly more likely to be performed as an MIH compared with those procedures with junior assistants.

**DISCUSSION**

Using categorization, we find that we can accurately predict difficulty of hysterectomy for benign disease, and thus accurately determine allocation of OR time and the need for assistance from an experienced surgeon with excellent MIH rates. In addition, we confirm the safety, quality, and efficiency of our 89% MIH rate with a complication and readmission rate of 4% and 3% respectively, consistent with rates from a recent review.*

Importantly, categorization of hysterectomy allows for more accurate research comparisons. We can now look to

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**Table 3. Complications and readmissions of hysterectomy for benign disease (N = 576)**

<table>
<thead>
<tr>
<th>Complication type</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bladder injury</td>
<td>9 (1.6)</td>
</tr>
<tr>
<td>Transfusion</td>
<td>8 (1.4)</td>
</tr>
<tr>
<td>Repeat surgery same admission</td>
<td>4 (0.7)</td>
</tr>
<tr>
<td>Ureter injury (1 week postoperative)</td>
<td>1 (0.2)</td>
</tr>
<tr>
<td>Ileus needing hospitalization</td>
<td>1 (0.2)</td>
</tr>
<tr>
<td>Bowel injury</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Total</td>
<td>23 (4.0)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Readmission reason</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaginal vault bleeding</td>
<td>1 (0.2)</td>
</tr>
<tr>
<td>Abscess</td>
<td>3 (0.5)</td>
</tr>
<tr>
<td>Hematoma</td>
<td>1 (0.2)</td>
</tr>
<tr>
<td>Fever</td>
<td>1 (0.2)</td>
</tr>
<tr>
<td>Wound infection</td>
<td>2 (0.3)</td>
</tr>
<tr>
<td>Bowel obstruction</td>
<td>2 (0.3)</td>
</tr>
<tr>
<td>Ureter repair</td>
<td>1 (0.2)</td>
</tr>
<tr>
<td>Pain</td>
<td>1 (0.2)</td>
</tr>
<tr>
<td>Pulmonary embolism</td>
<td>1 (0.2)</td>
</tr>
<tr>
<td>Cardiac disease</td>
<td>1 (0.2)</td>
</tr>
<tr>
<td>Urine retention with renal failure</td>
<td>1 (0.2)</td>
</tr>
<tr>
<td>Abscess, fever, and hematoma</td>
<td>1 (0.2)</td>
</tr>
<tr>
<td>Abscess, fever, IR drain, vesicovaginal fistula, and vaginal repair 2 months later</td>
<td>1 (0.2)</td>
</tr>
<tr>
<td>Total</td>
<td>17 (3.0)</td>
</tr>
</tbody>
</table>

IR = placed by Interventional Radiology.
find the best MIH procedure for length of surgery, short-term and long-term morbidity, LOS, readmissions, total costs, return-to-work timing, and patient satisfaction. We can also investigate the surgeon’s and assistant’s contribution to these outcomes. At some point, this method could also be used for determining relative value unit decisions related to hysterectomies for benign disease, recognizing the increased effort required to perform more complex surgeries. We as surgeons are the stewards of a major component of health care costs, and it is imperative that we maximize our value at the same time as we improve our surgical outcomes.

By using 4 preoperative parameters, the approximate surgical time for a hysterectomy for benign disease can be predicted. Identification of more difficult cases (Category 3) has allowed a proactive scheduling of cases with more experienced MIH assistants in most, but not all, cases. In our center of 39 general gynecologists, with 49% having less than 3 years of consultant experience, 576 hysterectomies were performed for benign indications, with an 89% MIH rate. With increasing category, there was a significant decrease in MIH overall.

These parameters were chosen because they were obtainable preoperatively and had individually been shown in the literature to affect surgical time and possibly LOS, complications, or readmissions. A review of these parameters follows with data related to any effects on hysterectomy.

Vaginal Delivery History

The medical literature was reviewed for studies that evaluated the effect of nulliparity or lack of vaginal delivery on hysterectomy and outcomes. Although most hysterectomy studies use parity as one of several case-control factors, very few directly compared nulliparous with parous outcomes. Most of the nulliparous patient studies were designed to refute the long-held belief that vaginal hysterectomy is contraindicated when there is no history of vaginal delivery. This has been done with great success and is well documented in the literature. Two studies have identified an increased length of surgery in the nulliparous patient compared with the parous patient. There was no difference in LOS postoperatively between nulliparous and parous patients having similar procedures. Regarding complications in nulliparous vs parous patients at hysterectomy, there are mixed reports in the literature. Two studies reported higher complication rates in the nullipara, and one study reported no difference in complication rates between nulliparous and parous patients. One study showed no difference in hospital readmission rates between nulliparous and parous patients after laparoscopic-assisted vaginal hysterectomy.

Uterine Size

Laparoscopic hysterectomy can be performed safely even in the presence of a large uterus, yet studies have reported complications such as bladder injury and ureteric injury directly related to uterine size. Some surgeons set an upper limit to uterine size when considering a laparoscopic approach to hysterectomy, of usually 15 to 16 weeks’ gestation or a weight of 500 g because of higher risk of bowel and urinary tract injury as well as hemorrhage.

### Table 4. Comparison factor by category of hysterectomy (N = 576)

<table>
<thead>
<tr>
<th>Factor</th>
<th>Category 1 experience (n = 140)</th>
<th>Category 2 experience (n = 279)</th>
<th>Category 3 experience (n = 157)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean BMI, kg/m² (SD)</td>
<td>26 (3)</td>
<td>31 (5)</td>
<td>36 (8)</td>
<td>&lt; 0.0001*</td>
</tr>
<tr>
<td>Mean uterine weight, g (SD)</td>
<td>162 (94)</td>
<td>250 (208)</td>
<td>586 (790)</td>
<td>&lt; 0.0001*</td>
</tr>
<tr>
<td>Previous major abdominal surgery, no. (% of category)</td>
<td>32 (23)</td>
<td>139 (50)</td>
<td>99 (63)</td>
<td>&lt; 0.0001*</td>
</tr>
<tr>
<td>Vaginal delivery, no. (% of category)</td>
<td>140 (100)</td>
<td>199 (71)</td>
<td>62 (39)</td>
<td>&lt; 0.0001*</td>
</tr>
<tr>
<td>Mean incision to close, minutes (SD)</td>
<td>96 (43)</td>
<td>122 (54)</td>
<td>146 (61)</td>
<td>&lt; 0.0001*</td>
</tr>
<tr>
<td>Mean length of stay, hours (SD)</td>
<td>20 (19)</td>
<td>23 (18)</td>
<td>32 (25)</td>
<td>&lt; 0.0001*</td>
</tr>
<tr>
<td>Complication, no. (% of category)</td>
<td>5 (4)</td>
<td>8 (3)</td>
<td>7 (4)</td>
<td>0.768</td>
</tr>
<tr>
<td>Readmission, no. (% of category)</td>
<td>4 (3)</td>
<td>7 (3)</td>
<td>6 (4)</td>
<td>0.656</td>
</tr>
</tbody>
</table>

* Statistically significant at p < 0.05.

BMI = body mass index; SD = standard deviation.

### Table 5. Surgeon-assistant pairing* and likelihood of MIH

<table>
<thead>
<tr>
<th>Surgeon (N = 576)</th>
<th>Assistant</th>
<th>No MIH, no. (%)</th>
<th>MIH, no. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Junior (n = 250)</td>
<td>Resident</td>
<td>1 (7)</td>
<td>13 (93)</td>
</tr>
<tr>
<td></td>
<td>Junior</td>
<td>10 (18)</td>
<td>45 (82)</td>
</tr>
<tr>
<td></td>
<td>Midlevel</td>
<td>18 (13)</td>
<td>123 (87)</td>
</tr>
<tr>
<td></td>
<td>Senior</td>
<td>1 (3)</td>
<td>39 (97)</td>
</tr>
<tr>
<td>Midlevel (n = 284)</td>
<td>Resident</td>
<td>5 (14)</td>
<td>30 (86)</td>
</tr>
<tr>
<td></td>
<td>Junior</td>
<td>19 (17)</td>
<td>90 (83)</td>
</tr>
<tr>
<td></td>
<td>Midlevel</td>
<td>9 (9)</td>
<td>9 (91)</td>
</tr>
<tr>
<td></td>
<td>Senior</td>
<td>1 (3)</td>
<td>35 (97)</td>
</tr>
<tr>
<td>Senior (n = 42)</td>
<td>Resident</td>
<td>0 (0)</td>
<td>6 (100)</td>
</tr>
<tr>
<td></td>
<td>Junior</td>
<td>0 (0)</td>
<td>15 (100)</td>
</tr>
<tr>
<td></td>
<td>Midlevel</td>
<td>0 (0)</td>
<td>13 (100)</td>
</tr>
<tr>
<td></td>
<td>Senior</td>
<td>0 (0)</td>
<td>8 (100)</td>
</tr>
</tbody>
</table>

* See “Methods” section in the text for an explanation of levels of provider experience.

MIH = minimally invasive hysterectomy.

An increase in operative time and greater estimated blood loss have been observed to parallel increasing uterine size. With greater estimated blood loss, there is also a greater risk of blood transfusion associated with increasing uterine weight. This is true for both abdominal and laparoscopic hysterectomy. Also, an increase in the conversion rate from a laparoscopic approach to an open surgical procedure has been reported with larger uteri.

Body Mass Index

Studies show an increased operative time with larger BMI. Another study showed no statistical difference in the length of surgery in obese patients compared with nonobese patients, but difficult cases were performed by a senior attending physician as opposed to a junior attending or resident. Another study showed no difference in operating time with higher BMI during robotic hysterectomies. There was no change in LOS in obese women undergoing abdominal hysterectomies.

There was no change in the complication rate depending on BMI except for one study indicating an increased...
Safe Increase the Minimally Invasive Hysterectomy Rate: A Novel Three-Tiered Preoperative Categorization System Can Predict the Difficulty for Benign Disease

Surgical Experience and Surgical Volume

A surgeon’s experience and/or volume of surgical cases has been a very difficult area to quantitate, yet can affect the outcomes of hysterectomy. One of many confounding variables is that high-volume surgeons tend to perform more complicated cases and be involved in teaching, which may be a factor in some studies that do not show a correlation with surgical times. On review, three studies showed a decrease in OR times for high-volume surgeons, \(^{26}\) whereas one study showed no significant difference. \(^{26}\) For complications, three studies have shown a reduction in high-volume surgeons, \(^{28-31}\) whereas three other studies showed no difference\(^{29,32,39}\) and one showed a significant decrease over time reflective of volume and experience. \(^{33}\) There was no difference in conversions between high- and low-volume surgeons, but among high-volume surgeons decreased conversions occurred over time. \(^{35}\) A minimally invasive surgical approach was offered more often by high-volume surgeons.\(^{28,34}\) Also, the cost for delivery of surgery was lower for high-volume surgeons, \(^{29,31}\) and the hospital LOS was reduced for high-volume surgeons.\(^{36,32}\)

Even though there were efforts to ensure that all Category 3 cases would have at least 1 member of the surgeon-assistant team be more experienced, we found that in 13% of these cases a junior surgeon was working with either another junior surgeon or a resident. In this subgroup, there was a 38% laparotomy rate. It was interesting to see that placing a senior assistant with any level surgeon significantly improved the likelihood of an MIH in Category 3 cases. Since the beginning of this study, we have found a steady increase in clinician experience in MIH procedures. A scoring system is being developed to quantitate the minimal amount of surgeon-assistant experience needed to take on each category of hysterectomy.

Surgical times, as an element of efficiency and value, affect overall utilization of the operating rooms, and categorization can accurately determine how many cases can be performed in an all-day operating room block. The surgical times of 1.5 hours, 2 hours, and 2.5 hours for Categories 1, 2, and 3, respectively, were significantly different. This creates the opportunity to add additional cases to all-day OR blocks with lower-category hysterectomies, leading to a more efficient strategy for operating room scheduling.

Study Strengths and Limitations

The primary strength of this article is that the authors reviewed all 576 hysterectomies for benign disease performed by 39 general gynecologists during an entire year.

The primary weakness is that this is an observational and retrospective study. We assigned surgeons to junior, midlevel, and senior on the basis of years of surgical experience and volumes of MIH cases performed. The technique for doing our surgeries did not change over the study period and did not require the use of power morcellation. When morcellation was required, it was primarily performed vaginally or via a 4-cm minilaparotomy. We have attempted to improve other perioperative parameters that could affect surgical times but have not found obvious improvement, especially during our study period. We believe that by using our patient characteristics categorization system, our comparisons were looking at equally difficult hysterectomies, thereby removing most bias.

CONCLUSIONS

We demonstrated that categorization of hysterectomies into three categories of complexity enables the surgeon to better predict the difficulty of hysterectomy and to determine the average operating time and the need for experienced surgical assistants while increasing our MIH rates safely and efficiently.

<table>
<thead>
<tr>
<th>Table 6. Likelihood of minimally invasive hysterectomy depending on surgeon and assistant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgeon-assistant pairing</td>
</tr>
<tr>
<td>Surgeon midlevel vs junior, all categories</td>
</tr>
<tr>
<td>Assistant resident vs junior, all categories</td>
</tr>
<tr>
<td>Assistant midlevel vs junior, all categories</td>
</tr>
<tr>
<td>Assistant senior vs junior, all categories</td>
</tr>
<tr>
<td>*Statistically significant at p &lt; 0.05. CI = confidence interval.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 7. Likelihood of minimally invasive hysterectomy depending on category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgeon-assistant pairing</td>
</tr>
<tr>
<td>Surgeon midlevel vs junior, all categories</td>
</tr>
<tr>
<td>Assistant resident vs junior, all categories</td>
</tr>
<tr>
<td>Assistant midlevel vs junior, all categories</td>
</tr>
<tr>
<td>Assistant senior vs junior, all categories</td>
</tr>
<tr>
<td>Surgeon midlevel vs junior, Category 3</td>
</tr>
<tr>
<td>Assistant resident vs junior, Category 3</td>
</tr>
<tr>
<td>Assistant midlevel vs junior, Category 3</td>
</tr>
<tr>
<td>Assistant senior vs junior, Category 3</td>
</tr>
<tr>
<td>*Bold highlights surgeon comparison vs other comparisons, which relate to assistants.</td>
</tr>
<tr>
<td>*Statistically significant at p &lt; 0.05. CI = confidence interval.</td>
</tr>
</tbody>
</table>

The primary strength of this article is that the authors reviewed all 576 hysterectomies for benign disease performed by 39 general gynecologists during an entire year.
Categorizing hysterectomies for benign disease also allows much more research to be done on equally difficult surgeries.

Disclosure Statement
The author(s) have no conflicts of interest to disclose.

Acknowledgment
Kathleen Louden, ELS, of Louden Health Communications provided editorial assistance.

References


ABSTRACT

Context: In its fee-for-service funding model for primary care, British Columbia, Canada, introduced incentive payments to general practitioners as pay for performance for providing enhanced, guidelines-based care to patients with chronic conditions. Evaluation of the program was conducted at the health care system level.

Objective: To examine the impact of the incentive payments on annual health care costs and hospital utilization patterns in British Columbia.

Design: The study used Ministry of Health administrative data for Fiscal Year 2010-2011 for patients with diabetes, congestive heart failure, chronic obstructive pulmonary disease, and/or hypertension. In each disease group, cost and utilization were compared across patients who did, and did not, receive incentive-based care.

Main Outcome Measures: Health care costs (eg, primary care, hospital) and utilization measures (eg, hospital days, readmissions).

Results: After controlling for patients’ age, sex, service needs level, and continuity of care (defined as attachment to a general practice), the incentives reduced the net annual health care costs, in Canadian dollars, for patients with hypertension (by approximately Can$308 per patient), chronic obstructive pulmonary disease (by Can$496), and congestive heart failure (by Can$96), but not diabetes (incentive cost about Can$148 more per patient). The incentives were also associated with fewer hospital days, fewer admissions and readmissions, and shorter lengths of hospital stays for all 4 groups.

Conclusion: Although the available literature on pay for performance shows mixed results, we showed that the funding model used in British Columbia using incentive payments for primary care might reduce health care costs and hospital utilization.

INTRODUCTION

We present the findings from an evaluation of a new funding model of providing primary care services in British Columbia (BC), Canada. The funding model is based on incentive payments in the fee-for-service payment system for general practitioners (GPs). We compared the costs and utilization of services for patients with several chronic conditions for which additional incentive payments are available. Our analyses show that the incentive payments can reduce overall costs to the health care system but the amount of cost avoidance depends on a number of factors, including the type of chronic condition. We conducted the analyses in two different ways, each reflecting a different approach, and found that both approaches lead to the same conclusions. Thus, the purpose of this article is twofold. First, we report the main findings about the effectiveness of incentive payments. Second, we report on the comparison of two analytic approaches, one based on interactive action research more familiar to health policy makers and the second based on more statistically rigorous propensity score analysis more familiar to analysts and economists.

Funding Model for Primary Care in British Columbia

To set the context for the incentive payments and the funding model in BC, we begin with a brief description of some background and history. (For more details about how primary care is delivered in BC, see the article by MacCarthy and Hollander.) In accordance with the Canadian Constitution, the provision of health care services is a provincial responsibility. The federal government collects both federal and provincial taxes. It then transfers funds to the provinces to pay for certain services such as health and education. Under the Canada Health Act, medical and hospital services are provided to Canadians without a charge or user fee.

In BC, Canada’s most western province, primary care and drugs are provincially insured services in which providers bill provincial government insurance programs directly. The majority of medical services are billed to the Medical Services Plan (MSP) on a fee-for-service basis. Eligible payments for drugs and pharmacy services are billed to the Pharmacare Plan. Hospital services and all other health services are provided by Regional Health Authorities (RHAs). Lump sum payments for these services are made by the Ministry of Health directly to the RHAs. There is a complex set of rules regarding copayments for other services, such as drugs, long-term care, and allied health services.

In Fiscal Year 2010-2011, 49.8% of GPs in BC worked in solo practices and 34.8% worked in small group practices of 2 to 4 GPs. Conceptually, a general practice is very similar to the US patient-centered medical home. Typically, one service is provided during one visit to a GP, although if a GP provides a service and a procedure during a single visit, s/he can bill for two activities. This allows GPs to care for a range of patients, including those needing complex care. On the basis of claims made to BC’s MSP and excluding part-time GPs (defined by Doctors of BC as those making less than Can$82,000 in the 2011-2012 fiscal year), the average annual payment to a GP was Can$255,522.

The impetus for introducing incentive payments in the fee-for-service model came from discussions with GPs about future directions in the late 1990s and early 2000s, when BC was experiencing a decline in the number of full-service family practitioners. In response to gov-

Evaluation of Incentive Payments and the Incentive Program

Do incentive payments, as a form of pay for performance, enhance primary care? The literature suggests that incentive payments have led to mixed results across various jurisdictions, including the Quality and Outcomes Framework in England and in Canada. Furthermore, the term pay for performance can have a range of meanings. In its true sense, pay for performance refers to payments for specific outcomes that improve the health of patients, populations, or both. In actual practice, however, pay for performance often refers to payments for conducting certain process-related activities or achieving "measures," such as performing immunizations or ordering certain tests (eg, for diabetes). The latter would be better labeled as pay for activity, not performance. With this distinction in mind, the incentive payments currently offered in BC are also a form of pay for activity, similar to those in other jurisdictions.

How then should the Incentive Program be evaluated as pay per performance for enhancing health outcomes? Several factors were considered in setting up the evaluation framework for the GPSC's Incentive Program. First, in recognition that there would be methodologic and other shortcomings in evaluating the performance of the program at the level of individual GPs, the GPSC decided to look at the performance of the program at the system level; for example, Is overall medical care improving? Has value for money increased? Second, because each incentive was introduced on a province-wide basis, it was not possible to conduct a formal evaluation (eg, using randomized controlled trials). Third—and importantly for the ongoing work and evolution of the GPSC—to be useful, evaluation results were needed reasonably quickly so that the GPSC could review its policy and program development on the basis of new knowledge specifically targeted to its needs, and make evidence-based course corrections as needed.

With these factors in mind, we chose an evaluation approach that was methodologically rigorous while being transparent and understandable to program developers and policy makers as well as to researchers. We refer to the approach as Applied Rapid Response Research (R³). It falls in the frame of reference of action research but is applied, rather than technical or basic research, and it has a major knowledge transfer and translation component. Like action research, R³ is rigorous, is aimed directly at key questions and decision points for policy makers, and is interactive between policy and program development and evaluation. It provides results that are clear and understandable to program developers and policy makers.

Working with the GPSC, we used the Applied R³ approach to provide quick results regarding the Incentive Program. The results have generated considerable knowledge transfer/translation across Canada and internationally. The findings from our analyses of the Incentive Program have generated empirical evidence for cost avoidance that is associated with increased continuity of care. Similarly, findings from our evaluation of the various learning modules of the Practice Support Program, a GPSC-funded continuing education program for physicians, have led to contributions to the primary care literature.

To evaluate the Incentive Program at the system level, we adapted the R³ approach to analyses of BC Ministry of Health’s administrative databases, with the goal of estimating and comparing the relative health care cost and utilization patterns of incentive-based care. We needed a rapid, rigorous approach that would allow nonresearchers to see the patterns of relationships for themselves in an easy, transparent manner. The basic idea behind the analyses was to create and to compare two groups of patients: one group who received incentive-based care and the comparison group who received standard (ie, nonincentive-based) care.

Because our main outcome variable was the total cost of care, the incentive-based and nonincentive patient groups needed to be similar to each other in terms of variables related to cost (see more on this in the next paragraph).
In working with the GPSC members, many of whom were not researchers, we developed and used an analytic adjustment procedure, where we equated, or adjusted, the two groups on these cost-related variables so that the GPSC members could see how the costs related to the incentives changed in the context of these variables. This approach is the same as indirect standardization in epidemiology, but rather than estimating outcome variables related to the incidence and/or prevalence of disease, our outcome variables were cost and service utilization patterns.

The specific cost-related variables on which the groups were adjusted were age, sex, level of service need, and continuity of care. Continuity of care was operationally defined as a patient’s attachment to practice and was found to be strongly and inversely related to health care costs.\(^{16,17}\) Attachment level is defined as the percentage of all primary care services provided by 1 practice. The rationale is provided by the following example. Suppose a patient has 12 services in a year, and 9 of those services are from 1 practice. The patient’s attachment level would be 75% (9 of 12 services provided by the main practice). However, if the main GP in the practice provides only 6 services and 3 other services are provided by locum tenens or colleagues in the GP’s practice (ie, the billings go through the same payee number) the attachment level for patients seen by the main GP would be 50% (6 of 12 services), whereas the attachment level for the overall practice would be 75%. Given that the 3 other services in the practice are provided on behalf of the main GP and not by other separate practices (drop-in clinics, or GP’s working in Emergency Departments), it was our

Table 1. Demographic description of patient groups in analyses by incentive status and Resource Utilization Band (RUB) level\(^{1}\)

<table>
<thead>
<tr>
<th>Demographic characteristic</th>
<th>Nonincentive-based care, no. (%)</th>
<th>Incentive-based care, no. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>RUB Level 3, N (%)</td>
<td>RUB Level 4, N (%)</td>
</tr>
<tr>
<td><strong>Diabetes</strong></td>
<td>(N = 104,037)</td>
<td>(N = 134,665)</td>
</tr>
<tr>
<td>No. (row %)</td>
<td>69,708 (67.0)</td>
<td>21,775 (20.9)</td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>33,173 (47.6)</td>
<td>10,600 (48.7)</td>
</tr>
<tr>
<td>Female</td>
<td>35,535 (52.4)</td>
<td>11,175 (51.3)</td>
</tr>
<tr>
<td><strong>Age group, years</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-39</td>
<td>1854 (2.7)</td>
<td>1016 (4.7)</td>
</tr>
<tr>
<td>40-49</td>
<td>9304 (13.3)</td>
<td>3864 (17.7)</td>
</tr>
<tr>
<td>60-69</td>
<td>13,874 (19.9)</td>
<td>5277 (24.2)</td>
</tr>
<tr>
<td>70-79</td>
<td>12,904 (18.5)</td>
<td>3920 (18.0)</td>
</tr>
<tr>
<td>80 or older</td>
<td>31,772 (45.6)</td>
<td>7698 (35.4)</td>
</tr>
<tr>
<td><strong>Attachment, percentage</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-39</td>
<td>1854 (2.7)</td>
<td>1016 (4.7)</td>
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<tr>
<td>40-49</td>
<td>9304 (13.3)</td>
<td>3864 (17.7)</td>
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<tr>
<td>60-69</td>
<td>13,874 (19.9)</td>
<td>5277 (24.2)</td>
</tr>
<tr>
<td>70-79</td>
<td>12,904 (18.5)</td>
<td>3920 (18.0)</td>
</tr>
<tr>
<td>80 or older</td>
<td>31,772 (45.6)</td>
<td>7698 (35.4)</td>
</tr>
<tr>
<td><strong>Hypertension</strong></td>
<td>(N = 189,670)</td>
<td>(N = 172,744)</td>
</tr>
<tr>
<td>No. (row %)</td>
<td>136,961 (72.2)</td>
<td>36,642 (19.3)</td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>56,387 (41.2)</td>
<td>15,885 (43.4)</td>
</tr>
<tr>
<td>Female</td>
<td>80,574 (58.8)</td>
<td>20,757 (56.6)</td>
</tr>
<tr>
<td><strong>Age group, years</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-39</td>
<td>1854 (2.7)</td>
<td>1016 (4.7)</td>
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<tr>
<td>40-49</td>
<td>9304 (13.3)</td>
<td>3864 (17.7)</td>
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<td>60-69</td>
<td>13,874 (19.9)</td>
<td>5277 (24.2)</td>
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<tr>
<td>70-79</td>
<td>12,904 (18.5)</td>
<td>3920 (18.0)</td>
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<tr>
<td>80 or older</td>
<td>31,772 (45.6)</td>
<td>7698 (35.4)</td>
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<tr>
<td><strong>Attachment, percentage</strong></td>
<td></td>
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<tr>
<td>0-39</td>
<td>3967 (2.9)</td>
<td>1908 (5.2)</td>
</tr>
<tr>
<td>40-49</td>
<td>19,970 (14.6)</td>
<td>6848 (18.7)</td>
</tr>
<tr>
<td>60-69</td>
<td>29,389 (21.5)</td>
<td>9142 (24.9)</td>
</tr>
<tr>
<td>70-79</td>
<td>27,003 (19.7)</td>
<td>6718 (18.3)</td>
</tr>
<tr>
<td>80 or older</td>
<td>56,632 (41.3)</td>
<td>12,026 (32.8)</td>
</tr>
</tbody>
</table>

(Continued on next page)
view that the more appropriate indicator of continuity of care is attachment to the practice of the main GP.

For level of service need, we used a matching variable the patients’ Resource Utilization Band (RUB) designation, which is available in the BC Ministry of Health administrative databases. The RUB designation is a classification system developed by Johns Hopkins University, Baltimore, MD.22 The main groupings are categorized into Adjusted Clinical Groups, which are clinical groupings that incorporate age, sex, and the number and type of different diagnostic conditions the patient has. These can then be rolled up into 6 broader RUB categories ranging from 0 to 5, with 5 indicating very high care needs. (The interested reader is referred to the Johns Hopkins Web site for more details.23) This system is in wide use not only in the US but also internationally.22-26

For presenting results to a scientific audience, we also analyzed the administrative data using propensity score analyses, which are increasingly used in health services research to assess treatment effectiveness in observational studies when randomized control trials are not possible. For example, propensity score analysis has been used to assess the quality of diabetes care,13 COPD maintenance therapies,27 the costs and lengths of stay of total hip replacement,28 the cost-effectiveness of open laparoscopic appendectomies,29 and the cost-effectiveness of drug-eluting stents in patients with acute myocardial infarction.30

In summary, we were interested in exploring the impact of the Incentive Program on health care costs while controlling for several key cost-related variables. Having access to the BC Ministry of Health administrative databases, which consist of a series of registries that contain the records of people with chronic conditions, we were able to examine and compare costs and hospital utilization patterns for patients on the registries for diabetes, CHF, COPD, and hypertension.

(Continued from previous page)

<table>
<thead>
<tr>
<th>Congestive heart failure</th>
<th>(N = 48,583)</th>
<th>(N = 16,834)</th>
</tr>
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<tbody>
<tr>
<td>No. (row %)</td>
<td>21,020 (43.3)</td>
<td>12,864 (26.5)</td>
</tr>
<tr>
<td>Sex</td>
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</tr>
<tr>
<td>Male</td>
<td>10,777 (51.3)</td>
<td>6966 (54.2)</td>
</tr>
<tr>
<td>Female</td>
<td>10,243 (48.7)</td>
<td>5898 (45.8)</td>
</tr>
<tr>
<td>Age group, years</td>
<td></td>
<td></td>
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<tr>
<td>0-44</td>
<td>605 (2.9)</td>
<td>197 (1.5)</td>
</tr>
<tr>
<td>45-59</td>
<td>2374 (11.3)</td>
<td>1102 (8.6)</td>
</tr>
<tr>
<td>60-69</td>
<td>4327 (20.6)</td>
<td>2137 (16.6)</td>
</tr>
<tr>
<td>70-79</td>
<td>6090 (29.0)</td>
<td>3637 (28.3)</td>
</tr>
<tr>
<td>80 or older</td>
<td>7624 (36.3)</td>
<td>5791 (45.0)</td>
</tr>
<tr>
<td>Attachment, percentage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-39</td>
<td>395 (1.9)</td>
<td>1040 (8.1)</td>
</tr>
<tr>
<td>40-59</td>
<td>2187 (10.4)</td>
<td>3033 (23.6)</td>
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<tr>
<td>60-79</td>
<td>3885 (18.5)</td>
<td>3677 (28.6)</td>
</tr>
<tr>
<td>80-89</td>
<td>3919 (18.6)</td>
<td>2234 (17.4)</td>
</tr>
<tr>
<td>90-100</td>
<td>10,634 (50.6)</td>
<td>7990 (62.1)</td>
</tr>
<tr>
<td>COPD</td>
<td>(N = 56,444)</td>
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<tr>
<td>No. (row %)</td>
<td>29,187 (51.7)</td>
<td>11,600 (20.6)</td>
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<tr>
<td>Sex</td>
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<tr>
<td>Male</td>
<td>14,088 (48.3)</td>
<td>6220 (53.6)</td>
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<tr>
<td>Female</td>
<td>15,099 (51.7)</td>
<td>5380 (46.4)</td>
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<tr>
<td>Age group, years</td>
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<tr>
<td>45-59</td>
<td>5138 (17.6)</td>
<td>1594 (13.7)</td>
</tr>
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<td>60-69</td>
<td>8927 (30.6)</td>
<td>2589 (22.3)</td>
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<td>70-79</td>
<td>8797 (30.1)</td>
<td>4069 (33.2)</td>
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<tr>
<td>80 or older</td>
<td>6325 (21.7)</td>
<td>3985 (34.4)</td>
</tr>
<tr>
<td>Attachment, percentage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-39</td>
<td>671 (2.3)</td>
<td>871 (7.5)</td>
</tr>
<tr>
<td>40-59</td>
<td>3430 (11.8)</td>
<td>2778 (23.9)</td>
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<tr>
<td>60-79</td>
<td>5895 (20.1)</td>
<td>3426 (39.5)</td>
</tr>
<tr>
<td>80-89</td>
<td>5604 (19.2)</td>
<td>1992 (17.2)</td>
</tr>
<tr>
<td>90-100</td>
<td>13,623 (46.7)</td>
<td>2533 (21.8)</td>
</tr>
</tbody>
</table>

* Some percentages do not total to 100% because of rounding.
* British Columbia Ministry of Health Services, Primary Care Data Repository, Fiscal Year 2010-2011.
* COPD = chronic obstructive pulmonary disease.
METHODS

Patient Selection

The BC Ministry of Health administrative database contains a series of registries of people with chronic conditions. To place patients on a registry, the Ministry uses a complex formula based on diagnostic codes from hospital and primary care visits and common drugs used to treat the given condition.

For our analyses, we extracted all patients in Fiscal Year 2010-2011 who did and did not receive incentive-based care and who were on the registries for each of the following four chronic conditions: diabetes, CHF, COPD, and hypertension. Patients in a given registry, such as diabetes, may have diabetes alone or may have diabetes plus other chronic conditions, and may thus appear on more than one registry. It should also be stressed that we were not dealing with samples in our analyses. Rather, we were dealing with a subset of the population, which included all BC patients who met our selection criteria.

Patient selection was made with the following additional considerations. For each chronic condition, we excluded people who died and who were estimated to be in a long-term care facility during Fiscal Year 2010-2011 because we wanted to include only patients who resided mostly in the community for an entire year. We also excluded patients with hospital costs greater than Can$100,000, the rationale being that if the average hospital cost is Can$1000 per day, an annual cost of Can$100,000 would imply the patient stayed in hospital for 100 days. Our focus in these analyses is on primary care; thus, we wanted to select patients who spent most of their time living in the community. The number of patients excluded on the basis of this criterion ranged from 7 (fewer than 0.01% of diabetes) to 29 (0.06% of COPD) patients per registry at RUB Level 4, and 261 (0.76% hypertension) to 296 (1.30% COPD) patients at RUB Level 5. For other analyses,16,17 patients with billings made by more than 25 different payees or service providers were also excluded because this would make them atypical users ("outliers") of the health care system. However, no patients were eliminated on the basis of this criterion in the current study.

As most incentives were developed for patients receiving care for a chronic condition, we selected people with something higher care needs and those who saw their GP on at least a moderately regular basis. First, we selected people in RUB Levels 3 through 5. Second, we selected patients who had at least 5 GP services in a given year; these could be, but were not required to be, visits related to the particular chronic condition. Relatively few patients in RUB Levels 3 to 5 had fewer than 5 GP services in Fiscal Year 2010-2011 (10.5% of diabetes, 14.8% of hypertension, 7.3% of CHF, and 8.9% of COPD, with most of these at RUB Level 3).

Access to data for our analyses was obtained through a BC Ministry of Health Privacy Impact Assessment in conformance with the Freedom of Information and Protection of Privacy Act (Privacy Act). Approval of the Privacy Impact Assessment ensures that any collection, use, and disclosure of information conforms to all existing legislation, including the Privacy Act. The requirements for conducting research under the Privacy Impact Assessment agreement are similar to those imposed by ethics review boards.

Outcome Variables

Our outcome variables were the total annual (Fiscal Year 2010-2011) costs of health care and a number of indicators of hospital utilization. Specifically, cost variables included costs to the government from the provincial MSP (ie, GP costs, specialist costs, and diagnostic facility costs), hospital costs, pharmacy costs, and total costs (the sum of all cost categories). The utilization variables included were the number of hospital days per 1000 patients, net number of admissions, readmission rates, and average length of stay.

Analytic Adjustment Procedure

Many readers will have been trained in a health-related discipline and will be familiar with concepts from epidemiology such as age and sex standardization. Many social science disciplines also adjust data to control for confounders based on differential age and sex distributions (and distributions for other key variables). Thus, epidemiologic standardization is actually a subset of a broader concept of adjustment, which “encompasses both standardization and other procedures for removing the effects of factors that distort or confound comparison.”32

The 2 groups, those who did and those who did not receive incentive-based care, were adjusted on 4 key cost-related variables. Those variables were as follows: 1) age, categorized into 5 groups or strata: 0 to 44 years, 45 to 59 years, 60 to 69 years, 70 to 79 years, and 80 years and older; 2) sex: male or female; 3) RUB: Levels 3 through 5; and 4) attachment to practice, defined as the percentage of all services provided by the primary care practice that provided the most services to the patient,16,17 with categories or strata of 0% to 39% attachment, 40% to 59% attachment, 60% to 79% attachment, 80% to 89% attachment, and 90% to 100% attachment.

Because of the highly variable nature of the costs of the different incentives and services associated with the different comorbidities, the use of constructed variables such as number of comorbidities as a matching variable was not considered to be appropriate in our cost analyses.

Propensity Score Analyses

The method for propensity score analysis is basically a 2-stage analysis. In Stage 1, each patient in the “treatment” group (corresponding to our incentive-based care group) is first matched with a patient in the comparison group who matches him/her on each of the other “matching” variables (eg, age, sex). The matching is done by computing a propensity score for each patient (a linear combination score of the matching variables) and matching the patients in the 2 groups on these propensity scores. In Stage 2 of the analysis, the 2 groups of matched patients are compared on the outcome variables of primary interest.
For further discussion of this method and some of the key issues that must be considered, see Arbogast et al.,33 Austin,34 Baser,35 Manca and Austin,36 Schneeweiss et al.,37 Wilde and Hollister,38 Rosenbaum and Rubin,39 and Dunn et al.40

Estimates of patients’ propensity scores were obtained using probit regression.40 For matching patients on the propensity scores, we used one-to-one nearest neighbor matching without replacement; because of the size of our data sets, there were large and similar numbers of patients in each of the two groups (incentive and nonincentive) with identical propensity scores. The quality of the matching was assessed for each analysis. Once matched, the average costs for patients who received incentive-based care were compared with their matched counterparts who did not receive incentive-based care, using paired samples t tests.38

As was the case for the adjustment procedure, the matching was done on age group, sex, RUB level, and attachment level. Matching patients on comorbidities in the propensity analyses was not feasible. Some groupings of all possible combinations of the main comorbidities resulted in very small numbers of patients who could not be matched adequately. Furthermore, as noted earlier, using constructed variables such as simple counts of comorbidities as a matching variable was not appropriate in our cost analyses because the incentive and other costs associated with different comorbidities are highly variable. Thus, for these analyses, we selected patients who had only diabetes (ie, they did not have CHF, COPD, hypertension, or other comorbidities for which an incentive could be billed) and, similarly, patients who had only

<table>
<thead>
<tr>
<th>Type of Condition</th>
<th>Type of cost</th>
<th>Raw costs2 (no adjustments)</th>
<th>Costs adjusted for age, sex, Resource Utilization Band, and attachment levelb</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes:</td>
<td></td>
<td>No incentive</td>
<td>Incentive</td>
</tr>
<tr>
<td>Incentive (n = 134,665); No incentive (n = 104,037)</td>
<td>GP</td>
<td>588</td>
<td>750</td>
</tr>
<tr>
<td></td>
<td>Specialist</td>
<td>645</td>
<td>560</td>
</tr>
<tr>
<td></td>
<td>Diagnostic facility (DF)</td>
<td>476</td>
<td>470</td>
</tr>
<tr>
<td></td>
<td>Subtotal (GP + Specialist + DF)</td>
<td>1709</td>
<td>1780</td>
</tr>
<tr>
<td></td>
<td>Hospital</td>
<td>2538</td>
<td>1965</td>
</tr>
<tr>
<td></td>
<td>Pharmacy</td>
<td>979</td>
<td>1128</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>5226</td>
<td>4873</td>
</tr>
<tr>
<td></td>
<td>Incentive-based cost difference</td>
<td>353</td>
<td>-148</td>
</tr>
<tr>
<td>Hypertension:</td>
<td></td>
<td>No incentive</td>
<td>Incentive</td>
</tr>
<tr>
<td>Incentive (n = 172,794); No incentive (n = 189,670)</td>
<td>GP</td>
<td>486</td>
<td>505</td>
</tr>
<tr>
<td></td>
<td>Specialist</td>
<td>503</td>
<td>407</td>
</tr>
<tr>
<td></td>
<td>Diagnostic facility</td>
<td>392</td>
<td>357</td>
</tr>
<tr>
<td></td>
<td>Subtotal (GP + Specialist + DF)</td>
<td>1381</td>
<td>1269</td>
</tr>
<tr>
<td></td>
<td>Hospital</td>
<td>1751</td>
<td>1202</td>
</tr>
<tr>
<td></td>
<td>Pharmacy</td>
<td>511</td>
<td>470</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>3643</td>
<td>2941</td>
</tr>
<tr>
<td></td>
<td>Incentive-based cost difference</td>
<td>702</td>
<td>309</td>
</tr>
<tr>
<td>COPD:</td>
<td></td>
<td>No incentive</td>
<td>Incentive</td>
</tr>
<tr>
<td>Incentive (n = 25,043); No incentive (n = 56,444)</td>
<td>GP</td>
<td>800</td>
<td>997</td>
</tr>
<tr>
<td></td>
<td>Specialist</td>
<td>739</td>
<td>608</td>
</tr>
<tr>
<td></td>
<td>Diagnostic facility</td>
<td>546</td>
<td>519</td>
</tr>
<tr>
<td></td>
<td>Subtotal (GP + Specialist + DF)</td>
<td>2085</td>
<td>2124</td>
</tr>
<tr>
<td></td>
<td>Hospital</td>
<td>4048</td>
<td>3119</td>
</tr>
<tr>
<td></td>
<td>Pharmacy</td>
<td>1386</td>
<td>1466</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>7521</td>
<td>6709</td>
</tr>
<tr>
<td></td>
<td>Incentive-based cost difference</td>
<td>812</td>
<td>496</td>
</tr>
<tr>
<td>Congestive heart failure:</td>
<td></td>
<td>No incentive</td>
<td>Incentive</td>
</tr>
<tr>
<td>Incentive (n = 16,834); No incentive (n = 48,583)</td>
<td>GP</td>
<td>929</td>
<td>1185</td>
</tr>
<tr>
<td></td>
<td>Specialist</td>
<td>1026</td>
<td>878</td>
</tr>
<tr>
<td></td>
<td>Diagnostic facility</td>
<td>716</td>
<td>742</td>
</tr>
<tr>
<td></td>
<td>Subtotal (GP + Specialist + DF)</td>
<td>2871</td>
<td>2805</td>
</tr>
<tr>
<td></td>
<td>Hospital</td>
<td>6105</td>
<td>5213</td>
</tr>
<tr>
<td></td>
<td>Pharmacy</td>
<td>1513</td>
<td>1532</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>10,289</td>
<td>9550</td>
</tr>
<tr>
<td></td>
<td>Incentive-based cost difference</td>
<td>739</td>
<td>96</td>
</tr>
</tbody>
</table>

a Totals in cost columns may differ from the sum of the component parts because of rounding.
b British Columbia Ministry of Health Services, Primary Care Data Repository, Fiscal Year 2010-2011.

COPD = chronic obstructive pulmonary disease; GP = general practitioner.
hptension. We chose diabetes and hypertension because these two conditions had the largest numbers of patients of the four conditions without any comorbidities.

Finally, because we needed to be able to communicate the findings from our analyses to diverse audiences, we employed two different analytic methods in our analyses of the provincial data. Use of these methods enabled us to compare the findings across methods and across chronic conditions.

RESULTS

Table 1 provides the basic demographic description of the patients in our analyses. A scan of the percentages indicates that there were some differences between the incentive and nonincentive groups across sex, age, RUB level, and level of attachment; thus, adjusting for these variables was warranted.

We present the results of the cost analyses in four sections. First, we present the cost estimates, in terms of cost avoidance, for incentive-based care obtained by the analytic adjustment method, and compare these with unadjusted, or raw, costs for each of the four chronic conditions. Second, we present and compare the cost estimates for diabetes and hypertension obtained using the propensity score analyses. Third, we report estimates of the overall cost avoidance that include the cost of the incentives themselves for each of the four chronic conditions, to provide an overall financial picture. Finally, using the adjustment method we report the impact of the Incentive Program on hospital utilization patterns.

Impact of Incentives on Costs Based on Analytic Adjustment Method

Table 2 presents the cost estimates for the 4 major chronic conditions using the analytic adjustment method. It shows the raw costs (ie, simple comparisons of costs for patients who did and did not receive incentive-based care, without adjustment) as well as the costs adjusted for age, sex, and RUB and attachment levels. Raw, unadjusted cost estimates indicate that patients who received incentive-based care cost, on average, less than those who did not, with raw annual cost differences ranging from Can$353 for diabetes to Can$812 for COPD (see “Raw Cost” columns in Table 2).

Costs adjusted for age, sex, RUB level, and attachment level (see right side of Table 2), however, led to different results. Specifically for diabetes, on the basis of the adjusted costs, patients who received incentive-based care actually cost, on average, Can$148 (2.99%) more than patients who did not. After adjusting for only age, sex, and RUB level (not shown here), the costs were similar for patients who received incentive-based care (Can$4993) and those who did not (Can$5059). Although the difference of Can$66 was small, these estimates were considerably lower for patients with incentive-based care adjusted for age, sex, RUB level, and attachment level, hospital costs were considerably lower for patients with incentive-based care (in all disease groups). However, pharmacy costs were higher for patients with diabetes and COPD (but not CHF and hypertension).

The impact of adjusting for comorbidities was examined for diabetes and hypertension. Findings are presented in Table 3 for patients who appeared only on the diabetes registry (and no other registries) or only on the hypertension registry. Compared with the estimates in Table 2, we noted that even though the overall total costs were lower for both incentive and nonincentive groups (by about Can$1700 for diabetes and Can$500 for hypertension), the

---

**Table 3. Average annual costs per patient, adjusted for Resource Utilization Band, attachment, sex, and age group, fiscal year 2010-2011 (Canadian dollars)**

<table>
<thead>
<tr>
<th>Cost category</th>
<th>Diabetes-only patients*</th>
<th>Hypertension-only patients*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No incentive (n = 64,627)</td>
<td>Incentive (n = 82,674)</td>
</tr>
<tr>
<td>GP</td>
<td>463</td>
<td>620</td>
</tr>
<tr>
<td>Specialist</td>
<td>450</td>
<td>430</td>
</tr>
<tr>
<td>Diagnostic facility (DF)</td>
<td>372</td>
<td>376</td>
</tr>
<tr>
<td>Total MSP (GP + Specialist + DF)</td>
<td>1285</td>
<td>1426</td>
</tr>
<tr>
<td>Hospital</td>
<td>1300</td>
<td>1157</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>658</td>
<td>807</td>
</tr>
<tr>
<td>Average annual total costs</td>
<td>3243</td>
<td>3390</td>
</tr>
<tr>
<td>Incentive-based cost difference</td>
<td>-147</td>
<td>269</td>
</tr>
</tbody>
</table>

* Totals in cost columns may differ from the sum of the component parts because of rounding.
1 British Columbia Ministry of Health Services, Primary Care Data Repository, Fiscal Year 2010-2011.
GP = general practitioner; MSP = Medical Services Plan of British Columbia.
Incentive-Based Primary Care: Cost and Utilization Analysis

adjusted cost differences were comparable, including the change in the direction for diabetic patients. For patients with only diabetes who received incentive-based care, the average annual total cost per patient was Can$33390, which was Can$147 higher than the average cost for diabetic patients who did not receive incentive-based care. For hypertension-only patients, those who received incentive-based care had average annual costs of Can$2674, which was Can$269 less per patient than those who did not receive incentive-based care. This provides some evidence that the pattern of results was similar for patients with only 1 chronic condition and those with multiple chronic conditions.

Impact of Incentives on Costs Based on Propensity Score Analyses

The effectiveness of the matching of patients, using propensity scores based on the 4 variables, is displayed in Table 4, which shows the group means on the 4 variables before and after propensity score matching. The numeric values of the means are not meaningful in and of themselves (because these are categorical variables with the numbers indicating category “labels”), but they do show how the 2 groups became more similar after the matching procedure. For the diabetes-only patients, the overall reduction in bias ranged from 16% (for sex) to 96% reduction for RUB level (Table 4, last column). For the hypertension-only patients, the reduction ranged from 50% on each of the covariates except sex (which was already very small before the matching procedure, at 1.6%). Note that the matching was always done for the N of the smaller of the 2 groups. For diabetes, the nonincentive group was smaller (N = 60,535), which means all nonincentive group members were matched with a patient from the larger incentive group, and their means remained the same after matching, but those of the incentive group changed. The converse can be seen for the hypertensive patients.

The main results of this analysis were the paired samples t tests conducted on the 2 matched groups of patients for each cost variable (Table 5). After matching on age group, sex, RUB level, and attachment level, diabetes-only patients who received incentive-based care cost an overall Can$97 more than those who did not receive incentive-based care. It is also interesting to look at the different cost categories; when looking only at hospital costs, patients

**Table 4. Before and after propensity score matching results by patient variable for fiscal year 2010-2011**

<table>
<thead>
<tr>
<th>Covariate variable</th>
<th>Before matching</th>
<th>After matching</th>
<th>Reduction in bias (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>Mean of incentive group</td>
<td>Mean of nonincentive group</td>
<td>Standardized bias</td>
</tr>
<tr>
<td>Diabetes-only patients</td>
<td>76,513</td>
<td>60,535</td>
<td>16.6</td>
</tr>
<tr>
<td>Age group</td>
<td>2.988</td>
<td>2.800</td>
<td>-9.5</td>
</tr>
<tr>
<td>Sex</td>
<td>0.489</td>
<td>0.537</td>
<td>-7.5</td>
</tr>
<tr>
<td>RUB level</td>
<td>3.238</td>
<td>3.279</td>
<td>-7.5</td>
</tr>
<tr>
<td>Attachment level</td>
<td>4.094</td>
<td>3.807</td>
<td>24.6</td>
</tr>
</tbody>
</table>

**Table 5. Costs for patients after propensity score matching: effects of incentive-based care for fiscal year 2010-11 (Canadian dollars)**

<table>
<thead>
<tr>
<th>Type of cost</th>
<th>Patients with incentive-based care</th>
<th>Patients without incentive-based care (PS matched)</th>
<th>Difference in cost</th>
<th>t value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes-only patients</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. of patients</td>
<td>60,535</td>
<td>60,535</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospital</td>
<td>1121.99</td>
<td>1278.35</td>
<td>-156.36</td>
<td>-5.79</td>
</tr>
<tr>
<td>MSP</td>
<td>1409.27</td>
<td>1288.55</td>
<td>120.72</td>
<td>16.64</td>
</tr>
<tr>
<td>Pharmacologic care</td>
<td>767.71</td>
<td>635.42</td>
<td>132.28</td>
<td>12.73</td>
</tr>
<tr>
<td>Total</td>
<td>3298.96</td>
<td>3202.32</td>
<td>96.64</td>
<td>2.75</td>
</tr>
<tr>
<td>Hypertension-only patients</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. of patients</td>
<td>154,896</td>
<td>169,484</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospital</td>
<td>1060.75</td>
<td>1361.96</td>
<td>-301.21</td>
<td>-18.00</td>
</tr>
<tr>
<td>MSP</td>
<td>1197.15</td>
<td>1248.53</td>
<td>-51.78</td>
<td>-11.75</td>
</tr>
<tr>
<td>Pharmacologic care</td>
<td>404.13</td>
<td>425.67</td>
<td>-21.54</td>
<td>-3.99</td>
</tr>
<tr>
<td>Total</td>
<td>2662.03</td>
<td>3036.57</td>
<td>-374.53</td>
<td>17.77</td>
</tr>
</tbody>
</table>

*All values in Canadian dollars except No. of patients and t values.
*Given the large sample sizes, all these t values would be considered statistically significant at the 0.01 level (2-tailed).
*British Columbia Ministry of Health Services, Primary Care Data Repository, Fiscal Year 2010-2011.
*MSP = Medical Services Plan of British Columbia; PS = propensity score.
who received incentive-based care cost Can$156 less than those without incentive-based care, after matching on the 4 covariates.

For hypertension-only patients, incentive-based care made a larger difference in the impact on the costs. For each type of cost, patients who received incentive-based care had lower costs. Overall, the incentive-based care recipients with hypertension only had total health care costs of Can$375 less than patients without incentive-based care (Table 5).

These results can be compared with those obtained on the same subpopulation of patients using the adjustment method shown in Table 3. The two sets of results are shown in Table 6. The findings were very similar, providing support for the adjustment method. The adjustment method provided a more conservative estimate of cost avoidance than did the propensity score analysis.

Additional Analyses: Overall Costs of Incentive Payment Program

The cost estimates presented in Table 2 are only for patients who were selected for analysis using our inclusion and exclusion criteria, which allowed us to compare costs across the two groups for high-care-needs patients. However, to obtain a more complete picture of the cost (or cost avoidance) of the incentive payment program for the entire health care system, we estimated the overall cost, including the cost of the incentives, for all patients in each of the four chronic conditions (ie, including patients at all RUB levels and those with fewer than five services).

Table 7 presents the overall cost avoidance of the Incentive Program for the four chronic conditions. Where the cost reductions from the incentives were less than the costs of the incentives (see negative net values in Table 7), the incentives constitute an additional cost to the health care system. Conversely, where the savings from incentives are positive but less than the costs of the incentives, this represents a partial return on investment. The overall cost estimates presented in Table 7 show that the Incentive Program resulted in cost avoidance for patients with CHF, COPD, and hypertension, but not diabetes. However, it should be noted that the costs presented in Table 7 are not additive across chronic conditions because the subpopulations of patients in these analyses overlap.

Impact of Incentives on Service Utilization

The Incentive Program also had an impact on hospital utilization outcome measures. Using the adjustment method, we compared hospital utilization for patients who received incentive-based care with those who did not. Across all four chronic conditions, patients who received incentive-based care had fewer admissions, fewer days in the hospital, fewer readmissions, and shorter lengths of stay (Table 8).

DISCUSSION

Our analyses bore interesting results. Incentive payments can and do avoid costs for the health care system—although it depends which costs and which chronic conditions are looked at—and in general reduce patients' utilization of more costly hospital services. The incentives are associated with cost avoidance for patients with CHF, COPD, and especially hypertension, but not for patients with diabetes. This difference appears to be because of the incentive-based cost avoidance for hospital costs being lower in both the raw and adjusted costs for the diabetes group. For example, Table 2 shows that the hospital cost differential for the diabetes group, using adjusted costs, was Can$187 (Can$2318-Can$2131) compared with Can$248 for hypertension, Can$629 for COPD, and Can$397 for CHF. In addition, although all 4 conditions showed a decrease in the measures of hospital utilization in the incentive group, the decrease was consistently comparatively smaller in the diabetes group. For example, Table 8 shows the difference in the number of hospital days per 1000 patients (236 fewer days in the incentive group) was smaller for diabetes than for each of the other chronic conditions (257 fewer days for hypertension, 536 for COPD, and 419 for CHF). Similarly, the difference in the net number of admissions per 1000 patients was smallest for diabetes (12.5 admissions) compared with hypertension (22.1 admissions), COPD (32.5 admissions), and CHF (21.2 admissions).

Regarding the two analytic methods, we showed that the adjustment method used for presenting the cost and utilization findings to health care policy makers was sound. Because we conducted each analysis separately for

<table>
<thead>
<tr>
<th>Table 6. Comparisons of estimates from two methods of matching groups (Canadian dollars)1</th>
<th>Diabetes-only patients</th>
<th>Hypertension-only patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estimation method</td>
<td>Incentives</td>
<td>No incentives</td>
</tr>
<tr>
<td>Adjustment</td>
<td>3389</td>
<td>3243</td>
</tr>
<tr>
<td>Propensity</td>
<td>3299</td>
<td>3202</td>
</tr>
</tbody>
</table>

1 British Columbia Ministry of Health Services, Primary Care Data Repository, Fiscal Year 2010-2011.

<table>
<thead>
<tr>
<th>Table 7. Overall cost avoidance adjusted for age, sex, Resource Utilization Band, and attachment level for fiscal year 2010-2011 (Canadian dollars)1</th>
<th>Costs</th>
<th>Diabetes</th>
<th>Hypertension</th>
<th>COPD</th>
<th>CHF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total dollar cost (-) or savings using adjusted rates excluding incentives</td>
<td>-3,068,294</td>
<td>61,860,252</td>
<td>15,558,305</td>
<td>3,716,020</td>
<td></td>
</tr>
<tr>
<td>Total cost of incentives</td>
<td>-21,632,125</td>
<td>-11,525,650</td>
<td>4,636,805</td>
<td>-2,510,250</td>
<td></td>
</tr>
<tr>
<td>Net dollar cost (-) or savings</td>
<td>-24,700,419</td>
<td>50,334,602</td>
<td>10,921,500</td>
<td>1,205,770</td>
<td></td>
</tr>
</tbody>
</table>

1 British Columbia Ministry of Health Services, Primary Care Data Repository, Fiscal Year 2010-2011. CHF = congestive heart failure; COPD = chronic obstructive pulmonary disease.
Table 8. Service utilization rates adjusted for age, sex, Resource Utilization Band, and attachment level for fiscal year 2010-20111

<table>
<thead>
<tr>
<th>Service utilization</th>
<th>Diabetes</th>
<th>Hypertension</th>
<th>COPD</th>
<th>CHF</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No incentive</td>
<td>Incentive</td>
<td>No incentive</td>
<td>Incentive</td>
</tr>
<tr>
<td>Hospital days per 1000 patients</td>
<td>2079.0</td>
<td>1842.8</td>
<td>1368.3</td>
<td>1111.1</td>
</tr>
<tr>
<td>Net admissions per 1000 patients (excluding transfers, daycare)</td>
<td>231.9</td>
<td>219.4</td>
<td>165.7</td>
<td>143.6</td>
</tr>
<tr>
<td>Readmissions within 7 days per 1000 net admissions</td>
<td>54.9</td>
<td>54.6</td>
<td>43.6</td>
<td>43.0</td>
</tr>
<tr>
<td>Readmissions within 15 days per 1000 net admissions</td>
<td>90.2</td>
<td>88.0</td>
<td>69.4</td>
<td>64.6</td>
</tr>
<tr>
<td>Readmissions within 30 days per 1000 net admissions</td>
<td>133.4</td>
<td>128.5</td>
<td>100.2</td>
<td>91.5</td>
</tr>
<tr>
<td>Average length of stay per regular admission</td>
<td>7.3</td>
<td>6.8</td>
<td>6.3</td>
<td>5.7</td>
</tr>
<tr>
<td>Average length of stay per hospital stay</td>
<td>7.9</td>
<td>7.3</td>
<td>6.8</td>
<td>6.1</td>
</tr>
<tr>
<td>Average length of stay per hospital stay episode</td>
<td>9.1</td>
<td>8.4</td>
<td>7.6</td>
<td>6.8</td>
</tr>
</tbody>
</table>

1 British Columbia Ministry of Health Services, Primary Care Data Repository, Fiscal Year 2010-2011. CHF = congestive heart failure; COPD = chronic obstructive pulmonary disease.

each chronic condition, there was some overlap in the populations that were selected for the analyses reported here. As we show in the results section, the findings were consistent across analyses of patients with only one chronic condition and those who had several chronic conditions. Thus, comorbidities did not present an issue in our interpretation of the Incentive Program.

As we hoped, we effectively validated the adjustment method by comparing its estimates with those obtained from the propensity score matching analyses. The two methods provided similar results regarding the impact of the incentives on health care costs, when adjusting or matching (ie, controlling) for four patient cost-related variables, and the similarities of the cost estimates across the two methods strengthen the conclusions drawn from both analyses. Thus, overall results indicate both cost avoidance and reduced hospital utilizations for patients who received guidelines-based care supported by incentive payments.

One limitation of our study is that even though we matched the patients in the two groups on age, sex, RUB level, and attachment level, we do not fully know how similar the two groups were on other potentially relevant variables. However, previously published studies of cost analyses that used a wider range of independent variables (ie, patient’s median household income, and physician’s sex, age, and place of graduation) indicated that these other variables had a comparatively much smaller impact on costs in BC.19 In this regard, a second limitation is that the results of this study are specific to the BC context and thus are not directly generalizable to other contexts. We hope that the findings reported here spur further research in other jurisdictions and are of broader interest, particularly to health care policy makers and funders.

Our analyses examined the cost-effectiveness of the incentive-based model introduced in BC. The findings do not, however, address the bigger issue of whether the operational solution introduced to resolve an operational problem (ie, the Incentive Program) is more cost-effective than a structural solution.1 It would be informative and interesting to compare the BC approach to other innovations in primary care delivery and funding models across Canada, such as community clinics and/or large group practices, and to assess the benefits and shortcomings of each approach using the same outcome measures. Such a broader study would provide health care policy makers with information for evidence-based funding and delivery decisions in primary care.

CONCLUSION

Although the available literature on pay for performance shows mixed results, we showed that the funding model in BC using incentive payments for primary care might, on balance, reduce health care costs and hospital utilization.

Disclosure Statement

Hollander Analytical Services Ltd has a contract to evaluate General Practice Services Committee (GPSC) activities. To ensure the independence and objectivity of evaluations conducted by Hollander Analytical Services Ltd, which are funded by the GPSC, the BC Ministry of Health and the Doctors of BC (formerly the BC Medical Association) have signed an agreement, on behalf of the GPSC, that guarantees the integrity, objectivity, and independence of any evaluations conducted for the GPSC by Hollander Analytical Services Ltd. There are no competing interests.

Acknowledgments

We would like to acknowledge the funding provided for this paper by the General Practice Services Committee (GPSC), a partnership between the British Columbia Ministry of Health and the Doctors of BC (formerly the BC Medical Association). We would also like to acknowledge Angela Tessaro for her exceptional programming skills and ability to work with large administrative
Heading Home
lithograph, original size 18” x 14”
Cathleen VanBergen

This lithograph is from a body of work exploring the construction of the historic San Francisco Transbay Terminal. The transportation hub was completed in 1939 and served bus and rail lines from surrounding Bay Area communities. The terminal was closed in 2010 and later demolished. A new transit center and multiple skyscrapers are under construction at the site of the Transbay Terminal.

Ms VanBergen is a Clinical Esthetician in the Cosmetic Dermatology Department at Park Shadelands Medical Offices in Walnut Creek, CA. Her artwork is currently represented by Christian Daniels Gallery in San Francisco, CA.
Anxiety’s Impact on Length of Stay Following Lumbar Spinal Surgery

Hollis Floyd; Mazen Sanoufa, MD; Joe Sam Robinson, MD

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http://dx.doi.org/10.7812/TPP/15-022

INTRODUCTION

It is well established that psychological factors affect spinal surgery outcomes.1,2 Surgical literature suggests that anxiety may affect length of stay (LOS).3,4 However, in a time of increasing number and cost of spinal procedures, relatively little inquiry exists regarding the influence of anxiety on LOS in neurosurgical literature. By way of inquiry we conducted the following retrospective study and our cohort was not subjected to any treatments or implementations. Institutional review board approval was not necessary.

METHODS

At our institute, medical records of all patients (consecutively selected) who consecutively underwent elective lumbar decompression and fusion surgery from October 1, 2010, through September 30, 2013, were retrospectively reviewed. Each patient’s medications and comorbidities were determined using the medical history. The impact of their medications on LOS was studied using multivariate analysis. Linear regression was also used to assess the relationship between anxiolytic use and LOS. An independent sample t test was used to compare the mean LOS of the group of patients receiving muscle relaxants with that of the group who were not.

RESULTS

Those with a diagnosis of anxiety who were taking anxiolytics (n = 32) stayed 1.8 days longer than those with no diagnosis of anxiety and who were not taking anxiolytics (n = 224) after LDF surgery (p = 0.003). Those with a diagnosis of anxiety who were taking anxiolytics (n = 32) stayed 1.9 days longer than those with no diagnosis of anxiety and who were taking anxiolytics (n = 24) after LDF surgery (p = 0.003).

CONCLUSION

Our study suggests that those with a diagnosis of anxiety who take medications for that condition have a longer LOS than those with no diagnosis of anxiety and who are not medicated for the condition. This could be because these patients are more vulnerable to states of anxiety when required to be nil per os for 12 hours before surgery.

Variables Identified Using Linear Regression and Multivariate Analysis Showing Significant Independent Impact on Hospital Length of Stay

- Postoperative urinary retention
- Dural tear/cerebrospinal fluid leak
- Severe respiratory problems
- Postoperative pulmonary embolism
- Postoperative anemia severity
- Other mild postoperative problems
- Fever

* p < 0.001 for each of these variables.
Anxiety’s Impact on Length of Stay Following Lumbar Spinal Surgery

RESULTS

After applying the exclusion criteria, the total number of patients considered in this study was 307 (see Table 3 for a detailed cohort description). The mean (standard deviation) LOS was 5.0 (2.9) days. For more details about the 4 anxiety cohorts see Table 2.

Of the 55 variables considered in the linear regression analysis, the variables that showed an impact on LOS, the confounding variables, were number of operated levels (p = 0.033), postoperative hemoglobin levels (p < 0.001), dural tear (p < 0.001), postoperative pulmonary embolism (p < 0.001), and postoperative urinary retention (p = 0.012).

Studying the LOS difference between the 4 anxiety cohorts using multivariate analysis and considering the confounding variables attained the following results: The LOS in cohort 1 was significantly longer than that of cohort 3 (mean difference, 1.9 days; p = 0.012) and cohort 4 (mean difference, 1.8 days; p = 0.003), with no differences between cohort 2 and the other cohorts.

DISCUSSION

Some of our study limitations were that the collection of variables, including comorbidity history, was taken from the patients’ medical charts and not determined by diagnostic testing methods; also, LOS is always a weak outcome indicator because it can be affected by numerous and complicated factors.

Despite their both having histories of anxiety, cohort 1 stayed significantly longer than cohort 3. We believe cohort 3 possibly experienced situational as opposed to chronic anxiety, because they were not receiving any medications, making their psychological states similar to those of cohort 4. Cohort 2 did not significantly stay longer than any of the other groups. This is probably because their anxiolytic medications may have been taken for mental disorders other than anxiety.

Pursuant to the observed impact of psychological variables upon hospital LOS, several suggestions arose:

Table 1. Collected variables

<table>
<thead>
<tr>
<th>General characteristics</th>
<th>Variables</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Measures</td>
<td>Age</td>
</tr>
<tr>
<td></td>
<td>Sex</td>
</tr>
<tr>
<td></td>
<td>Number of operated levels</td>
</tr>
<tr>
<td></td>
<td>Payer class</td>
</tr>
<tr>
<td></td>
<td>Postoperative hemoglobin level</td>
</tr>
<tr>
<td></td>
<td>Preoperative hemoglobin level</td>
</tr>
<tr>
<td></td>
<td>Pre- to postoperative hemoglobin drop</td>
</tr>
<tr>
<td></td>
<td>Race</td>
</tr>
<tr>
<td></td>
<td>Need for blood transfusion</td>
</tr>
<tr>
<td>Comorbidities</td>
<td>Asthma</td>
</tr>
<tr>
<td></td>
<td>Arrhythmia</td>
</tr>
<tr>
<td></td>
<td>Body mass index</td>
</tr>
<tr>
<td></td>
<td>Chronic obstructive pulmonary disease</td>
</tr>
<tr>
<td></td>
<td>Congestive heart failure</td>
</tr>
<tr>
<td></td>
<td>Constipation</td>
</tr>
<tr>
<td></td>
<td>Coronary artery disease</td>
</tr>
<tr>
<td></td>
<td>Diabetes mellitus</td>
</tr>
<tr>
<td></td>
<td>Hearing loss</td>
</tr>
<tr>
<td></td>
<td>Hypertension</td>
</tr>
<tr>
<td></td>
<td>Hypothyroidism</td>
</tr>
<tr>
<td></td>
<td>Inflammatory arthritis</td>
</tr>
<tr>
<td></td>
<td>Major depression</td>
</tr>
<tr>
<td></td>
<td>Memory loss</td>
</tr>
<tr>
<td></td>
<td>Morbid obesity</td>
</tr>
<tr>
<td></td>
<td>Neuromuscular disorders</td>
</tr>
<tr>
<td></td>
<td>Noninflammatory arthritis</td>
</tr>
<tr>
<td></td>
<td>Obesity</td>
</tr>
<tr>
<td></td>
<td>Peptic ulcer disease</td>
</tr>
<tr>
<td></td>
<td>Preoperative anemia</td>
</tr>
<tr>
<td></td>
<td>Renal failure</td>
</tr>
<tr>
<td></td>
<td>Seizure</td>
</tr>
<tr>
<td></td>
<td>Sleep apnea</td>
</tr>
<tr>
<td></td>
<td>Stroke</td>
</tr>
<tr>
<td></td>
<td>Total comorbidity number</td>
</tr>
<tr>
<td></td>
<td>Transient ischemic attack</td>
</tr>
<tr>
<td></td>
<td>Vision loss</td>
</tr>
<tr>
<td></td>
<td>Vitamin D deficiency</td>
</tr>
<tr>
<td>Medications</td>
<td>Anticoagulant use</td>
</tr>
<tr>
<td></td>
<td>Antidiabetic medications</td>
</tr>
<tr>
<td></td>
<td>Anxiolytic use</td>
</tr>
<tr>
<td></td>
<td>Steroids</td>
</tr>
<tr>
<td></td>
<td>Total number of medications used on daily basis</td>
</tr>
<tr>
<td>Intra-/Postoperative complications</td>
<td>Asthma/chronic obstructive pulmonary disease exacerbation</td>
</tr>
<tr>
<td></td>
<td>Constipation</td>
</tr>
<tr>
<td></td>
<td>Dural tear/cerebrospinal fluid leak</td>
</tr>
<tr>
<td></td>
<td>Dysphagia</td>
</tr>
<tr>
<td></td>
<td>Fever with no clear infection</td>
</tr>
<tr>
<td></td>
<td>Infection</td>
</tr>
<tr>
<td></td>
<td>Postoperative anemia severity</td>
</tr>
<tr>
<td></td>
<td>Psychiatric symptoms</td>
</tr>
<tr>
<td></td>
<td>Pulmonary embolism</td>
</tr>
<tr>
<td></td>
<td>Total number of complications</td>
</tr>
<tr>
<td></td>
<td>Urinary tract infection</td>
</tr>
<tr>
<td></td>
<td>Urinary retention</td>
</tr>
<tr>
<td></td>
<td>Wound infection</td>
</tr>
</tbody>
</table>

Table 2. The 4 patient cohorts based on history of anxiety and anxiolytic use

<table>
<thead>
<tr>
<th>History</th>
<th>Cohort 1</th>
<th>Cohort 2</th>
<th>Cohort 3</th>
<th>Cohort 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anxiety</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Anxiolytic use</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

Table 3. Detailed description of total study cohort

<table>
<thead>
<tr>
<th>Patient characteristic</th>
<th>N = 307</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (years)</td>
<td>58 ± 10.7</td>
</tr>
<tr>
<td>Female sex, n (%)</td>
<td>178 (58)</td>
</tr>
<tr>
<td>Male sex, n (%)</td>
<td>129 (42)</td>
</tr>
<tr>
<td>White race, n (%)</td>
<td>210 (68)</td>
</tr>
<tr>
<td>African American race, n (%)</td>
<td>91 (30)</td>
</tr>
<tr>
<td>Other race, n (%)</td>
<td>6 (2)</td>
</tr>
<tr>
<td>Body mass index, mean (kg/m²)</td>
<td>31 ± 6.5</td>
</tr>
<tr>
<td>Length of stay, mean (days)</td>
<td>5.0 ± 2.9</td>
</tr>
</tbody>
</table>
Better Preoperative Psychological Assessment

Several studies have proved successful in using the Minnesota Multiphasic Personality Inventories test preoperatively to categorize patients as having anxiety.1 These studies suggest that the lower the anxiety score, the more successful the patient’s recovery. So, performing preoperative psychological tests would be of significant benefit.

On the basis of the patient’s anxiety score, interventions could be implemented (ie, anxiolytic medications or education about the surgery) to help lower anxiety titers and thus decrease LOS. The cost of performing this test is approximately $25, according to our institute’s psychologist; however, an extra day at the hospital costs approximately $2000.6

Better Preoperative Counseling

We further suggest providing preoperative education about the surgery that the patient is about to undergo to help ease anxiety. Despite preoperative education’s ability to decrease anxiety before surgery, its effects on LOS are still unclear.7

Better Assessment of Preoperative Medications

Patients receiving psychotropic medications for long periods before the surgery may be getting extra pain medications. Their pain protocols need to be further investigated. If patients taking psychotropic medications are getting extra pain medications and this is affecting their ability to ambulate, this could be prolonging their LOS. Still, further prospective studies in this regard are warranted.

CONCLUSION

Our study suggests that those with a diagnosis of anxiety who are medicated for that condition have a longer LOS than those with no diagnosis of anxiety and who are not medicated for the condition. Further prospective perioperative studies appear warranted.

Disclosure Statement

The author(s) have no conflicts of interest to disclose.

Acknowledgment

Mary Corrado, ELS, provided editorial assistance.

References


Anxiety

[The physician] realizes that a state of acute or chronic anxiety induces important physiological reactions, as well as destructive and interpersonal ones.

— Philip A Tumulty, 1912-1989, professor of medicine, Johns Hopkins University
Navigating the Next Accreditation System: A Dashboard for the Milestones

Samir Johna, MD; Brandon Woodward, MD

ABSTRACT

Introduction: In July 2014, all residency programs accredited by the Accreditation Council for Graduate Medical Education (ACGME) were enrolled in a new system called the Next Accreditation System. Residency programs may not be clear on how best to comply with these new accreditation requirements. Large amounts of data must be collected, evaluated, and submitted twice a year to the council’s Web-based data collection system. One challenge is that the new “end-of-rotation” evaluations must reflect specialty-specific milestones, on which many faculty members are not well versed. Like other residency programs, we tried to address the challenges using our local resources.

Methods: We used our existing electronic goals and objectives for each rotation coupled with appropriate end-of-rotation evaluations reflecting the specialty-specific milestones through a process of editing and mapping.

Results: Data extracted from these evaluations were added to an interactive dashboard that also contained evaluations on additional program-specific modifiers of residents’ performance. A resident’s final overall performance was visually represented on a plot graph. The novel dashboard included features to save evaluations for future comparisons and to track residents’ progress during their entire training. It proved simple to use and was able to reduce the time needed for each resident evaluation to 5 to 10 minutes.

Conclusion: This tool has made it much easier and less challenging for the members of our Clinical Competency Committee to start deliberation about each resident’s performance.

INTRODUCTION

Beginning in 1999, the Accreditation Council for Graduate Medical Education (ACGME) launched a series of changes, revamping medical education in the US. The accreditation of every academic residency program was shifted from being “process oriented” to “outcome oriented” through implementation of teaching and assessment of six core competencies. In July 2013, public and political pressure to train physicians capable of practicing cost-conscious and patient-centered care led to the development and implementation of Next Accreditation System (NAS). A year later, all residency programs were enrolled in the NAS system.

The Vision

The primary goal of the NAS, the ACGME hopes, is to transform the accreditation system into a less administratively burdensome process. The council envisions 2 mechanisms to achieve this goal. First, it wants to create a continuous accreditation model via annual data submission to the ACGME. The Residency Review Committees will evaluate trends in key performance measures on an annual basis, thus eliminating the 1- to 5-year review cycles and the Program Information Form. Instead, a self-study every 10 years will be in order. Unlike the old Program Information Form’s periodic follow-ups, it will allow programs to present their innovative achievements.

Second, the Residency Review Committees’ primary mechanism to confirm the program compliance with published educational standards will be via the biannual data submission. The provided information reflects all the dynamic changes in the residency program.

Two additional data sources are used:

1. The educational milestones represent the behavioral and clinical expectations that residents must achieve throughout their training. They also facilitate the identification of deficiencies so that proper remediation can be implemented in a timely manner. The newly formed Clinical Competency Committee will be responsible for making decisions regarding the progress of the residents.

2. The visit for the clinical learning environment review will focus on the learning environment, which is expected to be conducive to teaching and learning. It also looks at specific program achievements: patient safety, quality improvement, transitions of care, resident supervision, duty hours and fatigue recognition and mitigation, and professionalism.

What is the Problem?

Residency programs are still not clear on how best to comply with the new NAS requirements. Large amounts of data must be collected, evaluated, and submitted twice a year to the ACGME Web-based data collection system. Some of the challenges are not new, such as the delays in completing faculty evaluations on time. To further complicate matters, the new “end-of-rotation” evaluations must reflect the specialty-specific milestones.
Navigating the Next Accreditation System: A Dashboard for the Milestones

in which many faculty members are not well versed.

Although every Residency Review Committee has developed its own specialty-specific milestones, they are not meant to replace the end-of-rotation evaluations. Rather, they are summative descriptions of the cognitive, affective, and psychomotor domains of a resident’s performance over the course of every six months in training. Furthermore, the provided milestones are neither rotation specific nor specific to level of training.

**METHODS**

To address some of our challenges in implementing the NAS at our residency program, we conducted a self-study to look at options available to empower our newly formed Clinical Competency Committee. We started with our goals and objectives and our end-of-rotation evaluation for each index rotation.

We had two options available:
1. Use the specialty-specific milestones to rewrite a new set of goals and objectives, and end-of-rotation evaluations.
2. Use the current goals and objectives, and keep the same evaluation system after mapping each question in the evaluations to the appropriate milestone that matched the level of complexity of the question.

Given that we have more than 50 different rotations over the course of 5 years of training, the first option would have been a tremendously time-consuming and labor-intensive task. There was also a concern with the lack of proper faculty training on the new evaluation system. The second option seemed more practical because the required adjustments would be much easier to achieve.

We mapped every question in each end-of-rotation evaluation to reflect the appropriate level milestone, as shown in the Sidebar: Existing Evaluation Questions Mapped to the Milestones. This was feasible because most commercial evaluation software programs support such features.

Once the resident’s evaluation was completed, we could generate reports that reflected the resident’s performance on each milestone. However, these programs do not yet offer the Likert scale of 0 to 4 required by the NAS. Therefore, such scores must be converted to a Likert scale of 0 to 4.

**RESULTS**

To address all the earlier-mentioned issues, we created a dashboard, or a user interface on a computer display, using a spreadsheet program (Microsoft Excel 2010, Microsoft, Redmond, WA). The dashboard was created with a user interface for entering averages derived from evaluations linked to each milestone in our electronic evaluation system.

**Existing Evaluation Questions Mapped to the Milestones**

<table>
<thead>
<tr>
<th>Medical Knowledge</th>
<th>Patient Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>• MK 1A: Rate the resident’s ability to demonstrate an understanding of diagnosis and treatment of thoracic, intraabdominal, and retroperitoneal organ injuries.</td>
<td>• PC 1: Rate the resident’s ability to understand implications for a chest tube in trauma patients and understand management of chest tubes and chest drains.</td>
</tr>
<tr>
<td>• MK 1B: Rate the resident’s ability to diagnose and understand hemorrhagic shock.</td>
<td>MK = medical knowledge; PC = patient care.</td>
</tr>
<tr>
<td>• MK 2A: Rate the resident’s ability to outline the basic techniques of evaluation and resuscitation of trauma patients using the Advanced Trauma Life Support protocol.</td>
<td></td>
</tr>
<tr>
<td>• MK 2B: Rate the resident’s ability to show basic understanding of the principles of traumatic brain injury.</td>
<td></td>
</tr>
</tbody>
</table>

ICS = interpersonal and communication skills; MK = medical knowledge; OSCE = objective structured clinical examination; PBLI = practice-based learning and improvement; PC = patient care; PROF = professionalism; SBP = system-based practice.
A “modifiers” category was created for entering evaluation criteria on the basis of program-specific categories not included in our electronic evaluation system. Each category was divided into 4 levels with gradient bonuses or penalties scaled by postgraduate year (PGY). The assumption underlying the scaling was that fifth-year residents should be held to a higher standard and thus subject to more dramatic penalties and bonuses. A goal score of 1.5 was set for PGY-1, 2.0 for PGY-2, 2.5 for PGY-3, 3.0 for PGY-4, and 3.5 for PGY-5. The scale was such that if the resident achieved minimal goals as set by the Clinical Competency Committee, then s/he would meet or exceed the goal as signified by the gray line on the radar plot. The possibility existed for a resident to reach approximately 1 level above his/her training in particular categories. A radar plot was chosen because of the ease of graphical display of multiple data points simultaneously.

Additional features included an ability to save entered data for each resident, including semiannual evaluations for side-to-side comparison of progress of each resident. The summary page provided a 1-page analysis of a resident’s progress by combining a radar plot display of milestone achievements with program-specific modifiers and raw data in a table format (Figure 1). On the left side of the summary page we placed a snapshot of a resident’s performance on the milestones. In the middle of the page we gave a snapshot of the performance on the modifiers. On the right of the page a radar plot was generated to summarize the overall performance in a visual representation (Figure 2). The software was programmed to convert the Likert scale of 0 to 9 to a Likert scale of 0 to 4. This change allowed us to factor in modifiers that are important for residents’ progress such as logging hours and cases on time; to add performance on the American Board of Surgery in-training examination; to add performance on the objective structured clinical examination; to add scholarly activities; to add peers’, students’, and nurses’ evaluations; and so on.

The target performance for each resident was programmed to be specific to the level of training. The target level was colored red, and the resident’s performance was colored blue for easier visual identification. The visual representation offered by the radar plot was of paramount importance and represented a good starting point for members of the Clinical Competency Committee during deliberation about the progress of the resident. Furthermore, residents were provided with their own radar plots to help them envision and monitor their performance over time.

The initial evaluation of our dashboard was promising. It is simple to use, practical, and able to reduce the time needed for each resident evaluation to 5 minutes to 10 minutes instead of 45 minutes to 60 minutes, which is what the residency program directors entering the milestone evaluations before us said it required. So far, we have completed one year of evaluations (2 cycles). It validates our hypothesis regarding the utility of this new tool.

CONCLUSION

Our residency program was able to create a tool to store and evaluate residents’ progress through both graphical and numeric tracking on a one-page document (dashboard) in compliance with the milestones set forth by the ACGME while also incorporating program-specific modifiers.

This platform can be easily shared with other programs to help them catch up in this critical transition period.

Disclosure Statement

The author(s) have no conflicts of interest to disclose.

Acknowledgment

Kathleen Louden, ELS, provided editorial assistance.

References

The interactions of scarlet macaws around clay licks have been the focus of decades of extensive research. The iconic parrots seem to get sodium and other minerals from licking the clay deposits, and their use of the licks appears related to climate variations, food supply, and breeding times. Scarlet macaws inhabit tropical rainforest regions of the Americas. This large and beautiful species has suffered major population declines in recent years.

Dr Hahn retired from The Permanente Medical Group in 2010. He specializes in both wildlife and landscape photography. For further information about his artwork, Dr Hahn can be contacted at: hahnsk@sbcglobal.net.
SQUIRE 2.0 (Standards for QUality Improvement Reporting Excellence): Revised Publication Guidelines from a Detailed Consensus Process

Greg Ogrinc, MD, MS; Louise Davies, MD, MS; Daisy Goodman, DNP, MPH; Paul Batalden, MD; Frank Davidoff, MD; David Stevens, MD

ABSTRACT

Since the publication of Standards for Quality Improvement Reporting Excellence (SQUIRE 1.0) guidelines in 2008, the science of the field has advanced considerably. In this manuscript we describe the development of SQUIRE 2.0 and its key components. We undertook the revision between 2012 and 2015, using 1) semistructured interviews and focus groups to evaluate SQUIRE 1.0 plus feedback from an international steering group; 2) two face-to-face consensus meetings to develop interim drafts; and 3) pilot testing with authors and a public comment period. SQUIRE 2.0 emphasizes the reporting of three key components of systematic efforts to improve the quality, value, and safety of health care: the use of formal and informal theory in planning, implementing, and evaluating improvement work; the context in which the work is done; and the study of the intervention(s). SQUIRE 2.0 is intended for reporting the range of methods used to improve health care, recognizing that they can be complex and multidimensional. It provides common ground to share these discoveries in the scholarly literature (www.squire-statement.org).

INTRODUCTION

In 2005, draft publication guidelines for quality-improvement reporting debuted in Quality and Safety in Health Care. At that time, publications of scholarly work about health care improvement were often confusing and of limited value. Leaders in the field were working to consolidate the evidence for a science of improvement and without guidance on how to write their findings, authors struggled to report their improvement work in a reliable and consistent way. These factors influenced the initial publication in 2008 of the Standards for Quality Improvement Reporting Excellence (SQUIRE), which we will refer to as SQUIRE 1.0. The guidelines were developed in an effort to reduce uncertainty about the information deemed to be important in scholarly reports of health care improvement, and to increase the completeness, precision, and transparency of those reports.

In the intervening years, the reach of systematic efforts to improve the quality, safety, and value of health care has grown. Health professions education worldwide now includes improvement as a standard competency. The science of the field also continues to advance through guidance on applying formal and informal theory in the development and interpretation of improvement programs; stronger ways to identify, assess, and describe context; and recommendations for clearer, more complete descriptions of interventions and development of initial guidance on how to study an intervention.

In this setting, we have undertaken a revision of SQUIRE 1.0. When we began, it rapidly became apparent that a wide variety of approaches had developed for improving health care, ranging from formative to experimental to evaluative. Rather than limit the revised guidelines to only a few of these, we fashioned them to be applicable across the many methods that are used. We aimed to reflect the dynamic nature of the field, and support its further development. This article describes the development and content of SQUIRE 2.0 (Table 1).

SQUIRE 2.0 DEVELOPMENTAL PATH

We developed SQUIRE 2.0 between 2012 and 2015 in three overlapping phases: 1) evaluation of the initial SQUIRE guidelines, 2) early revisions, and 3) pilot testing with late revisions.

We began the evaluation of SQUIRE 1.0 by collecting data to assess its clarity and usability. Semistructured interviews and focus groups with 29 end-users of SQUIRE 1.0 revealed that many found SQUIRE 1.0 helpful in planning and doing improvement work, but less so in the writing process. This issue was especially apparent in efforts to write about the cyclic, iterative process that often occurs with improvement interventions. SQUIRE 1.0 was seen by many as unnecessarily complex with too much redundancy and lacking a clear distinction between “doing improvement” and “studying...
the improvement.” A recent independent study and editorial also documented and addressed some of these challenges.20,21

In the second phase, we convened an international advisory group of 18 experts that included editors, authors, researchers, and improvement professionals. This group met through 3 conference calls, reviewed SQUIRE 1.0 and the results of the end-user evaluation, and provided detailed feedback on successive revisions. This advisory group and additional participants attended 2 consensus conferences in 2013 and 2014 where they engaged in intensive analysis and made recommendations that further guided the revision process.

In the third phase, 44 authors used an interim draft version of the updated SQUIRE guidelines to write sections of a manuscript. Each author then provided comments on the utility and understandability of the draft guidelines, and in their submitted section, identified the portions of their writing sample that fulfilled the items of that section.22 We also obtained detailed feedback about this draft version through semistructured interviews with 11 biomedical journal editors. The data from this phase revealed areas needing further clarification and which specific items were prone to misinterpretation. Finally, a penultimate draft was e-mailed to more than 450 individuals around the world, including the advisory group, consensus meeting participants, authors, reviewers, editors, faculty in fellowship programs, and trainees. This version was also posted on the SQUIRE Web site with an invitation for public feedback. We used the information from this process to write SQUIRE 2.0 (Table 1).

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<thead>
<tr>
<th>Text section and item name</th>
<th>Section or item description</th>
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<tr>
<td>Notes to authors</td>
<td>The SQUIRE guidelines provide a framework for reporting new knowledge about how to improve health care. The SQUIRE guidelines are intended for reports that describe system-level work to improve the quality, safety, and value of health care, and used methods to establish that observed outcomes were due to the intervention(s). A range of approaches exists for improving health care; SQUIRE may be adapted for reporting any of these.Authors should consider every SQUIRE item, but it may be inappropriate or unnecessary to include every SQUIRE element in a particular manuscript. The SQUIRE glossary contains definitions of many of the key words in SQUIRE. The Explanation and Elaboration document provides specific examples of well-written SQUIRE items, and an in-depth explanation of each item. Please cite SQUIRE when it is used to write a manuscript.</td>
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<tr>
<td>Title and abstract</td>
<td>Indicate that the manuscript concerns an initiative to improve health care (broadly defined to include the quality, safety, effectiveness, patient-centeredness, timeliness, cost, efficiency, and equity of health care). Provide adequate information to aid in searching and indexing. Summarize all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local problem, methods, interventions, results, conclusions.</td>
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<tr>
<td>Introduction</td>
<td>Why did you start?</td>
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<td>Problem description</td>
<td>Nature and significance of the local problem</td>
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<tr>
<td>Available knowledge</td>
<td>Summary of what is currently known about the problem, including relevant previous studies</td>
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<tr>
<td>Rationale</td>
<td>Informal or formal frameworks, models, concepts, and/or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s), and reasons why the intervention(s) was expected to work</td>
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<td>Specific aims</td>
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<td>Context</td>
<td>Contextual elements considered important at the outset of introducing the intervention(s)</td>
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<td>Intervention(s)</td>
<td>Description of the intervention(s) in sufficient detail that others could reproduce it. Specifics of the team involved in the work.</td>
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<tr>
<td>Study of the intervention(s)</td>
<td>Approach chosen for assessing the impact of the intervention(s). Approach used to establish whether the observed outcomes were due to the intervention(s).</td>
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<td>Measures</td>
<td>Measures chosen for studying processes and outcomes of the intervention(s), including rationale for choosing them, their operational definitions, and their validity and reliability. Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency, and cost. Methods employed for assessing completeness and accuracy of data.</td>
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<tr>
<td>Analysis</td>
<td>Qualitative and quantitative methods used to draw inferences from the data. Methods for understanding variation within the data, including the effects of time as a variable.</td>
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<tr>
<td>Ethical considerations</td>
<td>Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest.</td>
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SQUIRE 2.0 (Standards for QUality Improvement Reporting Excellence): Revised Publication Guidelines from a Detailed Consensus Process

SQUIRE 2.0

Many publication guidelines, including CONSORT (randomized trials), STROBE (observational studies), and PRISMA (systematic reviews) focus on a particular study methodology (www.equator-network.org). In contrast, SQUIRE 2.0 is designed to apply across the many approaches used for systematically improving the quality, safety, and value of health care. Methods range from iterative changes using Plan-Do-Study-Act (PDSA) cycles in single settings to retrospective analyses of large-scale programs to multisite randomized trials. We encourage authors to apply other publication guidelines—particularly those that focus on specific study methods—along with SQUIRE, as appropriate. Authors should carefully consider the relevance of each SQUIRE item but recognize that it is sometimes not necessary, nor even possible, to include each item in a particular manuscript.

SQUIRE 2.0 retains the IMRaD (Introduction, Methods, Results, and Discussion) structure. Although used primarily for reporting research within a spectrum of study designs, this structure expresses the underlying logic of most systematic investigations and is familiar to authors, editors, reviewers, and readers. We continue to use A Bradford Hill’s four fundamental questions for writing: Why did you start? What did you do? What did you find? What does it mean? In our evaluation of SQUIRE 1.0, novice authors found these questions to be straightforward, clear, and useful.

SQUIRE 2.0 contains 18 items but omits the multiple subitems that were a source of confusion for SQUIRE 1.0 users. A range of approaches exists for improving health care, and SQUIRE may be adapted for reporting any of these. As stated above, authors should consider every SQUIRE item, but it may be inappropriate or unnecessary to include every SQUIRE item in a particular manuscript. In addition, authors need not use items in the order in which they appear. Major changes between SQUIRE 1.0 and 2.0 are concentrated in four areas: 1) terminology, 2) theory, 3) context, and 4) studying the intervention(s).

Terminology

The elaborate detail in SQUIRE 1.0 was seen by users as both a blessing and a curse: helpful in designing and executing quality-improvement work but less useful in the writing process. The level of detail sometimes led to confusion about what to include or not include in a manuscript. Consequently, we made the items in SQUIRE 2.0 shorter and more direct.

A major challenge in the reporting of systematic efforts to improve health care is the multiplicity of terms used to describe the work, which is challenging for novices and experts alike. Improvement work draws on the epistemology of a variety of fields, and depending on one’s field of study, the same words can carry different connotations, a particularly undesirable state of affairs. Terms such as “quality improvement,” “implementation science,” and “improvement science” refer to approaches that

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<th>Results</th>
<th>What did you find?</th>
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<td>Results</td>
<td>Initial steps of the intervention(s) and their evolution over time (e.g., time-line diagram, flow chart, or table), including modifications made to the intervention during the project.</td>
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<td>Details of the process measures and outcome.</td>
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<td>Contextual elements that interacted with the intervention(s).</td>
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<td>Observed associations between outcomes, interventions, and relevant contextual elements.</td>
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<td>Unintended consequences such as unexpected benefits, problems, failures, or costs associated with the intervention(s).</td>
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<td>Details about missing data.</td>
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<th>Discussion</th>
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<td>Summary</td>
<td>Key findings, including relevance to the rationale and specific aims.</td>
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<td>Particular strengths of the project.</td>
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<td>Interpretation</td>
<td>Nature of the association between the intervention(s) and the outcomes.</td>
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<td>Comparison of results with findings from other publications.</td>
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<td>Impact of the project on people and systems.</td>
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<td>Reasons for any differences between observed and anticipated outcomes, including the influence of context.</td>
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<td>Costs and strategic trade-offs, including opportunity costs.</td>
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| Limitations | Limits to the generalizability of the work. |
|            | Factors that might have limited internal validity such as confounding, bias, or imprecision in the design, methods, measurement, or analysis. |
|            | Efforts made to minimize and adjust for limitations. |

| Conclusions | Usefulness of the work. |
|            | Sustainability. |
|            | Potential for spread to other contexts. |
|            | Implications for practice and for further study in the field. |
|            | Suggested next steps. |

| Other information | Sources of funding that supported this work. Role, if any, of the funding organization in the design, implementation, interpretation, and reporting. |

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have many similarities but can also connote important (and often-debated) differences. Other terms such as “health care delivery science,” “patient safety,” and even simply “improvement” are also subject to surprising variation in interpretation. To address this problem in semantics, we created a glossary of terms used in SQUIRE 2.0 (see Sidebar: Glossary of Key Terms Used in SQUIRE 2.0). The glossary provides the intended meaning of certain key terms as we have used them in SQUIRE 2.0 (Table 1). These definitions may be helpful in other endeavors but are not necessarily intended to be adopted for use in other contexts. Overall, we sought terms and definitions that would be useful to the largest possible audience. For example, we chose “intervention(s)” to refer to the changes that are made. We decided not to use the word “improvement” in the individual items (although it remains in the SQUIRE acronym) to encourage authors to report efforts that did not lead to changes for the better. Reporting well-done, negative studies is vital for the learning in this discipline.

Theory
SQUIRE 2.0 includes a new item titled “Rationale.” Biomedical and clinical research is driven by iterative cycles of theory building and hypothesis testing. Health care improvement work has not consistently based the planning, design, and execution of its programs solidly in theory, to the detriment of the work. For this reason, SQUIRE 2.0 explicitly includes an item devoted to theory, although we chose to use the broader and less technical label “Rationale,” to encourage authors to be explicit in reporting formal and informal theories, models, concepts, or even hunches as to why they expected a particular intervention to work in a particular context. A plain language interpretation of “Rationale” might be, “Why did you think this would work?” A recent narrative review of the nature of theory and its use in improvement describes the many types and applications of theory, and considers pitfalls in using, and not using, theory.12

The addition of the “Rationale” item is intended to encourage clarity around assumptions about the nature of the intervention, the context, and the expected outcomes. The presence of a well thought-out rationale will align with appropriate measures and with the study of the intervention; it may also be the starting point for the next round of work. The “Summary” item in the Discussion section encourages authors to revisit the original rationale in the light of its findings and in the larger context of similar projects.

GLOSSARY OF KEY TERMS USED IN SQUIRE 2.0

This Glossary provides the intended meaning of selected words and phrases as they are used in the SQUIRE 2.0 Guidelines. They may, and often do, have different meanings in other disciplines, situations, and settings.

Assumptions: Reasons for choosing the activities and tools used to bring about changes in health care services at the system level.

Context: Physical and sociocultural makeup of the local environment (for example, external environmental factors, organizational dynamics, collaboration, resources, leadership, and the like), and the interpretation of these factors (“sense-making”) by the health care delivery professionals, patients, and caregivers that can affect the effectiveness and generalizability of intervention(s).

Ethical aspects: The value of system-level initiatives relative to their potential for harm, burden, and cost to the stakeholders. Potential harms particularly associated with efforts to improve the quality, safety, and value of health care services include opportunity costs, invasion of privacy, and staff distress resulting from disclosure of poor performance.26

Generalizability: The likelihood that the intervention(s) in a particular report would produce similar results in other settings, situations, or environments (also referred to as external validity).

Health care improvement: Any systematic effort intended to raise the quality, safety, and value of health care services, usually done at the system level. We encourage the use of this phrase rather than “quality improvement,” which often refers to more narrowly defined approaches.

Inferences: The meaning of findings or data, as interpreted by the stakeholders in health care services—improvers, health care delivery professionals, and/or patients and families.

Initiative: A broad term that can refer to organization-wide programs, narrowly focused projects, or the details of specific interventions (for example, planning, execution, and assessment)

Internal validity: Demonstrable, credible evidence for efficacy (meaningful impact or change) resulting from introduction of a specific intervention into a particular health care system.

Intervention(s): The specific activities and tools introduced into a health care system with the aim of changing its performance for the better. Complete description of an intervention includes its inputs, internal activities, and outputs (in the form of a logic model, for example), and the mechanism(s) by which these components are expected to produce changes in a system’s performance.17

Opportunity costs: Loss of the ability to perform other tasks or meet other responsibilities resulting from the diversion of resources needed to introduce, test, or sustain a particular improvement initiative.

Problem: Meaningful disruption, failure, inadequacy, distress, confusion, or other dysfunction in a health care service delivery system that adversely affects patients, staff, or the system as a whole, or that prevents care from reaching its full potential.

Process: The routines and other activities through which health care services are delivered.

Rationale: Explanation of why particular intervention(s) were chosen and why it was expected to work, be sustainable, and be replicable elsewhere.

Systems: The interrelated structures, people, processes, and activities that together create health care services for and with individual patients and populations. For example, systems exist from the personal self-care system of a patient, to the individual provider-patient dyad system, to the microsystem, to the macrosystem, and all the way to the market/social/insurance system. These levels are nested within each other.

Theory or theories: Any “reason-giving” account that asserts causal relationships between variables (causal theory) or that makes sense of an otherwise obscure process or situation (explanatory theory). Theories come in many forms, and serve different purposes in the phases of improvement work. It is important to be explicit and well-founded about any informal and formal theory or theories that are used.
Context

SQUIRE 2.0 accepts “context” as the key features of the environment in which the work is immersed and which are interpreted as meaningful to the success, failure, and unexpected consequences of the intervention(s), as well as the relationship of these to the stakeholders (e.g., improvement team, clinicians, patients, families, etc.). Systematic efforts to improve health care should contain clear descriptions and acknowledgment of context, rather than efforts to control it or explain it away. SQUIRE 1.0 included context with items in all sections of the manuscript, but context did not rise to the level of a distinct item itself. SQUIRE 2.0 recognizes context as a fundamental item in the Methods section, but its relevance is not limited to this section. In addition to affecting the development of the rationale and subsequent design of the intervention(s), context plays a key role in the iterations of intervention(s) and the outcomes. Although it is often not simple to capture or describe context, understanding its impact on the design, implementation, measurement, and results make it a vital contributor in identifying and reporting the factors and mechanisms responsible for the success or failure of the intervention(s).

Studying the Intervention(s)

The study of the intervention is, perhaps, the most challenging item in SQUIRE. In the evaluation of SQUIRE 1.0 and in the pilot testing, many were perplexed by this item and its sub-elements. This item was intended to encourage a more formal assessment of the intervention and its associated outcomes. In SQUIRE 2.0, this section is called, “Study of the Intervention(s)” (Table 1).

“Doing” an improvement project is fundamentally different from “studying” it. The primary purpose of “doing” improvement is to produce better local processes and outcomes, rather than to contribute to new generalizable knowledge. In contrast, the reason for “studying” the intervention is mainly to contribute to the body of knowledge about the efficacy and generalizability of efforts for improving health care. Both “doing” and “studying” are required for a deep understanding of the nature and impact of the intervention(s) as well as the possible underlying mechanisms. “Study of the Intervention(s)” focuses mainly on whether and why an intervention “works.” It should align with the rationale and may include, but is not limited to, preplanned formal testing of the proposed theory that the intervention(s) actually produced the observed changes, as well as the impact of the intervention(s) on the context in which the work was done.

SQUIRE 2.0 asks authors to be as transparent, complete, and as accurate as possible about reporting “doing” and “studying” improvement work as both aspects of the work are key to scholarly reporting. The “Summary” and “Interpretation” items in the Discussion encourage authors to explain potential mechanisms by which the intervention(s) resulted (or failed to result) in change, thereby developing explanatory theories that can be subsequently tested.

CONCLUSIONS

The development of SQUIRE 2.0 consisted of a detailed analysis of SQUIRE 1.0, input from experts in the field, and thorough pilot testing. Many methods and philosophical approaches to improve the quality, safety, and value of health care are available. The systematic efforts to improve health care are often complex and multidimensional, and their effectiveness is inherently context dependent. SQUIRE 2.0 provides common ground on which the discoveries contributed by the various approaches can advance the field by sharing them in the published literature.

At the same time, we recognize that simply publishing SQUIRE 2.0 will not effect this change; additional efforts and resources are required. For example, we have created an explanation and elaboration (E&E) document to accompany this article. For each item in SQUIRE 2.0, the E&E provides one or more examples from the published literature and a commentary on how the example(s) meets or does not meet the item’s standards; this information brings the content of each item to life. The SQUIRE Web site (www.squire-statement.org) contains a number of resources in addition to the guidelines themselves, including interactive E&E pages and video commentaries. The Web site supports an emerging online community for the continuous use, conversation about, and evaluation of the guidelines.

Writing about improvement can be challenging. Sharing successes, failures, and developments through scholarly literature is an essential component of the complex work required in order to improve health care services for patients, professionals, and the public. 

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References


Publication

Various advantages result even from the publication of opinions; for though they are very liable to error in forming them, yet their promulgation, by exciting investigation, and pointing out the deficiencies of our information, cannot be otherwise than useful in the promotion of science.

— John Abernethy, FRS, 1764-1831, English surgeon
Primary Epithelial Neuroendocrine Tumors of the Retroperitoneum

Ahmed Dehal, MD; Sean Kim, MD; Aamna Ali, MD; Thomas Walbolt, DO

INTRODUCTION

Primary retroperitoneal tumors account for 0.16% to 0.20% of all human neoplasms. The most frequent primary tumors of the retroperitoneum are lymphoproliferative disorders, soft-tissue neoplasms, and germ cell tumors.1 Primary neuroendocrine tumors (NETs) arising in the abdominal cavity mainly originate from the gastrointestinal tract and pancreas. NETs found in the retroperitoneum are mostly metastatic.2 Tumors of the neuroendocrine system are commonly divided into two main groups on the basis of cytoskeleton filaments. The neural group, which includes paraganglioma, is characterized by the predominant expression of neurofilaments; and the epithelial group, such as carcinoid, shows typically a cytoskeleton formed of keratins and occasionally neurofilaments.3 Although neural tumors, particularly paraganglioma, are frequently reported in the literature,1,3 epithelial NETs of the retroperitoneum are exceedingly rare. We present a case of primary epithelial NET of the retroperitoneum that was discovered incidentally during exploratory laparotomy for small-bowel obstruction. We also present a comprehensive review of the literature and a summary of all reported cases.

CASE REPORT

A 65-year-old otherwise healthy woman presented to the emergency room with a 3 days of abdominal pain, constipation, and repeated emesis. She had no prior surgical operations. She was tachycardic and her abdomen was diffusely tender. Laboratory data was significant for a white cell count of 33,000/mm$^3$. She was taken emergently to the operating room and underwent an exploratory laparotomy. She was found to have necrotic bowel caused by an adhesive band leading to a closed loop obstruction, ischemia, and gangrene. The necrotic segment was resected and viable bowel was re-anastomosed. Upon further exploration of the abdomen, the patient was noted to have an approximately 6 cm × 7 cm mass located to the left of midline adjacent to the left kidney, and anterior to the left ureter. The mass did not appear to originate from the aorta, kidney, or adrenal gland; was not related to the adhesive band; and was not involved in the intestinal obstruction. A decision was made to perform an intraoperative incisional biopsy; the biopsy specimen was sent for pathologic examination along with the resected bowel specimen. Computed tomography (CT) scan of the abdomen was performed after the surgery and showed a mass in the left retroperitoneum consistent with operative findings (Figure 1).

Figure 1. Computed tomography scan of the abdomen showing the left retroperitoneal mass.
The postoperative course was uneventful and the patient was discharged to home 3 days after surgery in good condition. Histopathologic examination of the resected intestine revealed findings consistent with ischemia secondary to obstruction with no evidence of malignancy. Histologic examination of the incisional biopsy specimen of the mass showed oval and round tumor cells arranged in a trabecular pattern with less than 1 mitosis/10 high-power fields and 2% Ki-67 proliferation rate. Tumor cells were positive for cytokeratin, chromogranin, and synaptophysin (Figures 2 and 3). The diagnosis of low-grade, well-differentiated epithelial NET was made. The patient was seen in the clinic 2 weeks after surgery; further questioning revealed no recent history of flushing, diarrhea, breathing difficulty, or weight loss.

Octreotide scan at that time showed a somatostatin-avid tumor in the left abdomen consistent with the previously noted mass (Figure 4). The remainder of the full-body octreotide scan was unremarkable. CT scan of the chest was negative for any metastatic disease. Biochemical evaluation, including urine 5-hydroxyindoleacetic acid and chromogranin, were within normal limits. The patient was then referred to gastroenterology for upper and lower gastrointestinal tract endoscopical examination. Colonoscopy was normal except for a 3 mm polyp in the sigmoid colon that was removed. Histopathologic examination was consistent with mucosal prolapse without evidence of malignancy. Esophagogastroduodenoscopy with endoscopic ultrasonographic examination was completely normal except for a small area, less than 1 cm, of mucosa in the second portion of the duodenum that was mildly nodular. Multiple biopsies were performed and found to be negative for malignancy. The patient was seen in the clinic one month after the surgery; further surgical resection was recommended but the patient declined surgery at that time.

Six months later, the patient returned to the clinic and wanted to proceed with surgery. Repeat CT imaging showed the mass stable in size with no new lesions elsewhere in the body, and the decision was made to proceed with surgery. Considering the proximity of the mass to the left kidney and ureter, a left ureteral stent was placed preoperatively by urology. Upon abdominal exploration, the peritoneum, liver, pancreas, intestines, uterus, and ovaries were examined. No evidence of tumor was seen. We then proceeded with resection of the mass. The left colon was mobilized laterally to medially along the white line of Todt, and the colon was reflected medially. The left ureter was identified. The stent was palpated and dissection was carried inferosuperiorly to the level of the mass. The mass was noted to lay anteriomedially to the ureter, with a distinct plane between the two. Using both sharp and blunt dissection, the mass was carefully dissected off the surrounding structures of the retroperitoneum. The resected mass was solid, ovoid, and approximately 7.5 cm in diameter (Figure 5). Cross-sectioning revealed a tan-red, focally hemorrhagic, and necrotic cut surface. In addition to the removal of the mass, the grossly normal appendix was removed in a standard open fashion to rule out the possibility of a primary appendiceal NET. Subsequent pathologic examination of the appendix revealed no significant abnormality. The postoperative course was uneventful and the patient was discharged home 1 week after surgery in good condition. Histopathologic
and immunohistochemical examination of the resected mass was consistent with the initial biopsy. The patient was seen in the clinic 2 weeks after the surgery and was doing well.

DISCUSSION

The retroperitoneum is a large area extending from the thoracic to the pelvic diaphragm between the iliac crests and the tips of the twelfth ribs laterally. There is a great variety of tissues in the retroperitoneum, including mesothelial, connective, and nervous tissues that are potential sites for tumor formation. We describe a case of epithelial NET that was found incidentally during exploratory laparotomy for small-bowel obstruction. Retroperitoneal tumors with neuroendocrine features most commonly represent metastatic tumors with either a known or unknown primary. The primary tumors are usually neural NETs, such as paraganglioma, heterotrophic pancreas, or adrenal tissues. In this case, the tumor was completely isolated from alimentary organs, including the pancreas and gut. On histologic examination, the tumor showed no evidence of lymph node, paraganglia, pancreatic, or adrenal tissues. Moreover, extensive evaluation failed to reveal any evidence of primary tumor elsewhere in the body. Finally, the anatomic location, the macroscopic and microscopic histologic examination, as well as the immunohistochemical analysis of the tumor were similar to the three other reported cases in the literature. It is therefore thought likely that this epithelial NET was a primary lesion originating in the retroperitoneal cavity.

The possibility that the tumor in this case is a metastatic disease of a missed small primary tumor somewhere else is a possibility. Neither the biochemical nor the radiologic investigations that are used in the evaluation of metastatic NETs is reliable in ruling out such possibility. The sensitivity of the 24-hour urinary 5-hydroxyindoleacetic acid testing has been reported to be as low as 35% and the specificity approximately 88%. Chromogranin A, however, has a very high sensitivity though it still has poor specificity. Overall sensitivity of the octreotide scan is reported to be as high as 90%; however, false negatives (ie, failed detection) may result from various technical issues including small tumor size, or from inadequate expression of somatostatin receptors. CT and magnetic resonance imaging (MRI) are important modalities used in the localization of carcinoid primaries and/or metastases. The median detection rate and sensitivity of CT and/or MRI have been estimated at 80%; detection rates by CT alone vary from 76% to 100%, whereas MRI detection rates vary from 67% to 100%. CT and MRI are better for initial localization of the tumor than for metastatic disease because both imaging techniques may miss tiny lesions. One study has shown that metastatic lesions in 50% of patients were missed, especially in lymph nodes and extrahepatic locations.

No well-established staging system exists for NETs. Despite the inability to establish a single system of nomenclature, grading, and staging for NETs of all sites, there are common features to form the basis of most systems. Those features include size, mitotic count, vascular and perineural invasion, nuclear polymorphisms, and Ki-67 labeling index. The most recent World Health Organization classification divides NETs into well-differentiated endocrine tumors (benign or low-grade malignancy), well-differentiated endocrine carcinomas, poorly differentiated endocrine carcinomas, and tumor-like lesions. This differentiation is based on the tumor’s histology, tumor size, morphology, and presence or absence of local invasion or metastasis. This case was diagnosed by this classification as a low-grade, well-differentiated NET.

We conducted a literature review of all published cases of primary retroperitoneal NETs in the English language. To date, there have been only 4 reported cases. The first case was a 37-year-old woman who presented with an incidentally found retroperitoneal mass compressing the right colon. At surgery, the mass was located in the retroperitoneum lateral to the right kidney without connection to the colon, kidney, or adrenal gland. The mass had a thick fibrotic capsule and was filled with hemorrhagic fluid. Histologic examination revealed a uniform population of round to oval cells arranged in sheets and nests. Mitotic figures were

<table>
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<th>Author, year</th>
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<td>Pack and Tabah,19 1954</td>
<td>120</td>
<td>17 (14.2)</td>
<td>103 (85.8)</td>
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<tr>
<td>Tidrick and Goldstein,19 1955</td>
<td>32</td>
<td>2 (6.2)</td>
<td>30 (93.8)</td>
</tr>
<tr>
<td>North,20 1960</td>
<td>17</td>
<td>5 (29.4)</td>
<td>12 (70.6)</td>
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<tr>
<td>Braasch and Mon,20 1967</td>
<td>101</td>
<td>13 (12.9)</td>
<td>88 (87.1)</td>
</tr>
<tr>
<td>Mehta et al,21 1981</td>
<td>42</td>
<td>7 (16.7)</td>
<td>35 (83.3)</td>
</tr>
<tr>
<td>Singh et al,21 1984</td>
<td>5</td>
<td>1 (20)</td>
<td>4 (80.0)</td>
</tr>
<tr>
<td>Alivi et al,21 1993</td>
<td>6</td>
<td>0 (0)</td>
<td>6 (100.0)</td>
</tr>
<tr>
<td>Pol et al,24 2005</td>
<td>42</td>
<td>14 (33.3)</td>
<td>28 (66.7)</td>
</tr>
<tr>
<td>Kalszewski et al,24 2010</td>
<td>7</td>
<td>6 (85.7)</td>
<td>1 (14.3)</td>
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<tr>
<td>Viresa Rodriguez et al,24 2010</td>
<td>37</td>
<td>6 (16.2)</td>
<td>31 (83.8)</td>
</tr>
</tbody>
</table>
observed. On immunohistochemistry, the tumor cells were positive for cytokeratin, Ber-HP4, CD56, synaptophysin, and chromogranin, but negative for CD99, D2-40, and S-100, consistent with a diagnosis of NET. No other hypermetabolic lesions were detected on imaging and a diagnosis of primary retroperitoneal NET with an epithelial origin was given.11

The second case was reported in a 71-year-old woman who presented with left abdominal pain and a mass.12 Imaging demonstrated the mass to be in the superolateral left retroperitoneum, displacing the left kidney medially. Further imaging showed no other masses. At surgery, the mass was noted to be adhered to the aortoiliac perivascular tissues. Macroscopically, the tumor appeared to be a large cyst with a thin fibrous capsule and filled with hemorrhagic fluid. Microscopically, the tumor was composed of a uniform population of round neoplastic cells arranged in trabeculae and nests. Nuclear polymorphism was mild and mitotic figures were absent. Tumor cells were immunoreactive to cytokeratin, epithelial membrane antigen, neuron-specific enolase, chromogranin A, pancreatic polypeptide, and gastrin. Tumor cells were also weakly positive for Grimelius stain and negative for Masson-Fontana stain. Ultrastructural observation of neurosecretory granules confirmed the neuroendocrine nature of the tumor and the diagnosis of primary epithelial retroperitoneal NET was rendered. However, in light of the anatomic location of the tumor, which was tightly adherent to the perivascular at the same site where the organ of Zuckerkandl is normally located, and the presence of scattered S-100 positive cells, the possibility of a paraganglionic origin was considered.12

The third reported case was that of a 41-year-old woman who had left flank pain and was found to have a left abdominal mass on physical examination.13 Imaging revealed a mass in the left retroperitoneum. At surgery, the mass was noted to be located in the retroperitoneal cavity isolated from other organs. The mass was solid and once again had a thick fibrous capsule. Further imaging revealed no other lesions and urine 5-hydroxyindoleacetic acid was within normal limits. Histologically, the tumor showed a trabecular pattern with a positive reaction for Grimelius stain, but negative reaction for Masson-Fontana stain. Tumor cells were negative for argentaffin and positive for argyrophil reactions. Immunohistochemically, vasoactive intestinal polypeptide, human chorionic gonadotropin-alpha, and somatostatin were identified. Electron microscopy revealed numerous neurosecretory granules in the tumor cells. No signs of lymph nodes, osseous or cartilaginous tissues, paraganglia, or pancreatic tissues were found on histopathologic examination. These findings, therefore, led the authors to conclude that the tumor was likely a primary NET of epithelial origin originating from the retroperitoneum.13

The 4th case was reported in a 14-year-old boy who presented with 3 months of vomiting.14 Imaging showed a 4-cm × 3-cm-sized solid homogeneous mass located in front of the pancreas and dissociated from pancreatic and liver tissue. The mass was removed surgically. Surgical exploration of the mass showed no evidence of hepatic, pancreatic, or other metastatic disease or pathologic lymph node. Gross examination of the tumor showed a sharply demarcated solid grayish-tan colored lesion that was 3.5 cm × 3.5 cm in size, with punctuate foci of hemorrhage. Microscopically, the tumor was composed of nests and trabecular growth pattern. Immunohistochemically, tumor cells showed reactivity for pankeratin, neuron-specific enolase, synaptophysin, S-100, and CD 56. The rate of Ki-67 ranged from 2% to 5%. Histopathologic examination and immunohistochemical findings of the specimen were consistent with NET. Further evaluation was negative and the diagnosis of primary retroperitoneal NET was rendered.14

Since Morgagni first described retroperitoneal tumors in 1761, a large series of primary retroperitoneal tumors have been reported (Table 1). Thirteen series have reported a total of 699 cases of primary retroperitoneal tumors from 1946 to 2010.15–26 The majority of these tumors originated from mesothelial and connective tissues of the retroperitoneal space. Approximately 82% of these tumors were malignant. The most common malignant tumors in this group were sarcomas and lymphomas. The most common age group affected was between the 4th and 7th decades of life; male to female distribution was equal. Interestingly, NETs were not reported in any of these series.

CONCLUSION

We present a case of a retroperitoneal NET that was discovered incidentally during exploratory laparotomy for small-bowel obstruction. The tumor was completely isolated from other retroperitoneal organs, and operative exploration did not reveal any other foci of carcinomatosis, metastases, or other primary lesions. Extensive biochemical and radiologic evaluation did not reveal any other primary or metastatic disease. Pathologically, there was no evidence of lymph node, paraganglia, pancreatic, or adrenal tissues present in the specimen. Finally, the gross description of capsule and hemorrhagic components as well as the histobiochemistry corroborate the findings of the other four case reports, with some very minor deviation of detail. Thus, we believe that this may be only the fifth reported case of primary epithelial NET arising within the retroperitoneum to date. Although exceedingly rare, the possibility of such a diagnosis should be considered in the differential diagnosis of a retroperitoneal tumor with similar clinical, anatomical, and pathologic features. However, in the absence of a biochemical test or an imaging tool with 100% sensitivity in detecting very small tumors, the possibility that this tumor might be a metastatic disease cannot be completely excluded and should be considered as well.

Conflicts of Interest

The author(s) have no conflicts of interest to disclose.

Acknowledgment

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Primary Epithelial Neuroendocrine Tumors of the Retroperitoneum

Reference


Scientific Solution

To conserve health and to cure disease: Medicine is still pursuing a scientific solution of this problem, which has confronted it from the first.

— Claude Bernard, 1813-1878, French physiologist, one of the first to suggest the use of blind experiments to ensure the objectivity of scientific observations
CASE REPORTS

High-Dose *Viscum album* Extract Treatment in the Prevention of Recurrent Bladder Cancer: A Retrospective Case Series

Tido von Schoen-Angerer, MD, MPH; Johannes Wilkens, MD; Gunver S Kienle, MD; Helmut Kiene, MD; Jan Vagedes, MD, MA

ABSTRACT

**Introduction:** *Viscum album* extract (European mistletoe), containing immunoactive compounds with dose-dependent cytotoxic activity, is being used as an adjuvant cancer treatment in Europe. Few studies have yet been done with high-dose, fever-inducing *Viscum album* treatment.

**Objective:** To explore whether subcutaneous injections of high-dose *Viscum album* have a preventive effect on risk of recurrence of bladder cancer.

**Methods:** We retrospectively analyzed the case records of patients with resectable bladder cancer who underwent initiation of high-dose *Viscum album* treatment at our clinic between January 2006 and December 2012.

**Main Outcome Measures:** We calculated tumor recurrence and progression risk and explored case records to assess whether treatment had a likely, possible, or unlikely beneficial effect.

**Results:** Eight patients were identified, 7 of whom had nonmuscle-invasive bladder cancer and 1 with muscle-invasive cancer. Four patients had frequently recurring tumors before treatment. Among the 8 patients, 28 episodes of recurrence were observed. Median tumor-free follow-up duration was 48.5 months. High-dose *Viscum album* showed a possible beneficial effect in 5 of 8 patients, could not be assessed in 2 patients, and had an uncertain effect in 1 patient. No tumor progression was observed. Treatment was generally well tolerated and no patient stopped treatment because of side effects.

**Conclusion:** High-dose *Viscum album* treatment may have interrupted frequently recurring tumors in individual patients with recurrent bladder cancer. Prospective studies are needed to assess whether this treatment offers an additional, bladder-sparing preventive option for patients with intermediate- to high-risk nonmuscle-invasive bladder cancer.

INTRODUCTION

There are an estimated 386,000 new cases of bladder cancer reported globally each year, with 150,000 deaths.\(^1\) Approximately 70% of patients with bladder cancer present with nonmuscle-invasive cancer, with recurrence in 50% to 70% of cases and progression to muscle-invasive cancer in 10% to 20% of cases.\(^2\) Active and passive tobacco exposure is the main risk factor for bladder cancer, followed by occupational exposure to benzene derivatives and arylamines.\(^3\)

Radical cystectomy with neoadjuvant chemotherapy is the standard therapy for muscle-invasive bladder cancer.\(^3\) Treatment of nonmuscle-invasive bladder cancer, which includes pathology Stages Ta, T1, and Tis, is transurethral resection. Intravesical bacillus Calmette-Guérin immunotherapy is used to reduce recurrence and progression risk in these patients.\(^4\) Intravesical treatment with mitomycin C has also been shown to reduce tumor recurrences and is used in the immediate postoperative period after resection of nonmuscle-invasive cancer.\(^5\) Cystectomy should be considered for patients at high risk of recurrence and is indicated when intravesical bacillus Calmette-Guérin immunotherapy fails.\(^3\)

Whole plant extract of *Viscum album* (European mistletoe) contains a variety of immunoactive compounds with dose-dependent cytotoxic activity and is used as adjuvant cancer therapy in Europe.\(^6,7\) The immunoactive compounds include mistletoe lectins, viscosotoxins, and other low-molecular-weight proteins, including VisalbCBA (*Viscum album* chitin-binding agglutinin), oligosaccharides and polysaccharides, flavonoids, and triterpene acids. The whole plant extract and several of its compounds on their own are cytotoxic, and mistletoe lectins in particular have strong apoptosis-inducing effects. The antitumor activity of mistletoe lectins, including a prophylactic effect, has also been linked to their immunostimulatory effect, including in vitro and in vivo activation of monocytes/macrophages, granulocytes, natural killer cells, T cells, dendritic cells, and the induction of a variety of cytokines.\(^8,9\) Furthermore, *Viscum album* extracts appear to interfere with tumor angiogenesis.\(^6\) A recent trial showed survival benefit in patients with advanced pancreatic cancer who were receiving *Viscum album* extracts,\(^12,13\) and durable tumor regression has been documented in case reports.\(^14\)
Most studies to date have tested the effects of low doses of *Viscum album* extract.\(^6\) However, more recently, clinicians have explored the use of high doses of the extract in light of its strongly dose-dependent cytotoxic activity\(^6,7\) and with the aim of increasing the immunostimulatory and fever-inducing effect of this treatment at initial doses.\(^8\) Careful patient monitoring with high-dose treatment is important. Manufacturers recommend starting with the lowest strength, titrating upward until a mild fever and/or local inflammatory reaction occurs. Anaphylactic reactions to *Viscum album* extracts have been reported but are rare.\(^9\) High-dose fever-inducing *Viscum album* extract treatment had a tumor-reducing effect in patients with advanced hepatocellular carcinoma.\(^10\) Fever or hyperthermia has direct cytotoxic effects in human beings, activates antitumor immune mechanisms, and results in improved drug delivery to tumor sites through vasodilatation.\(^11\) Tumor remissions in the context of febrile infections have been well documented,\(^12\) which has led to the development of hyperthermia treatment for cancer. Combining intravesical hyperthermia treatment with intravesical mitomycin C treatment has been shown to reduce bladder cancer recurrence by 59%.\(^13\) In a recent pilot study, hyperthermia treatment alone, when used before transurethral resection in patients with intermediate- to high-risk non-muscle-invasive bladder cancer, resulted in 53% of patients showing complete tumor remission.\(^14\) New targets for immunotherapy, beyond classic intravesical bacillus Calmette-Guérin immunotherapy, are also showing promising results.\(^15\)

However, to our knowledge, no studies have yet been done to explore the effect of high-dose, fever-inducing *Viscum album* extract treatment on bladder cancer recurrence. Therefore we did a retrospective analysis of the case notes of a series of patients with bladder cancer undergoing treatment with subcutaneous injections of high-dose *Viscum album* (Salicis, grown on willow trees) extract at one hospital outpatient clinic, to explore the effect of high-dose treatment on tumor recurrence.

**METHODS**

We reviewed the case notes of all patients with bladder cancer being treated at the outpatient clinic of the Alexander von Humboldt Klinik, Bad Steben, Germany. This hospital is a specialty center for high-dose *Viscum album* extract treatment.\(^22\) Inclusion criteria were patients with confirmed, resectable (nonmuscle-invasive or muscle-invasive), urothelial bladder cancer who had undergone treatment with at least three injections of high-dose *Viscum album* (Salicis) extract between January 2006 and December 2012. We excluded patients who had had a cystectomy or those with advanced, inoperable bladder cancer. We reviewed patient data until December 31, 2013. Patients were contacted to verify their personal details, and we acquired written informed consent. We conducted brief interviews, which included exploration and documentation of patients' experiences during treatment with high-dose *Viscum album* extract treatment. Formal ethics approval was not required to carry out this case series. All patients were sent copies of our final analysis.

We calculated recurrence and progression risk in these patients using the European Organisation for Research and Treatment of Cancer (EORTC) risk tables.\(^23\) In cases where patients had not responded to intravesical bacillus Calmette-Guérin immunotherapy, defined as recurrence of a high-grade tumor at 3 months after treatment, or recurrence after intravesical bacillus Calmette-Guérin immunotherapy, we used the progression risk of more than 25% after 5 years as reported by Davis et al.\(^24\)

We assessed the pattern of bladder cancer recurrence in included cases and categorized patients into 1 of 4 groups: likely beneficial effect, possible beneficial effect, unlikely beneficial effect, and not possible to assess. We considered high-dose *Viscum album* extract to have a likely beneficial effect when recurrence and progression risk was close to 100% and there was no more than 1 tumor recurrence after treatment. We considered there to be a possible beneficial effect when patients had no further recurrences 1 month after the start of treatment, tumor-free follow-up more than 30 months after treatment, and recurrence risk at time of treatment initiation between 62% and 78% (based on an EORTC score). We considered treatment to have an unlikely beneficial effect when patients had more than 1 recurrence after treatment. Patients with other circumstances explaining tumor nonrecurrence—for example, patients already tumor-free after another treatment or when tumor-free follow-up was less than 30 months—were categorized as not possible to assess.

For all included patients in this analysis, the treatment used was Iscucin Salicis (Wala Heilmittel GmbH, Bad Boll, Germany), an aqueous extract of *Viscum album* (European mistletoe) grown on willow trees (Salicis). Preparation involves extraction from freeze-dried whole plant with isotonic solution over 14 days without fermentation or heating, in accordance with methods reported in the German Homeopathic Pharmacopoeia (Rule 38).\(^25\) One ampoule (1 mL) of a 1:20 concentration (5%, Strength H) contains 50 mg of the “mother extract” (including approximately 5.9 μg/mL of lectin, a key active ingredient);\(^26\) concentration 1:400 (0.255%, Strength G) contains 2.5 mg; concentration 1:8000 (0.0125%, Strength F) contains 0.125 mg; and concentration 1:160,000 (0.000625%, Strength E) contains 0.00625 mg. Strengths F, G, and H fulfilled our criteria for high dose. Iscucin Salicis is licensed for the German market by the German Federal Institute for Drugs and Medical Devices.

For included patients in this series, the schedules of *Viscum album* extract treatment were individualized but followed general principles. All injections were given as 1-mL aqueous solutions subcutaneously in the lower aspect of the abdomen or upper part of the thigh. An initial dose of Iscucin Salicis at the highest strength, H (except Strength F in Case 2), was given in the outpatient clinic to observe reaction. Patients who responded with high fever and inflammatory reactions at the injection site received further injections, usually once
weekly for 3 to 8 weeks. If no or little reaction occurred, injections were continued daily over 3 to 4 days to achieve the required inflammatory reaction. In patients with little or no reaction even after daily administration, Strength H was followed by weekly or twice-weekly injections of Iscucin Salicis Potency series II (a set containing Strengths D, E, F, and G) given in the order of 2×G, 2×F, 3×E, and 3xD and repeated over several months. One patient (Case 8) also received other types of Viscum album extract preparations.

Because the Alexander von Humboldt Klinik does not provide specialized urology services, all patients were followed up simultaneously by a private-practicing urologist or at a urology center.

**CASE SUMMARIES**

We identified eight patients who met our inclusion criteria: seven with nonmuscle invasive bladder cancer (pTa and pT1) and one with muscle-invasive bladder cancer (pT2a) who had refused cystectomy. Three cases are reported here in detail.

**Case 1**

A 59-year-old woman presented in February 2006 with 2 months of right-sided, colicky abdominal pain. Her medical history highlighted the removal of a uterine myoma and right-knee arthrosis with prosthetic replacement. She was a smoker (20 cigarettes per day since early adulthood). A urothelial carcinoma of the right renal pelvis, Stage pT3G1, was diagnosed by computed tomographic (CT) scan and renal biopsy. Nephroureterectomy was performed in February 2006. During cystoscopy in April 2006, 4 superficial bladder tumors were removed. (Upper urinary tract urothelial cancer has a 20% to 50% risk of recurrence, as does bladder cancer.) She received 6 rounds of intravesical bacillus Calmette-Guérin immunotherapy (BCG Medac, Hamburg, Germany) at weekly intervals beginning in May 2006. Two new tumors—I was high-grade (World Health Organization Grade 3)—were removed in November 2006. Cystectomy was not recommended to her (although 2013 European guidelines recommend cystectomy for failure to respond to bacillus Calmette-Guérin immunotherapy). In November 2006, the patient was treated with high-dose Viscum album extract treatment, which was provided as follows:

- **Month 1:** Iscucin Salicis Strength H was given in twice-weekly injections, with the first injection at the clinic, then self-administered at home. The patient’s temperature reached up to 40°C, and she experienced redness and 2 to 3 cm of swelling at the injection site within hours after each injection.
- **Months 2 to 4:** Iscucin Salicis Potency Series II was given in twice-weekly injections. No fever or local reaction occurred.
- **Cotreatment:** Aurum muriaticum D12, a homeopathic remedy, was given orally to address depressed mood. This treatment started simultaneously with Viscum album extract treatment and was given during Months 1 to 4.

There was no further recurrence of bladder cancer tumors after the initiation of Viscum album extract treatment at follow-up with annual cystoscopy/ureterorenoscopy and CT scan in 2007, and with magnetic resonance imaging in 2009 and 2012. This patient took early retirement in 2008 unrelated to her medical condition, feels well today, and remains socially active. She has reduced smoking to 7 or 8 cigarettes a day.

The patient told us: “The mistletoe treatment was intense, like I imagine chemotherapy [would be] but without nausea and vomiting. Shortly after starting mistletoe treatment I began feeling better and felt my strength return. Without the regular encouragement by Dr W, I would not have been able to tolerate the fever reactions. I think mistletoe stopped my tumors from returning.”

**Case 2**

A 62-year-old woman presented with hematuria and received a diagnosis of superficial bladder cancer in 1991 (pathology records were missing). Her medical history was remarkable for longstanding essential hypertension and for hysterectomy for treatment of multiple uterine myomas at age 40 years. She smoked 7 to 10 cigarettes per day.

In 1997 and 2001, she had bladder cancer recurrences, Stage pTaG2 (data obtained from medical records; pathology reports were missing). After 2 further recurrences in May and June 2005, Stage pTaG1 and pTis, respectively, she received intravesical instillation of mitomycin C and a single course of bacillus Calmette-Guérin immunotherapy consisting of 6 intravesical treatments. Intravesical bacillus Calmette-Guérin immunotherapy was not continued because it induced cystitis. In June 2008, she had a multifocal pTaG2 and pTisG3 recurrence, causing right ureteral ostium stenosis with hydronephrosis, which was alleviated by placement of a ureteral stent. In July 2008, clear cell adenocarcinoma of the left kidney, a cancer of different cellular origin than urothelial cancer, was diagnosed (pT1aG2L0M0), and a partial nephrectomy was performed. In August 2008, a multifocal bladder tumor (Stage pTisG3) was found. Cystectomy was recommended, but the patient declined treatment.

She looked for additional treatment options and began Viscum album extract treatment in November 2008. Strength F rather than Strength H was selected because she appeared too fragile to tolerate a high fever. The treatment schedule was as follows:

- **Months 1 to 3:** Iscucin Salicis Strength F was given in once-weekly injections. No fever or local reaction occurred.
- **Months 4 to 59** (end of study): Iscucin Salicis Strength F was given in twice-weekly injections. No fever or local reaction occurred.
- **Cotreatment:** Argentum nitricum compositum and Arsenicum album as supportive homeopathic remedies were given at different times.

No further recurrence was observed at annual cystoscopy assessments. Her quality of life, however, was affected by frequent bladder infections...
with dysuria, probably because of the ureteral stent. Antibiotic treatments provided limited, temporary relief. Dysuria stopped with placement of a new stent in November 2013 (1 month before study completion). Because of the last transurethral resection she has incontinence, as she is unaware when her bladder is full.

The patient told us: “Since the mistletoe treatment I no longer live in fear of the cancer returning. However, I have been in constant discomfort and pain because of my urinary [tract] infections.”

Case 8

After hematuria developed in a 64-year-old woman, a high-grade, muscle-invasive urothelial bladder cancer (Stage pT2aG3) was diagnosed in May 2007. The tumor was resected transurethrally. No local tissue infiltration and no metastases were found after a CT scan and bone scintigraphy. The patient had worked for 15 years in a polyvinyl chloride factory, a known risk factor for liver cancer, but not bladder cancer. She had never smoked. Her medical history was unremarkable. She was offered a cystectomy but felt overwhelmed by the cancer diagnosis and refused any invasive procedures.

She contacted different physicians for alternative treatment options and began Viscum album extract treatment in May 2007. She received no mitomycin C instillations, no chemotherapy, and no radiotherapy. Viscum album extract treatment was provided as follows:

- Months 1 to 4: Iscucin Salicis
- Months 5 to 10: Iscucin Salicis
- Months 11 to 15: AbnobaVISCUM Betulae (Abnoba Heilmittel GmbH, Pforzheim, Germany; Viscum album from a birch tree). There was a reaction of local redness, itching, nausea, and headache only after the first 2 injections. After the following injections, she reported an increase in energy.

### Table 1a. Patient overview

<table>
<thead>
<tr>
<th>Case No.</th>
<th>Sex</th>
<th>Age at diagnosis, years</th>
<th>Cancer description and stage</th>
<th>Cystectomy</th>
<th>Chemotherapy/ radiotherapy (excluding mitomycin C)</th>
<th>Number of recurrence episodes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a</td>
<td>F</td>
<td>59</td>
<td>Renal urothelial cancer, pT3G1; bladder recurrence, pTaG3</td>
<td>No</td>
<td>No</td>
<td>Recurrences from diagnosis: 2, Recurrences after BCG: 1, Not received: 0</td>
</tr>
<tr>
<td>2a</td>
<td>F</td>
<td>62</td>
<td>pTaG2 and Tis</td>
<td>No</td>
<td>No</td>
<td>Recurrences after mitomycin C: 6, 2, 2, 0</td>
</tr>
<tr>
<td>3a</td>
<td>M</td>
<td>68</td>
<td>pTaG2</td>
<td>No</td>
<td>No</td>
<td>Not received: 4, 4, 0</td>
</tr>
<tr>
<td>4a</td>
<td>M</td>
<td>53</td>
<td>pTaG2</td>
<td>No, refused</td>
<td>No</td>
<td>Not received: 4, 2, 3</td>
</tr>
<tr>
<td>5a</td>
<td>M</td>
<td>59</td>
<td>pT1aG1</td>
<td>No</td>
<td>No</td>
<td>Not received: 3, 0</td>
</tr>
<tr>
<td>6a</td>
<td>M</td>
<td>74</td>
<td>pT1G1</td>
<td>No</td>
<td>No</td>
<td>Not received: 2, Not received: 1</td>
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<tr>
<td>7a</td>
<td>M</td>
<td>50</td>
<td>pT1G3</td>
<td>No</td>
<td>Radiochemotherapy</td>
<td>Not received: 6, 0, Not received: 0</td>
</tr>
<tr>
<td>8a</td>
<td>F</td>
<td>63</td>
<td>pT2aG3 and Tis</td>
<td>No, refused</td>
<td>No</td>
<td>Not received: 1, 0, Not received: 1</td>
</tr>
</tbody>
</table>

### Table 1b. Patient overview

<table>
<thead>
<tr>
<th>Case No.</th>
<th>5-year risk at Viscum album initiation</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a</td>
<td>62, Recurrence risk, %: 25, Progression risk, %: 7</td>
<td>7 years tumor-free since V album treatment</td>
</tr>
<tr>
<td>2a</td>
<td>78, Recurrence risk, %: 17, Progression risk, %: 5</td>
<td>5 years tumor-free since V album treatment</td>
</tr>
<tr>
<td>3a</td>
<td>62, Recurrence risk, %: 6, Progression risk, %: 32 months tumor-free since V album treatment</td>
<td></td>
</tr>
<tr>
<td>4a</td>
<td>62, Recurrence risk, %: 6, Progression risk, %: Recurrences after V album treatment; now 35 months tumor-free</td>
<td></td>
</tr>
<tr>
<td>5a</td>
<td>62, Recurrence risk, %: 6, Progression risk, %: 5 years tumor-free; was already 18 months tumor-free before V album treatment</td>
<td></td>
</tr>
<tr>
<td>6a</td>
<td>62, Recurrence risk, %: 45, Progression risk, %: Stage Tis 4 years after V album treatment; now 30 months tumor-free</td>
<td></td>
</tr>
<tr>
<td>7a</td>
<td>78, Recurrence risk, %: 45, Progression risk, %: Recurrences after radiochemotherapy; tumor-free since BCG and V album treatment (6 years since V album)</td>
<td></td>
</tr>
<tr>
<td>8a</td>
<td>Very high risk, Recurrence risk, %: Very high risk, Progression risk, %: 5 years tumor-free since V album treatment and BCG despite muscle-invasive cancer</td>
<td></td>
</tr>
</tbody>
</table>

1 Non-muscle-invasive bladder cancer.
2 Muscle-invasive bladder cancer.
3 From Sylvestor et al. and Davis et al.
4 Outcomes are as of December 31, 2013.
5 BCG = bacillus Calmette-Guérin immunotherapy; F = female; M = male.
High-Dose Viscum album Extract Treatment in the Prevention of Recurrent Bladder Cancer: A Retrospective Case Series

- Months 43 to 45: After a 6-month treatment break, Iscucin Pini (Viscum album from a pine tree) Potency Series II was given weekly.
- Cotreatment: Argentum D30/Echinacea D6 aa (Weleda, Schwäbisch Gmünd, Germany), a homeopathic remedy designed to improve temperature distribution and control, was injected with each Iscucin injection during Months 1 to 8. Other supportive homeopathic medications were given orally at differing times (Thuja e summatibus D12, Argentum nitricum compositum, Staphisagria LM, Equisetum arvense Silicea cultum D3, Senecio compositum, Tendo/Allium cepa compositum).

In September 2008, 16 months after the initial diagnosis, she had recurrence (Stages pTaG2 and pTisG3 tumors), for which she underwent transurethral resection. Treatment with Viscum album extract was continued as mentioned earlier, but she also received intravesical bacillus Calmette-Guérin immunotherapy in November 2008 (Month 12), which caused gross hematuria. Intravesical bacillus Calmette-Guérin immunotherapy was restarted in April 2009, again causing gross hematuria, and she received 1 instillation every 3 months until the end of 2012. The patient meticulously kept urologist appointments, initially with quarterly (and since 2010 approximately once every 6 months) cystoscopies and abdominal ultrasound examinations. She has been tumor-free for more than 5 years’ follow-up.

The patient told us: “When I had the initial mistletoe injections it felt like my abdomen was cooking and as if it was an anthill. Today I feel even better and stronger than before my bladder cancer diagnosis.”

RESULTS

Tables 1a and 1b highlight the number of tumor recurrences and the outcomes for each patient. Reported tumors were removed by transurethral resection in all cases. Figure 1 shows a timeline of tumor recurrences and treatment for each patient.

Among the 8 patients, 28 episodes of recurrence were observed from diagnosis until December 2013 (median = 3.5 recurrences per patient; range = 1-6 per patient). After intravesical bacillus Calmette-Guérin immunotherapy or mitomycin C therapy (received by 7 patients), 12 episodes of recurrence occurred over 694 months of follow-up (median = 1.5 recurrences per patient; range = 0-4 recurrences; 5-year cumulative incidence = 1.0). Following initiation of treatment with high-dose Viscum album extract, 5 recurrences occurred over 523 months of follow-up (median = 0 recurrences per patient; range = 0-3 recurrences; 5-year cumulative incidence = 0.55). These outcomes were not comparable, however, because the interventions overlapped considerably. Among the 4 patients who received intravesical bacillus Calmette-Guérin immunotherapy, 2 patients had further recurrences but stopped having recurrences once Viscum album extract treatment was initiated (see Figure 1, Patients 1 and 2). The tumor-free follow-up from initiation of Viscum album extract treatment until December 31, 2013 was 421 patient months (median = 48.5 tumor-free months per patient; range = 32-86 tumor-free months). Final cystoscopy controls

![Figure 1. Treatment timeline.](image)

BCG = bacillus Calmette-Guérin immunotherapy.
High-Dose *Viscum album* Extract Treatment in the Prevention of Recurrent Bladder Cancer: A Retrospective Case Series

Possible Beneficial Effect

- **Case 1:** The patient is 7 years tumor-free since the start of *Viscum album* extract treatment, after failure of intravesical bacillus Calmette-Guérin immunotherapy. This is a positive outcome for a patient for whom cystectomy was indicated.

- **Case 2:** The patient is 5 years tumor-free since the start of *Viscum album* extract treatment, despite frequent prior recurrences (including after intravesical bacillus Calmette-Guérin immunotherapy and mitomycin treatment) and a 78% recurrence risk. We did not define her recurrences as a failure of intravesical bacillus Calmette-Guérin immunotherapy because she had not received maintenance treatment.

- **Case 3:** The patient had frequent tumor recurrence despite mitomycin C treatment and is now 32 months tumor-free after *Viscum album* extract treatment.

- **Case 6:** This patient was at high risk of progression because of initial pT1 pathology. A Stage T1G1 tumor recurrence was detected within less than 1 month of initiation of *Viscum album* extract treatment; this recurrence could have been preexisting when treatment was started and therefore was not included in our analysis of recurrences. This patient went on to have a Stage pT1c (carcinoma in situ) recurrence but is now 30 months tumor-free.

- **Case 8:** This patient had a poor prognosis because of a diagnosis of muscle-invasive disease and refusal to have cystectomy and chemotherapy. A 12-week delay in cystectomy can reduce 3-year cancer survival to 35%.

The fact that she had only 1 nonmuscle-invasive recurrence and 5 years of tumor-free survival was therefore very unexpected, and we considered that *Viscum album* extract treatment together with intravesical bacillus Calmette-Guérin immunotherapy could have influenced the outcome in this patient. The effect of *Viscum album* extract treatment therefore seems likely, because her risk of recurrence and progression without cystectomy and chemotherapy was almost 100%. However, given the difficulty in attributing the effect to either intravesical bacillus Calmette-Guérin immunotherapy or *Viscum album* extract treatment, we conservatively rate the effect as a possible beneficial effect.

Unlikely or Uncertain Beneficial Effect

- **Case 4:** This patient had an unlikely beneficial effect because of 2 recurrences despite *Viscum album* extract treatment. The patient now has 30 months of tumor-free follow-up.

- **Case 5:** The effect could not be assessed in this patient. He had 6 recurrences and is now 5 years tumor-free. He was already 18 months tumor-free before receiving *Viscum album* extract treatment, and therefore assessment was not possible.

- **Case 7:** Assessment was not possible. This patient had a high-risk Stage pT1G3 tumor and five Ta recurrences, one of which was high-grade, despite radiochemotherapy. He then had seven years of tumor-free survival after two courses of intravesical bacillus Calmette-Guérin immunotherapy and *Viscum album* extract treatment, which we consider a very satisfactory outcome. We were unable to distinguish between the beneficial effect of intravesical bacillus Calmette-Guérin immunotherapy and *Viscum album* extract treatment because these treatments were given in relatively short succession after the last tumor recurrence.

In summary, an effect from *Viscum album* extract treatment appeared to be a possibility in five patients (Cases 1, 2, 3, 6, and 8), could not be assessed in two cases (Cases 5 and 7), and was unlikely in one patient (Case 4).

Tolerability

Most patients experienced fever up to 40°C and local redness at the injection site (less than 5 cm in diameter in all cases) as part of the intended immune reaction. One patient had nausea and headache after using a particular additional *Viscum album* extract preparation, from a birch tree (Case 8). No patient needed to stop treatment because of side effects.

DISCUSSION

We present retrospective data from a series of eight patients with recurrent bladder cancer who had been treated with high-dose *Viscum album* extract treatment. Seven patients had nonmuscle-invasive cancers with frequently recurring tumors, one of whom had not responded to intravesical bacillus Calmette-Guérin immunotherapy; therefore, they were a difficult patient group to manage. Patients had either intermediate-risk or high-risk tumors, as defined by European guidelines. One patient with muscle-invasive cancer had refused standard therapy, and so tumor recurrence and progression was almost certain. However, our analysis shows substantial and consistent decrease of recurrences in this series of patients. Despite unfavorable prognoses, we observed mainly positive outcomes after *Viscum album* extract treatment. Recurrences occurred in only three patients, and only one of those patients had three recurrences, and the patients had consistent, long, tumor-free periods subsequent to these recurrences, with no patient progressing. We therefore consider individual variation a less likely explanation, and a beneficial effect of *Viscum album* extract treatment as a possible explanation.

The analysis was not designed to compare recurrence incidence between intravesical bacillus Calmette-Guérin immunotherapy/mitomycin C treatment and *Viscum album* extract treatment. It also is not our intent to suggest management of muscle-invasive cancer without cystectomy. High-dose...
subcutaneous injections with *Viscum album* (*Salicis*) extract may, however, have a preventive role in frequent recurrences of bladder cancer. Few studies exist regarding the effect of *Viscum album* extract treatment in recurrence of bladder cancer. In one small study, intravesical treatment with lectin-standardized *Viscum album* extract seemed to have preventive effect at 12-month follow-up, similar to intravesical bacillus Calmette-Guérin immunotherapy-treated historical controls. A small, prospective, randomized study in which low-dose, subcutaneous injections of lectin-standardized *Viscum album* extract were compared with no prophylactic intervention showed no benefit. A randomized trial in 60 patients, comparing intravesical *Viscum fraxini*-2 with intravesical bacillus Calmette-Guérin immunotherapy found a recurrence rate of 73% vs 30%; muscle-invasive bladder cancer developed in 5 patients in each group. A Phase 1b/2a dose-escalation study of intravesical treatment with *Viscum album* extract showed promising results and is currently being followed by a Phase 3 study. The treatment approach used in the patients in our case series differed from the approaches used in these other studies; the physicians at our clinic used subcutaneous application (more convenient than intravesical) and *Viscum album* extract grown on the willow tree (*Salicis*), which was selected on the basis of positive clinical experience. A potential mechanism of action for *Viscum album* extract in preventing recurrence of bladder cancer is its known antitumor and immune-modulating activity and the potential beneficial effect of fever in cancer treatment as described earlier. We note, however, that *Viscum album* extract induced fever after the first 2 to 3 doses only and thus may not be considered fever therapy. A recurring theme reported by patients in this case series was that the initially exhausting fever reaction was followed by a gain in energy and strength. This is consistent with systematic reviews on the beneficial effect on quality of life and cancer-related fatigue of *Viscum album* extract treatment. Some patients experienced the treatment as a turning point in their treatment course, after which they felt more confident that they had overcome the cancer.

This report has several limitations. First, it is retrospective, and there are considerable differences among patients in terms of follow-up and treatment. Second, defining patients into certain categories after data mining is subject to researcher bias. Rather than a cohort, we present a series of individual cases, each assessed individually. The strengths of this report are that we provide direct observation from clinical practice, provide a qualitative judgment of each individual patient history, and have not merely provided an analysis of the best cases.

**CONCLUSION**

A prospective study is now needed to assess whether high-dose subcutaneous *Viscum album* (*Salicis*) extract can be an additional, bladder-sparing preventive option for patients with medium- to high-risk nonmuscle-invasive bladder cancer.

**Disclosure Statement**

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**Authors’ Contributions**

Johannes Wilkens, MD, treated patients with *Viscum album* extract, provided patient information, and reviewed the manuscript. Tido von Schoen-Angerer, MD, MPH, conceptualized the report, wrote the manuscript, and prepared Figure 1. Gunvier S Kienle, MD; Helmut Kiene, MD; Jan Vagedes, MD; and Johannes Wilkens, MD, critically reviewed the manuscript. All authors read and approved the final manuscript.

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**References**

High-Dose Viscum album Extract Treatment in the Prevention of Recurrent Bladder Cancer: A Retrospective Case Series


Apothecary

—the garden is the poor man’s apothecary.

—German proverb
COMMENTARY

Strategies to Increase Physical Activity

Phillip Tuso, MD, FACP, FASN

ABSTRACT

The benefits of physical activity are well known and well publicized. Healthy People 2020 has determined that physical activity is one of their key interventions to improve health in America. Despite wide acceptance that physical activity is a low-cost alternative to disease treatment and prevention, most Americans still do not exercise the recommended minimum of 150 minutes per week. Underpinning such recommendations is the growing concern that unless we change our behavior around active living, health care costs to treat preventable disease will become unsustainable and have a substantial impact on the financial health of the US. For this reason, physicians, health care executives, and community leaders are working together to improve total health for all Americans. One key intervention to prevent preventable diseases and to make health care more affordable is to increase the percentage of Americans who are physically active. No single intervention will increase activity rates, but a group of interventions working together in synergy may be the stimulus needed to get Americans moving. The five strategies discussed in this paper include 1) measure physical activity as a vital sign; 2) encourage patients to be physically active at least 150 minutes per week; 3) create healthy environments by making it easier for patients to be physically active where they live, learn, work, play, and pray; 4) monitor disease incidence of patients who are physically active vs those who are not physically active; and 5) spread best practices.

INTRODUCTION

The benefits of physical activity are well known and well publicized. Despite wide acceptance that physical activity is a low-cost alternative to disease treatment and prevention, most Americans still do not exercise the recommended minimum of 150 minutes per week. During the past several years organizations like Kaiser Permanente, Intermountain Health, and Mayo Clinic have started to measure physical activity as a vital sign. In addition, many community groups and organizations have joined together in the Every Body Walk! campaign in an attempt to get America walking and overcome behavior change and social barriers that keep people from being physically active. During the past decade, the American College of Sports Medicine, the Centers for Disease Control and Prevention, and the National Institutes of Health have all recommended regular physical activity as an option for those who are inactive. In addition, Healthy People 2020 now has physical activity as one of their key interventions to improve health in America.

Underpinning such recommendations is the growing concern that unless we change our behavior around active living, health care costs to treat preventable disease will become unsustainable and have a substantial impact on the financial health of the US. For this reason, physicians, health care executives, and community leaders are working together to improve total health for all Americans. One key intervention to prevent preventable diseases and to make health care more affordable is to increase the percentage of Americans who are physically active.

Since the publication in 1996 of Physical Activity and Health: A Report of the Surgeon General and the 2008 Physical Activity Guidelines for Americans, there has been a widespread call for action to prevent preventable disease and to improve the care provided to individuals with chronic disease through physical activity. Strong evidence exists that both children and adults benefit from being physically active. Benefits of physical activity include lower risk of chronic diseases such as obesity, heart disease, diabetes, cancer, and depression. Exercise may even help improve academic performance and help us live longer.

Physical activity is widely recognized as a means for the primary prevention of chronic diseases. Moreover, activity has beneficial effects on an individual’s health and well-being. Despite the benefits of regular physical activity, the percentage of physically inactive adults in the world is high. Environmental and policy approaches that aim to increase physical activity require evidence from studies investigating disease mechanisms as well as controlled clinical trials. A meta-analysis reported in 2007 that physical activity was associated with a reduction of the incidence of chronic major diseases. The strongest evidence exists for colon cancer, breast cancer, and cardiovascular diseases. The maximal magnitudes of the risk reduction reported were 22% for colorectal cancer, 75% for breast cancer, and 49% for cardiovascular diseases.

Researchers in Taiwan performed a prospective cohort study on 416,175 individuals between 1996 and 2008 to evaluate the effect physical activity has on life expectancy. Participants were placed in 5 categories on the basis of the amount of weekly exercise indicated in a self-administered questionnaire. The 5 categories were inactivity, low,
medium, high, and very high activity. Results showed that compared with individuals in the inactive group, those in the low activity group, who exercised for an average of 15 minutes per day, had a 14% reduced risk of all-cause mortality and had a 3-year longer life expectancy. Each additional 15 minutes of daily exercise beyond the minimum amount of 15 minutes a day further reduced all-cause mortality by 4% and all-cancer mortality by 1%. These benefits were applicable to all age groups and both sexes, and to those with cardiovascular disease risks.

Recent data show that areas with high obesity rates have low exercise rates and areas with low obesity rates have high exercise rates. Data from Healthy People 2020 demonstrate that we can subjectively measure physical activity as a vital sign, but we have not figured out how to substantially increase the percentage of the population who are physically active. Therefore just measuring exercise rates does not increase exercise rates. Social networking may be a new innovative way to increase exercise rates. During the past few years there has been a growing interest in understanding behavior change of an individual and of a population around the issue of physical activity. Changing behaviors is a key step to long-term health and disease prevention.

The 2008 Physical Activity Guidelines for Americans recommends at least 60 minutes per day of physical activity for children and 30 minutes per day for adults. Despite evidence of the health benefits of physical activity as outlined above, most US adults and children are not meeting the recommendation in the 2008 Physical Activity Guidelines for Americans. Data from Healthy People 2020 show that the percentage of adults engaging in regular physical activity increased only from 43.5% in 2008 to 48.8% in 2011. Data from the Centers for Disease Control and Prevention show that only 1 in 3 adults who have seen a physician have been advised to be physically active.

Despite advice from physicians, most patients do not meet daily exercise goals. Research has shown there are many barriers to getting Americans to be more active. Although level of education and economic status seem to play a critical role in being physically active, there also appear to be other factors that prevent physical activity for all age groups. A central theme appears to be support from family and friends and the environment we live in. It is clear there is much work to do to help Americans be more active. This information suggests we need to use a broader systemic organized approach to understanding the correlates of physical activity. Just asking patients about physical activity is not enough to make them more physically active.

Physicians and community leaders need to better understand community influences on physical activity. Because current interventions have not significantly increased physical activity rates, community leaders including physicians must work together to understand how we can increase physical activity rates to prevent disease.

The purpose of this article is to outline 5 strategies to increase physical activity in Americans. To achieve total health in America, we must encourage Americans to be more physically active. Brown et al reported that behavior interventions have been effective with diverse populations and in a variety of settings. For example, one study showed that a point-of-decision prompt to encourage the use of stairs (i.e., a sign next to the elevator that encourages using the stairs to improve health) was effective in increasing the number of people who choose to use the stairs instead of taking an elevator.

Promoting healthy behaviors is a key part of helping patients to be more active. The US Department of Health and Human Services published Physical Activity and Health: A Report of the Surgeon General in 1996. This report supports the fact that activity is better than inactivity and activity has health care benefits. Patients can help themselves to be more active by building social networks. Social support interventions focus on changing physical activity behavior through building, strengthening, and maintaining social networks that provide supportive relationships for behavior change. These include setting up buddy systems with friends and families to hold each other accountable for meeting weekly physical activity goals.

STRATEGIES TO INCREASE PHYSICAL ACTIVITY

Measure Physical Activity as a Vital Sign

Healthy People 2020 has been measuring activity rates by survey since 2008. Since that time, exercise rates in America have increased by only a few percentage points. One intervention that may significantly increase exercise rates in America is to implement a national process in which during each visit with a physician, the patient is asked the number of minutes per week the patient participates in a physical activity. This question lets the patient know that exercise is an important part of health just like other vital signs of health (e.g., blood pressure). If the patient is not meeting exercise goals, then the physician can start a conversation about the importance of physical activity in health. Ultimately, patients must be responsible for their health and their level of physical activity. Understanding what is expected of them is the first step. The second step is learning how to change behavior from inactivity to daily physical activity.

Encourage Patients to be Physically Active at Least 150 Minutes Per Week

Behavior change occurs when motivation aligns with ability and triggers. Good health should be the main motivator for an individual to be physically active. As stated above, physical activity has many health benefits. Some patients will need education on how to be physically active (ability) and triggers to remind them to be physically active.

Behavioral interventions have been shown to significantly increase physical activity that results in improved control of diabetes and body mass index. Behavior interventions can prompt patients to be more physically active. Behavioral interventions have been effective with diverse populations and in a variety of settings. For example, one study showed that a point-of-decision prompt to encourage the use of stairs (i.e., a sign next to the elevator that encourages using the stairs to improve health) was effective in increasing the number of people who choose to use the stairs instead of taking an elevator.
Create Healthy Environments by Making It Easier to be Physically Active Where We Live, Learn, Work, Play, and Pray

Patients have complex lives and have many barriers to being physically active. The time has come to work together to create environments where it is easier to be physically active. This may include a family being physically active together on weekends, students participating in school-based physical education programs, employees participating in employer-based physical activity programs, and faith-based groups encouraging community members to be physically active at faith-based functions.

An identified barrier to physical activity is the lack of safe environments to walk, bike, and play. Creation of places for physical activity combined with education on where to find places to be physically active will certainly help adults and children to be more physically active. Physicians and patients should work together with community leaders to promote communitywide campaigns and support families who want to be physically active. These communitywide campaigns can form multidisciplinary teams that focus on using community resources to promote physical activity where we live, learn, work, play, and pray. These interventions need not be complicated and may be as simple as asking people to walk to school instead of driving. Other more difficult interventions may involve changing our infrastructure to promote health and wellness. These include healthy physical environments (eg, accessible stairwells for walking), healthy activity at work (eg, time and space for physical activities), and activating physicians and patients to work with employer groups to implement lifestyle management programs into the workplace environment.

Monitor Disease Incidence of Patients Who are Physically Active vs Those Who are not Physically Active

Healthy People 2020 has developed physical activity objectives and goals for the future. The objectives are aligned with the 2008 Physical Activity Guidelines for Americans and set objectives and goals for adults, children, schools, and physicians. Although the goals appear to be conservative, they do represent an initial attempt to get Americans moving more by the year 2020. Of note is the expectation for schools to increase the percentage of time students have for physical education and for physicians to counsel patients who will most benefit from physical activity (those with obesity and comorbidities).

Once we set goals it will be important for physicians and health plans to monitor disease incidence as it relates to physical activity to demonstrate the relationship between physical activity, wellness, and health care affordability. Physical activity will lower health care costs, prevent preventable disease, and save lives. Monitoring the relationship between health care costs and disease incidence for individuals who are physically active compared with individuals who are not physically active will help us understand how physical activity can be used as medicine to treat and prevent disease.

Spread Best Practices

To help Americans meet physical activity goals, physicians and patients will need to identify and spread best practices. To achieve total health in the future, we will need healthy people and healthy communities to promote and maintain health. Because patients spend very little time with their physicians, our communities must be healthy and self-learning. Part of self-learning is identifying something that works and sharing with other communities. Every day thousands of patients look for ways to be more active. Currently there is no organized systematic Web-based approach to locate these services that also allows for community organizations to see the services previously accessed by a patient. In addition, there is no objective way to know whether a service provided to a community improves health care outcomes. We must develop a Web-based physical activity resource to help match patients with a specific community resource that will help patients be more active where they live, learn, work, play, and pray. This program will help identify a physical activity best practice in one patient or community and share the resource or idea with another patient or community. Many communities have a plethora of opportunities; others do not. Sharing what works in one community with other communities will encourage America to be more active. One of the best ways to accomplish this goal is to publish data on disease incidence and physical activity on the Internet and let communities around the country see which communities have lowered their disease incidence by becoming more active. Successful communities can share with other communities how they overcame barriers to success and became more physically active.

CONCLUSION

It is clear that the wide range of policies and programs described in this paper are needed to promote more physically active lifestyles for the patients we serve. Like tobacco use and obesity prevention, public health goals for physical activity are more likely to be achieved if policies and interventions are guided by approaches known to effectively meet the needs of all members of the communities we serve. To achieve success we should establish a program to evaluate and to learn from other programs so we can identify and spread best practices quickly and efficiently. The key to success will be overcoming barriers to helping patients become more physically active. Attention should be given to addressing both the challenges of individual behavior change and the challenges of overcoming environmental barriers that inhibit a populationwide effort to transition from an inactive to an active lifestyle. Resources for walking paths, bike paths, parks, and community outreach programs will encourage physical activity in daily living and should be linked to health care cost savings as an opportunity to prevent disease and make health care more affordable. Health care systems cannot do this alone and must partner with communities to achieve success.

To accomplish our goal of achieving high rates of physical activity for all
Americans, we will need behavior medicine specialists, sociologists, physiologists, recreation specialists, physicians, architects, city planners, and engineers working together to engage schools, worksites, religious institutions, and communities to create opportunities to promote physical activity. To create lasting behavior change, patients must do patient work, physicians must do physician work, community leaders must do community leader work, and government leaders must do government leader work. There is no easy fix to the inactivity crisis we have in America. Measuring blood pressure as a vital sign without adjusting treatment may not improve blood pressure control rates. However, holding physicians and patients accountable for blood pressure control rates has significantly increased the percentage of the population whose blood pressure is now under control with medication and/or lifestyle management.

To improve physical activity rates, we must hold patients and physicians accountable for physical activity as a vital sign. The first step is to measure physical activity as a vital sign. The second step is to motivate patients who are inactive to be more physically active. The third step is to create environments and triggers that give people the ability to be more active. The fourth step is to identify those who are physically active have lower disease incidence. The fifth and final step is to spread best practices. Although these strategies appear easy and straightforward, the implementation of these strategies across America will require hard work and widespread policy change. This should lead to longer-lasting changes where we live, learn, work, play, and pray that ultimately will prevent preventable disease, lower health care costs, and save lives.

Disclosure Statement
The author(s) have no conflicts of interest to disclose.

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**Invigorator**

The sovereign invigorator of the body is exercise, and of all exercises walking is the best.

— Thomas Jefferson, 1734-1826, American Founding Father, principal author of the Declaration of Independence, and third President of the United States
Research Letter: Sensor-Based Systems and the Objective Measure of Physical Activity

Phillip Tuso, MD, FACP, FASN

Recently the American College of Sports Medicine American Fitness Index revealed the percentage of Americans surveyed who met the Centers for Disease Control and Prevention aerobic activity guidelines for physical activity was only 28%. Unlike traditional vital signs, such as blood pressure, heart rate, and body mass index, activity is a vital sign that cannot be measured objectively in a physician’s office. However, technology is now available that can objectively, and remotely, measure the activity of large populations accurately, reliably, securely, and efficiently.

At its annual conference in May 2014 in Orlando, FL, the American College of Sports Medicine used the sensor-based system (SBS), Tractivity (Kinetiks Corporation, Vancouver, British Columbia, Canada), to measure physical activity of 300 health care professional attendees to demonstrate the possibility of using this system to monitor the physical activity of large patient populations. Before the conference, registered attendees were e-mailed an invitation to participate in a 3-day pilot of the new SBS technology during the conference. Upon arrival, participants were given the SBS device, which was activated via Bluetooth over the Internet. Once activated, each participant was randomly assigned to 1 of 8 teams. Activity (miles and steps per day) was gathered for individuals and teams. Individuals downloaded activity or accessed personal activity information on a smart phone, laptop, tablet, or personal computer. Team information was available at several conference locations. A unique feature was that activity was automatically uploaded using Bluetooth technology, even if the participant did not actively upload his/her activity. Table 1 shows the steps, miles, and rank of each team.

During the 3 days of the conference, participants averaged approximately 7000 steps per day (3 miles per day). Of 330 participants, 162 (49%) recorded at least 10,000 steps per day; 89 (27%) recorded more than 15,000 steps per day (Table 2). Not demonstrated in the data is the anecdotal observation of increased activity rates over time through competition.

On the basis of the information we collected, activity is an objective, measurable vital sign of population health that can be monitored in real time. Activity-monitoring sensors continue to be made available, and it is probable that they will become commonplace in the future. The integration of these activity systems with the electronic medical record of large health care organizations will enable physicians to use this data to encourage patients. Similar to medication adherence, objective measures of physical activity may allow physicians to improve activity rates among individual patients and patient populations, which should improve health care outcomes. SBS may become a best practice for objective measurement of physical activity and the management of physical activity programs. Given the ease of tracking with these new devices and the ability to upload information automatically, SBS is a potentially powerful tool for physicians to measure and encourage physical activity in their patients, thus potentially preventing preventable disease and lowering health care costs.

Table 1. Team, rank, steps, and miles chart of sensor-based systems pilot at the 2014 American College of Sports Medicine conference

<table>
<thead>
<tr>
<th>Team</th>
<th>Rank</th>
<th>Steps</th>
<th>Miles</th>
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<tr>
<td>A</td>
<td>#3</td>
<td>1,381,812</td>
<td>659</td>
</tr>
<tr>
<td>B</td>
<td>#6</td>
<td>1,233,298</td>
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</tr>
<tr>
<td>C</td>
<td>#4</td>
<td>1,330,388</td>
<td>645</td>
</tr>
<tr>
<td>D</td>
<td>#8</td>
<td>1,040,844</td>
<td>503</td>
</tr>
<tr>
<td>E</td>
<td>#7</td>
<td>1,195,574</td>
<td>570</td>
</tr>
<tr>
<td>F</td>
<td>#1</td>
<td>1,524,978</td>
<td>734</td>
</tr>
<tr>
<td>G</td>
<td>#5</td>
<td>1,292,054</td>
<td>618</td>
</tr>
<tr>
<td>H</td>
<td>#2</td>
<td>1,518,416</td>
<td>729</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>10,517,364</td>
<td>5040</td>
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Table 2. Goals achieved in the sensor-based systems pilot at the 2014 American College of Sports Medicine conference

<table>
<thead>
<tr>
<th>Participants</th>
<th>Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retrieved data into the system</td>
<td>330 (66)</td>
</tr>
<tr>
<td>Less than 5000 steps per day</td>
<td>104 (31)</td>
</tr>
<tr>
<td>5000 to 10,000 steps per day</td>
<td>64 (19)</td>
</tr>
<tr>
<td>10,000 to 15,000 steps per day</td>
<td>73 (22)</td>
</tr>
<tr>
<td>More than 15,000 steps per day</td>
<td>89 (27)</td>
</tr>
<tr>
<td>At least 10,000 steps per day</td>
<td>162 (49)</td>
</tr>
</tbody>
</table>

References

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NARRATIVE MEDICINE

Primary Health Care and Narrative Medicine

John W Murphy, PhD

ABSTRACT

Primary health care has received a lot of attention since the Alma Ata Conference, convened by the World Health Organization in 1978. Key to the strategy to improve health care outlined at the Alma Ata conference is citizen participation in every phase of service delivery. Although the goals of primary health care have not been achieved, the addition of narrative medicine may facilitate these ends. But a new epistemology is necessary, one that is compatible with narrative medicine, so that local knowledge is elevated in importance and incorporated into the planning, implementation, and evaluation of health programs. In this way, relevant, sustainable, and affordable care can be provided. The aim of this article is to discuss how primary health care might be improved through the introduction of narrative medicine into planning primary health care delivery.

INTRODUCTION

Primary health care (PHC) is receiving significant attention nowadays. Most discussions about care, for example, center on the need for early intervention, education, and prevention. Although this approach is driven mostly by economics, other factors are involved. Particularly since the Alma Ata Conference, convened by the World Health Organization and held in Kazakhstan in 1978, PHC is recognized to have political and other significant social dimensions. Indeed, an entirely new philosophy and practice of care are advanced. Nonetheless, although the promise has been great, only a piecemeal strategy has been adopted to implement this outlook.

Noteworthy is the challenge to traditional biomedicine; PHC is by nature more holistic. The reason for this expansion is quite simple: interventions are not directed at persons or communities divorced from their mediating social conditions. The focus, therefore, extends beyond biological factors and includes the social and cultural determinants of health. The phrase that has been introduced to characterize this orientation is ‘person-in-environment.’

PHC interventions are more expansive than those associated with the biomedical model. Many factors that were once thought to be ancillary to formulating an adequate treatment plan are now central. What is thought to constitute evidence and adequate practice has expanded. Using a standard checklist or symptom scale to gather patient information, for example, is no longer adequate. Furthermore, persons are understood to engage their environments. In other words, they operate on the basis of conceptual schemes and definitions that are vital to competent planning. Local or community knowledge is crucial to formulating an appropriate and successful intervention. In this regard, joining narrative medicine and PHC might bring to fruition the alternative provided by PHC.

PHC is not passive. Practitioners do not wait to act until problems arise and persons decide to pursue treatment. Particularly important is that health practitioners attempt to gain entry to the lives of persons or communities to become attuned to their respective knowledge bases, perspectives on problems, and views of appropriate remedies. At this time, community health workers of various forms—community nurses, lay community health workers, and curanderos—are working daily to bring health care closer to persons and communities. Care is thus offered in a timely and relevant manner.

PRIMARY HEALTH CARE

As can be imagined, this shift to PHC requires that typical health systems be entirely revamped. Often parallel and competing modes of care exist. For example, individual physicians, private clinics, and general hospitals often serve as rival points of entry, with communities left out of the picture. Given this scheme, persons can choose to go to their own physician if they have health insurance, or a public emergency room if they lack this source of payment. Entry into the health system is variegated, and often haphazard, with highly variable costs.

Although definitions are difficult to pin down, PHC extends beyond primary care. Whereas primary care often represents simply an expansion of basic medical practices to a community, PHC includes universally accessible services that are offered in a socially appropriate manner. Furthermore, these preventive, promotive, and curative practices are grounded in the context of substantial community participation. Partners in Health has used this strategy quite successfully through the use of an accompaniment model. As a result, relevant and affordable services are made available.

A significant by-product of this change is that access to the health system is streamlined. Specifically, because of the emphasis placed on local knowledge and customs, the community serves as the single point of entry. Lay community health workers, for example, have become very skilled at identifying problems, applying remedies, and making referrals in low-income countries. Through this sort of ‘task-sharing,’ care is decentralized. The operative principle is that most

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of the problems encountered by persons are dealt with at the level of the community. Additionally, any further treatment is directed through a stepwise series of advances in care.

On the basis of local knowledge, a program of education, prevention, and support can be designed that keeps persons out of emergency rooms and hospitals. And if more sophisticated treatment is needed, for broken bones or other injuries, a rational and progressive regimen is followed. All the while, and particularly noteworthy, persons and communities are learning to monitor and protect their health.18

This entire process, however, is predicated on the idea of early and community-sensitive interventions.19 Through education, for example, local health workers can inform their neighbors, identify problems, and make treatment suggestions that seem feasible. As a result of this regular contact, bonds are established that foster insight that is often inaccessible to traditional medical professionals. These community-based interventions have proven to be effective and sustainable.20

Also because of this new point of entry, problems are addressed in their environments. Indeed, holism is almost unavoidable when persons and communities are understood to be far more than organic in nature. In fact, in PHC personal and community problems are enmeshed in a social-cultural environment. Persons, or the so-called hosts, are presumed to interact with their surroundings, although in the medical model this connection is often minimized.21 How communities interpret or construct the onset of illness, including their responses to any maladies, is not a part of this truncated holism. In the end, PHC elevates in importance factors that biomedicine acknowledges only reluctantly, if at all.

LIMITS TO BIOMEDICINE

As part of this shift to holism, another facet of biomedicine is challenged. That is, problems are viewed no longer as primarily physical. In a classic article in 1977, Engel22 argued that the only acceptable approach to health is one that is biopsychosocial. Most important about this change is that these elements are neither autonomous nor represent separate dimensions of illness. Such descriptions would only upgrade minimally the biomedical model. What occurs when biology is sequestered from psychosocial considerations in these ways is that psychological states or social factors are thought to either aggravate or ameliorate physical ailments.

In this abbreviated holism, the physiology of an illness may be modified slightly by mental conditions, although persons remain psychophysical mechanisms.23 What Engel and others have in mind, however, is far more reaching. According to this scenario, the biological dimension is enmeshed in social life and, as a result, is mediated fully by this influence. In other words, biological changes cannot be encountered outside of how they are interpreted, classified, and addressed. The biological realm has no identity without a connection to the psycho and social spheres of existence.

Although criticized by Engel, in PHC the dualism, sometimes known as Cartesianism, that justifies sequestering these elements is dismissed.24 Owing to the fact that persons and communities engage their environments, the impact of this action should not be ignored or downplayed. How persons interpret themselves, others, and their respective situations provides a framework for assessing and remedying physical problems. Some contemporary writers refer to this confluence of action and everyday existence as the “life-world.”25

With regard to PHC, this shift in terminology is very important. When a community is understood as a life-world, the human quotient is elevated in significance. Specifically noteworthy is that the body is penetrated by interpretation, along with other facets of life, and thus illness is a matter of perception and evaluation. The seriousness of an issue, for example, depends on the interpretive scripts that are operative.26

Now an activist strategy is truly needed to identify and prevent problems. Because bodies, persons, and communities are no longer objects, gaining entry to the accompanying information pool is not optional or secondary to the discovery of the physical causes of illness. Borrowing from Pollner,27 the so-called mundane experiences of pain or injury hold the key to creating a successful health program. The stories persons tell about themselves and their communities, in other words, are essential to the proper identification and analysis of a health issue.28

ENTER NARRATIVE MEDICINE

Narrative medicine is usually associated with the work of Rita Charon,9,10 but in the past few years the contributions to this area have been expanding. Although not necessarily linked to community practice, the narrative perspective is clearly relevant to initiatives such as PHC. Charon9,10 defines narrative medicine as the ability to “recognize, absorb, interpret, critically understand, and be moved by a patient’s story of illness.” Note, this version of narrative is not merely an expanded medical history. Charon and others have something much more profound in mind. In short, the point is to discover the meaning or the existential character of illness.

At the core of this approach to medicine is the literary theory that rose to prominence during the 1990s with the arrival of poststructuralism.29,33-51 The emphasis at that time turned to interpretation—the so-called “linguistic turn”—and the impact of language use.10 Particularly significant was the recognition of Wittgenstein’s view of language and the subversion of the standard indexical theory. Specifically, Wittgenstein31 argued that language functions not like a pointer but like a game. According to the indexical thesis, language indicates, highlights, or differentiates the content of perception. All the time, however, these elements are presumed to be objective. Physical symptoms, for example, are considered to be real markers, although they can be obscured by personal or collective perspectives.

Stories of Lives are Informative

Wittgenstein, on the other hand, proposed that how the language game is played shapes perception. The content of perception, accordingly, is not objective but given meaning and arranged by language use. Because language has this
power, those who practice narrative medicine contend that the stories persons weave about their lives are truly informative. A lot of vital information is missed, they maintain, if these narratives are obscured by biology. In other words, interpretations do not merely conceal physical reality but shape how these factors are known; these interpretations, therefore, embody the reality of persons and should not be dismissed as impediments to acquiring accurate health data.

Within the context of Wittgenstein’s philosophy, biology constitutes simply another descriptive. Proponents of biomedicine, however, elevate this narrative to such a degree that all others are marginalized. The result is a style of reductionism, couched in science, which many practitioners do not recognize. That is, biology is treated as the naturally dominant, and thus most accurate, source of information. Physiologic symptoms and markers, therefore, are the obvious indices of disease.

Proponents of narrative medicine claim that this focus is too narrow. Their point is that many other narratives may be operative, and if these stories are not consulted medical interventions will be poorly designed. After all, how persons interpret, evaluate, and react to symptoms plays a crucial role in whether a problem is understood to exist. A problem, in short, does not reside in a realm free of narratives.

The Clash of the Physician and Patient Stories

Often the clinical or technical story desired by a physician and the cultural or economic narrative told by a patient clash. A physician may want to know how long certain symptoms have been present and whether treatment had been sought earlier. A patient, on the other hand, might want to talk about his or her past experiences with physicians, what any symptoms mean, and why treatment was not an earlier option. What should be noted is that the patient’s narrative offers vital insight into the path of treatment and how services might be offered effectively.

In the past, these stories were viewed to be a distraction. At that time, biology was the sole valid explanation of any problem, and other narratives were treated as simply unreliable for making decisions. These personal or collective experiences did not accurately depict reality. In conventional medical practice, the biases present in these tales had to be overcome before sound interventions could be developed and implemented.

Biology as Narrative

In narrative medicine this trend is altered. Biology is not excluded but becomes one of the many narratives that should inform a diagnosis or treatment plan. In terms of Wittgenstein’s proposal on language use, nothing, not even biology, is immune to interpretation. All narratives, therefore, must vie for relevance, since none is more valid inherently than any other. In point of fact, no objective conditions are available to make this determination. In narrative medicine, nonetheless, the application of these stories is not haphazard. The values, beliefs, and commitments of persons or communities are central to identifying the narratives that are pertinent to examining properly a condition.

In PHC, these stories are not add-ons. They do not merely supplement more profound biological data but are central to correctly deciphering symptoms and why persons react in one way or another to these signs. So-called physiologic markers, the gold standard for making predictions, are now contingent on the basis of the narrative that emerges as dominant. This process of emergence encompasses many features of a person’s individual existence or life in a community and is not easy to predict. Nonetheless, health behavior cannot be extricated from this activity.

NARRATIVE AND COMMUNITY

Because of the importance of narratives in community work, PHC requires a situated response—the relevant narrative provides the standpoint that should be used to judge an intervention. But at this juncture a particular caveat is important that is not stressed in narrative medicine. Specifically, narratives are never written or judged alone. Narratives, in other words, are a collective endeavor.

Narratives are always written with others, such as neighbors, friends, acquaintances, and rivals. No one exists in isolation; no one is an island. As a result, only in rare instances will a community offer a single narrative of any phenomenon, particularly health. Hardy any community is this homogeneous. In most cases, similar to the stories told by individuals, a community will provide many, often conflicting narratives.

How a community views illness, and responds to the onset of a problem, will be varied and shifting, and represent several logics. This diversity, however, does not mean that the presence of various storytellers undermines any prospect of a coherent analysis. This diversity does not mean that no rationale is available for analyzing a community’s problems. But any final explanation is going to be variable and multifaceted. Those who work in PHC must be attuned to where these narratives merge and diverge, and how these shifts occur.

Narrative medicine, accordingly, consists basically of listening attentively to patients and, possibly, exhibiting some empathy. But these methods may not go far enough to capture the narratives present in a community. Making sure that a symptom checklist is understandable may not be sufficient in this regard. The following examples represent attempts to extend the principles of narrative medicine.

Two Examples of Engaging Story in Community

The first two examples are drawn from a recent health project on the island country of Grenada. In this project, community members were trained to become lay community health workers who would eventually administer a general health status survey. These persons were allowed to review and to correct this instrument to ensure that the proper questions were asked and the appropriate language used. In this way, the health narrative of communities could be correctly engaged.

But in such a project the parameters of a community must be understood, so that interventions can be targeted properly.
Therefore, a process of community mapping was undertaken. The basic idea is to walk around a community and identify households, resources, streets, and, if possible, the boundaries of this locale. Often, as part of this activity, persons come out of their houses, answer the questions posed by the mappers, and debate issues, such as where a community begins and ends. This input is crucial to creating a community map that reflects the everyday experiences of persons and the local reality.

The final example relates to a health project that is ramping up in a Hispanic community in Los Angeles. In this project, community members will be trained to be lay community health workers. Especially noteworthy, a community health committee will be organized to guide every facet of this project. This group will be responsible for creating all assessment instruments and interview guides, along with interpreting any findings and formulating the policies derived from this data.

More Than Listening

The aim of these examples is to demonstrate that gaining access to the narratives of persons or communities may require more than simply listening. For example, an interview grounded in narrative theory is unique in several ways. In a traditional methodology, an interview schedule is preconstructed, standardized, and designed to be clear. One that is based in narrative medicine, on the other hand, is co-constructed with patients, situationally relevant, and intended to gain insight into persons’ lives. The purpose of this co-construction is to increase the prospects for real listening and the creation of situationally appropriate interventions.

In narrative medicine, active participation in the care process is required to provide relevant treatment. After all, if the proper questions are not asked, and irrelevant language is used, patients may not be addressed in a manner that elicits accurate information. Clinicians, accordingly, must be willing to examine critically their interview guides and similar instruments, and offer the opportunity for correctness to be provided by their patients. An interview in narrative medicine is dialogical, with all participants actively involved, whereas a standard checklist or other typical strategy is constructed and guided by professionals and thus not conducive to dialogue.

Those who are interested in this strategy must recognize that persons may create very different illness narratives, although they share a common social space. Likewise, individuals may construct conflicting narratives of themselves. Why certain narratives have validity, while others do not, is clearly important to organizing a proper intervention. Additionally, the procedure whereby stories gain traction, and become dominant, is essential to understanding how particular perspectives achieve longevity and others disappear. As a result of appreciating these dynamics, a holistic picture of persons and their community can be provided.

But a community is not simply a composite of discrete narratives. Although all stories are not necessarily dispersed evenly throughout a community, they are associated in many ways. Why and how different narratives become acceptable provides a point of access for understanding an entire community’s perception of and reaction to illness. The ability to map these differences, moreover, provides the basis for a unified and informed picture. As noted by Niklas Luhmann, the recognition of differences supplies the framework required for a unified gestalt.

CONCLUSION

Certainly the preservation of health is truly an existential issue, and PHC is no exception. At times health status enhances options, whereas at other times, it limits what persons can expect and accomplish. Specifically, a core existential issue is the ability of persons to choose freely and to act on the basis of these decisions. Obviously health plays a key role in this process.

How persons define themselves, and plot their futures, is a story that extends beyond biology. Interventions that are designed to perpetuate or to restore health, accordingly, require a holistic and culturally sensitive focus. After all, most persons do not conceive normality in solely physical terms. Their aim, instead, is to achieve a healthy existence and resume their usual tasks. Their obligations, for example, are social and not necessarily focused on biology.

In PHC, owing to the emphasis placed on persons and their environments, narratives assume a collective character. Whether persons choose to seek treatment, for example, is often influenced by a range of stories, some of which are dominant only at particular times. The source of this influence may be not the biological narrative but those related to gender, race, or poverty. The physician should allow the proper narrative to emerge and begin to shape clinical and other discussions about health.

What should be clear is that PHC is not simply an extension or modification of biomedicine. A new model is proposed that treats the various dimensions of illness as existential and embedded in narratives, while expanding the traditional role of physicians. The biological narrative, accordingly, may not necessarily be dominant among particular persons or communities. But such a decision does not automatically signal irrationality but simply the acceptance of a different order of values and commitments. Those who engage in PHC must make sure that these persons’ stories are correctly identified and told, rather than dismissed because a particular narrative might deviate from medical convention.

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References

Primary Health Care and Narrative Medicine


Story

The doctor may also learn more about the illness from the way the patient tells the story than from the story itself.

— James B Herrick, 1861-1954, American physician
BOOK REVIEW

The Lost Art of Retinal Drawing
by Stephen R Russell and LuAnn Dvorak

Review by Mark Cohen, MD
Perm J 2015 Fall;19(4):95
http://dx.doi.org/10.7812/TPP/15-053

Most physicians are familiar with direct ophthalmoscopy, which produces an upright, unreversed, and virtual image of approximately 15 times magnification. Binocular indirect ophthalmoscopy produces a stereoscopic inverted, reversed, and aerial image of 2 to 5 times magnification (depending on the power of the field lens) between the patient and examiner. The advantages of the direct ophthalmoscope are its relative portability and the ease of learning its use. Its disadvantages are a flat image and an inability to view the anterior fundus. The main advantages of the binocular indirect ophthalmoscope relate to its ability to view “the big picture” stereoscopically and, with manual depression, the ability to see out to the ora serrata and sometimes further. The biggest disadvantage is learning to master the techniques that require use of both hands simultaneously, a steady hand, and good hand-eye coordination.

To this end Charles Schepens, who is most responsible for popularizing the indirect exam, taught and required by example the meticulous drawing of all the structures and abnormalities viewed. His method was adopted by most, if not all, ophthalmic training programs. Considering that in using this technique the examiner is seeing the image upside down and backwards, accommodation is made by having the patient lie down on a Gurney with the clipboard holding the drawing paper placed upside down on the patient’s chest. An array of colored pencils is used to draw the structures and pathology. Such examination, especially when indenting the globe through the eyelids to view the periphery, may take an hour or more, even when learning the technique. In recent years, with the advent of vitrectomy and other modern tools and techniques, there is no longer a need for detailed drawings in the operating room. Because of this and economic necessities, retinal drawing has become “The Lost Art.”

As the authors point out, these drawings were considered so precious that at the University of Iowa they were kept separate from the patients’ records. When Stephen R Russell, MD, returned to become the Director of the Vitreoretinal Diseases and Surgery Service in 1997 (where he had completed his retinal fellowship in 1988), he wondered what happened to those old drawings. By serendipity they were rediscovered when an employee from a storage facility asked if they could be destroyed. The Lost Art of Retinal Drawing is the product of a loving endeavor, previously documented in The Permanente Journal.1 The authors tell the story well and have accompanied the drawings with the personal anecdotes of their creators who all cherished memories of this golden era. As I read this book and hovered over the drawings, my mind wandered back to my own time of learning. What I remembered was a shared intimate experience with the patient. Because of the time needed and the necessary discomfort caused by the exam, I needed to reassure my patient that this effort would insure the best possible outcome. We also were able to explore and discuss expectations and fears; in short getting to know the person, not only the pathology. In the end I was also proud to put my signature on my drawing, which was an outcome of practicing the art of medicine. To paraphrase the authors’ summary, in the efficiency of modern medicine are we in danger of trading our role as healers to that of technicians? This book should be a welcome addition to any medical library and to anyone with an interest in medical history.

Reference

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Physicians may earn up to 1 AMA PRA Category 1 Credit™ per article for reading and analyzing the designated CME articles published in each edition of The Permanente Journal. Each edition has four articles available for review. Other clinicians for whom CME is acceptable in meeting educational requirements may report up to four hours of participation. The CME evaluation form may be completed online or via mobile Web at www.tpjcme.org. The Certification of Credit form will be e-mailed immediately upon successful completion. Alternatively, this paper form may be completed and returned via fax or mail to the address listed below. All Sections must be completed to receive credit. Certification of Credit will be mailed within two months of receipt of the paper form. Completed forms will be accepted until January 2017. To earn CME for reading each article designated for AMA PRA Category 1 Credit, you must:
• Score at least 50% in the posttest
• Complete the evaluation and provide your contact information

Section A.

Article 1. (page 4) Study of the Use of Lipid Panels as a Marker of Insulin Resistance to Determine Cardiovascular Risk

The lipid panel can estimate the probability of a patient being insulin resistant. Which of the following statements is most accurate?

☐ a. a triglyceride to high-density lipoprotein cholesterol (TG/HDL-c) ratio greater than 3.0 is 64% sensitive and 68% specific for insulin resistance
☐ b. a TG/HDL-c ratio of 1 is probably very insulin sensitive
☐ c. a triglyceride level greater than 130 mg/dL is 77% sensitive and 71% specific for insulin resistance
☐ d. extracting information about insulin resistance from triglyceride levels above 400 mg/dL is easy because there is a lot of data above 400 mg/dL; removing the influences of familial hypertriglyceridemias from such a high triglyceride level is simple

Which confers a lower risk of incurring a cardiovascular event: having low-density lipoprotein cholesterol (LDL-c) but high triglyceride to high-density lipoprotein cholesterol (TG/HDL-c) ratio or the reverse, having a high LDL-c but low TG/HDL-c ratio?

☐ a. the TG/HDL-c ratio is not as important a cardiovascular risk factor as the LDL-c and the difference between total cholesterol and HDL-c
☐ b. having an unhealthy LDL-c but a low TG/HDL-c ratio confers a lower risk in male Danes; but in a more heterogeneous population such as Northern Californians, unhealthy LDL-c is more important in predicting risk
☐ c. having an unhealthy LDL-c but a low TG/HDL-c ratio confers a lower risk both in male Danes and in Northern Californians
☐ d. risk calculators such as the Framingham, the Reynolds, or the American College of Cardiology/American Heart Association incorporate more data on a patient’s health than the lipid panel contains; nonetheless, the metrics in the lipid panel are as accurate at assessing cardiovascular risk as the TG/HDL-c ratio

In this study, the usage of narcotic pain medication:

☐ a. found requirements for analgesics were significantly reduced in GI patients
☐ b. did not vary among groups
☐ c. found requirements for analgesics were significantly reduced in M patients
☐ d. both M and GI groups required more medication than the UC group

Article 3. (page 36) Safely Increase the Minimally Invasive Hysterectomy Rate: A Novel Three-Tiered Preoperative Categorization System Can Predict the Difficulty for Benign Disease

You are an experienced gynecologic surgeon assisting with a minimally invasive hysterectomy. The patient is a 38-year-old woman (G1 P1 [cesarean]) with a body mass index of 35 and a clinical uterine size of 14 weeks with no other significant surgery. What category hysterectomy would this be, and about how much surgical time should be scheduled?

☐ a. Category 1 with an average surgical time of 1.5 hours
☐ b. Category 2 with an average surgical time of 2 hours
☐ c. Category 3 with an average surgical time of 2.5 hours
☐ d. Category 4 with an average surgical time of 3 hours

In this study, when a junior attending was assisted by another junior attending or resident, the laparotomy times for both GI and M compared with Usual Care (UC)

☐ a. both GI and M showed the greatest reduction in anxiety postintervention
☐ b. though M showed the greatest reduction in pain vs GI and UC at all intervention points, GI showed the greatest reduction in anxiety postintervention
☐ c. primary outcome measures of pain and anxiety reduction met anticipated expectations at all intervention times for both GI and M compared with Usual Care (UC)
☐ d. the preoperative Categorization System burdens the surgeon in terms of patient safety, costs, and time

Article 2. (page 18) Effect of Structured Touch and Guided Imagery for Pain and Anxiety in Elective Joint Replacement Patients—A Randomized Controlled Trial: M-TURP

The “Minor Junior P” showed that anxiety and pain were significantly affected by both “M” technique (M) and guided imagery (GI) when used in elective knee and hip joint replacement patients. Which of the following statements is most accurate?

☐ a. primary outcome measures of pain and anxiety reduction met anticipated expectations at all intervention times for both GI and M compared with Usual Care (UC)
☐ b. though M showed the greatest reduction in pain vs GI and UC at all intervention points, GI showed the greatest reduction in anxiety postintervention
☐ c. both GI and M showed significant decreases in pain and anxiety at nearly all intervention points compared with the UC group but did not show differences comparing pain and anxiety levels on postoperation day 2 compared with preoperation assessments
☐ d. M showed the greatest reduction in anxiety comparing pre- and postinterventions, but GI resulted in greater pain reduction

Section B.

Referring to the CME articles, how likely is it that you will implement this learning to improve your practice within the next 3 months?

Objective 1  Integrate learned knowledge and increase competence/confidence to support improvement and change in specific practices, behaviors, and performance.

Objective 2  Lead in further developing “Patient-Centered Care” activities by acquiring new skills and methods to overcome barriers, improve physician/patient relationships, better identify diagnosis and treatment of clinical conditions, as well as, efficiently stratify health needs of varying patient populations.

Objective 3  Implement changes and apply updates in services and practice/policy guidelines, incorporate systems and quality improvements, and effectively utilize evidence-based medicine to produce better patient outcomes.

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Section C.

What other changes, if any, do you plan to make in your practice as a result of reading these articles?

Section D. (Please print)

Name __________________________

☐ Physician ☐ Non-Physician

Title __________________________

E-mail __________________________

Address __________________________

Signature __________________________

Date __________________________
**Original Research & Contributions**

4. **Study of the Use of Liquid Powders as a Marker of Insulin Resistance to Determine Cardiac Risk.**

    Richard Bell, MD, PHD, FACPC, Mark L Mintz, MD, FAC, FACC;
    John J. Flynn, MD, FACS; Mary E. Allen, MD, FACP;
    and Robert C. Carneal, MD, FACC

    Insulin resistance, as manifested by a high triglyceride/HDL cholesterol ratio, was associated with cardiovascular outcomes more than other lipoprotein abnormalities (dominated by low-density lipoprotein cholesterol), which had little concordance.

11. **Right-Sided Colon Ischemia: Clinical Features, Large Vascular Artery Occlusion, and Long-Term Follow-Up.**

    George F. Longmire, MD, FACP, FAC, FAC, Robert J. Hahn, MD, FAC, FAPS

    Large vascular artery occlusion (LVAO) could underlie right-side colon ischemia (RSC) but is little known. In a retrospective observational study in an integrated health care system, 19 of 49 patients underwent surgery—5 of 6 developed RSC in hospital following surgical procedures and 14 of 43 had RSC before hospitalization. Among 44 survivors (median follow-up of 1.9 years), excluding 15 of 16 operated cases, had symptoms, LVAO, and underwent angiography and stent placement. Patients with LVAO may have symptomatic LVAO, therefore, we advise they undergo careful history and physical to assess for abdominopelvic angina and exclude vascular artery imaging.

18. **Effect of Structured Touch and Guided Imagery for Pain and Anxiety in Elective Joint Replacement Patients—A Randomized Controlled Trial.**

    John Brent Forward, MD, FACP, ABHP, Nancy Elizabeth Greuter, RN, LMT, John J. Flynn, MD, FACS; Thomas Delate, PhD, Nathan P. Clark, PharmD, FCP, BCPS, Dione Karrz, Enzil M. Wol, PharmD, FCP, BCPS

    In a randomized controlled trial, patients undergoing elective total hip or knee replacement (M, a registered method of structured touch, guided imagery, or usual care) showed decreased in both pain and anxiety 1 day after surgery. M showed the largest predicted decrease in both pain and anxiety between groups. There was no significant difference in narcotic pain medication use between groups. Patient satisfaction survey ratings were highest for M, followed by guided imagery.

29. **Patient Satisfaction after Thoracoscopic Sympathectomy for Palmar Hyperhidrosis: Do Method and Level Matter?**

    Amy Cheng, MD, Hugo Johnson, MD, Michael V. Chang, MD

    Although surgery is widely recognized as the best treatment for palmar hyperhidrosis (PH), the technique is based on surgeon preference. In a retrospective medical chart review, 70 patients underwent bilateral thoracoscopic procedures for PH between 1995 and 2010, and 210 (33%) responded to the questionnaires. Sixteen surgeons performed 100 sympathectomies, 83 thoracotomies, and 19 ligations with electrocautery. Mean follow-up was 5.5 years. Most patients reported relief of their PH and were satisfied with surgical intervention, regardless of method used.

33. **An Education Program for Patient Self-Management of Varicose Veins.**

    Stuart Hahn, MD, PhD, John D. O’Brien, MD, FACV, FACO, Jeannine W. Jannes, MD, FACO, FACS, Robert C. Carneal, MD, FACP, FACC

    The primary outcome was ischemic heart disease. Insulin resistance, as manifested by a high triglyceride/HDL cholesterol ratio, was associated with cardiovascular outcomes more than other lipoprotein abnormalities (dominated by low-density lipoprotein cholesterol), which had little concordance.

50. **SOUL OF THE HEALER**

    **17. Umbrellas for Sale.**

    Stuart Hahn, MD

    In this NBAE step 2 CS case, Dr. Hahn expresses his frustration with the difficulty for patients with atrial fibrillation to self-manage warfarin. He also discusses palliative care and the best treatment for palmar hyperhidrosis. A nonlaparotomic route is recommended for this surgery because it is less invasive and has a shorter hospital stay. The authors followed 103,646 members of the health plan. Subjects were categorized as insulin sensitive or resistant on the basis of triglyceride and high-density lipoprotein cholesterol (HDL-C) in the index year. The primary outcome was ischemic heart disease. Insulin resistance, as manifested by a high triglyceride/HDL cholesterol ratio, was associated with cardiovascular outcomes more than other lipoprotein abnormalities (dominated by low-density lipoprotein cholesterol), which had little concordance.

75. **Heading Home**

    Two Envelopes

    Nicholas Morell

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    Paperback: 550 pages

    $19.95
ABSTRACT

Context: A top-down evaluation of the costs of operating rooms (ORs) is not commonly done because it is relevant mostly in a publicly funded system.

Objective: This study was conducted to determine the costs and utilization of ORs in a public hospital in Trinidad, West Indies, for two one-year periods using a top-down model.

Design: Quantitative observational study.

Main Outcome Measures: A “cost-block” model suggested for evaluation of intensive care unit costs was adapted to suit ORs. Data were obtained from personal interviews, records, and surveys from the appropriate hospital departments. Adjusted OR utilization times also were recorded for both years.

Results: The total annual costs of 4 ORs for the years 2006 and 2009 were approximately US $2.2 and $3.2 million, respectively. Capital expenditure contributed to 70% of the costs, followed by consumables (15%) and medical staff salary (8%). The daily cost of running the ORs was US $62,442 in 2006, which rose to $86,731 in 2009. The cost of unutilized OR time was approximately US $298,342 in 2006 and was reduced to $198,315 during 2009.

Conclusion: The adapted cost-block model was useful to evaluate the costs of ORs in a public hospital in Trinidad and can be used from the government’s expenditure perspective. Because the cost of running the ORs was high, efficiency must be improved to minimize waste.

INTRODUCTION

Operating rooms (ORs) are one of the most resource-intensive areas of a hospital to provide surgical care. A recent release from the US Healthcare Cost and Utilization Project found that the cost of a hospital stay after a surgical procedure in an OR was 2.5 times more expensive than that of a hospitalized patient not requiring a surgical procedure. The infrastructure and equipment capacity may vary between the hospitals in accordance with the surgical procedures, and hence most cost evaluation studies of ORs focus on the cost of individual procedures. However, in a publicly funded health care system, the proportion of expenditure for ORs is more relevant, because contemporary ORs require a major proportion of the hospital’s budgetary allocation. Many published studies pertaining to OR management focus on costs, as there is an agreed position that ORs represent one of the most critical areas of a hospital for financial allocation.

There are many reasons ORs are resource intensive. The infrastructural aspects of the ORs consist of many engineering issues, such as OR space, controlled temperature and humidity, sterile environment, and electricity backup systems, which require careful attention and continuous maintenance. ORs also extensively use consumables, they hold equipment requiring regular maintenance because their failure results in delays and cancellations of surgery. The human resources component in ORs is always multidisciplinary, including clinical and nonclinical staff members, which is another major contribution to the cost.

Reviewing the cost of ORs and comparing the cost with the efficiency of its utilization is essential in every hospital regardless of whether the hospital is publicly or privately funded. Although there have been published reports applying various management tools and mathematical modeling algorithms to improve the efficiency of ORs, few studies, to our knowledge, have looked into the cost aspect of ORs from the perspective of public health expenditures.

A study done in the United Kingdom (UK) highlighted the common problems encountered by OR managers, showing a need to ensure the full utilization of the OR sessions to minimize the substantial financial impact likely to be incurred by the hospital. OR times are precious throughout the world, and it is therefore important that such an expense facility be utilized efficiently. It has been acknowledged that more data are needed from different parts of the world in this area of hospital-based health care.

There are three major public health institutions in Trinidad, West Indies: Port-of-Spain General Hospital, Eric Williams Medical Sciences Complex, and San Fernando General Hospital. All three hospitals are equipped with ORs, offering free surgical care to patients. The availability of operating times in these ORs is currently limited. Presently there is little documentation on the status of the costs of running ORs in Trinidad’s public hospitals.

This study seeks to determine from a funding agency’s (governmental) perspective the cost of ORs as a whole unit in a public teaching hospital, and to evaluate the utilization of the ORs to quantify the cost-efficiency.
METHODS

Approval was obtained before the study from the Ethics Committee of the Faculty of Medical Sciences, The University of the West Indies, St Augustine, Trinidad and Tobago, and from the hospital authorities. Because this was a quantitative observational study that collected data exclusively on costs and utilization of ORs in public hospitals in Trinidad and Tobago and involved no patient clinical data, the committee approved a waiver for informed consent. All data were collected prospectively by personal visits to the various departments of the hospital and by obtaining relevant information from records to minimize the chances of missing data.

The cost of the ORs was determined using a “cost-block” model developed in the UK for estimating costs of intensive care units (ICUs). This is a top-down model and is well applicable to the objective of the study, which was to estimate costs from the governmental perspective. The costs were broken down into six blocks: 1) capital expenditure, 2) estate, 3) nonclinical support services, 4) clinical support services, 5) consumables, and 6) staff. The definitions of each block for ICU in the original model were adapted to suit ORs (see Sidebar: Definitions of Cost Blocks Used for Operating Rooms).

Data were obtained from the Human Resources, Administration, Finance, Pharmacy, Stores, and Biomedical Engineering Departments of each hospital. Study team members collected data concerning the infrastructure of the OR on a scheduled visit. Each team member personally observed and noted all the equipment in the ORs. From the office records, costs of equipment were calculated. Similar data were collected for consumables and drugs.

Data also were collected by interviewing the managers and the staff attached to the related departments regarding the overall staffing pattern. Data regarding human resources were collected by recording the availability of the number of nurses, physicians, and support staff. The salaries of the staff working exclusively in the ORs were recorded, and salaries of staff who also contribute to other parts of the hospital such as general wards and outpatient clinics were apportioned by the time they contributed in the ORs.

The cumulative costs of all the blocks were used to derive the annual costs of the ORs during 2006 and 2009, from which the average daily costs were calculated. The study was actually conducted during 2010; hence, 2009 was chosen as the base period. Because the research team was aware that the OR was poorly utilized in the past, the year 2006 was chosen as a period for comparative evaluation.

Data regarding the amount and types of surgeries performed during the designated time frame was obtained from medical records at the Surgery Department. The total amount of consumables and other equipment used each month in the specified period was averaged by looking at the relevant stock request sheets. Information regarding the cost in 2006 and 2009 of each item used and the total cost of maintenance for each month during the specified timeframe (utility bills, etc) was also obtained from relevant sources such as the Departments of Purchase, Pharmacy, Finance, and Engineering.

From all these collected data, the total cost of managing the ORs during the specified period was calculated using Microsoft Excel spreadsheet software (Microsoft, Redmond, WA).

After allowance for turnover time, OR utilization times were calculated for both years, and the time utilized and unutilized during elective surgery hours was calculated.

The total cost of running the ORs vs the utilization times was calculated for each year (2006 and 2009), and comparisons were made.

RESULTS

The OR complex in the public teaching hospital studied consisted of eight rooms, although only four rooms were in use during the study period. The ORs had state-of-the-art equipment, which included modern anesthesia machines with microprocessor-controlled mechanical ventilators, noninvasive and invasive monitoring modalities, laparoscopic equipment, endoscopes for all specialties, a C-arm x-ray machine, infusion pumps, and consumables, including anesthetic and perioperative drugs. Both elective and emergency surgical procedures were performed for all age groups.

The ORs had a full complement of medical and nursing staff, which included consultant surgeons in most surgical

Definitions of Cost Blocks Used for Operating Rooms

**Capital expenditures:**
- Cost price of anesthesia machines, anesthetic equipment including fiberoptic scopes, surgical instruments including orthopedic and neurosurgical drills, C-arm x-ray machines, surgical endoscopes of all specialties, laparoscopic equipment, arthroscopic equipment, operating room beds, intravenous poles, autoclaves, operating room lights, diathermy, intraoperative cell salvage equipment (cell saver), cardiopulmonary bypass machines, arterial blood gas machines, and others, with 10% depreciation per year since the year of purchase

**Estate:**
- Costs of water, electricity, telephone, scrub production and laundry, laminar flow and scavenging, and sterilization services

**Clinical support:**
- Salaries of nursing staff including head nurses, registered nurses, enrolled nursing assistants, patient care assistants, Anesthesia Department assistants, orthopedic technicians, radiographers, perfusionists

**Nonclinical support:**
- Salaries of housekeeping personnel, patient escorts, customer service representatives, clerical staff

**Consumables:**
- Cost price of sutures, gloves, drugs, intravenous fluids, piped gases, syringes and needles, anesthetic equipment (endotracheal tube, laryngeal mask airway, etc), disposable gowns, disposable diathermy equipment, other disposable surgical equipment, suction catheters, and others

**Staff:**
- Salaries of consultants, registrars, house officers in Anesthesia and Surgery, interns in Surgery apportioned to the time spent in operating rooms
specialties, consultant (physician) anesthetists, registrars, house officers, a head nurse, registered nurses, scrub nurses, nursing assistants, patient escorts, and other support staff. Although the recovery room had the physical infrastructural capacity with all facilities to hold 10 patients, only 4 receiving areas were equipped with monitors and staff, making it a 4-bed unit, to provide 1:1 nursing care.

During 2006, the number of elective surgical patients who were operated on in the 4 rooms was 1476, which increased to 1995 during 2009.

Figures 1 and 2 show the cost blocks for 2006 and 2009, respectively. Capital expenditure was the highest cost block and contributed 70.5% of the expenditure during 2006 and 68% during 2009. Consumables were the second most expensive block, which contributed 17% (average for both years) of the total expenditure. Staff salary contributed 7.5% (average for both years), whereas estate, clinical support, and nonclinical support contributed the remainder.

Table 1 shows the cost variables such as total annual costs, costs for the 4 ORs, average cost per OR, cost per patient, and cost per hour for both years studied. The annual total costs of running ORs for 2006 amounted to US $2,278,455, which increased to $3,328,862 during 2009.

The cost of running the whole OR complex was approximately US $6242 per day during 2006 and $8873 during 2009. This amounted to US $1560 and $2218 per OR for the respective years. From these, the cost of 1 hour of OR time was calculated at US $65 in 2006 and $92 during 2009.

Table 2 shows the adjusted utilization of elective surgery time during the study periods. The total number of adjusted utilization time for all ORs during 2006 was 3223 hours, which increased to 4235 hours in 2009 during elective surgery time slots; approximately 4588 hours were unutilized during 2006 and 2145 hours were unutilized during 2009. In terms of fiscal quantification, this unutilized time amounted to US $298,342 during 2006 and $198,315 during 2009.

Table 3 shows the individual costs for each cost block for the two years of study.

DISCUSSION

The present study establishes the potential applicability of the cost-block model to evaluate costs of running ORs in public hospitals using a top-down method. The cost-block model was developed for evaluating costs of ICUs, which was earlier applied in Trinidad. We adapted the model to evaluate the costs of ORs, which to our knowledge has never been reported.

The cost-block method study group for ICUs has suggested that some of the blocks such as estate and nonclinical support services could be excluded, and there have been some reports of ICU costs without using these blocks. However, we adapted all the cost blocks suggested initially for cost evaluation of ICUs for OR cost blocks and included all in our study to get a better result of the adaptation. Additionally, we also collected data by conducting personal interviews and observations and did not use a self-administered questionnaire. We calculated the costs by working with the various relevant sources and departments in the hospital. Because the top-down model is relatively new for computing costs of ORs, we wanted to minimize error as much as possible.

The comparison of costs between the years 2006 and 2009 revealed some interesting facts. Notwithstanding the finding that the overall proportions of the individual cost blocks were similar, the total annual costs increased by almost US $1 million in 3 years, despite only a 35% increase in the number of patients operated on (from 1476 to 1995).

The cost-block for staff was smaller than the capital expenditure and consumables blocks in both study years (Table 3). This may be because, in the model we adopted, the nursing staff in the rooms was grouped under the clinical support block, which would have increased the proportion of this block while decreasing that of the staff block. The proportion for the capital expenditure block was higher, which may possibly be because all equipment in the ORs, including anesthetic machines, monitors, and mechanical ventilators, usually is imported from other countries such as the UK and the US. The high costs involved in this process is understandable; however, the dominance of the capital expenditure over the staff block is a unique finding that is different from the previous applications of the cost-block models for ICU, where the staff proportion of the cost blocks always took the lead.
The broad application of the formula for calculating OR utilization times. 

The broad application of the term efficiency in an OR situation is also disputed because there can be allocative efficiency vs technical efficiency. In our view, the wide individual variations in the many factors such as public vs private hospitals, different methods of scheduling, different surgical durations, and OR slot allocation procedures dictate that there cannot be a one-size-fits-all formula for calculating OR utilization. This may be one of the reasons for the dispute between the applicability of the model developed in the US and that developed in the UK. Even in the UK, there have been reports that the formula suggested for calculating OR utilization may not be exactly applicable in different hospitals. Hence, we used a simple adjusted utilization time in our study.

### Table 1. Cost variables for years 2006 and 2009 in a public hospital in Trinidad, West Indies

<table>
<thead>
<tr>
<th>Variable</th>
<th>2006 (US $)</th>
<th>2009 (US $)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total annual costs</td>
<td>2,276,455</td>
<td>2,388,622</td>
</tr>
<tr>
<td>Cost of running all operating rooms per day</td>
<td>6242</td>
<td>8873</td>
</tr>
<tr>
<td>Cost per operating room per day</td>
<td>1560</td>
<td>2218</td>
</tr>
<tr>
<td>Cost per operating room per hour</td>
<td>65</td>
<td>92</td>
</tr>
</tbody>
</table>

### Table 2. Utilization of operating time for years 2006 and 2009 in a public hospital in Trinidad, West Indies

<table>
<thead>
<tr>
<th>Variable</th>
<th>2006</th>
<th>2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of operated-on patients (elective)</td>
<td>1476</td>
<td>1995</td>
</tr>
<tr>
<td>Total time utilized (hours)</td>
<td>3223</td>
<td>4235</td>
</tr>
<tr>
<td>Total time unutilized (hours)</td>
<td>4588</td>
<td>2145</td>
</tr>
<tr>
<td>Cost of unutilized time (US $)</td>
<td>298,342</td>
<td>198,315</td>
</tr>
<tr>
<td>Cost of unutilized time % of total costs</td>
<td>13</td>
<td>6</td>
</tr>
</tbody>
</table>

a Total costs: 2006 = US $2,276,455; 2009 = US $3,238,622.

Additionally, because capital expenditure is the biggest proportion of costs, this infrastructure is available whether there is increased productivity or not. This point is salient for the managers of the hospital system to increase the number of cases by employing more staff, bringing in economies of scale, and increasing the productivity with minimal increase in costs.

The comparison costs per patient showed that there was not much difference between the years studied. This also may be evidence of potential economies of scale in the years studied. The cost of all other blocks formed only a small part of the total expenditure.

It is also interesting to note that there was a 25% increase in the OR utilization time between 2006 and 2009; 41% of the elective surgery time was utilized during 2006, which increased to 66% during 2009. However, the cost of the wasted time for the year 2006 was 13% of the total annual expenditure, which almost halved to 6% of the total annual expenditure during 2009. This is despite the fact that the difference in the total annual expenditure between the 2 study years was almost US $1 million. This is an indication that by increasing the productivity of the ORs even by smaller amounts, a great deal of money can be saved. However, productivity may not always mean that the number of cases must be increased; rather, only the utilization time of ORs must be increased because there can be varying durations for the same type of surgery when performed by different surgeons.

Because the cost-block model is a top-down model, this was the most appropriate model for our scenario, where hospitals are government funded. Most cost studies involving ORs use a bottom-up approach, by activity-based costing, including each consumable used. Additionally, most studies involve costing specific surgical procedures, rather than averaging the cost from the total expenditure. We chose to use the top-down model because of the following reasons:

1. In a public health care system such as in Trinidad and Tobago, service is offered free to citizens.
2. From the government’s perspective, it may be pertinent to elucidate the appropriateness of the utilization for the investment made in ORs.
3. The overall costs and the costs per hour information will be very helpful in policy decision making, including allocation of OR time to surgeons.
4. The individual cost-block information may also assist in policy decision making, such as staff recruitment and investment in capital equipment.
5. This method has, to our knowledge, never been adopted to evaluate the costs of ORs in a publicly funded setting.

Cost-effectiveness analysis involves the evaluation of the ratio of the cost of an intervention to the patient outcomes measured by quality-of-life indexes. However, the aim of the present study was not to evaluate the cost-effectiveness of a particular surgery or individual surgical intervention where cost of surgery is compared with patient outcomes. The objective of the present study was to evaluate the cost of ORs as a functioning whole system. When a system is evaluated, efficiency is more meaningful than effectiveness because efficiency may mean how well the processes of the system are run, whereas effectiveness may imply whether a treatment or intervention is useful.

Many methods and formulae have been suggested to calculate OR utilization times. The broad application of the term efficiency in an OR situation is also disputed because there can be allocative efficiency vs technical efficiency. In our view, the wide individual variations in the many factors such as public vs private hospitals, different methods of scheduling, different surgical durations, and OR slot allocation procedures dictate that there cannot be a one-size-fits-all formula for calculating OR utilization. This may be one of the reasons for the dispute between the applicability of the model developed in the US and that developed in the UK. Even in the UK, there have been reports that the formula suggested for calculating OR utilization may not be exactly applicable in different hospitals. Hence, we used a simple adjusted utilization time in our study.
LIMITATIONS

There are several limitations to the present study. The short duration of the study may be a drawback. Data collection for costs is cumbersome and susceptible to errors, especially with varying interpretations of the definitions. To minimize errors, we made sure that the same team member who understood the definition of the cost block collected data for the cost block by interviewing the personnel and reviewing the records in the respective department. Another limitation is that the top-down model averages only the costs of entire ORs, which is not applicable to cost an individual surgical procedure. Using the top-down model was another reason that we could not compare our findings with other published reports from the rest of the world, which predominantly use activity-based costing for individual procedures. We did not obtain cost figures for other public hospitals, which would have provided a better comparison. In addition, OR utilization times are calculated in many different ways throughout the world, and we followed a simple adjusted utilization time.

CONCLUSION

The cost-block method provided a useful framework to evaluate the costs of running ORs in a public hospital in Trinidad and Tobago and the opportunity for government and policy planners to improve cost-efficiency.

Disclosure Statement

The author(s) have no conflicts of interest to disclose.

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References

An Unusual Presentation of Dengue Fever: Association with Longitudinal Extensive Transverse Myelitis

ABSTRACT
Association of dengue fever with transverse myelitis in the form of extensive spinal cord involvement is a rare entity described in the literature. We describe a middle-aged man who presented with dengue fever and in whom weakness of the bilateral lower limbs and urinary incontinence developed on the third day of fever. Magnetic resonance imaging confirmed the diagnosis of longitudinally extensive transverse myelitis. Over a four-week course of corticosteroids with supportive management, the patient recovered without any residual neurologic deficit.

INTRODUCTION
Dengue virus is a cause of widespread morbidity and mortality in the tropical and subtropical areas of India, with 47,209 cases and 242 deaths reported in 2012 from the government hospital sector in India alone. Of the 4 strains of dengue virus implicated in the disease, DEN1, DEN2, and DEN3 are the prominent serotypes in India. DEN2 has been reported in more than 75% of the cases in breakouts since 2010. Although the first recognized epidemics of dengue fever were known as early as the 1780s, the neurotropic effects came to light only 2 decades ago. Neurologic involvement owing to direct central nervous system involvement of the virus during the acute phase leads to encephalitis, meningitis, and myelitis. The postinfection phase may be associated with acute disseminated encephalomyelitis, neuromyelitis optica, optic neuritis, Guillain-Barré syndrome, myelitis, oculomotor palsy, phrenic neuropathy, and chronic fatigue syndrome, with encephalitis being the most common. Involvement of the spinal cord appears to be rare and occurs mostly in the form of transverse myelitis. Spinal cord involvement in the form of longitudinally extensive transverse myelitis (LETM) has been described only once in the literature to our knowledge.

We report a case of LETM in a previously healthy middle-aged man presenting with dengue fever associated with bilateral lower limb weakness and urinary incontinence. The patient responded to corticosteroids and eventually had complete neurologic recovery.

CASE SUMMARY
A 42-year-old man, a resident of an ongoing dengue outbreak area, presented with 4 days of fever and 1 day of bilateral lower limb weakness to the Emergency Department of Guru Teg Bahadur Hospital in Delhi, India. The fever was high grade with chills, myalgia, arthralgia, headache, and petechial rash. Bilateral lower limb weakness that had developed 3 days after the onset of fever was associated with urinary retention. The motor weakness was associated with sensory impairment in the lower limbs extending to the level of the umbilicus. However, there was no associated bowel involvement. There was no history of bleeding tendency, recent vaccination, or unusual medical history. The patient was admitted to the hospital.

Results of the general examination were unremarkable except for hyperthermia (temperature = 38.9°C [102°F]) and multiple petechiae all over the body. Neurologic findings revealed flaccid paralysis of bilateral lower limbs with hypotonia and muscle strength of 2/5 at the hip, knee, ankle flexors, and extensors. Deep tendon reflexes were absent, and Babinski sign was positive. Abdominal reflexes were absent. The level of sensory deficit extended upward until the umbilicus, corresponding to T10. Neurologic examination of the upper limbs and the cranial nerves were normal.

Initial laboratory investigations revealed a hemoglobin level of 10.2 g/dL, leukopenia (leukocytes = 3 × 10^9/µL), and thrombocytopenia (platelets = 18 × 10^9/µL). The platelet count increased during the hospital stay, without the need for transfusion. Results of the NS1 (non-structural protein 1) antigen test and the immunoglobulin M antibody test for dengue were negative. Cerebrospinal fluid analysis could not be carried out because the patient did not consent to a lumbar puncture. Table 1 denotes the laboratory investigations of the patient at hospital admission and at discharge. Magnetic resonance imaging of the spine revealed continuous intramedullary T2 hyperintense signal intensity in the long segment of the dorsal cord extending from T5 to the conus medullaris and from T10 to the conus medullaris.

**Table 1.** Laboratory Investigations of the Patient at Hospital Admission and Discharge

<table>
<thead>
<tr>
<th>Test</th>
<th>Admission</th>
<th>Discharge</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemoglobin</td>
<td>10.2 g/dL</td>
<td>10.2 g/dL</td>
</tr>
<tr>
<td>White blood cell count</td>
<td>3 × 10^9/µL</td>
<td>3 × 10^9/µL</td>
</tr>
<tr>
<td>Platelet count</td>
<td>18 × 10^9/µL</td>
<td>18 × 10^9/µL</td>
</tr>
<tr>
<td>C-reactive protein</td>
<td>32 mg/L</td>
<td>11 mg/L</td>
</tr>
<tr>
<td>D-dimer</td>
<td>300 ng/mL</td>
<td>150 ng/mL</td>
</tr>
<tr>
<td>Procalcitonin</td>
<td>0.1 ng/mL</td>
<td>0.1 ng/mL</td>
</tr>
</tbody>
</table>

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Contrary to the usual association of LETM with neuritis, rash, thrombocytopenia, leukopenia, and positive NS1 antigen and immunoglobulin M serologic findings for dengue virus. With all these features and the lack of any other important physical findings, LETM in this patient was probably the result of active dengue infection. The patient responded dramatically to corticosteroid treatment, and the neurologic deficit recovered fully by 3 weeks.

In our patient, myelitis developed in the acute parainfectious phase of dengue illness, similar to earlier case reports. There is only a single case report of myelitis in the postinfectious phase, occurring 16 days after the onset of illness. The pathogenesis of myelitis in our case is likely direct spinal neuronal involvement of the dengue virus, but the exact mechanism is not clear. It has been shown that dengue virus can lead to involvement of the spinal cord by direct invasion of the cord or by active replication within the spinal cord. It was also postulated that acute parainfectious dengue infection presents with flaccid paralysis, whereas late-stage (postinfectious) dengue infection presents with spastic weakness, and our case had similar findings of flaccid paralysis. Usually, LETM is associated with a poor prognosis; however, our patient showed a dramatic improvement in neurologic deficit after treatment with corticosteroids. Contrary to the case previously reported by Larik et al., in which the patient showed improvement only after treatment with antivirals and intravenous immunoglobulins, our patient recovered with corticosteroids (similar to the case by Seet et al) and other supportive treatment in the form of physical therapy.

We were unable to determine the strain of dengue in our patient, and a review of the previous case report on LETM failed to reveal the strain implicated in that case. However, it would be interesting to know the epidemiology for future such cases.

### DISCUSSION

Neurologic manifestations associated with dengue fever received little attention initially, but in the last 20 years there has been increasing recognition of their possible importance. After a thorough search of the literature, we found only 5 case reports of dengue illness associated with spinal cord involvement in the form of transverse myelitis. The association between dengue infection and LETM has been described only once in the literature to our knowledge.

Our patient had typical features of dengue fever with a clinical history, rash, thrombocytopenia, leukopenia, and positive NS1 antigen and from the C2 to C4 level of the cervical spinal cord (Figure 1). Magnetic resonance imaging of the brain revealed unusual mild diffuse cerebral atrophy.

The patient was treated with supportive management and intravenous pulse therapy with methylprednisolone at a dosage of 1 g/day for 3 days and then was shifted to a regimen of oral prednisolone. The oral prednisolone dosage was started at 40 mg/day and then was tapered gradually over 4 weeks. The patient’s bladder was catheterized for the first 3 weeks, and then the catheter was removed after intermittent clamping and bladder training. Rehabilitation physical therapy exercises were done simultaneously with medical treatment.

The weakness dramatically improved with corticosteroids, and the patient was able to walk by the third week of treatment. He was discharged after 27 days of inpatient treatment, with no residual neurologic deficits.

### CONCLUSION

Even though transverse myelitis is a rare neurologic manifestation of dengue infection, manifesting mostly during parainfectious phases and sometimes after the infection has resolved, it is important that clinicians are aware of this entity. It is vital that clinicians look for dengue virus as a cause of transverse myelitis or other inflammatory neurologic manifestations in patients presenting with typical dengue fever symptoms and living in or visiting dengue-endemic areas.

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**Disclosure Statement**

The author(s) have no conflicts of interest to disclose.
An Unusual Presentation of Dengue Fever: Association with Longitudinal Extensive Transverse Myelitis

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Kathleen Louden, ELS, of Louden Health Communications provided editorial assistance.

References
Caring Science: Transforming the Ethic of Caring-Healing Practice, Environment, and Culture within an Integrated Care Delivery System

Anne Foss Durant, RN, MSN, NP, NEA-BC; Shawna McDermott, MBA; Gwendolyn Kinney, RN, MSN; Trudy Triner

ABSTRACT

In early 2010, leaders within Kaiser Permanente (KP) Northern California’s Patient Care Services division embarked on a journey to embrace and embed core tenets of Caring Science into the practice, environment, and culture of the organization. Caring Science is based on the philosophy of Human Caring, a theory articulated by Jean Watson, PhD, RN, AHN-BC, FAAN, as a foundational covenant to guide nursing as a discipline and a profession. Since 2010, Caring Science has enabled KP Northern California to demonstrate its commitment to being an authentic person- and family-centric organization that promotes and advocates for total health. This commitment empowers KP caregivers to balance the art and science of clinical judgment by considering the needs of the whole person, honoring the unique perception of health and healing that each member or patient holds, and engaging with them to make decisions that nurture their well-being. The intent of this article is two-fold: 1) to provide context and background on how a professional practice framework was used to transform the ethic of caring-healing practice, environment, and culture across multiple hospitals within an integrated delivery system; and 2) to provide evidence on how integration of Caring Science across administrative, operational, and clinical areas appears to contribute to meaningful patient quality and health outcomes.

INTRODUCTION

In early 2010, leaders within Kaiser Permanente (KP) Northern California (KPNC) Patient Care Services division agreed to adopt Caring Science as a common shared framework to guide professional nursing practice across the Region (21 Medical Centers). Caring Science is based on the philosophy of Human Caring, a theory first articulated by Jean Watson, PhD, RN, AHC-BC, FAAN, in 1979, as a foundational covenant to guide nursing as a discipline and a profession. The theory seeks to deepen understanding of the universal, ethical, and person-centered roots of caring and healing for self, system, and others. In her more recent writings, Dr. Watson reinforces the core concepts of Caring Science through the definition of “10 Caritas Processes” that explore themes of loving-kindness, compassion, authentic presence, transpersonal relationships, unity of being, healing environments, and caring-healing modalities.

Over the past few decades, Caring Science has become widely known and integrated into nursing education curricula and has been adopted as a model of professional nursing practice by organizations around the world. With this context, Caring Science was one of several theories evaluated by KPNC leaders as the decision was made to adopt a common shared framework to guide professional nursing practice within the Northern California Region. Caring Science was selected, in part, for its strategic and philosophical alignment with the overarching mission of the organization to provide affordable, high-quality health care services and to improve the health of our members and the communities we serve. In addition, it was believed that Caring Science was relevant and applicable to caregivers across disciplines and professions, and thus facilitative of KPNC’s commitment to promote and to advocate for total health. Thus, efforts to embrace and embed core tenets of Caring Science have intentionally evolved beyond nursing, taking root among social workers, physical therapists, spiritual care professionals, patient quality and safety professionals, physicians, environmental service workers, and ombudsmen.

Although Caring Science defines a broad and universal construct for caring consciousness and action, the education, outreach, and resources developed at the regional level of the organization have sought to consistently reinforce three core guiding principles for KP caregivers:

- Cocreate Caring-Healing-Nurturing Environments—This includes attentiveness to the design and sensory impact of physical spaces, and the use of caring-healing-energy modalities, such as healing art programs, aromatherapy, healing touch/massage, guided imagery, pet therapy, and music, as well as the interpersonal dynamics that nurture authentic connection between a patient and his/her caregiver team.

- Foster Helping-Trust-Relating-Integrated Relationships—This includes attentiveness to practices that convey loving-kindness, compassion, and empathy, and that generate

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collaborative inquiry and insight across four distinct relationships: 1) the relationship we hold with our self, the relationship we hold with our caregiver teams, the relationship we hold with our patients and their families, and the global relationship we hold with the communities we serve.

- Honor Health, Healing, and Wholeness—This includes attentiveness to the psychosocial, emotional, and spiritual needs that influence and affect the clinical/medical/physical diagnosis, with the intent to integrate subjective and objective data and to co-create solutions and plans of care that nurture total health and well-being. 1-3,22,23

These principles were promoted and supported at a philosophical level and intentionally not linked to any specific tactic or initiative. This approach reflected the belief that Caring Science has the potential to serve as a foundational ethic at both an individual and a collective level and was consistent with a broader organizational commitment to create a "culture of accountability" 24 and to foster "appreciative inquiry." 25 In addition, prior and ongoing experience with the Institute for Healthcare Improvement’s frameworks for Transforming Care at the Bedside 26-28 and efforts to establish systems and processes for identifying and implementing rapid cycle innovation 29 validated the perspective that transformational change is best achieved when opportunities for experiential learning and direct engagement of frontline managers and staff are facilitated. 30-31 Accordingly, regional efforts to spur Caring Science integration (CSI) focused on building an infrastructure for education, awareness, and spread that encouraged an organic, creative process for local teams to adopt, adapt, and frame Caring Science within their daily practice and at their Medical Centers. In this article, we outline some of these practices, provide an overview of our regional Caring Science strategy, and begin to provide evidence on how integration of Caring Science across administrative, operational, and clinical areas within a Medical Center appears to contribute to meaningful patient quality and health outcomes.

METHODS
Our Journey
In this section, our goal is to provide an overview of the specific activities that defined our Caring Science strategy over time, because we believe that the degree of adoption, spread, and integration we have observed is related to the intentionality, scope, and sequence of what was developed and orchestrated at a regional level. Accordingly, once the decision to adopt Caring Science as the framework to guide professional nursing practice was made in the spring of 2010, a small regional team dedicated to CSI was formed with the initial objective to organize a series of educational forums to provide senior hospital operations leaders, chief nursing officers, nursing managers and educators, and frontline nursing staff from across the KPNC Region the opportunity to learn about the philosophy and theory of human caring directly from Dr Watson. These forums were structured to allow time for interactive dialogue and idea generation on how nursing practice within KPNC could be informed and inspired by Caring Science. Participant feedback was extremely positive and indicated a sense that adopting Caring Science would revitalize the identity of our nurses and rekindle their passion as caregivers. The nature of this sentiment is beautifully articulated by operating room staff nurse Carole Weller, RN: “I always believed in caring science; I just didn’t know how to define it by name. But I always believed in it in principle. The way in which Caring Science has changed my practice here now is that I’ve been able to recall everything I’ve always hoped to do and wanted to do, and now I have support for it. I actually have a framework, and I have a support from leadership to practice this.”

In 2011, the focus of the regional CSI team was 2-fold: 1) to create a leadership infrastructure for the transformational change desired in professional practice, and 2) to facilitate spread of concrete activities and projects undertaken locally that demonstrated core concepts of the theory. Toward the first aim, the CSI team developed 4 teaching-learning modules for frontline nursing managers and educators on how to “Lead with Care.” The modules identified core concepts of Caring Science as context and perspective for concrete leadership and interpersonal practices that sought to foster helping-trusting-collaborative relationships. Each module was dedicated to 1 of 4 key relationships: self, caregiver team, patients and family, or communities we serve. Reflective, mindfulness-based practices were interwoven into the modules, and participants were given time to individually and collectively practice how to engage in and to encourage caring-healing conversations, actions, and interactions. To facilitate rapid spread and to deepen Caring Science leadership advocacy across the Region, the modules were taught using a “train the trainer” model, resulting in the responsibility for the delivery of these

“Caritas in Action” Awareness Campaign Installment: SCIENCE
As Kaiser Permanente caregivers, we are committed to keeping our patients:
Safe: we take precautions and we are reliable in our adherence to safety standards, including those that protect ourselves
Comfortable: we create caring-healing environments and proactively manage our patient’s comfort
Informed: we engage in respectful dialogue and take the time to check for understanding
Engaged: we involve our patients in the course of their care
Nurtured: we demonstrate the capacity for understanding and kindness
Connected: we connect to our patients as individuals and serve as their voice when they are unable to speak for themselves
Empowered: we encourage our patients to make decisions throughout their care journey that strengthen their mind, body, and spirit

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modules to be owned by local leaders within each of the 21 Medical Centers. Driven by the second aim, the CSI team organized a Caritas Consortium in May 2011 (titled Nurturing Hearts, Transforming Care) to bring together caregivers from across the Northern California Region to recognize and to explore the transformative practices that demonstrate KP’s commitment to being an authentic person- and family-centric organization that promotes and advocates for total health. Subsequent consortia were organized in June 2012 (Caring Connections, Catalyst for Change), July 2013 (Holding Space for Human Flourishing), June 2014 (Honoring Health, Healing and Wholeness), and July 2015 (Journey to Shared Wisdom: Co-Creating Understanding). Over the course of 3 to 4 days, each consortium provided the opportunity for approximately 1200 caregivers— including acute care, home health and hospice nurses, inpatient physicians, physical therapists, respiratory care practitioners, patient care coordinators, quality coordinators, social workers, ombudspersons, and professionals from within spiritual care and community benefit—to hear directly from respected internal and external leaders on themes and research aligned with Caring Science and to learn about specific projects and activities undertaken by frontline staff and managers that held the greatest potential for spread and innovation across the Region (see examples outlined in the “Evidence of Transformation” section).

In late 2012, the regional CSI team launched a Caritas in Action campaign

### Evidence of Practice

**Caring Science as a lens to reframe and revitalize the HAPU Prevention Program**—To integrate three constructs of Caring Science principles into the design of the HAPU (hospital-acquired pressure ulcers) Prevention Program: 1) teaching and learning, 2) holistic care, and 3) creating a healing environment.

**Integration of Caring Science into new hospital construction**—To apply Caring Science principles of caring-healing, compassion, and love into the overall “Total Health Environment” branding concept guiding the new San Leandro Hospital design and construction.

**Caring-centric implementation of sleep and pain initiatives**—To translate elements of the Quiet at Night (sleep) and Pain Management initiatives from a Caring Science perspective, increasing attentiveness on how to cocreate a caring-healing-nurturing environment and to foster helping-trusting-collaborative relationships.

**Donate Life Flag Program: spiritual and emotional support for donor families**—To transform the routine actions associated with organ donation into a meaningful honoring and healing ritual guided by the principles of Caring Science.

**Leaving a legacy to their children from young parents with life-limiting illness**—To reflect Caring Science constructs into a research study designed to assist young parents with an oncology diagnosis to meet the end of their lives with dignity. To assess 1) whether creating a “Living Legacy” video has a relationship to improving parents’ quality of life as measured by the Chan and Pang2 instrument on quality at end of life, 2) whether creating the video influences the parent’s willingness to accept hospice/comfort care, and 3) whether the parent will accept dying at home.

**Holding sacred space: Schwartz Center Rounds**—To explore the Schwartz Center Rounds practice developed by the Schwartz Center for Compassionate Healthcare from a Caring Science perspective. Within this context, the practice seeks to create a safe and sacred space for caregivers across all disciplines to share the psychological, emotional, and spiritual dimensions of particularly challenging cases, encouraging grief, gratitude, and grace to rise to the surface.

**A bouquet of wisdom: staff perspectives on Caring Science**—To assess whether use of video that relies upon the power of storytelling and observed behaviors of staff to capture caring-healing at the bedside is perceived as an effective teaching and learning method of Caring Science theory. Specifically, the videos explored three constructs of Caring Science: 1) intentionality, 2) the transpersonal-caring relationship, and 3) human dignity.


to bring the theoretical concepts of Caring Science into language that would appeal to frontline managers and staff with the intent to transform their approach to caring-healing at the bedside and as a foundational ethic. There have been 7 campaign “installments” released to date through wide internal e-mail distribution and through posting on an internal Caring Science Web site (http://kpnursing.org/_NCAL/practice/caritas/action/index.html). Local leaders are encouraged to share the content during regularly scheduled forums, including staff “huddles,” department meetings, and governance councils. Accordingly, each installment has a set of resource tools designed to encourage dynamic dialogue around the concepts and themes being explored. A core component is inclusion of both a facilitator guide and a participant handout to promote a 10- to 20-minute reflective exercise. In addition, most installments include short video segments featuring frontline KP caregivers and leaders sharing the meaning that Caring Science has had for them in their personal and professional lives.

Installments to Date:

- **CARING**—focus on how, as KP caregivers, we are committed to being Caring, Authentic, Responsible, Intentional, Nurturing, and Growth-oriented
- **SCIENCE**—focus on how, as KP caregivers, we are committed to keeping our patients Safe, Comfortable, Informed, Engaged, Nurtured, Connected, and Empowered (see Sidebar: “Caritas in Action” Awareness Campaign Installment: SCIENCE)
- **Nursing process**—focus on how Caring Science informs and inspires the nursing process for our KP nursing professionals
- **Caring Science integration**—focus on how Caring Science serves as a “lens” by which we, as KP caregivers, exhibit the values, behaviors, and beliefs that enable the organization to be known as a quality leader, deliver an exceptional care experience, ensure care without delay, and foster a highly skilled and motivated workforce, which are four tenets upheld by hospital leadership
- **Team collaboration**—focus on open communication, clinical competence, and shared intentionality as key elements of fostering helping-trusting-collaborative relationships within and across interprofessional teams
- **Human flourishing**—focus on the concept of “holding space for human flourishing” and how acting with heart-centered intentionality cultivates resilience, creativity, and regenerative practices
- **Health, healing and wholeness**—focus on the concept of “honoring health, healing, and wholeness” and the power and possibilities of awakening to healing, seeing the whole person, and fostering a culture of care.

**RESULTS**

**Evidence of Transformation**

There are two primary means by which we have evaluated the spread and impact of Caring Science on KPNC practice, environment, and culture.

1. **Annual Caritas Consortium**

Five annual Caritas Consortium have been held to date (2011 to 2015). Although the prevalence of projects in the first two years were focused on Self, such as the creation of caring-healing staff lounges or Caring Science educational content, we have seen increasingly more depth and breadth in projects and intentionality year after year. Each of the exemplars below were presented at one of the consortia and were selected for their deep level of creativity and collaboration across teams (several of these main stage presentations included or represented team members from professions other than nursing), alignment and integration with hospital quality and care experience efforts, and active engagement of patients and their family members as well as the broader communities in which we serve. All of these have since resulted in some level of adoption or adaptation across disciplines and Medical Centers, demonstrating tangible evidence of spread and integration (see Sidebar: Evidence in Practice).

The value, meaning, and influence of the consortia are perhaps best captured by feedback shared by participants as well as one of our keynote speakers:

“One of the things I will take away from this experience is how important it is to connect, listen, and care. With gratitude comes joy and joy impacts positively. I am encouraged and honored to be a part of the change.”

—Consortium participant

“I have participated in all four of [KPNC’s] Caritas conferences as a keynote speaker and performer. I have been deeply moved by the depth of commitment [KP] has made to the work of Jean Watson’s brilliant Caring Science theory, as well as by the authentic way the various teams and facilities have integrated the principles and practices in their work routines and protocols. The Caritas Consortium event has become a centerpiece for this widespread work and is, in my opinion, the most effective, inspirational, and practical health care conference I have attended.”

—Bruce Cryer, CEO, Lissa Rankin Inc, senior advisor, HeartMath Inc.

2. **Evidence-in-Practice Assessment Tool**

In 2013, an on-site survey assessment tool was developed by the regional CSI team to evaluate the integration of Caring Science at each Medical Center. Specifically, 13 evidence-in-practice indicators were defined to capture the range of actions and authentic practices believed to be informed by Caring Science. The indicators were grouped into 4 categories, 2 designed to assess the level of awareness and adoption, and 2 designed to assess the scope of integration and transformation (Table 1).

- **Awareness and adoption:** Education, awareness, and spread (three indicators) and staff practices and behaviors (three indicators)
- **Integration and transformation:** Caritas Council leadership (four indicators) and administrative implementation (three indicators).

Each on-site assessment was conducted by a member of the regional CSI team in coordination and collaboration with local leadership, with the evaluation based on observation of practice and environmental cues, review of documentation, and elicitation of stories and...
exemplars from staff and management. A regional leader, not involved in any of the site visits and who had deep knowledge of Caring Science, was assigned sole responsibility to review the resulting narrative and supporting materials for each Medical Center with the intent to mitigate variation and issues of interrater reliability. For each indicator, the expert reviewer established a numeric score within the range of 1 (low) to 5 (high):

- 1 = No knowledge or no evidence of the indicator
- 5 = Indicator consistently performed, completed, and/or evidenced in all units

Assessments were completed for all 21 Medical Centers in 2013, providing a quantifiable means to explore the link between Caring Science, patient satisfaction, and patient quality outcomes. Accordingly, 3 patient satisfaction and 4 patient safety outcome metrics were selected for a comparative analysis to the overall average Caring Science assessment score. Four Medical Centers were excluded from the comparative analysis because their Caring Science assessment was conducted at a service area level (East Bay: Oakland and Richmond; Central Valley: Manteca and Modesto) and thus, it was not possible to establish a direct link between

| Table 1. Caring Science evidence-in-practice assessment tool: 13 indicators, by dimension and category |
|-------------------------------------------------|---------------------------------|---------------------------------|---------------------------------|
| Dimension and transformation | Category                           | Measure                                    | Action/authentic practice                                    | Evidence in practice                                    |
| Integration and transformation | Caritas Council leadership  | 1A Councils                  | Monthly or bimonthly  Caritas Councils held                  |                                               |
|                                  |                                  | 2A Charter                      | Charter, vision, mission statement developed                  |                                               |
|                                  |                                  | 3A Disciplines other than nursing | Caritas Council projects shared with other disciplines (respiratory therapy, rehabilitation, social work, chaplaincy, etc.) |                                               |
|                                  |                                  | 4A Hospital design and programs | Caritas Council projects manifested in hospital design or programs |                                               |
| Adoption and awareness         | Education, awareness, and spread | 5B Staff education and resources  | Caring Science awareness/education/resources provided for staff |                                               |
|                                  |                                  | 6B Unit-level education           | “Caritas in Action” education used for in-servicing on the unit level |                                               |
|                                  |                                  | 7B Caritas practice sharing      | Poster/presentation at June 2012 or July 2013 Caritas Consortium |                                               |
| Staff practices and behaviors   |                                  | 8C Incorporation in staff meetings | Centering, caring story; team sharing used for huddles/meetings |                                               |
|                                  |                                  |                                  |                                                                  |                                               |
|                                  |                                  | 9C Centering practices evident   | Staff articulated a technique for awareness/focus            |                                               |
|                                  |                                  | 10C Caring behaviors evident     | Staff articulated caring behaviors used to connect with their patients on a daily basis |                                               |
| Integration and transformation  | Administrative implementation    | 11D Documentation/daily processes/quality | Caring Science incorporated into daily processes, informational resources, documentation, and/or patient quality outcomes |                                               |
|                                  |                                  | 12D Interview questions          | Caring Science question used for job interviews               |                                               |
|                                  |                                  | 13D Policy/procedures            | All nursing policies updated with Caring Science principles or with a Caring Science policy statement |                                               |

| Table 2. Caring Science assessment tool score compared with key patient satisfaction and patient safety outcome data |
|-------------------------------------------------|---------------------------------|---------------------------------|---------------------------------|
|                                                 |                                 | Average score                 | Rate hospitalb | Nurse communicationc | Caritas nursingd | HAPU 3++ | Falls with injurye | C-diff | ICU BSIi   |
| High—both dimensions                            | 2                               | 4.08                          | 78.4          | 79.0              | 75.1             | 0.00    | 0.0            | 3.1    | 3         |
| High—composite                                  | 3                               | 3.93                          | 74.7          | 77.4              | 74.7             | 0.00    | 0.0            | 3.8    | 2         |
| Mid—composite                                   | 10                              | 3.24                          | 73.3          | 75.2              | 71.5             | 0.06    | 0.3            | 5.0    | 1         |
| Low—composite                                   | 3                               | 2.49                          | 69.6          | 73.7              | 70.1             | 0.07    | 0.3            | 5.3    | 2         |

a Tier assignment is based on the average numerical score across indicators for each Medical Center; High ≥ 3.75 and Low is ≤ 2.75; accordingly, Mid is 2.76-3.74.
b HCAHPS: (Hospital Consumer Assessment of Healthcare Providers and Systems survey): the first national, standardized, publicly reported survey of patients’ perspectives of hospital care.
c Avatar: a Centers for Medicare and Medicaid Services-approved provider of the HCAHPS survey; Avatar offers clients a powerful research tool that incorporates fully customized service- or specialty-related items.
d Rate hospital: a global HCAHPS survey question regarding the overall rating of the hospital by the patient.
e Nurse communication: a composite of three HCAHPS survey questions: During this hospital stay, how often did nurses 1) treat you with courtesy and respect; 2) listen carefully to you; and 3) explain things in a way you could understand?
f Caritas nursing: a composite of two Avatar survey questions: 1) My nurses consistently provided care to me with loving-kindness; and 2) My nurses accepted and supported my cultural traditions and spiritual beliefs.
g HAPU 3+: the incidence of hospital-acquired pressure ulcers (HAPU) that were documented as stage 3 or above.
h Falls with injury: the incidence of patient falls that resulted in an injury.
i C-diff: the incidence of Clostridium difficile bacteria infection acquired during hospital stay; one of several health care-associated infections considered to be a leading threat to patient safety by the Agency for Healthcare Research and Quality.
j ICU BSI: the incidence of central line-associated bloodstream infection (BSI) acquired during hospital stay within the intensive care unit (ICU); one of several health care-associated infections considered to be a leading threat to patient safety by the Agency for Healthcare Research and Quality.
their assessment scores and the patient satisfaction and patient safety metrics that are documented at the independent hospital level.

To delineate the degree to which Caring Science was embedded in practice, environment, and culture within each Medical Center, a tier designation was established and assigned by the regional CSI team on the basis of the overall average Caring Science assessment score. An average score at or above 3.75 was considered indicative of a high level of integration and an average score at or below 2.75 was considered indicative of a low level of integration, with the mid-tier reflecting scores in between.

Comparative analysis of overall average Caring Science assessment scores appears to correlate and give context to scores on key patient satisfaction and patient safety outcome data (Table 2). The average scores for hospitals in the high tier had more positive outcomes on the seven patient-centric metrics we reviewed than those in the mid tier and low tier. This distinction was even more definitive when we looked at the average of the two hospitals that scored in the high tier on both the adoption and awareness dimension and the integration and transformation dimension of the Caring Science indicator evidence-in-practice tool. This leads us to an emerging hypothesis that as the leaders, frontline managers, and staff within our Medical Centers move from a shared understanding of Caring Science theory to a shared foundational ethic of caring-healing that informs practice, environment, and culture across administrative, operational, and clinical areas, they are more likely to demonstrate high quality and highly reliable performance on key patient-centric metrics.

**DISCUSSION**

**Limitations**

We recognize that there are several limitations to the use of this tool and its associated scores and findings. First, the assessment tool and site visits were conducted only once for each hospital in the Region (in 2013), and thus we did not have either a pre-Caring Science baseline score or a year-over-year score to gauge change or progression of Caring Science evidence in practice over time. Although information to validate multiple indicators of the tool was collected by request, portions of the assessment reflect the limited snapshot of activity that was observed on the specific day of the on-site visit. In addition, the wave of assessments occurred during several months, thus hospitals that were visited later in the year inadvertently had more time to develop and deepen Caring Science practices relative to those that were visited earlier in the year. Finally, because the number of professionals qualified and resources available to conduct the assessments was limited, the tool did not undergo a rigorous process for data validity and interrater reliability, although attentiveness to consistency was built into the design. Despite these limitations, the results of this first-wave assessment were compelling and our hypothesis that Caring Science is a meaningful component in delivering high-quality outcomes and patient-centric care will, we hope, guide further evaluative analysis and assessment at KPNC.

**Inquiry, Insight, and Innovation**

It is notable to acknowledge that all 21 Medical Centers had several distinct service, quality, and patient safety initiatives in place before and during the CSI efforts outlined, and that these also played a meaningful role in fostering a culture of caring-healing within the organization. The interconnectedness between Caring Science and these patient-facing areas is believed to be a significant factor in the transformation we have seen. Leaders across these areas engaged in collaboration and inquiry to ensure alignment with the core guiding principles of Caring Science. For example, Caring Science was one of several motivating factors that led the organization to reframe the term service to care experience and has directly influenced the approach and language used in care experience initiatives. Perceived as a valuable tenet of KPNC’s person- and family-centered focus, Caring Science is trusted for bringing greater attentiveness to the covenant we hold as caregivers, encouraging us to honor and to hold the patient/family perspective, to promote total health and well-being from a whole-person identity, and to take time to nurture our souls as healers.

At its core essence, Caring Science captures the heart-centered intentionality of KP caregivers to promote human flourishing, acknowledging the power that is theirs for affecting change and transforming care. At the individual level, Caring Science expands the concept of accountability, inspiring behavior that is authentic, responsible, and intentional, and promoting reliance on psychosocial-emotional-spiritual wisdom as well as intellectual-tactical knowledge. At the system level, given our study design, integration of Caring Science across administrative, operational, and clinical areas within a Medical Center appears to demonstrate positive interconnectivity toward higher patient satisfaction scores and patient quality outcomes.

**CONCLUSION**

Implementing Caring Science as a consistent framework for process and culture change across a large integrated care delivery system has provided a platform for meaningful dialogue at all levels within the organization. Caring Science provides a language that resonates with caregivers, re-engaging them in the purpose and value of their work. It serves as the lens by which they can see the interconnectedness between their values, behaviors, and beliefs and the strategic priorities, programs, policies, and initiatives that guide practice within KPNC. This awareness and alignment inspire more cohesive orchestration at the individual, team, and system levels. These observations and early evidence can guide future research on how Caring Science or other professional practice models can serve as a foundation to transform the ethic of caring-healing practice, environment, and culture in alignment with the industrywide
Caring Science: Transforming the Ethic of Caring-Healing Practice, Environment, and Culture within an Integrated Care Delivery System

momentum for broadening a commitment to total health that focuses on healing, well-being, and wholeness. 31 32

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References
Acute posterior wall myocardial infarction (PMI) occurs in up to 20% of cases of acute myocardial infarction (MI), with the vast majority occurring along with inferior or lateral acute MI. A true PMI is considered more rare, with an incidence of approximately 3.3%. The term PMI is used for necrosis of the part of the left ventricle located beneath the atrioventricular sulcus. The majority of patients with the typical electrocardiogram (ECG) abnormalities of PMI have a stenosis or occlusion of the left circumflex coronary artery. The ECG diagnosis of PMI is difficult because no specific leads of the standard ECG directly represent this area. In addition, the lack of ST-segment elevation (as seen in typical ST-elevation MI) combined with misinterpreting the anterior ST-segment depressions as indicating ischemia rather than posterior infarction frequently lead to missing the diagnosis of PMI.

In PMI, there is loss of electrical forces in a dorsal direction, so the typical infarction pattern only appears in the electrodes placed dorsally between the spine and left scapula on the ECG. On the standard ECG of a true PMI, the leads V6 and V7 are a mirror image of the V1 and V2 leads of the anterior MI, resulting in ST-segment depression in leads V6 and V7 in PMI (Figure 1) rather than ST-segment elevation seen in acute anterior MI.

The QRS complex on the vector cardiogram points ventrally during PMI because of losses of normally dorsally aimed electrical forces, resulting in a prolonged R wave. An increase in the R/S ratio > 1.0 can occur in leads V1 and V2 as a case of PMI evolves. The increase of the R wave during PMI is the opposite to the Q wave associated with traditional ST-segment elevated MI. The ST segment points in the direction of the infarcted area, and ST-segment depression occurs in the precordial leads in the acute phase. The T wave points away from the infarcted area. As a result, a forward movement of the T wave can frequently be seen in patients with PMI. The combination of right precordial horizontal ST-segment depression with tall, upright T waves indicates an early ECG sign of acute ischemia of the posterior wall during a progressive PMI.

The addition of posterior leads V7 to V9 significantly increases the ability to detect posterior injury patterns compared with the standard 12-lead ECG. Lead V7 should be placed at the level of lead V6 at the posterior axillary line, lead V8 on the left side of the back at the tip of the scapula, and lead V9 halfway...
between lead V₈ and the left paraspinal muscles. When using posterior leads to diagnose PMI, ST-segment elevation in leads V₇ through V₉ is defined as elevation of at least 0.5 mm in 2 or more of the leads (Figure 2), on the basis of the increased distance between the posterior chest wall and the heart.⁷ Posterior ECG leads greatly improve sensitivity and specificity when identifying patients with isolated PMI.⁷

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References
Isolated Pancreatic Histoplasmosis: An Unusual Suspect of Pancreatic Head Mass in an Immunocompetent Host

Avin Aggarwal, MD; Shashank Garg, MD

ABSTRACT
Histoplasmosis is endemic to the Mississippi and Ohio River valley regions in the US. It usually affects patients with underlying immunodeficiency but can also be seen in immunocompetent hosts. Although gastrointestinal involvement is common in the setting of disseminated histoplasmosis, isolated gastrointestinal involvement is uncommon. We report a case of isolated pancreatic histoplasmosis in an immunocompetent patient, presenting as painless jaundice and pancreatic head mass.

INTRODUCTION
Histoplasma infection is endemic to the Mississippi and Ohio River valley regions in the US. Although it can involve the gastrointestinal system primarily or as part of disseminated disease, most of such cases are asymptomatic and found on autopsy. Only 3% to 12% of these cases manifest clinically, mostly involving the small intestine or colon. We present a case of isolated pancreatic histoplasmosis presenting as painless jaundice and pancreatic head mass.

CASE REPORT
A 37-year-old woman was referred to the gastroenterology clinic for incidentally noticed conjunctival icterus of unknown duration and abnormal liver function tests by her primary care physician. She did not report any constitutional or systemic symptoms. Her medical history was significant for Roux-en-Y gastric bypass for obesity and cholecystectomy 4 years earlier. She had been born and brought up in Minnesota and previously worked at a fast food restaurant. She also had a 14-pack-year history of smoking. Family history was unremarkable for malignancy, and social history was unremarkable for recent travel, sick contacts, or any domesticated pets.

At the time of presentation, her vital signs and physical examination were unremarkable except for scleral icterus. Laboratory evaluation revealed elevated liver enzymes (alkaline phosphatase [1137 U/L], alanine aminotransferase [422 U/L], aspartate aminotransferase [223 U/L]), total bilirubin (5.3 mg/dL), and direct bilirubin (4.3 mg/dL). Complete blood count, electrolytes, renal function, serum albumin, lipase, international normalized ratio, and cancer antigen 19-9 were within normal limits. Abdominal ultrasound showed a 5 cm × 4 cm mass in the head of the pancreas with intra- and extrahepatic biliary dilatation. A follow-up computed tomography

Figure 1. Abdominal computed tomography scan axial view with intravenous contrast: pancreatic head mass with amorphous internal calcifications (long arrow) abutting the portal vein (short arrow) and intrahepatic biliary dilatation (double arrow).

Figure 2. Abdominal computed tomography scan coronal view with intravenous contrast: Pancreatic head mass (long arrow) with portal vein compression (short arrow) and intrahepatic biliary dilatation (black arrow).

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Isolated Pancreatic Histoplasmosis: An Unusual Suspect of Pancreatic Head Mass in an Immunocompetent Host

(CT) scan of the abdomen and pelvis with intravenous contrast confirmed a 5 cm × 4.2 cm × 3.7 cm pancreatic head mass with coarse internal calcifications, portal vein compression, and possible local invasion posteriorly into the inferior vena cava and left renal vein (Figure 1). No abdominal lymphadenopathy was noted on CT scan. Magnetic resonance imaging of the abdomen with and without intravenous contrast was performed to assess the vascular invasion seen on the CT scan. It showed a large (4.3 cm × 4.2 cm × 4 cm) mass in the head of the pancreas with numerous foci of amorphous calcification (Figure 2). The mass had numerous large cystic components measuring up to 2.3 cm in size, separated by thick enhancing septae (Figure 3). Common bile duct occlusion and portal vein narrowing from extrinsic compression by the mass were also noted. However, no vascular invasion was seen. Radiologic features were highly suggestive for a mucinous neoplasm, particularly mucinous cystadenocarcinoma. Endoscopic ultrasound was not feasible because of the Roux-en-Y anatomy. Given the high likelihood of malignancy and absence of any metastasis, the pancreateobiliary surgeon decided to proceed with surgical resection.

Intraoperative pathologic examination of frozen section revealed benign necrotizing granulomatous tissue of pancreatic origin, and a Whipple pancreatectomy was performed. Pathologic examination of the resected specimen revealed caseating granulomas and chronic follicular pancreatitis with no dysplastic or neoplastic changes (Figure 4). Fungal yeast forms were seen in the pancreatic and portal lymph node tissue with Gomori methenamine silver stain (Figure 5). However, fungal culture from the resected specimen did not grow any organism. Fungal antibody screen postoperatively was positive for anti-\textit{Histoplasma} immunoglobulin G antibody (titer 1:16, normal < 1:8). A diagnosis of pancreatic histoplasmosis was made on the basis of pathologic and serologic findings.

Postoperatively, the only recognizable risk factor for histoplasmosis was a history of growing up at a chicken farm. However, there was no history of frequent infections during childhood or presence of immunodeficiency disorders in the family. The patient tested negative for common immunocompromised states including human immunodeficiency virus, tuberculosis, syphilis, hepatitis B, and hepatitis C. She was subsequently started on itraconazole suspension but could not tolerate it. Itraconazole was replaced with voriconazole 200 mg twice a day, but she had an adverse event with this dose of voriconazole (vision change: white color appearing yellow). The adverse effect resolved after the voriconazole dose was reduced to 100 mg twice a day. Her voriconazole level 1 week after initiating the treatment was within normal limits. She was prescribed a 3-month course of voriconazole.
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DISCUSSION

To our knowledge, this is the first reported case of symptomatic histoplasmosis localized to the head of the pancreas in an immunocompetent host. Gastrointestinal histoplasmosis has been reported in the literature in immunocompetent hosts. Cappell et al. and Lamps et al. reported 77 and 52 cases of gastrointestinal histoplasmosis, respectively. The disease affected immunocompetent patients in 48% to 75% of cases. The most common sites involved were the small intestine (56% to 79%) and colon (55% to 62%). Pancreatic involvement was reported by Lamps et al. in 3 patients (6%). However, it is not entirely clear whether the pancreatic involvement was associated with disseminated histoplasmosis or immune suppression. Similarly, Suh et al. reported asymptomatic pancreatic enlargement on imaging in 2 cases with acquired immune deficiency syndrome. However, isolated symptomatic pancreatic involvement has not been described before in either immunocompetent or immunocompromised hosts.

There are several unique features in this case. The patient did not have any predisposing factors for histoplasmosis except the history of potential exposure in childhood. Her postoperative evaluation was negative for common immunodeficiency disorders or extrapancreatic disease. It may be prudent to rule out underlying immunodeficiency states and disease dissemination in patients diagnosed with isolated gastrointestinal histoplasmosis.

Pancreatic involvement by *Histoplasma* on gastrointestinal imaging bore a remarkable resemblance to pancreatic malignancy. Lee et al. described a case of disseminated histoplasmosis presenting as a fungating mass in the transverse colon resembling a colon cancer for which the patient underwent a colectomy. Tuberculosis is another granulomatous disease that can mimic malignancy in the head of the pancreas including vascular invasion. Endoscopic ultrasound was technically not feasible in our case owing to prior Roux-en-Y gastric bypass. A CT-guided biopsy could have helped in differentiating malignancy from *Histoplasma* infection. However, the patient did not have any symptoms, signs, or apparent risk factors for *Histoplasma* or tuberculosis to warrant such testing. *Histoplasma* has been reported to form caseating or noncaseating granulomas, cystic lesions, and tissue microcalcifications in the gastrointestinal tract. All of these pathologic changes were seen in the pancreatic tissue on imaging or pathologic examination of resected specimen.

The diagnosis in this case was based on recognition of the yeast form of *Histoplasma* in the pancreatic tissue with Gomori methenamine silver stain and subsequent confirmation with positive antibody titer. The urine and serum antigen and the tissue fungal cultures were negative, indicating low fungal burden. This pattern of negative antigen testing and tissue cultures along with a positive serology is more likely to be seen in an immunocompetent state where the immune system will result in a low fungal burden. Immuno compromised hosts, on the other hand, are more likely to have higher fungal burden with positive antigen tests and culture results and a negative serology.

Itraconazole is considered the treatment of choice in noncritically ill patients with histoplasmosis. However, gastric acid is required for adequate absorption of itraconazole pills and hence could not be used in this case owing to prior Roux-en-Y gastric bypass. Itraconazole suspension can be used in this situation, but the patient could not tolerate it. Voriconazole was chosen as an alternate, and the patient tolerated it well after the initial dose adjustment with therapeutic drug levels.

CONCLUSION

Histoplasmosis can present with isolated symptomatic pancreatic involvement in immunocompetent hosts. Tissue sampling should be considered to make a definite diagnosis of malignancy of the head of the pancreas in areas endemic for histoplasmosis or other granulomatous disease, before undertaking surgical resection.

Disclosure Statement

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