California Lilac: Title page layout, watercolor
Latifat Apatira, MD

From Dr Apatira: ‘Nature painting’ is a centuries-old printmaking technique used to create detailed, illustrated images of natural objects such as plants for study and art. Image transfer occurs by directly applying ink to a freshly picked plant, sandwiching the plant between 2 sheets of paper, and rolling the surface of the plant by hand, capturing a precise and clear impression of the plant.

Dr Apatira is a plant enthusiast, mixed-media artist, nature photographer, and Occupational Medicine Physician at the Kaiser Permanente San Francisco Medical Center in CA. More of Dr Apatira’s work can be seen at www.tllayola.com.

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The observational study involved sequential implementation of a multidisciplinary team, protocols, and a transparency pathway. Retrospective review and data management of 380 consecutive coronary revascularization cases from 2009-2017 revealed reduced coronary complication rates, a reduction of medical in-hospital mortality, increased need for repeat hospitalization, and a decreased incidence of percutaneous coronary intervention. A structured and timely discharge summary is an important tool for continuous monitoring of quality and efficacy of care. The authors present outcome data, including coronary indications, operative timing, complications, functional outcomes, delays in discharge, and discharge destinations using the coronary discharge summary.

11 PROVENTIVE FACTORS FOR EARLY RELAPSE IN MULTIPLE MYELOMA AFTER AUTOLOGOUS HEMATOPOLYTIC STEM CELL TRANSPLANTANT

Andrew Mayer Pourmoussa, MD; Paul T Akins, MD, PhD; Amit Banerjee, MD; Luis Pacheco, MD; Mario Cerdan, MD; Richard Khoshbin, OMS; Leonardo Farol, MD; Thai Cao, MD; Firoozeh Sahebi, MD

A total of 141 patients were included in this retrospective analysis. Factors found to be associated with inferior progression-free survival were distance less than 10 miles from the time of hematopoietic stem cell transplant (HCTC), no use of maintenance therapy after HCTC, International Staging System stage III, and high-Febrile Comorbidity Index. Disease status less than complete response, stage III, higher Febrile Comorbidity Index, use of maintenance therapy, and male sex were the most predictive factors for early relapse (< 18 months). These results highlight the need for consideration of alternative therapy in this instance.

18 LIFESTYLE INTERVENTIONS AND CAROTID PLAQUE BURDEN: A COMPARATIVE ANALYSIS OF TWO LIFESTYLE INTERVENTION PROGRAMS IN PATIENTS WITH CORONARY ARTERY DISEASE

Rachid Elkahkhi, MD, MPH, Omar M Nakhil, MD, Columbus D Batista, MD, Adina Mierse, MD; Maria Robinson, MD, Darlene Newton, EPHR, Raoul Baruch, MS, MS; Cynthia Cooksey, RVT; Heidi Patterson, MPH, Mohamed Imam, MD, MPH

In a randomized, single-center, single-blinded study in 120 patients with established coronary artery disease (CAD), neither the Complete Health Improvement Program (CHIP) nor Keys to Health, noncomparative combination of various healthy-living classes was effective in inducing plaque regression in patients with established CAD after a 6-month period. However, both programs in improving several CAD risk factors, which shows that the noncomparative offering of the CHIP lifestyle programs can lead to similar outcomes as a formal, sequential, establishment program (CHIP) in many aspects.

23 SPONTANEOUS CORONARY ARTERY DISSECTION: CLINICAL CHARACTERISTICS, MANAGEMENT, AND OUTCOMES IN A RACIALLY AND ETHNICALLY DIVERSE COMMUNITY-BASED COHORT

Stephanie Chen, MD; Michaela Norton, MD, MPH; Kenneth N Mayer, MD; Robert J Landstrom, MD, Sahar Nakar, Anna D OnReh, MD, MPH

A retrospective cohort study of patients (mean age 46, 69% women, 49.5% nonwhite) with spontaneous coronary artery dissection (SCAD) at Kaiser Permanente Northern California during a 10-year period compared 311 SCAD cases with 333 healthy, matched control participants. Pregnancy and hyperlipidemia were associated with SCAD compared with controls. Fifty-five patients (17%) were successfully treated without revascularization; of the 54 who had urgent percutaneous coronary intervention: 2 required coronary artery bypass grafting for SCAD extension. For the SCAD cases, major adverse cardiovascular events occurred in 81%, and race did not influence outcomes.

28 Fixing a Fragmented System: Impact of a Comprehensive Geriatric Hip Fracture Program on Long-Term Mortality
Mary Anderson Wallace, MD, Andrew Harmon, MD, MSc; Ethan Cumbler, MD; Kelly McDevitt, RN, MS, ONC; Nichole E Carlson, PhD; Stephanie Chen, MD; Raoul Burchett, MA, MS; Sajita Amin, MD

The Effectiveness of Geriatric Hip Fracture Program Implementations (CHIP) in reducing mortality (10/2014). The postintervention cohort (28/2016) compared to the preintervention cohort (135 before and 108 after a comprehensive geriatric hip fracture program implementation (10/2014). The postintervention cohort trended toward a lower unadjusted 1-year mortality rate (15.7% vs 24.4%). The difference in survival was not statistically significant (log-rank test, P = .19). However, both were effective in improving mortality rate (15.7% vs 24.4%).

29 Improving Care for Patients with Coronary Artery Disease: Trends in Characteristics and Outcomes of Patients Treated at Kaiser Permanente Northern California 2000-2009

Charles R Elder, MD, MPH; FACCP; Leslea D Elder, MD

The 9/11 terrorist attacks significantly increased overall mortality rate (15.7% vs 24.4%). The difference in survival was not statistically significant (log-rank test, P = .19). However, both were effective in improving mortality rate (15.7% vs 24.4%).
34 Diffusion of Excellence: Accelerating the Spread of Clinical Innovation and Best Practices across the Nation’s Largest Health System. Ryan Vega, MD, MSHA; George L Jackson, PhD, MHA; Blake Henderson; Carolyn Clancy, MD; Jennifer McPhail, MS; Sarah L Cuttore, MD, MPH; Laura J Damschroder, MS, MPH; Saurabh Bhatnagar, MD

Using a 5-step systematic approach refined over time, 1676 practices have been submitted by frontline Veterans Health Administration (VHA) staff since the Diffusion of Excellence Initiative’s inception; 47 of these have been selected as high-impact, Gold Status practices. These Gold Status practices have been replicated 412 times in VHA hospitals across the country, reaching an estimated 100,000 Veterans and creating approximately $22.6 million in cost avoidance for VHA. More importantly, practices such as Project HAPPEN (Hospital-Acquired Pneumonia Prevention by Engaging Nurses to complete oral care) have saved Veteran lives.

42 Association of Type and Frequency of Post-surgery Care with Revision Surgery after Total Joint Replacement. Heather A Prentice, PhD; Pitcilla F Chan, MD; Robert S Namba, MD; Maria CS Inacio, PhD; Art Sedrakyan, MD; Elizabeth W Paxton, MA, PhD; Blake Henderson; Carolyn Clancy, DO, MPH; James Wong, MD; Benjamin Ha, MD

Postmarket surveillance is limited in the ability to detect medical device problems. Using an integrated health care system’s total joint arthroplasty (TJA) registry, the authors identified primary TJA (22,953 knees and 9004 hips) from 4/2001-6/2013. Knee arthroplasty recipients with 3 or more outpatient orthopedic allied health/nurse visits within 90 days had a 2.2 times higher risk of revision within 2 years postoperatively and 10.1 times higher risk after 2 years. Patients with 6 or more outpatient orthopedic office visits had a 15.7 times higher risk of revision.

50 Clinical Use Cases for a Tool to Assess Risk in Superficial Bladder Cancer. Carmit K McMullen, PhD; Maureen O’Keeffe, MD; Elizabeth W Paxton, MA, PhD; Jennifer McPhail, MS; Sarah L Cuttore, MD, MPH; Laura J Damschroder, MS, MPH; Saurabh Bhatnagar, MD

Feasibility of a Telemedicine-Administered, Pharmacist-Staffed, Protocol-Driven, Multicenter Program for Kidney Stone Prevention in a Large Integrated Health Care System: Results of a Pilot Program. Mark E Gasparini, MD; Toby W Chang, PharmD; Mark St Lezin, MD; John E Skerry, MD; Andy Chan, PharmD; Krishna A Ramaswamy, MD

Among 500 patients (referred from 3 Northern California Kaiser Permanente facilities) enrolled for 3 months, 99% self-reported compliance with at least 3 of 5 aspects of dietary advice. A significant improvement in all urinary parameters occurred in 52 patients with calcium stones who repeated 24-hour urine testing. A telemedicine-administered, pharmacist-staffed, protocol-driven program can provide dietary advice and obtain compliance with metabolic testing for patients at high risk of recurrent kidney stones. This report represents the first telemedicine-administered, pharmacist-staffed, kidney stone prevention program published in the literature.

55 The Mindful Doctor. Michael Chun, MD

The author used to wake up on Monday mornings with the typical blues, thinking of what had happened the few days before and his plans for the weekend. Now, he wakes up looking forward to the day and that moment, knowing that the current moment is the most important one and the only one that he can control. Mindfulness can make every patient encounter, every day, and every moment as good as it can be, and could bring back the joy in medicine and life to physicians and their patients.

73 Treating Vitamin D Deficiency and Insufficiency in Chronic Neck and Back Pain and Muscle Spasm: A Case Series. Chunbo Cai, MD, MPH

It is estimated that more than 70% of health care dollars are spent addressing the result of unhealthy lifestyles, which are increasing the rates of obesity, diabetes, and cardiovascular disease. There is also a severe and worsening epidemic of physician burnout in the US, which threatens the health of physicians and patients alike. The author shares why a whole-foods, plant-based diet is a powerful prescription for optimal health and the answer to health care, and physician wellness.

CLINICAL PRACTICES

70 The Mindful Doctor. Michael Chun, MD

Some patients with cardiac stents will need thoracic surgery during the dual antiplatelet therapy (DAPT) period. When surgery cannot be safely delayed to allow 1 year of uninterrupted DAPT, appropriate perioperative management of anticoagulation is critical. This ticagrelor-eptifibatide perioperative bridge resulted in decreased preoperative hospitalization compared with eptifibatide alone. There were no associated perioperative cardiac or bleeding complications.

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76 Novel Antiplatelet Perioperative Bridging Protocol for Lung Lobectomy: A Case Report. Sora Ely, MD; Dana A Dominguez, MD; Jeffrey B Velotta, MD

Poststreptococcal Reactive Arthritis: Diagnostic Challenges. Colleen Chun, MD; Daniel J Kingsbury, MD

Vitamin D deficiency and insufficiency can cause or worsen neck and back pain and muscle spasm. Correction of vitamin D deficiency and insufficiency plays an important role in the treatment of chronic neck and back pain and muscle spasm among patients having concurrent vitamin D deficiency and insufficiency because it can be prevented and treated easily, and can increase the quality of care but also reduce the cost.
92 Maintaining our Humanity in the Digital Age of Medicine. Jeffrey Siegel, MD

This critique on the changes in health care delivery is from a physician’s viewpoint. He believes that modifying these changes, with humanistic values in mind, will benefit both patients and clinicians going forward.

94 Time to Revamp Nutrition Education for Physicians. Vandia Rahman, MD

Ample scientific evidence supports that nutritional interventions involving plant-based diets can be effective in the prevention and treatment of obesity, diabetes, and cardiovascular disease. The author launched programs to educate our physicians and patients about the benefits of plant-based diets, with an overwhelmingly positive response. Because physicians are at the forefront of fighting the obesity epidemic, it is imperative to emphasize nutrition education for current and future physicians.

97 Assessing Impact of Biomedical Scholarship in the Information Age: Observations on the Evolution of Biomedical Publishing and a Proposal for a New Metric. Robert Hogan, MD

This essay contains a discussion on the state of the art of biomedical publication and the history and development of indexing, its evolution, and complexity. A traditional method of journal assessment is in use—the journal impact factor—but it is compromised by well-documented deficiencies. Present-day alternatives to the journal impact factor are listed, and a proposal to develop a novel metric of merit in publication, the influence factor, is described.

98 Strength and Vulnerability. Shankar Mundluru, MD

My uncle made a full recovery, and since his shattering health crisis, his vulnerability in that moment made him see the beauty in life, despite life’s delicate propensity for tragedy. Subsequently, he got a law degree in his 70s, traveled around the world, and wrote a biography of my grandfather.

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A 10-Year Analysis of 3693 Craniotomies During a Transition to Multidisciplinary Teams, Protocols, and Pathways

Paul T Akins, MD, PhD; Amit Banerjee, MD; Kern Guppy, MD, PhD; James Silverthorn, DO; John Fitzgibbon, MD; Yogesh Nandan, MD; Elaine O Yu; Luis Pacheco; Jack Rozance, MD; Rob Azevedo, MD; James Chang, MD; Mark W Hawk, MD

ABSTRACT

Introduction: A Cochrane review of teams, protocols, and pathways demonstrated improved care efficiency and outcomes over a traditional model. Little is known about this approach for craniotomy.

Methods: This observational study involved sequential implementation of a multidisciplinary team, protocols, and a craniotomy pathway. Data on 3693 admissions were retrospectively reviewed at a tertiary care neurosurgery center from 2008 to 2017 for the top 6 diagnosis-related group codes. In June 2016, a searchable discharge summary template in the electronic medical record was implemented to capture data regarding quality, efficiency, and outcomes.

Results: Staffing transitioned to a team of neurosurgeons, neurointensivists, neurohospitalists, and midlevel practitioners. Order sets, protocols, and pathways were developed. Quality improvements were observed for craniotomy and cranioplasty surgical site infections, ventriculitis, coagulopathy reversal, and decompressive hemicraniectomy rates for stroke. Case volume increased 73%, yet craniotomy hospital days decreased from 2768 in 2008 to 2599 in 2017 because of reduced length of stay. We accommodated service line growth without hospital expansion or case backlogs. With an average California hospital day rate of $3341, the improved length of stay decreased costs by $14,666,990/y. We also present outcomes data, including craniotomy indications, operative timing, complications, functional outcomes, delays in discharge, and discharge destinations using the craniotomy discharge summary.

Conclusion: Multidisciplinary teams, protocols, and pathways reduced craniotomy complication rates, improved hospital length of stay by 63%, reduced costs, and increased professional collegiality and satisfaction. A searchable craniotomy discharge summary is an important tool for continuous monitoring of quality and efficiency of care.

INTRODUCTION

Under the traditional model for hospital care, an attending physician directly oversees all aspects of care and consults with specialists when needed. However, for certain diagnoses or procedures, care delivery using multidisciplinary teams, protocols, and care pathways may improve outcomes and care efficiency. For this team approach to work, clinicians must first agree on a uniform approach to a specific clinical problem or procedure using evidence-based guidelines and consensus. In the fee-for-service model, individual physicians and physician groups may directly compete for patients and surgical case volume. This competition can be a barrier to developing protocols and pathways. Conflicts and disputes may also arise when care is coordinated between teams of surgeons and nonsurgical physicians. Physicians may resist developing procedures and protocols because of loss of physician autonomy and valid concerns about individual patient variations and personalized medical care. Because transitioning from a traditional care model to a team-oriented model may require considerable effort and time, most reports investigating care pathways have strategically focused on high-volume costly diagnoses such as cardiac disease and joint replacement surgeries.

A 2010 Cochrane review evaluated the effects of clinical pathways on clinical documentation, quality of care such as mortality or patient complications, acute-care length of stay (LOS), and cost of care. The study included 27 reports and 11,398 participants. The authors concluded that pathways were associated with reduced complications, improved clinical documentation, and decreased hospital costs and LOS. We were unable to find publications cited in the Cochrane review regarding craniotomy care, but the review did find favorable results for acute stroke care and complex surgeries such as coronary artery bypass grafting. A few small studies have investigated the feasibility of avoiding intensive care unit (ICU) admissions for craniotomies and same-day surgery for craniotomy.

We present a descriptive study of our transition from 2008 to 2017 to the care of patients undergoing craniotomy using a multidisciplinary team model, protocols, and pathways at Kaiser Permanente (KP) Sacramento Medical Center, a tertiary care neurosurgery center in Sacramento, CA. An important advantage of the KP model of integrated health care is the shared alliance between physicians and hospital services.

METHODS

The study was approved under an institutional review board protocol. This observational study involved sequential implementation of a multidisciplinary team, standardized protocols, and a craniotomy care pathway using retrospective review of data.

We reviewed qualitative and quantitative results aimed to address the 5 key criteria identified in the Cochrane review for clinical pathways. These criteria were 1) a multidisciplinary care team; 2) development of a pathway through use of guidelines and...
A 10-Year Analysis of 3693 Craniotomies During a Transition to Multidisciplinary Teams, Protocols, and Pathways

**RESULTS**

Inpatient Neurosurgery Service Redesign

The inpatient neurosurgery program at KP Sacramento Medical Center underwent a marked transformation between 2008 and 2017. Before implementation of an integrated inpatient neurosurgery service, the care of patients was shared between neurosurgeons for operative cases and hospitalists for nonoperative admissions such as small traumatic contusions or subdural hematomas. This model had evolved because of on-call demands on the neurosurgeons, operating room (OR) physical restraints on neurosurgeons, and a long-standing and robust hospitalist program. This shared model of care led to staff conflict because the hospitalists had variable levels of expertise and clinical confidence managing nonoperative neurosurgical admissions. The ICU used an open staffing model. Pulmonary medicine faculty comanaged neurosurgical patients receiving mechanical ventilation but signed off after successful extubations. Neurosurgeons managed their ICU patients who were not intubated, often with the assistance of hospitalists. The first neurocritical care specialist was recruited in 2007.

Summit meetings involving leadership and key stakeholders from neurosurgery, neurocritical care, and hospitalists created strong support for an integrated inpatient neurosurgery service that would include all operative and nonoperative patients directly admitted or transferred to the medical center for tertiary care neuroscience expertise. A series of loosely structured, off-site dinner meetings was held to air past complaints, to broker disputes, to mend collegial relationships, and to debate solutions.

The process built consensus for a redesign of the inpatient neurosurgery service centered around a 3-legged staffing model by neurosurgeons, neurointensivists, and “neurohospitalists.” A wary subgroup of hospitalists volunteered to rotate on a weekly basis on the inpatient neurosurgery service, and we called these pioneers neurohospitalists. To provide more consistent care and to improve communication, the group agreed to use standardized order sets, discharge instructions, posthospital discharge follow-up, and treatment-specific protocols. A closed neurocritical care unit was created, and all patients requiring ICU-level care were also seen daily and comanaged by neurointensivists. Protocols and care pathways

---

**Table 1. Example of data collection using diagnosis-related group (DRG) craniotomy codes (2017, N = 475)**

<table>
<thead>
<tr>
<th>DRG code</th>
<th>Definition</th>
<th>No.</th>
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<tbody>
<tr>
<td>23</td>
<td>Craniotomy with major device implant or acute complex central nervous system principal diagnosis with MCC</td>
<td>65</td>
</tr>
<tr>
<td>24</td>
<td>Craniotomy with major device implant or acute complex central nervous system principal diagnosis without MCC</td>
<td>36</td>
</tr>
<tr>
<td>25</td>
<td>Craniotomy and endovascular intracranial procedures with MCC</td>
<td>191</td>
</tr>
<tr>
<td>26</td>
<td>Craniotomy and endovascular intracranial procedures with CC</td>
<td>50</td>
</tr>
<tr>
<td>27</td>
<td>Craniotomy and endovascular intracranial procedures without CC/MCC</td>
<td>91</td>
</tr>
<tr>
<td>614</td>
<td>Adrenal and pituitary procedures with CC/MCC</td>
<td>42</td>
</tr>
</tbody>
</table>

CC = complications and comorbidities; MCC = major complications and comorbidities.
were created using neurosurgery department subcommittees. Draft protocols and pathways were presented and critiqued during off-hours journal club dinner meetings and circulated via an intradepartmental email for comments. The finalized protocols and pathways were reviewed and adopted at departmental meetings (see Sidebar: Standardized Protocols List).

In January 2008, the inpatient neurosurgery service was implemented. All patients on the service were reviewed at daily interdisciplinary morning rounds (as described in the next section). Within months, we observed fewer conflicts between neurosurgeons and hospitalists. The new model also improved collegial relationships with physicians at outlying medical centers who requested urgent referrals and patient transfers. The neurocritical care unit worked with referring practitioners to coordinate the transfer and to address care needs before transfer, such as blood pressure management, airway protection, anticonvulsants, corticosteroids, and reversal of coagulopathy.

Since 2010, the daily inpatient neurosurgery service census increased from an average of 15 to an average of 45. This increased service volume is reflected in the 73% rise in the number of craniotomy admissions (Figure 1). As additional staffing was needed because of growth of the inpatient service, we recruited midlevel practitioners to coordinate care for patients on the medical and surgical units and to assist with operations. This 4-legged staffing model (neurosurgeons, neurointensivists, neurohospitalists, and midlevel practitioners) was implemented in 2011 and remains a successful strategy to manage our growing case volume and case complexity.

### Multidisciplinary Morning Report

A vital component of the day-to-day operation is a formal morning rounds to review all patients admitted to the inpatient neurosurgery service. The morning rounds are attended by neurosurgeons, neurointensivists, neurohospitalists, physiatrists, midlevel practitioners, and patient care coordinators. Nursing leadership from the neurocritical care unit, neurostepdown unit, and medical-surgical units also participates. Additional time is devoted to new admissions and to patients with complex care concerns or acute problems, and a treatment strategy is developed with input from the multidisciplinary team. A major advantage of morning rounds is that hospital throughput and staffing needs can be calculated up or down on the basis of anticipated daily admissions, transfers, and discharges. The rounds also provide practical educational value and promote team unity.

### Neurosurgery and Neurocritical Care Protocols and Order Sets

During this transition in the inpatient neurosurgery service, HealthConnect, an Epic-based EMR, was implemented. We leveraged the EMR to standardize and improve care delivery. Protocols were created using published guidelines and group consensus (see Sidebar: Standardized Protocols List). Neurosurgery and neurocritical care order sets were developed around these protocols.

Rapid reversal of coagulopathy protocols and order sets underwent several revisions during this period using a multidisciplinary team of neurosurgeons, neurointensivists, and hematologists. The inpatient neurosurgery service stopped using fresh frozen plasma and adopted more effective agents such as recombinant factor 7 and prothrombin complex concentrates. This order set underwent revision to include reversal strategies for patients receiving direct oral anticoagulants. A standardized approach was used to improve recognition and management of platelet dysfunction related to medications and trauma, particularly in unstable patients with active intracranial bleeding or requiring urgent intracranial procedures. Using platelet function assays, we observed a 38% rate (22/58 patients) of platelet dysfunction in patients with subdural hematoma, despite having adequate platelet counts.

### Reductions in Craniotomy, Cranioplasty, and External Ventricular Drain-Related Infections

In 2008, ventriculitis rates trended above the national average (Figure 2). The EVD insertion, wound care, cerebrospinal fluid sampling procedures, weaning protocols, and periprocedural antibiotic use were standardized, with a gratifying resolution of this problem. The craniotomy SSI rate was 2.3%, which is similar to the American College of Surgeons National Surgical Quality Improvement Program database rate of 2.04%.
<table>
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<td>___ Education to patient and family craniotomy about possible DC home date</td>
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<td>___ Education to patient and family craniotomy about possible DC home date</td>
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<td>___ Neuro-oncology follow up for primary brain tumors</td>
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</table>

Figure 3. Example of the craniotomy pathway form implemented in 2013. AED = antiepileptic drug; BM = bowel movement; BP = blood pressure; c/a/p = chest/abdomen/pelvis; CBC = complete blood cell count; Chem 7 = chemistry panel 7; CT = computed tomography; DC = discharge; DMV = Department of Motor Vehicles; DNR = do not resuscitate order; Dx = diagnostic; exam = examination findings; Foley = Foley catheter; H&P = history and physical examination; INR = international normalized ratio; IV = intravenous; IVF = intravenous fluids; MD = physician; MRI = magnetic resonance imaging; NPO = nothing by mouth; OOB = out of bed; OR = operating room; PACU to ICU = transfer from the postanesthesia care unit to the intensive care unit; pre-op = preoperative; PO = per os; POD = postoperative day; post op = postoperative; PRBC = packed red blood cells; Pt = patient; Rehab PT/OT = rehabilitation; physical therapy and/or occupational therapy; Q8hrs = every 8 hours; RN = registered nurse; SC = subcutaneous; SCD = sequential compression devices; SNF = skilled nursing facility; STEALTH = surgical navigation system (StealthStation, Medtronic); T/C = type and crossmatch.
A 10-Year Analysis of 3693 Craniotomies During a Transition to Multidisciplinary Teams, Protocols, and Pathways

We observed the following complication rates without (n = 21) bundle and published the results of our improved outcomes. We developed a perioperative cranioplasty bundle and published the results of our improved outcomes. We observed the following complication rates without (n = 21) bundle and published the results of our improved outcomes.

### Table 2. Craniotomy indication data collected using standardized craniotomy discharge summaries (N = 596)

<table>
<thead>
<tr>
<th>Craniotomy indication</th>
<th>Percentage*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary brain tumor, intraaxial</td>
<td>22</td>
</tr>
<tr>
<td>Primary brain tumor, extraaxial</td>
<td>14</td>
</tr>
<tr>
<td>Endonasal approach for mass</td>
<td>14</td>
</tr>
<tr>
<td>Subdural hematoma, subacute or chronic</td>
<td>11</td>
</tr>
<tr>
<td>Deep brain stimulator</td>
<td>10</td>
</tr>
<tr>
<td>Neurovascular disease (aneurysm, vascular malformation)</td>
<td>8</td>
</tr>
<tr>
<td>Acute subdural hematoma</td>
<td>5</td>
</tr>
<tr>
<td>Ventricular shunt</td>
<td>5</td>
</tr>
<tr>
<td>Metastatic brain tumor</td>
<td>4</td>
</tr>
<tr>
<td>Postoperative craniotomy infection</td>
<td>2</td>
</tr>
<tr>
<td>Primary intracerebral hemorrhage</td>
<td>2</td>
</tr>
<tr>
<td>Combined HNS/NS tumor resection</td>
<td>1</td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
</tr>
</tbody>
</table>

* Sum of complications is less than 100% because of rounding. HNS = head and neck surgeon; NS = neurosurgeon.

### Table 3. Postoperative complications during hospital stay for consecutive craniotomy discharge summaries (N = 649)

<table>
<thead>
<tr>
<th>Postoperative complication</th>
<th>Percentage*</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>92</td>
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<tr>
<td>New cranial nerve deficit</td>
<td>2.5</td>
</tr>
<tr>
<td>Seizure</td>
<td>1.5</td>
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<tr>
<td>Diabetes insipidus</td>
<td>1.5</td>
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<tr>
<td>Encephalopathy prolonging stay</td>
<td>1.4</td>
</tr>
<tr>
<td>New motor deficit</td>
<td>1.2</td>
</tr>
<tr>
<td>Unplanned return to OR</td>
<td>1.2</td>
</tr>
<tr>
<td>New neurocognitive deficit</td>
<td>0.8</td>
</tr>
<tr>
<td>CSF leak</td>
<td>0.8</td>
</tr>
<tr>
<td>Lower extremity DVT</td>
<td>0.6</td>
</tr>
<tr>
<td>Symptomatic postoperative hematoma</td>
<td>0.3</td>
</tr>
<tr>
<td>Pulmonary embolus</td>
<td>0.3</td>
</tr>
<tr>
<td>CAUTI</td>
<td>0.3</td>
</tr>
<tr>
<td>Ventilator-associated pneumonia</td>
<td>0.2</td>
</tr>
</tbody>
</table>

* Sum of complications is above 100% because patients may have had more than 1 complication. CAUTI = catheter-acquired urinary tract infection; CSF = cerebrospinal fluid; DVT = deep venous thrombosis; OR = operating room.

### Craniotomy Pathway Development and Implementation

In May 2013, the craniotomy pathway was implemented (Figure 3). The development and implementation was coordinated with nursing leadership in the neurocritical care unit, neurostep-down unit, and the medical–surgical nursing units. Further reductions in hospital LOS were observed after the implementation of the pathway, and these reductions have been sustained over 4 years (Figure 4). Unplanned 30-day hospital readmission rates in 2017 were 8.2% (39/475) due to SSI (1.7%), nonsurgical infections (1.7%), delayed intracranial bleeding largely due to recurrent subdural hematomas (1.5%), thromboembolic events (1%), seizures (0.6%), and other causes (1.7%).

### Data Collection Using Craniotomy Discharge Summary Template

Using DRG–based data collection, we were confident that hospital LOS for patients who underwent craniotomy was improving (Figure 4). The searchable data elements in the EMR did not capture detailed information about hospital complications, outcomes, and reasons for delays in hospital discharge. A manual review of craniotomy electronic charts is time-consuming and not a sustainable solution.

In June 2016, the department developed and implemented an EMR-based, searchable standardized craniotomy discharge summary (see Supplemental Material, available at: www.thepermanentejournal.org/files/2019/18-209-App.pdf). This template captures important details about craniotomy indications (Table 2), timing of craniotomy (20% emergent, 18.6% urgent, 61.4% elective, n = 681), complications (Table 3), functional outcomes (Figure 5), causes for delayed hospital discharges (Table 4), and postdischarge destinations (Table 5). Current use of the craniotomy discharge summary template over the last 6 months of 2017 averaged 84%. There is ongoing work using related EMR templates to capture important clinical information during preoperative craniotomy planning and outpatient postoperative care. We are currently reviewing information regarding delays in hospital discharge to identify opportunities to further improve care.

### Cost-Savings Analysis

Using 2017 craniotomy volume data (Table 1), we calculated a reduction of 4390 hospital days compared with 2008 LOS data. In 2017, the 475 patients who underwent craniotomy required 2599 hospital days, but they would have required 6989 hospital days using 2008 LOS data. On the basis of an average hospital-adjusted...
expenses per inpatient day rate of $3341, the reduction in hospital days indicates a decrease in hospital expenses of $14,666,990/y.12
The improvements related to EVD-related ventriculitis, MRSA-related craniotomy SSIs, cranioplasty-related SSI, and reductions in hemicraniectomy after hemispheric stroke all led to a reduction in hospital costs. For example, treatment of deep SSIs after craniotomy usually requires repeated hospitalization, return to the OR for wound washout and removal of bone flap and hardware, and typically 6 weeks of extended intravenous antibiotics. Additional costs arise from an additional surgical procedure (cranioplasty) to manufacture and replace the explanted bone flap (cranioplasty) with a custom prosthesis.

**DISCUSSION**

We observed major improvements in quality and care efficiency during a stepwise transition of craniotomy care to multidisciplinary teams, protocols, and care pathways. To our knowledge, this is the first published report regarding the effect of this treatment model on craniotomy hospital care. During this period, the inpatient neurosurgery service at KP Sacramento Medical Center experienced substantial growth in case volume and complexity for patients who underwent craniotomy. The improved care quality and efficiency are key reasons the medical center was able to accommodate the increased craniotomy volume without expanding ICU or medical-surgical unit beds or creating a craniotomy case backlog. For example, 275 patients who underwent craniotomy required 2768 hospital days in 2008, compared with 475 patients who underwent craniotomy requiring 2599 hospital days in 2017. Once hospital bed capacity is outstripped, costs further escalate related to hospital construction costs or outsourcing of patient care.

The 4-legged staffing model recognizes and leverages the different skill sets that each clinician brings to the inpatient service. Previously, the on-call neurosurgeon was juggling patient referrals, OR, rounding, and discharging. The current practice model delegates many aspects of this care to the neurointensivists, neurohospitalists, and midlevel practitioners under structured protocols. Because of the craniotomy pathway and morning rounds, patient transfers and discharges are anticipated early in the workday. The neurosurgeon is off-loaded from this work and experiences fewer delays and interruptions while prioritizing on-call duties, new patient consultations, preoperative planning, OR duties, and availability for postoperative complications.

An important advantage of the craniotomy care pathway is the transparency of the care process throughout the inpatient stay. Patients and families experience greater staff cohesion regarding postcraniotomy care, including the hospital discharge process and outpatient postoperative care. The protocols and pathways have improved care consistency regarding postdischarge medications, instructions, wound care, activity level, and appointments. The recent work using the craniotomy discharge summary template has provided more accurate answers to questions by patients and families about postcraniotomy care, complications, and outcomes. For urgent and elective craniotomies, much of this information can be introduced to patients and families during the preoperative stage.

During the transition period from 2008 to 2017, the neurosurgery program expanded to include 2 additional hospitals providing Level II trauma and also elective neurosurgery procedures. The investment to develop the protocols and pathways at our center paid off tremendously when bringing these additional programs on board. These protocols and order sets were implemented with minimal changes at the new neurosurgery sites. To staff these additional centers, neurosurgeons were recruited and the group grew from 5 to 15. The new faculty were quite accepting of these protocols and order sets, because they had been developed and vetted by more senior neurosurgeons. Also, the nursing and pharmacy staff were quite familiar with them.

We are currently using the expanded data elements collected from the searchable craniotomy discharge summary template.
to continuously monitor quality and efficiency of care. We have also found it useful during conversations with patients and families. For example, we can discuss hospital outcomes related to the indications and the timing of craniotomy (Figure 5). For example, rates of death or serious disability (modified Rankin scores deceased to 4 and 5, respectively) at hospital discharge vary from 27% for emergent craniotomies, 12% for urgent craniotomies, and 8% for elective craniotomies. When patients deviate from the expected craniotomy pathway, the staff understand the importance of looking for causes and remedies, particularly medical and surgical complications (Tables 3 and 4). The improved granularity of data collection at hospital discharge has been helpful to measure the success of inpatient care and to focus on opportunities to improve care (Tables 3 and 4).

The level of evidence of this study is Level II-3, which is “evidence obtained from multiple time series designs with or without the intervention” based on definitions from the US Preventive Services Task Force. 13 Because of the multitude of changes that occurred during this transition period, we are unable to measure the impact of individual interventions. A strength of the study is its fulfillment of Cochrane review standards. The KP model of care closely integrates and aligns physicians and hospital-based care. Although there are always internal conflicts between specialists and hospital-based service lines, the KP group practice model and compensation strategies reduce conflicts over traditional turf wars for patient referrals and procedural volume. Because this is a single-center study, future studies are needed to determine whether these findings can be reproduced in other care settings. The long-term utility of the craniotomy discharge summary template will require further study. The hospital-based focus of this study does not include posthospital discharge data regarding functional outcomes and posthospital discharge-related complications. Formal measures of patient and physician satisfaction and quality of life indexes were not included in this report.

CONCLUSION

Our observational study suggests that the transition of craniotomy care from the traditional model to a model incorporating multidisciplinary teams, protocols, and pathways has reduced complication rates, improved hospital LOS, and increased professional collegiality and satisfaction. ❖

Disclosure Statement

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

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Kathleen Louden, ELS, of Louden Health Communications performed a primary copy edit.

How to Cite this Article


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12. Hospital adjusted expenses per inpatient day [Internet]. San Francisco, CA: Henry J Kaiser Foundation Family; 2016 [cited 2018 Jul 3]. Available from: www.kff.org/health-costs/state-indicator/expenses-per-inpatient-day/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.
Predictive Factors for Early Relapse in Multiple Myeloma after Autologous Hematopoietic Stem Cell Transplant

Andrew Mayer Pourmoussa, MD; Ricardo Spielberger, MD; Jillian Cai, MD; Odelia Khoshbin, OMS; Leonardo Farol, MD; Thai Cao, MD; Firoozeh Sahibi, MD

ABSTRACT

Introduction: Despite advances in therapy for multiple myeloma, patients have continued to experience relapse. We sought to better understand this.

Objective: To identify factors that predict early relapse in patients with multiple myeloma who receive autologous hematopoietic peripheral stem cell transplant (HSCT).

Methods: Retrospective analysis of Kaiser Permanente Southern California patients who received HSCTs between 2008 and 2012.

Results: A total of 141 patients were included. Factors found to be associated with inferior progression-free survival were disease status less than complete response at the time of HSCT, no use of maintenance therapy after HSCT, International Staging System stage III, and high Freiburg Comorbidity Index. Disease status less than complete response, stage III, higher Freiburg Comorbidity Index, no use of maintenance therapy, and male sex were the most predictive factors for early relapse (<18 months).

Discussion: Our results identified a subgroup of high-risk individuals with multiple myeloma who will continue to do poorly after HSCT with the best available treatment using a combination of proteasome inhibitors and immunomodulatory drugs. These results highlight the need for consideration of alternative therapy in such instances.

INTRODUCTION

Multiple myeloma is a neoplastic proliferation of plasma cells accounting for 10% of hematologic malignancies.1 Rapid advances in the understanding of genetics and biology of the disease have led to the introduction of new targeted therapeutic agents and clinically significant improvements in disease outcome.2,3 An induction regimen using a combination of immunomodulatory drugs, proteasome inhibitors, and dexamethasone followed by autologous hematopoietic stem cell transplant (HSCT) is considered standard treatment of newly diagnosed multiple myeloma in physically fit patients.4-6 The superiority of high-dose chemotherapy and autologous HSCT was initially shown in comparison to conventional chemotherapeutic agents.7,8 More recently, in the era of targeted therapies, several randomized clinical trials have confirmed improved progression-free survival (PFS)11-13 and overall survival (OS)11 in favor of a combination of new targeted therapies and early autologous HSCT. The beneficial role of maintenance treatment after autologous HSCT has also been examined in randomized clinical trials, supporting its use in this setting.14,15 Despite these advances, patients continue to experience relapse. Factors such as lack of response, stage, and high-risk cytogenetics have been linked to poor outcome.1,16-18 Scoring systems that consider additional factors such as age, comorbidities, and cognitive/physical conditions have been described in helping to predict survival.19,20

We examined PFS and OS in patients who received induction therapy using immunomodulatory drugs and/or proteasome inhibitor-based regimens followed by autologous stem cell transplant between 2008 and 2012. The objective of this study was to investigate prognostic factors that correlate with early relapse using the best available treatment in the modern era of new targeted agents, reflecting real-world practice. The electronic medical records were available for all patients, allowing for evaluation of all preexisting comorbidities and all health-related issues outside the transplant center—data that may not always be captured.

METHODS

The study was approved by the institutional review board of Kaiser Permanente Los Angeles Medical Center, Los Angeles, CA. Patients with multiple myeloma who were treated at Kaiser Permanente Southern California medical centers and received autologous HSCT between January 1, 2008, and January 1, 2012, were identified for chart review electronically through International Classification of Diseases, Ninth Revision (ICD-9) codes for multiple myeloma (203.0) and multiple myeloma post HSCT (41.0X). This chart review was carried out via an integrated electronic system (Epic, Epic Systems, Verona, WI), which allows access to patient medical records outside the transplant referral center. Protected health information was used in conducting our research in accordance with the Health Insurance Portability and Accountability Act (HIPAA).

All patients underwent induction therapy using combinations of immunomodulatory drugs, proteasome inhibitors, and dexamethasone followed by autologous HSCT. Data on age, sex, International Staging System (ISS) stage, type of induction therapy, bone marrow cytogenetics and/or fluorescence in situ hybridization (FISH) abnormalities, disease status at the time of HSCT, and use of maintenance therapy were collected (Tables 1 and 2).

High-risk cytogenetic abnormalities were defined by the presence of at least 1 of the following: del(17p), t(4;14), t(14;16), t(14;20), del(1p), and hypoploidy. The Freiberg Comorbidity Index (FCI) was evaluated as well. The FCI is a simple assessment that is used...
to determine risk relating to comorbidities in multiple myeloma. This index takes into account performance status, renal impairment, and lung disease. In this 0–3 point total scale, individual points are assigned for Karnofsky Performance Status less than or equal to 70% vs greater than 70%, a glomerular filtration rate less than 30 mL/min/1.73 m² vs greater than 30 mL/min/1.73 m², and the presence of moderate to severe lung disease vs absence of or mild disease.\textsuperscript{21} Compared with other comorbidity indexes, such as the Charlson Comorbidity Index, Hematopoietic Cell Transplantation-specific Comorbidity Index, Kaplan-Feinstein Index, and Satariano Index, the FCI has been reported to better stratify risk in patients with multiple myeloma.\textsuperscript{22}

### Statistical Analysis

We performed statistical analysis to study the following variables at the time of transplant: Age, sex, ISS classification, FCI, Karnofsky Performance Status, disease status, along with cytogenetics/FISH results, use of posttransplant maintenance therapy, best response after transplant, time to progression, time to last contact, and cause of death related to multiple myeloma. We also computed censoring variables for use in the Cox proportional hazards models in studying our main outcomes of interest: Time to progression in PFS, OS, and relapse in less than 18 months (early relapse). Each of these variables was included in a single-variable proportional hazards model of each outcome. A Kaplan-Meier survival analysis was also done with each corresponding proportional hazards regression for each single variable and the 3 outcomes. Confidence intervals (CIs) for the survival probabilities were calculated using the log transformation. Although the results were similar between these 2 analyses, the software-displayed output (SAS version 9.3, SAS Institute, Cary, NC) was different, which allowed checking different assumptions about the variables. These variables were collected together in main effects, multivariate Cox proportional hazards regression models, 1 for each of the outcomes. The multivariate models were run with hierarchical stepwise selection and also backward elimination with terms being retained at the 0.10 level. In addition, we ran a multivariate logistic regression of PFS less than 18 months vs at least 18 months using main effects with stepwise selection and backward elimination, retaining variables significant at the 0.10 level. Main effects were focused because of an inability to credibly examine interactions stemming from a relatively low sample size.

### RESULTS

A total of 141 patients were identified for our study. Patient characteristics are shown in Table 1. The median follow-up for the study group was 63.9 months (range = 6.2–103.3 months). Patients’ median age was 58 years (range = 30–70 years). Seventy-five patients were men and 66 were women. The median Karnofsky Performance Status was 90% (range = 60%–100%), and the median FCI was 0 (range = 0–2). The median time from diagnosis to HSCT was 7.4 months (range = 3.7–93.2 months). Forty-five patients (31.9%) had ISS stage I disease, 52 (36.9%) had ISS stage II, and 44 (31.2%) had ISS stage III. Twenty-four (17%) patients were in complete response at the time of the transplant, 24 (17.02%) had partial response, and 1 patient (0.7%) had no response. Ninety-three (66%) had standard-risk cytogenetics/FISH findings and 48 (34%) had high-risk findings. One hundred two patients (72.3%) received maintenance therapy after transplant. The practice for posttransplant maintenance therapy changed over the study period from primarily thalidomide (13 patients, 12.8%) to lenalidomide (74 patients, 72.6%). Fifteen patients received bortezomib alone or in combination with immunomodulatory drugs (14.7%) as maintenance therapy (Table 2).

### Table 1. Summary of variables for all patients in study (N = 141)

<table>
<thead>
<tr>
<th>Variable</th>
<th>No. (%) of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median age at diagnosis, y (range)</td>
<td>58 (30-70)</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>75 (53.19)</td>
</tr>
<tr>
<td>Women</td>
<td>66 (46.81)</td>
</tr>
<tr>
<td>International Staging System stage</td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>45 (31.91)</td>
</tr>
<tr>
<td>II</td>
<td>52 (36.88)</td>
</tr>
<tr>
<td>III</td>
<td>44 (31.21)</td>
</tr>
<tr>
<td>Disease status at time of transplant</td>
<td></td>
</tr>
<tr>
<td>Complete remission</td>
<td>24 (17.02)</td>
</tr>
<tr>
<td>Partial remission</td>
<td>116 (82.27)</td>
</tr>
<tr>
<td>Less than partial remission</td>
<td>1 (0.71)</td>
</tr>
<tr>
<td>Karnofsky Performance Status</td>
<td></td>
</tr>
<tr>
<td>60</td>
<td>1 (0.71)</td>
</tr>
<tr>
<td>70</td>
<td>5 (3.55)</td>
</tr>
<tr>
<td>80</td>
<td>29 (20.57)</td>
</tr>
<tr>
<td>90</td>
<td>80 (56.74)</td>
</tr>
<tr>
<td>100</td>
<td>26 (18.44)</td>
</tr>
<tr>
<td>Freiburg Comorbidity Index</td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>127 (90.07)</td>
</tr>
<tr>
<td>1</td>
<td>12 (8.51)</td>
</tr>
<tr>
<td>2</td>
<td>2 (1.42)</td>
</tr>
<tr>
<td>Cytogenetics/FISH results</td>
<td></td>
</tr>
<tr>
<td>Standard</td>
<td>93 (65.96)</td>
</tr>
<tr>
<td>High risk</td>
<td>48 (34.04)</td>
</tr>
<tr>
<td>Maintenance therapy after transplant</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>102 (72.34)</td>
</tr>
<tr>
<td>No</td>
<td>39 (27.66)</td>
</tr>
</tbody>
</table>

\* Data are number (percent) except for age at diagnosis. FISH = fluorescence in situ hybridization.

### Table 2. Frequency of maintenance therapy after HSCT (n = 102)

<table>
<thead>
<tr>
<th>Maintenance therapy</th>
<th>Number (%) of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lenalidomide</td>
<td>74 (72.55)</td>
</tr>
<tr>
<td>Bortezomib</td>
<td>15 (14.70)</td>
</tr>
<tr>
<td>Thalidomide</td>
<td>13 (12.75)</td>
</tr>
</tbody>
</table>

HSCT = hematopoietic stem cell transplant.
III, lower FCI, higher likelihood of receiving complete response, and receiving maintenance therapy in those with late relapse. Four-year PFS for the whole group was 41.8% (95% CI = 34.4% to 50.8%), and the OS was 81.5% (95% CI = 75.4% to 88.2%; Figures 1 and 2). The OS for the early relapse/progression group during the 4-year study period was 44.7% (95% CI = 31.4% to 63.7%; Figure 3). The median PFS for the whole group was 37 months (95% CI = 29–47 months), with a median PFS of 8.6 months (95% CI = 6.9 to 10.7 months) for those with early relapse/progression vs 62 months (95% CI = 47 months to absence of relapse) for those who did not experience relapse. The median PFS for patients receiving maintenance therapy was 47 months (95% CI = 34–67 months) vs 24 months (95% CI = 14–30 months) for those without maintenance therapy.

Table 3. Summary of variables for patients divided into early and late relapse groups

<table>
<thead>
<tr>
<th>Variable</th>
<th>Late relapse (≥18 mo PFS) (n = 103)</th>
<th>Early relapse (&lt;18 mo PFS) (n = 38)</th>
<th>p valueb</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median age at diagnosis, y (range)</td>
<td>57 (30–70)</td>
<td>60 (33–68)</td>
<td>0.4156</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>51 (49.5)</td>
<td>24 (63.2)</td>
<td>0.1512</td>
</tr>
<tr>
<td>Women</td>
<td>52 (50.5)</td>
<td>14 (36.8)</td>
<td></td>
</tr>
<tr>
<td>International Staging System stage</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>38 (36.89)</td>
<td>7 (18.42)</td>
<td>0.0145</td>
</tr>
<tr>
<td>II</td>
<td>38 (36.89)</td>
<td>14 (36.84)</td>
<td></td>
</tr>
<tr>
<td>III</td>
<td>27 (26.21)</td>
<td>17 (44.74)</td>
<td></td>
</tr>
<tr>
<td>Disease status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Complete remission</td>
<td>21 (20.39)</td>
<td>3 (7.89)</td>
<td>0.0451</td>
</tr>
<tr>
<td>Partial remission</td>
<td>82 (79.61)</td>
<td>34 (89.47)</td>
<td></td>
</tr>
<tr>
<td>Less than partial remission</td>
<td>0 (0)</td>
<td>1 (2.63)</td>
<td></td>
</tr>
<tr>
<td>Karnofsky Performance Status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>60</td>
<td>0 (0)</td>
<td>1 (2.63)</td>
<td>0.2592</td>
</tr>
<tr>
<td>70</td>
<td>3 (2.91)</td>
<td>2 (5.26)</td>
<td></td>
</tr>
<tr>
<td>80</td>
<td>21 (20.39)</td>
<td>8 (21.05)</td>
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<tr>
<td>90</td>
<td>58 (56.31)</td>
<td>22 (57.89)</td>
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<tr>
<td>100</td>
<td>21 (20.39)</td>
<td>5 (13.16)</td>
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</tr>
<tr>
<td>Freiburg Comorbidity Index</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>97 (94.17)</td>
<td>30 (78.95)</td>
<td>0.0078</td>
</tr>
<tr>
<td>1</td>
<td>5 (4.85)</td>
<td>7 (18.42)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>1 (0.97)</td>
<td>1 (2.63)</td>
<td></td>
</tr>
<tr>
<td>Cytogenetics/FISH results</td>
<td></td>
<td></td>
<td>0.874</td>
</tr>
<tr>
<td>Standard</td>
<td>94 (91.26)</td>
<td>35 (92.11)</td>
<td></td>
</tr>
<tr>
<td>High risk</td>
<td>9 (8.7)</td>
<td>3 (7.9)</td>
<td></td>
</tr>
<tr>
<td>Maintenance therapy after transplant</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>79 (76.7)</td>
<td>23 (60.5)</td>
<td>0.0577</td>
</tr>
<tr>
<td>No</td>
<td>24 (23.3)</td>
<td>15 (39.5)</td>
<td></td>
</tr>
</tbody>
</table>

*a Values are number (percent) of patients except for age at diagnosis. Some percentages do not total to 100% because of rounding.

*b The p values were calculated with the Kruskal-Wallis test.

**FISH = fluorescence in situ hybridization; PFS = progression-free survival.**
The median OS for the whole group was 109 months (95% CI = 94-151 months), with a median OS of 31.4 months for those with early relapse/progression (95% CI = 22.2-56 months) vs 115 months (95% CI = 109-151 months) for those who did not progress before 18 months.

In the Cox proportional hazards model, built using backward elimination for OS using continuous age at diagnosis, the factors associated with increased OS were younger age at diagnosis (p < 0.0001), complete response at the time of HSCT (p = 0.004), lower ISS (p = 0.005), and lower FCI (p = 0.024). Using age at diagnosis dichotomized younger than age 65 years at the time of HSCT, the factors associated with increased OS were maintenance therapy (p < 0.0001), complete response at the time of HSCT (p = 0.003), lower ISS stage (p = 0.010), lower FCI (p = 0.014), and younger age (p = 0.043).

In the final Cox proportional hazards model, built using backward elimination for OS using continuous age at diagnosis, the factors associated with increased OS were lower FCI (p = 0.019) and lower ISS stage (p = 0.066). With use of age at diagnosis dichotomized at less than 65 years vs 65 years or more, the factors associated with increased OS were lower FCI (p = 0.016), younger age (p = 0.093), and lower ISS stage (p = 0.099).

Factors associated with early relapse (< 18 months) were examined with logistic regression built using backward elimination. Using continuous age at diagnosis, the factors associated with early relapse/progression were lower FCI (p = 0.024), no use of maintenance therapy (p = 0.032), less than complete response at the time of HSCT (p = 0.063), and male sex (p = 0.064). The model was unchanged when we used age at diagnosis dichotomized at younger than age 65 years vs older than age 65 years.

**DISCUSSION**

Despite significant improvement in the outcomes of patients with multiple myeloma, relapse remains the main cause of treatment failure. Determination of patients destined for early progression is of particular importance in selecting those who are expected to have a poor outcome with best available treatment using a combination of proteasome inhibitors, immunomodulatory drugs, and autologous stem cell transplant.

Traditionally, patients receive a few cycles of induction therapy followed by stem cell transplant. The results of our study suggest that the achievement of complete response before transplant may help to prevent early relapse or progression of the disease. This is in accordance with prior observations where achievement of complete response or very good partial response before autologous stem cell transplant translated to better long-term outcomes. Therefore, efforts to achieve a deep cytoreduction and preferably complete response, which may be attainable with newer, more effective targeted agents and monoclonal antibodies, should be explored as a means to improve outcomes in future prospective trials. Indeed, achievement of a negative minimal residual state is the subject of ongoing studies.

Limitations of our study included broader categorization of pretransplant disease status as complete response vs less than complete response because of difficult extraction of very good partial response vs partial response status from medical records during the chart review process. We did not find any association between high-risk cytogenetics/FISH findings and early relapse. This may be related to the small number of patients with poor cytogenetics results. We did observe a statistically significant correlation between higher FCI and early relapse and progression. The FCI has shown a strong clinical relevance for OS and PFS in patients with multiple myeloma. To our knowledge, this is the first report that has shown a high FCI to predict early relapse/progression. This requires further examination to determine if the presence of other comorbidities promotes a permissive microenvironment for tumor growth.

In a study by the Mayo Clinic consisting of 511 patients, the authors reported serum albumin level below 3.5 g/dL and high-risk FISH results to be predictive of early relapse. A recent report by the Center for International Blood and Marrow Transplant Research group reported that the proportion of patients with early relapse was stable over time, at 35% to 38%. Similarly, this group reported a higher cancer stage, unresponsiveness to chemotherapy, and no use of post-HSCT maintenance therapy associated with early relapse.

Novel monoclonal antibodies daratumumab, isatuximab, and elotuzumab alone or in combination with other new targeted agents have been shown to have significant activity in relapsed refractory multiple myeloma. Our results, however, have identified a subgroup of high-risk patients who will continue to do poorly with the best available treatment and should be included in clinical trials investigating new therapeutic strategies such as novel monoclonal antibodies daratumumab, isatuximab, and elotuzumab. Indeed, ongoing clinical trials are examining the addition of these monoclonal antibodies as induction or consolidation therapy before and after HSCT. Other immune-modulating approaches such as vaccination and T-cell therapy (CAR T-cell, bispecific T-cell engagers, also called BiTE monoclonal antibodies) are also under investigation and hold promise for a better cytoreduction and long-term disease control for high-risk patients.

**CONCLUSION**

We conducted this retrospective analysis to identify the risk factors predictive of early relapse despite best available treatment. In our study, the risk factors identified were disease status of less than complete response at the time of HSCT, no use of maintenance therapy after HSCT, ISS stage III, and high FCI. We also examined factors predictive of early relapse within 18 months of transplant. Disease status less than complete response, ISS stage III, no use of maintenance therapy, and male sex were the most predictive for early relapse, supporting the need for better disease control prior to transplant.

**Disclosure Statement**

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

**Acknowledgments**

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References


Lifestyle Interventions and Carotid Plaque Burden: A Comparative Analysis of Two Lifestyle Intervention Programs in Patients with Coronary Artery Disease

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ABSTRACT
Background: The cardioprotective effects of intensive lifestyle regimens in primary prevention have been elucidated; however, there is a paucity of data comparing the effects of different lifestyle regimens in patients with established coronary artery disease (CAD) or CAD equivalent, specifically vis-à-vis carotid plaque regression.

Methods: We performed a randomized, single-center, single-blind study in 120 patients with established CAD. Patients were randomly assigned to either 9 months of the Complete Health Improvement Program (CHIP), an outpatient lifestyle enrichment program that focuses on improving dietary choices, enhancing daily exercise, increasing support systems, and decreasing stress; or to 9 months of an ad hoc, nonsequential combination of various healthy living classes offered separately through a health maintenance organization and referred to as the Healthy Heart program. Baseline and 9-month change in carotid intima-media thickness (CIMT) were measured.

Results: Among 120 participants, data were analyzed for 79, of which 68 (86%) completed the study. Both average CIMT and average maximum CIMT increased over 9 months, but the changes between groups were insignificant. There were marked differences in the mean body mass index favoring the CHIP group (-1.9 [standard deviation = 1.9]; p < 0.001) and statistically significant within-group improvements in blood pressure, triglyceride level, 6-minute walk test result, self-assessment well-being score, and Patient Health Questionnaire-9 score that were not observed between groups.

Conclusion: Neither the CHIP nor Healthy Heart was effective in inducing plaque regression in patients with established CAD after a 9-month period. However, both were effective in improving several CAD risk factors, which shows that the nonsequential offering of healthy lifestyle programs can lead to similar outcomes as a formal, sequential, established program (CHIP) in many aspects. These results have important implications as to how lifestyle changes will be implemented as tertiary prevention measures in the future.

INTRODUCTION
Coronary artery disease (CAD) continues to be a major cause of morbidity and mortality in developed countries and is the cause of one-fifth of deaths in the US. Although CAD death rates have declined worldwide since the turn of the century, it remains our leading cause of death. Modification of cardiovascular risk factors is responsible for nearly half of the decrease in deaths secondary to CAD, but much more effort is needed. Changes in lifestyle such as smoking cessation, regular physical activity, and combined dietary changes have been shown to reduce mortality by 20% to 35%. Among the dietary changes, a plant-based diet has been proposed as an effective way to reduce the massive CAD burden, mainly because cardiovascular disease rarely develops in populations that consume a plant-based diet. Additionally, meta-analyses have shown a reduced risk of CAD development and occurrence of CAD events or cerebrovascular disease events with a plant-based diet. It is for these reasons that a plant-based diet is one of the healthy eating patterns recommended by the 2015 to 2020 Dietary Guidelines for Americans.

Clinical trials have examined the use of lifestyle improvement with whole-foods, plant-based diets in the treatment of established CAD. Multiple prospective studies, reviews, and meta-analyses have demonstrated the positive effects that a plant-based diet has on various cardiac risk factors such as body mass index (BMI), non-high-density lipoprotein (HDL) cholesterol, blood pressure, type 2 diabetes, and metabolic syndrome.

Among the limitations of the aforementioned studies is a lack of a head-to-head comparison of lifestyle improvement programs using plant-based diets, a lack of testing such a program in a heterogenous group of people, and the lack of a validated test to serve as measure for the CAD burden. Because a substantial percentage of patients are surviving their initial cardiac event with improved short- and long-term outcomes, it would be valuable to determine if there is an optimal lifestyle improvement program for tertiary prevention of established CAD. We aimed to answer these questions by testing 2 types of lifestyle improvement programs head-to-head in a heterogenous population and by using carotid intima-media thickness (CIMT) as an indirect measure of the effect of these programs on CAD.

Lifestyle Improvement Programs
The Complete Health Improvement Program (CHIP) is an intensive outpatient lifestyle program that emphasizes a whole foods, low-fat, plant-based diet with moderate exercise and stress relief. It was
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...
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ORIGINAL RESEARCH & CONTRIBUTIONS

or 50% of the surrounding CIMT and/or demonstration of a CIMT greater than 1.5 mm. Software designed for this purpose was used to allow automated CIMT measurements, statistical analysis for scoring, storage of measurements for future reference, and evaluation of progression. An experienced sonographer, who was blinded to the study group that patients were assigned to, performed all ultrasonography.

Categorical variables are represented as frequencies and percentages, and continuous variables are shown as mean and standard deviation (SD). The $\chi^2$ test was used to compare categorical variables between groups. As for the continuous variables, differences between groups were assessed with the Wilcoxon rank sum test (Mann–Whitney test) at baseline and at the conclusion of the study. The Wilcoxon signed-rank test was used to look at differences within patients from the start to the end of the study, which were then compared between groups with another Wilcoxon rank sum test.

RESULTS

Of 1000 patients with CAD who met the study criteria, 120 initially agreed to participate and were randomly assigned to either the CHIP or HH group (Figure 1). However, when called for scheduling for the study, 11 and 12 patients declined from the CHIP and HH groups, respectively. Early in the study, an additional 9 patients from the CHIP group and 8 from the HH group quit the study for various reasons, including personal health, family, disagreement with concepts taught in CHIP, difficulty with traveling, and inconsistent attendance in the classes. Additionally, 1 patient in the CHIP group died shortly after the start of the study secondary to a stroke and was thus not included in the baseline data. Baseline data were available for 39 participants in the CHIP group and 40 in the HH group, with similar baseline characteristics in both groups (Table 1). During the course of the study, 3 participants did not complete follow-up and 1 died in the CHIP group, and 7 did not complete follow-up in the HH group. This left 35 and 33 participants in the CHIP and HH groups, respectively.

The effects that the studied lifestyle interventions had on QoL, various cardiac risk factors, blood markers, and CIMT are shown in Table 2. The QoL score improved significantly within the CHIP group (mean = -2, SD = 5; p = 0.004) but not within the HH group (p = 0.3) or between groups (p = 0.8). Although no significant difference was observed in the PHQ-9 scores between groups (p = 0.3), there was an improvement within the CHIP group (mean = -1.4, SD = 3.3; p = 0.01) and HH group (mean = -1.3, SD = 2.5; p = 0.01).

The BMI decreased significantly in the CHIP group (mean = -1.9, SD = 1.9; p < 0.001) but not in the HH group (p = 0.09). The difference between groups in the final BMI at 9 months was also significant (p = 0.01), as was the change with patients over the 9 months (p < 0.001). Waist–hip ratio also decreased significantly in the CHIP group (mean = -0.03, SD = 0.37). Patients with a BMI over 25 were designated as overweight.

Table 1. Baseline characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>HH group (n = 40)</th>
<th>CHIP group (n = 39)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y, mean (SD)</td>
<td>66.1 (7.7)</td>
<td>65.6 (10.5)</td>
<td>&gt; 0.99</td>
</tr>
<tr>
<td>Female, no. (%)</td>
<td>13 (33)</td>
<td>21 (54)</td>
<td>0.06</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>White</td>
<td>25 (63)</td>
<td>27 (69)</td>
<td>0.64</td>
</tr>
<tr>
<td>Black</td>
<td>6 (15)</td>
<td>7 (18)</td>
<td>0.64</td>
</tr>
<tr>
<td>Hispanic</td>
<td>6 (15)</td>
<td>4 (10)</td>
<td>0.64</td>
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<tr>
<td>Asian</td>
<td>2 (5)</td>
<td>0 (0)</td>
<td>0.64</td>
</tr>
<tr>
<td>Declined to state</td>
<td>1 (3)</td>
<td>1 (3)</td>
<td>0.64</td>
</tr>
<tr>
<td>QoL score, mean (SD)</td>
<td>23.9 (3.1)</td>
<td>43.4 (4.6)</td>
<td>0.37</td>
</tr>
<tr>
<td>6-min walk test, mean (SD), min</td>
<td>463 (92)</td>
<td>455 (96)</td>
<td>0.36</td>
</tr>
<tr>
<td>Anthropometric measures, mean (SD)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weight, kg</td>
<td>93.8 (19.9)</td>
<td>84.8 (16.7)</td>
<td>0.04</td>
</tr>
<tr>
<td>BMI, kg/m²</td>
<td>31.2 (6.1)</td>
<td>29.3 (6.7)</td>
<td>0.12</td>
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<td>Waist-hip ratio</td>
<td>0.96 (0.08)</td>
<td>0.94 (0.08)</td>
<td>0.30</td>
</tr>
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<td>Vital signs, mean (SD)</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>SBP, mmHg</td>
<td>136 (20)</td>
<td>139 (19)</td>
<td>0.46</td>
</tr>
<tr>
<td>DBP, mmHg</td>
<td>75 (12)</td>
<td>77 (12)</td>
<td>0.78</td>
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<td>Pulse, min</td>
<td>66 (10)</td>
<td>68 (14)</td>
<td>0.76</td>
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<td>Medication use, mean (SD)</td>
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</tr>
<tr>
<td>ACEI or ARB</td>
<td>0.75 (0.44)</td>
<td>0.64 (0.49)</td>
<td>0.30</td>
</tr>
<tr>
<td>Serology and lipid profile</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>CRP, mg/L</td>
<td>3.4 (4.9)</td>
<td>2.6 (3.2)</td>
<td>0.79</td>
</tr>
<tr>
<td>HDL-C, mg/L</td>
<td>68 (12)</td>
<td>6.4 (1.6)</td>
<td>0.26</td>
</tr>
<tr>
<td>Lpa, mg/L</td>
<td>104 (113)</td>
<td>81 (98)</td>
<td>0.31</td>
</tr>
<tr>
<td>LDL-C, mg/L</td>
<td>80 (36)</td>
<td>80 (27)</td>
<td>0.56</td>
</tr>
<tr>
<td>Triglycerides, mg/L</td>
<td>131 (79)</td>
<td>118 (56)</td>
<td>0.44</td>
</tr>
<tr>
<td>Total cholesterol, mg/L</td>
<td>151 (41)</td>
<td>151 (30)</td>
<td>0.65</td>
</tr>
</tbody>
</table>

**Table 1. Baseline characteristics**

**ACEI** = angiotensin-converting enzyme inhibitor; **ARB** = angiotensin receptor blocker; **BMI** = body mass index; **CHIP** = Complete Health Improvement Program; **CRP** = C-reactive protein; **DBP** = diastolic blood pressure; **HbA<sub>1c</sub>** = glycated hemoglobin; **HDL-C** = high-density lipoprotein cholesterol; **HH** = Healthy Heart; **LDL-C** = low-density lipoprotein cholesterol; **Lpa** = lipoprotein a; **PHQ-9** = Patient Health Questionnaire-9; **QoL** = quality of life questionnaire; **SBP** = systolic blood pressure; **SD** = standard deviation.
Lifestyle Interventions and Carotid Plaque Burden: A Comparative Analysis of Two Lifestyle Intervention Programs in Patients with Coronary Artery Disease

SD = 0.07; p < 0.001) and the HH group (mean = -0.02, SD = 0.05; p = 0.01). The difference between groups was also statistically significant (p = 0.02). Blood pressure at baseline and throughout the study was well controlled. Although there was no significant difference between systolic and diastolic blood pressures between groups (p = 0.5 for both), there was within both the CHIP group (systolic = -11.7 [SD = 18.1]; p = 0.001; diastolic = -6.4 [SD = 11.7]; p = 0.007) and the HH heart group (systolic = -14.1 [SD = 18.5]; p < 0.001; diastolic = -3.3 [SD = 12.8]; p = 0.04). Similarly, no significant difference was observed in the 6-minute walk test between groups (p = 0.9), but there was a difference within the CHIP group (mean = 51.5 min, SD = 50.1; p < 0.001) and HH group (mean = 43.1 min, SD = 72.7; p < 0.001).

An improvement in triglyceride levels was observed within the HH group (mean = -14.07, SD = 28.23; p = 0.01). However, there was no significant change in the CHIP group (p = 0.7) or between groups (p ≥ 0.99). Regarding the HbA1c, the CHIP group showed improvement (mean = -0.14, SD = 1.27; p = 0.01), but there was no significant change in the HH group (p = 0.09) or between groups (p = 0.08). As for the rest of the blood markers, there were no significant differences within or between groups for levels of total cholesterol, HDL cholesterol, LDL cholesterol, lipoprotein a, or C-reactive proteins as shown in Table 2.

The CIMT was measured using the right and left sides, the near and far walls, and the anterior, lateral, and posterior positions. The average of these 12 measurements, called average CIMT, and the average of the maximum of the 12 measures, called average maximum CIMT, were then calculated. Both the average CIMT and average maximum CIMT increased over 9 months, but the changes between groups were insignificant (p = 0.45 and p = 0.15, respectively). For the average CIMT, the changes within the CHIP group (0.02, SD = 0.12; p = 0.2) and HH group (0.03, SD = 0.12; p = 0.07) were insignificant. However, with respect to the average maximum CIMT, the changes within the CHIP group (0.30, SD = 0.50; p < 0.001) and within the HH group (0.32, SD = 0.90; p = 0.003) were significant (Figure 2). These differences seen within patients were not statistically significant compared between groups (p = 0.85).

**DISCUSSION**

Some clinical trials have demonstrated coronary plaque regression after an intensive lifestyle program in patients with established CAD. However, these studies are limited in that they did not definitely prove the superiority of one lifestyle program vs another because they either used a usual care control group or had no control group. They also used a more invasive or expensive method to evaluate their outcomes, such as coronary angiography.48,49 We aimed to do a comparative analysis of 2 lifestyle programs and use CIMT as a more feasible evaluation method. Other studies that have used CIMT in the past have fallen into 2 categories: Those that used mean CIMT and those that used maximal CIMT.44 This study used 12 measurements to look at both mean and maximal CIMT in the same population. Furthermore, various interesting secondary outcomes such as inflammatory markers and other serologic findings were examined, and all patients were part of an integrated health system where they received robust, optimal health care. They were well matched and represented the "real world" as a result of their socioeconomic and demographic characteristics.

This study demonstrated that neither CHIP nor HH effectively reversed plaque burden in the short term when used as a tertiary preventive measure in CAD. There was an increase in the average maximum CIMT within groups without a significant difference between the CHIP and HH groups. However, it is still possible that these programs could have slowed the progression of atherosclerotic disease.

Figure 1. Flow diagram demonstrating patient recruitment and attrition. CAD = coronary artery disease; CHIP = Complete Health Improvement Program; HH= Healthy Heart.
especially given that these patients were followed up only over 9 months. Most studies that showed the beneficial effects of lipid-lowering therapy, antihypertensive agents, and other medications on CIMT usually had a follow-up of 18 months or greater, sometimes as long as 4 years. It is thus possible that there may have been a significant reduction in CIMT that would have been appreciated if there was a longer follow-up period. Although more intensive lifestyle regimens have demonstrated plaque regression, this is likely owing to a combination of both longer follow-up times and the use of a control group as a comparator arm.

The current study showed significant differences in some of the secondary endpoints within groups. The CHIP group showed improvement in the QoL score, BMI, waist-hip ratio, and HbA<sub>1c</sub>. The BMI and waist-hip ratio were the

### Table 2. Impact of lifestyle interventions

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>HH group</th>
<th>CHIP group</th>
<th>p value&lt;sup&gt;b&lt;/sup&gt;</th>
<th>p value&lt;sup&gt;c&lt;/sup&gt;</th>
<th>p value&lt;sup&gt;d&lt;/sup&gt;</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>Follow-up</td>
<td></td>
<td></td>
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<tr>
<td>QoL score</td>
<td>23 (4), 39</td>
<td>24 (3), 28</td>
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<tr>
<td>PHQ-9 score</td>
<td>2.9 (3.1), 39</td>
<td>1.5 (2.1), 28</td>
<td>0.01</td>
<td></td>
<td></td>
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<td>Anthropometric measures</td>
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<td>BMI, kg/m&lt;sup&gt;2&lt;/sup&gt;</td>
<td>31.2 (6.1), 40</td>
<td>29.5 (6.4), 32</td>
<td>0.09</td>
<td>29.3 (5.7), 39</td>
<td>26.5 (4.7), 31</td>
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<td>Waist-hip ratio</td>
<td>0.96 (0.08), 39</td>
<td>0.95 (0.07), 33</td>
<td>0.01</td>
<td>0.94 (0.08), 39</td>
<td>0.91 (0.10), 36</td>
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<td>Vital signs</td>
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<tr>
<td>SBP, mmHg</td>
<td>136 (20), 40</td>
<td>125 (13), 32</td>
<td>&lt; 0.001</td>
<td>139 (19), 39</td>
<td>127 (12), 29</td>
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<td>DBP, mmHg</td>
<td>75 (12), 40</td>
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<td>77 (12), 39</td>
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<td>Pulse/min</td>
<td>66 (10), 40</td>
<td>66 (10), 32</td>
<td>0.55</td>
<td>68 (14), 38</td>
<td>67 (11), 29</td>
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<tr>
<td>6-min walk test</td>
<td>463 (92), 39</td>
<td>506 (89), 33</td>
<td>&lt; 0.001</td>
<td>455 (96), 39</td>
<td>504 (120), 36</td>
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<tr>
<td>Serology and lipid profile</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>HbA&lt;sub&gt;1c&lt;/sub&gt;, mg/dL</td>
<td>6.6 (1.2), 40</td>
<td>6.5 (1.2), 28</td>
<td>0.09</td>
<td>6.4 (1.6), 39</td>
<td>6.2 (1.1), 35</td>
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<tr>
<td>Lpa, mg/L</td>
<td>104 (113), 39</td>
<td>114 (127), 26</td>
<td>0.23</td>
<td>81 (98), 39</td>
<td>106 (108), 27</td>
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<td>LDL-C, mg/L</td>
<td>80 (36), 40</td>
<td>70 (25), 27</td>
<td>0.09</td>
<td>80 (27), 39</td>
<td>77 (25), 35</td>
</tr>
<tr>
<td>HDL-C, mg/L</td>
<td>46 (11), 40</td>
<td>49 (14), 28</td>
<td>0.14</td>
<td>48 (15), 39</td>
<td>47 (12), 35</td>
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<tr>
<td>Triglycerides, mg/dL</td>
<td>131 (79), 40</td>
<td>119 (90), 28</td>
<td>0.01</td>
<td>118 (56), 39</td>
<td>113 (68), 35</td>
</tr>
<tr>
<td>Total cholesterol, mg/dL</td>
<td>151 (41), 40</td>
<td>141 (37), 28</td>
<td>0.16</td>
<td>151 (30), 39</td>
<td>146 (32), 35</td>
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<tr>
<td>CRP, mg/L</td>
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<td>2.6 (5.1), 27</td>
<td>0.53</td>
<td>2.6 (3.2), 39</td>
<td>9.3 (31.3), 34</td>
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<td>Carotid intima-media thickness, mm</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average</td>
<td>0.89 (0.13), 39</td>
<td>0.92 (0.13), 33</td>
<td>0.07</td>
<td>0.89 (0.18), 39</td>
<td>0.91 (0.17), 35</td>
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<tr>
<td>Average maximum</td>
<td>1.77 (0.72), 39</td>
<td>2.08 (0.56), 33</td>
<td>0.003</td>
<td>1.61 (0.45), 39</td>
<td>1.91 (0.58), 35</td>
</tr>
</tbody>
</table>

<sup>a</sup> Values are mean (standard deviation), no. of patients. Impact of lifestyle interventions on quality of life cardiac risk factors, serologic findings, lipid profile, and carotid intima-media thickness.

<sup>b</sup> p value refers to within-group difference (baseline to follow-up).

<sup>c</sup> p value refers to between-group differences at the end of the study.

<sup>d</sup> p value compares between groups the differences within patients from the start to the end of the study.

ACE = angiotensin-converting enzyme inhibitor; ARB = angiotensin receptor blocker; BMI = body mass index; CHIP = Complete Health Improvement Project; CRP = C-reactive protein; DBP = diastolic blood pressure; HbA<sub>1c</sub> = glycated hemoglobin; HDL-C = high-density lipoprotein cholesterol; HH = Healthy Heart; LDL-C = low-density lipoprotein cholesterol; Lpa = lipoprotein a; PHQ-9 = Patient Health Questionnaire-9; QoL = quality of life questionnaire; SBP = systolic blood pressure.
only secondary endpoints that were significantly different even between groups. The HH group showed an improvement in triglyceride levels. Additionally, both groups had lower systolic and diastolic blood pressures as well as improvements in the PHQ-9 score and 6-minute walk test. This confirms that intensive lifestyle programs can positively affect multiple cardiac risk factors. Although this is clear and established, it also shows that the nonsequential offering of healthy lifestyle programs (HH) can lead to similar outcomes as a formal, sequential, established program (CHIP) in many aspects. This has important implications as to how lifestyle changes will be implemented as tertiary prevention measures in the future.

This study has some limitations. Although both CHIP and HH advocated for particular dietary patterns and although dietary questionnaires were used before and after, they are not the best forms of evidence for the effects of a particular dietary pattern. The first reason is that both programs encouraged broad lifestyle changes (exercise, stress relief, and diet), making it inappropriate to pinpoint diet alone as the cause of the outcome. The second reason is that complete dietary adherence is difficult to ascertain in the community setting and dietary questionnaires are subject to several biases. Thus, this study is better defined as one testing the outcomes of participation in a program rather than the outcomes of following a particular diet. The short duration of the study was cited earlier as a limitation as well. Furthermore, CIMT remains a controversial marker for cardiovascular disease and thus limits interpretation of these results.

CONCLUSION
Neither the CHIP nor HH was effective in inducing plaque regression in patients with established CAD after a 9-month period. However, both were effective in improving several CAD risk factors and could thus potentially reduce CAD, especially in conjunction with an exercise program. Further studies with longer follow-up and larger sample sizes can examine whether the risk factor improvement may lead to plaque regression.

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

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How to Cite This Article

References


ORIGINAL RESEARCH & CONTRIBUTIONS

Spontaneous Coronary Artery Dissection: Clinical Characteristics, Management, and Outcomes in a Racially and Ethnically Diverse Community-Based Cohort

Stephanie Chen, MD; Maqooda Merchant, MSc, MA; Kenneth N Mahrer, MD; Robert J Lundstrom, MD; Sahar Naderi, MD; Anne CH Goh, MBBS, MPH

ABSTRACT

Context: Spontaneous coronary artery dissection (SCAD) is a cause of acute coronary syndrome, which predominantly affects healthy women; however, few data define this vulnerable population.

Objective: To identify demographic and clinical characteristics of patients with SCAD and determine outcomes in a community-based cohort.

Design: Retrospective cohort study of patients with SCAD at Kaiser Permanente Northern California during a 10-year period. We compared 111 SCAD cases with 333 healthy, matched controls.

Main Outcome Measures: Predisposing factors, treatment modalities, and in-hospital and late outcomes.

Results: Patients with SCAD had a mean age (standard deviation) of 48.1 (11) years; 92.8% were women, and 49.5% were nonwhite. Of women, 9% were peripartum. Fibromuscular dysplasia was identified in 21.8% of femoral angiograms obtained. With conditional logistic regression, only pregnancy and hyperlipidemia were associated with SCAD compared with controls. Fifty-five patients (49.5%) were successfully treated without revascularization; of the 54 who had urgent percutaneous coronary intervention, 2 required coronary artery bypass grafting for SCAD extension. During a median follow-up of 2.6 years, major adverse cardiovascular events occurred in 8.1% of patients. Pregnancy-related SCAD was not associated with worsened outcomes. However, Emergency Department visits or hospitalizations because of recurrent chest pain occurred frequently for 54% of patients with SCAD.

Conclusion: The study cohort is comparable to published SCAD cohorts, but notable for a racially and ethnically diverse population. Compared with the controls, only pregnancy and hyperlipidemia were associated with SCAD. For the SCAD cases, major adverse cardiovascular events occurred in 8.1%, and race did not influence outcomes.

INTRODUCTION

Spontaneous coronary artery dissection (SCAD) is a rare and poorly understood cause of acute coronary syndrome and sudden cardiac death. The pathophysiology is caused by an intimal tear in the vessel wall or spontaneous hemorrhage within the vasa vasorum, leading to dissection of the vessel. The prevalence of SCAD is unknown but has been reported to range from 0.1% to 4% of all acute coronary syndrome presentations. SCAD appears to account for a larger percentage of myocardial infarction in women younger than the age of 50 years, representing 24% to 40% of cases. Of women without known risk factors for cardiovascular disease, fibromuscular dysplasia (FMD) may be diagnosed concomitantly with SCAD. Other risk factors are pregnancy, especially with advanced maternal age and multiparity, which potentially involves more proximal vessels and extensive dissections. Other precipitants include major emotional or physical stressors and hormonal factors, such as perimenopausal state, oral contraceptive pills (OCPs), hormonal replacement therapy (HRT), and infertility treatment. Several case series of SCAD have been published, but the total number of cases and outcomes reported remains small. This study attempts to identify demographic and clinical characteristics of patients with SCAD compared with healthy controls in a racially diverse, community-based cohort, as well as to report long-term outcomes of SCAD.

METHODS

We conducted a retrospective cohort study of all patients with a diagnosis of SCAD made at Kaiser Permanente (KP) Northern California (KPNC) between January 1, 2003, and December 31, 2012. KPNC is a large integrated health care delivery system providing comprehensive medical care to more than 4 million members (estimated to be more than one-fourth of the population of Northern California). The Kaiser Foundation Research Institute’s institutional review board approved this study with a waiver of consent.

Database searches included a combination of International Classification of Diseases, Ninth Revision (ICD-9) and Current Procedural Terminology, Fourth Edition (CPT-4) codes for dissection of coronary artery (414.12), dissection of other artery (443.29), and coronary aneurysm (414.11). In addition, angiograms of pregnant women with acute coronary syndrome were reviewed to identify additional patients for the SCAD cohort. Exclusion criteria included age younger than 18 years, less than 9 months of enrollment in KPNC in the 12 months before the SCAD date, end-stage renal disease treated with dialysis, and coronary angiogram unavailable for review.

Coronary angiography and available intravascular ultrasonograms from all potential SCAD cases were independently reviewed by 2 experienced interventional cardiologists (RL, KM). Cases were included in the study when there was consensus regarding the diagnosis of SCAD.

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Keywords: acute coronary syndrome, SCAD, spontaneous coronary artery dissection, sudden cardiac death
SCAD was confirmed to be present angiographically if clinically significant coronary atherosclerosis was absent, in addition to pathognomonic evidence of an intimal dissection with contrast retention in the arterial wall, multiple lumens, an abrupt change of arterial caliber, diffuse smooth narrowing typical of intramural hematoma, and/or confirmatory intravascular ultrasonography findings.10

Three controls for each case were obtained from the KPNC healthy population and matched to the SCAD case by age, sex, and follow-up time. The healthy population control group excluded patients with end-stage renal disease or any cardiovascular events occurring before the index date of the matched SCAD case. Each control had at least 9 months of enrollment in KPNC in the 12 months before the matched case date.

Demographics, clinical presentation, predisposing factors, treatment modalities, and inhospital and late outcomes were obtained through review of the medical records and analysis of subsequent coronary angiograms. FMD was defined by a “string-of-beads” appearance (ie, alternating stenoses and aneurysms) on imaging modalities of the arterial vessels, including femoral angiogram, computed tomography, or magnetic resonance imaging. Major adverse cardiovascular events (MACE), including recurrent SCAD, myocardial infarction, hospitalization because of congestive heart failure, and death, were obtained during follow-up. Death outcomes were ascertained from KPNC databases, State of California death records, and the Social Security Death Index. Peripartum was defined as during pregnancy or up to 3 months postpartum.

Statistical analysis was performed with statistical software (SAS 9.3, SAS Institute Inc, Cary, NC). Continuous data were summarized as means (standard deviation) and analyzed using the Student t-test with matched SCAD and control group data. Discrete variables were expressed as frequencies (percentages) and compared with a χ² test for unmatched data, and conditional logistic regression was used to evaluate predictors for SCAD in the matched case-control analysis. For patients with SCAD, a Cox proportional hazard model was used to evaluate predictors for follow-up events. A value of p < 0.05 was considered statistically significant.

RESULTS

The database search yielded 111 patients with confirmed SCAD from 2003 to 2012, and a corresponding 333 healthy controls were selected and matched by age, sex, and follow-up time. The clinical characteristics of the cases and controls are detailed in Table 1. Of the SCAD cases, the mean age (standard deviation) was 48.1 (11) years, and 92.8% of patients were women. This was a racially and ethnically diverse SCAD cohort, with 49.5% nonwhite patients, including 13.5% black, 16.2% Hispanic, and 18% Asian patients (Table 2). There were significantly more peripartum women in the SCAD cohort: 8.7% of patients with SCAD vs 1.3% of matched controls (p = 0.0002). With conditional logistic regression and limited to women, pregnancy was significantly associated with SCAD with an adjusted odds ratio of 7.5 (95% confidence interval = 1.9-28.1). Of note,
there was no significant difference in OCP use or postmenopausal HRT between the groups (Table 1). There was a statistically significantly higher rate of hyperlipidemia in the SCAD cohort compared with the control group, with an odds ratio of 1.9 (95% confidence interval = 1.2-3.1). Otherwise, there was no statistically significant difference in cardiovascular risk factors. Outcomes data were obtained for all cases and included an 86% retention rate of cases as KP members at the end date of the study.

The clinical presentation and angiographic distribution of SCAD cases are summarized in Table 3. The majority (91%) of SCAD cases presented with acute coronary syndrome, with 23.4% having ST-segment elevation. Precipitating emotional or physical stress was reported in 12.6% of SCAD cases. Two patients reported illicit drug use within 24 hours of SCAD presentation, and an additional 4 patients used illicit drugs within the past year; these illicit drugs included marijuana, methamphetamine, cocaine, and heroin. The left anterior descending coronary artery was the most frequently involved (65.8%) artery. The left main coronary artery was involved in 5 (4.5%) cases. Multivessel SCAD occurred in 20.7% of patients. Femoral angiography was performed in 49.5% of SCAD cases, and FMD was identified in 21.8% of femoral angiograms obtained.

Figure 1 illustrates the initial management of SCAD cases: 55 (49.5%) of 111 cases were successfully treated conservatively without revascularization. Four of 6 patients who received fibrinolytic therapy before transfer to an angiography facility required subsequent percutaneous coronary intervention (PCI). Among 54 (48.6%) of SCAD cases treated with PCI, 87% underwent successful PCI, and 2 required coronary artery bypass grafting (CABG) because of failed PCI. In our SCAD cohort at discharge, aspirin was prescribed in 94% of patients, clopidogrel in 82%, a statin in 81%, a β-blocker in 88%, and an angiotensin-converting enzyme inhibitor or angiotensin receptor blocker in 63%. At 1-year follow-up, 68% of patients continued to take aspirin; 48%, clopidogrel; 59%, statin; 60%, β-blocker; and 43%, angiotensin-converting enzyme inhibitor or angiotensin receptor blocker.

The mean length of follow-up (standard deviation) for cases was 3 (2.2) years, and the median (interquartile range) was 2.6 years (25th–75th percentiles = 1.4–4.3 years). Among SCAD cases, MACE occurred in 9 (8.1%). There were 8 cases with recurrent myocardial infarction, and all underwent repeated coronary angiography. Three angiograms showed new SCAD, 2 additional angiograms were without a new angiographic abnormality in the setting of early recurrent chest pain and troponin elevation, I showed early SCAD extension and hemopericardium, and 2 showed late recurrent myocardial infarctions, which were angiographically unexplained. Early recurrent symptoms or troponin elevation or both occurred within 30 days and typically represented propagation of the index dissection from unhealed SCAD, whereas late recurrence after 30 days was more likely because of de novo SCAD. All cases of late recurrent de novo SCAD occurred in women and in a different vessel location than the index episode. Hospitalization because of congestive heart failure was observed in 1 case. No deaths were observed among SCAD cases. Among controls, MACE occurred in only 1 patient with a noncardiovascular death (0.3%). A Cox proportional hazard model did not show

### Table 2. Racial or ethnic distribution

<table>
<thead>
<tr>
<th>Race or ethnicity</th>
<th>SCAD (n = 111), no. (%)</th>
<th>Controls (n = 333)</th>
</tr>
</thead>
<tbody>
<tr>
<td>White</td>
<td>56 (50.5)</td>
<td>175 (52.6)</td>
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<tr>
<td>Nonwhite</td>
<td>55 (49.5)</td>
<td>158 (47.4)</td>
</tr>
<tr>
<td>Black</td>
<td>15 (13.5)</td>
<td>38 (11.4)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>18 (16.2)</td>
<td>59 (17.7)</td>
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<tr>
<td>Asian</td>
<td>20 (18.0)</td>
<td>46 (13.8)</td>
</tr>
<tr>
<td>Other</td>
<td>2 (1.8)</td>
<td>15 (4.5)</td>
</tr>
</tbody>
</table>

SCAD = spontaneous coronary artery dissection.

### Table 3. Clinical presentation and angiographic distribution of SCAD cases (n = 111)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Valuea</th>
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<tbody>
<tr>
<td>Clinical presentation</td>
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<tr>
<td>ST-elevation myocardial infarction</td>
<td>26 (23.4)</td>
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<tr>
<td>Non-ST-elevation myocardial infarction</td>
<td>75 (67.6)</td>
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<tr>
<td>Unstable angina pectoris</td>
<td>4 (3.6)</td>
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<td>Ventricular fibrillation or ventricular tachycardia</td>
<td>6 (5.4)</td>
</tr>
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<td>Maximum troponin-I level, ng/mL, mean (SD)</td>
<td>15.1 (20.6)</td>
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<tr>
<td>Left ventricular ejection fraction, mean (SD), %</td>
<td>55.4 (11.1)</td>
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<td>Emotional stress triggering event</td>
<td>10 (9)</td>
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<td>Physical stress triggering event</td>
<td>4 (3.6)</td>
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<td>SCAD angiographic distribution</td>
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<tr>
<td>Left main coronary artery</td>
<td>5 (4.5)</td>
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<td>Left anterior descending coronary artery</td>
<td>73 (65.8)</td>
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<td>Mid and distal</td>
<td>67 (60.4)</td>
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<tr>
<td>Left circumflex coronary artery</td>
<td>42 (37.8)</td>
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<tr>
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</tr>
<tr>
<td>Mid and distal</td>
<td>39 (35.1)</td>
</tr>
<tr>
<td>Right coronary artery</td>
<td>20 (18)</td>
</tr>
<tr>
<td>Ostium and proximal</td>
<td>3(27)</td>
</tr>
<tr>
<td>Mid and distal</td>
<td>20 (18)</td>
</tr>
<tr>
<td>Ramus intermedius coronary artery</td>
<td>1 (0.9)</td>
</tr>
<tr>
<td>&gt; 1 SCAD lesion</td>
<td>23 (20.7)</td>
</tr>
<tr>
<td>Femoral angiogram</td>
<td>55 (49.5)</td>
</tr>
<tr>
<td>Fibromuscular dysplasia, no. (% of femoral angiogram)</td>
<td>12 (21.8)</td>
</tr>
</tbody>
</table>

a Value = no. (%) unless otherwise indicated.

SCAD = spontaneous coronary artery dissection; SD = standard deviation.
age, sex, race, PCI, number of SCAD lesions, or lesion site to be significantly associated with an increased risk of MACE. Limiting the model to women only, we found that pregnancy was not associated with MACE. During follow-up, 5 pregnancies occurred among SCAD cases with no recurrent SCAD episodes.

After the initial SCAD hospitalization, 60 (54.0%) of the SCAD cases had at least 1 Emergency Department visit or hospitalization because of chest pain; of these, 34 had repeated coronary angiography. Clinically driven repeated angiography was performed more than 20 days after the initial SCAD episode in 19 SCAD cases, with 15 (78.9%) of those showing complete healing of the initially dissected artery and new SCAD in 3 cases (as mentioned earlier regarding recurrent SCAD).

**DISCUSSION**

The baseline characteristics of this study cohort are comparable to those of other published SCAD cohorts. Our SCAD cohort was predominantly women (92.8%) with an average age of 48.1 years. This cohort was notable for a racially and ethnically diverse population, with 49.5% being nonwhite, higher than other cohorts in the literature, which reported 5% to 18% nonwhite patients. Outcomes do not differ between white and nonwhite patients. This study has comparable rates of cardiovascular risk factors, specifically hypertension, hyperlipidemia, and cigarette smoking compared with those in the literature (eg, published rates are 27% to 51% for hypertension, 23% to 52% for hyperlipidemia, and 0.6% to 3.4% for smoking). The rate of diabetes is higher in this study (7.2% of patients with SCAD in this study compared with 0% to 4.6% in the literature).

Although other studies have compared patients with SCAD to patients with acute coronary syndrome, this study is the first known case-control study comparing SCAD cases with a healthy population without known cardiovascular disease. There is a low prevalence of coronary artery disease risk factors in patients with SCAD compared with a control group with acute coronary syndrome. However, the prevalence of hyperlipidemia is higher in our SCAD population compared with healthy controls.

Although pregnancy was more associated with SCAD compared with the control group, most SCAD events did not occur peripartum. Our study showed peripartum status in 9 (8.7%) of 103 women, compared with 2% to 17% reported in other studies. There was no recurrent SCAD in 5 pregnancies after the initial SCAD event. None of the women who subsequently became pregnant had a pregnancy-associated index SCAD event. Tweet et al reported that 8 of 363 women in their registry became pregnant after SCAD; 7 did not experience recurrent SCAD, but 1 had recurrent SCAD involving the left main coronary artery requiring CABG. Our study also did not show a significant difference between patients with SCAD and controls with comparable rates of OCP and postmenopausal HRT.

As reported in other series, our study found FMD to be common in the SCAD cohort. Our iliofemoral artery FMD rate of 21.8% underestimates FMD prevalence because we did not perform routine screening studies of other vessels, nor did all patients have iliofemoral arteriography. Tweet et al detected FMD of the iliac artery in 50% of those who underwent limited angiography. Saw et al screened for FMD in 3 vascular territories and observed FMD in 72% of SCAD cases. There were no patients in the control cohort with a diagnosis of FMD, although the prevalence of FMD in the population is 3% to 4% based on renal transplant donor studies. The clinical manifestation of FMD is often asymptomatic, and as many as 25.7% of patients may present with dissection before receiving a diagnosis. In our SCAD cohort, most patients received a diagnosis of FMD after their index SCAD presentation; only 1 patient had a preceding diagnosis of FMD.

Optimal acute management of SCAD is not known, but most groups recommend conservative management for stable patients with low-risk anatomy and no evidence of ongoing ischemia or hemodynamic compromise. The reported technical failure rate with PCI is 9% to 31%, and the rate of bypass graft occlusion is high (> 70% at follow-up angiography). In our study, 49.5% of patients were successfully treated with a conservative approach. We experienced a low technical failure rate, including 13% of all PCIs, with 2 patients requiring CABG after failed PCI. We observed no deaths occurring in-hospital or during comprehensive follow-up in our SCAD cohort.

Overall, the MACE rate (8.1%) was low compared with that reported in other studies. Our recurrent myocardial infarction rate was 7.2%, with an angiographically proven SCAD recurrence rate of 2.7% during a median follow-up of 3.2 years (25th–75th percentiles = 1.6–4.3 years). In comparison, Tweet et al reported a recurrent SCAD rate of 17% with a median follow-up of 48.1 months (interquartile range = 18–106 months). Saw et al reported a recurrent SCAD rate of 13% with a much longer median follow-up of 6.9 years in their retrospective cohort. Their respective updated cohorts reported a recurrence rate of 16.8% to 18% with a median 2.3–3.1-year follow-up. Our lower recurrence rate could be because of high β-blocker prescription of 88% at discharge and 60% at 1-year follow-up. In one series, β-blockers were associated with a hazard ratio of 0.36 for recurrent SCAD. This cohort is more racially and ethnically diverse than those described in the literature, and more research is needed to assess whether MACE outcomes vary by race or ethnicity. In this study, most recurrent infarction with new troponin-I elevation occurred early within 30 days after the presenting SCAD without angiographic evidence of new SCAD, and it may be because of subtle extension of the index SCAD vessel. Failure to angiographically identify the cause of recurrent infarction may also reflect the insensitivity of angiography for detecting small-vessel involvement or microvascular mechanisms including endothelial dysfunction.

In our cohort, there was a high rate of Emergency Department visits or hospitalization (54%) because of chest pain after the initial SCAD episode; of these visits, 42% were within 30 days of the index SCAD presentation. Most of these episodes were troponin-negative, and more than half underwent repeated coronary angiography. Saw et al reported that 7.7% of their cohort required repeated hospitalization because of troponin-negative chest pain.

The strengths of this study include the sizable KPNC population, which includes at least one-fourth of the population of Northern California. We attempted to identify every case of SCAD in the KPNC
population via database query, which should reduce sampling bias. In addition, this study reflects a community-based setting and a racially and ethnically diverse population including 49.5% of nonwhite patients. The KP integrated electronic medical record system allows for a thorough assessment of long-term outcomes, and follow-up data were available for all our SCAD cases. There is a high retention rate of KP patients. Of note, 11 patients were excluded from this study because of nonmembership, but more than half of the patients enrolled for follow-up care. Further research is needed to determine if the lower MACE rate in our cohort correlates with continuity of care in the KP system. Whereas other studies have compared patients with SCAD and patients with acute coronary syndrome and atherosclerosis, this is the first case-control study of which we are aware that compares SCAD cases with a healthy population without known cardiovascular disease to ascertain potential predictors for SCAD.

There are a few limitations of this study because of its retrospective nature, including improvement in diagnostic recognition and treatment of SCAD during our study period from 2003 to 2012. In our study, the diagnoses of hyperlipidemia and diabetes were obtained by chart review, not from specific lipid or glucose levels measured before the SCAD episode; thereby, ascertainment bias is possible. Pregnancy-related elevation of lipid levels may have resulted in the diagnosis of hyperlipidemia in the SCAD cohort. Not all patients with SCAD were systematically screened for FMD, which likely underestimates the prevalence of FMD in our population. Compliance with medication prescription was not confirmed. Triggering events, genetic and connective tissue disease screening, and autoimmune disease were not routinely ascertained.

CONCLUSION

This case-control cohort study of SCAD included a racially diverse community population. Traditional cardiovascular risk factors, aside from hyperlipidemia, did not predict SCAD. There was a significantly higher rate of pregnancy in the SCAD cohort compared with controls. However, the rates of OCP and HRT prescription were similar. The SCAD recurrence rate was low, and the mortality rate was zero in this study. No variables, including subsequent pregnancy, were predictive of recurrent SCAD or other adverse events. Five patients had successful pregnancies without complications after their index SCAD event. However, there was a high rate of Emergency Department visits or hospitalization related to chest pain subsequently found to be troponin-negative. Further study is needed to elucidate the predictors of SCAD, determine optimal acute and preventive therapies, and define the risk of pregnancy in the SCAD population.

Disclosure Statement

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

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References


Fixing a Fragmented System: Impact of a Comprehensive Geriatric Hip Fracture Program on Long-Term Mortality

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ABSTRACT

Context: Geriatric hip fractures are increasingly common and confer substantial morbidity and mortality. Fragmentation in geriatric hip fracture care remains a barrier to improved outcomes.

Objective: To evaluate the impact of a comprehensive geriatric hip fracture program on long-term mortality.

Design: We conducted a retrospective cohort study of patients aged 65 years and older admitted to our academic medical center between January 1, 2012, and March 31, 2016 with an acute fragility hip fracture. Mortality data were obtained for in-state residents from the state public health department.

Main Outcome Measures: Mortality within 1 year of index admission and overall survival based on available follow-up data.

Results: We identified 243 index admissions during the study period, including 135 before and 108 after program implementation in October 2014. The postintervention cohort trended toward a lower unadjusted 1-year mortality rate compared with the preintervention cohort (15.7% vs 24.4%, p = 0.111), as well as lower adjusted mortality at 1 year (relative risk = 0.73, 95% confidence interval = 0.46-1.16, p = 0.18), although the differences were not statistically significant. The postintervention cohort had significantly higher overall survival than did the preintervention cohort (hazard ratio for death = 0.43, 95% confidence interval = 0.25-0.74, p = 0.002).

Conclusion: Fixing fragmentation in geriatric hip fracture care such as through an orthogeriatric model is essential to improving overall survival for this patient population.

INTRODUCTION

Hip fractures represent a major health burden for geriatric patients in the US, with more than 250,000 adults aged 65 years and older hospitalized with hip fractures annually. Hip fractures can be highly debilitating, resulting in loss of functional independence and a 1-year mortality rate approaching 30%. With the aging population, the worldwide incidence of hip fracture is expected to increase by 240% in women and 310% in men by 2050, compared with 1990.

Given the scope and importance of the problem, fragmentation in geriatric hip fracture care is a growing concern. Patients may be admitted to multiple different services and units in a single hospital, involvement of geriatric or hospital medicine consultants may be variable, and standardized care pathways may be lacking. Such inconsistency in inpatient care contributes to delays in surgery, discharge, and functional recovery; more hospital-acquired complications; higher readmission rates; failure to adhere to best practices in osteoporosis management; and poor coordination with outpatient clinicians. As a result, major professional societies, hospital regulatory agencies, insurers, and national and international health organizations have called for a population health management approach to geriatric hip fracture care.

We recently implemented a comprehensive geriatric hip fracture program to address fragmentation in care at our own institution. We previously reported short-term outcomes that included a 0.9-day reduction in hospital length of stay, a stable 30-day all-cause readmission rate, and improvements in pharmacologic osteoporosis treatment and outpatient follow-up that were sustained over nearly 18 months. The aim of this study was to evaluate the impact of a comprehensive geriatric hip fracture program on long-term mortality.

METHODS

Study Setting and Population

The design for our quality improvement initiative has been described in detail. The project was conducted at the University of Colorado Hospital, which is a 620-bed, urban, quaternary-care academic medical center in Aurora, CO, and carries a level II trauma center designation. Our study population included patients aged 65 years and older admitted with an acute fragility hip fracture between January 1, 2012, and March 31, 2016.

Intervention

Our comprehensive geriatric hip fracture program went live on October 29, 2014. It was designed to improve the fragmentation in care at our institution, namely: 1) a lack of a cohesive interprofessional team taking ownership of this patient population along the continuum of care and 2) a lack of standardized application of evidence-based care. Historically, geriatric patients with hip fractures could variably be admitted to the Orthopedic Surgery Service, with subspecialty consultation or hospitalist (nongeriatrician) comanagement if requested; to 1 of 8 general medicine teams...
if under age 75 years or to 1 of 2 acute care for the elderly teams if over age 75 years; to Family Medicine; or to subspecialty services. These services were staffed by rotating house staff, advanced practice practitioners, and attending physicians, which could include surgeons, hospitalists, general internists, geriatricians, family practitioners, or medical subspecialists.

In addition, geriatric patients with hip fractures could be admitted to numerous inpatient units. Each unit was staffed by different nurses, pharmacists, care managers, and social workers, and often by different physical and occupational therapists.

After discharge, geriatric patients with hip fractures could be cared for by practitioners at diverse skilled nursing facilities, inpatient rehabilitation facilities, or primary care clinics, either internal or external to our system.

This decentralized care model was accompanied by substantial variability in geriatric hip fracture care, including practitioner roles and expectations and the content, timing, and quality of the care itself. It also represented a barrier to process improvement, in that it was more difficult to design, implement, and iterate on standardized care pathways in the absence of a stable interprofessional team.

Our comprehensive geriatric hip fracture program therefore included the following key interventions: 1) admission of all ward-status patients to the Orthopedic Surgery Service with hospitalist comanagement; 2) geographic placement of patients with hip fractures on the Orthopedics Unit; and 3) use of standardized, evidence-based admission, preoperative, and postoperative electronic order sets. The order sets also included laboratory workup and pharmacologic treatment of osteoporosis and a streamlined workflow for discharge planning.

The primary outcomes of interest were: 1) mortality within 1 year of index admission and 2) overall survival based on available follow-up data.

**Statistical Analysis**

We did not perform an a priori power analysis because we believed that it was important to conduct our mortality analysis using the same study period as for our previous work, to be able to interpret our results in the context of our original process measures and short-term outcomes. Thus, patients with index admissions between January 1, 2012, and October 28, 2014, were included in the preintervention cohort and between October 29, 2014, and March 31, 2016, were included in the postintervention cohort.

Patient characteristics in the preintervention and postintervention cohorts were compared with a Student t-test for continuous variables (age, ASA score, total CCI score, and time to surgery) and the Fisher exact test for categorical variables (sex and fracture type).

Next, we investigated whether there were any time trends in mortality during either the preintervention or postintervention periods by fitting a segmented regression model. An analogous investigation on survival time was conducted by fitting a Cox proportional hazards model allowing the hazard to change over time for each of the preintervention and postintervention periods. In both these analyses, the time trends were insignificant (p > 0.19; data not presented), suggesting that a simpler pre-post analysis would be sufficient to evaluate intervention effects.

To assess whether mortality rates differed before and after intervention, a log-link binomial regression model was used. A Cox proportional hazards model was used to compare overall survival rates between the preintervention and postintervention cohorts, with data censored at the time of death or at the time of data extraction from the state health department. All models were adjusted for the following independent predictors of mortality: Age, sex, fracture type, ASA class, total CCI score, and time to surgery. Although other preoperative factors (eg, residence in an institution, prefracture mobility, cognitive impairment, abnormal...
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12-21 Descriptive statistics were used to compare the cause of death at 1 year between the preintervention and postintervention cohorts.

A 2-sided p value less than 0.05 was considered statistically significant. All data analyses were performed using R version 3.4.4 (R Project for Statistical Computing, Vienna, Austria).

RESULTS

We identified 243 index admissions among Colorado residents during the study period, including 135 before and 108 after program implementation. There was no difference in baseline patient characteristics between the 2 cohorts (Table 1).

The postintervention cohort had a lower unadjusted 1-year mortality rate compared with the preintervention cohort, although the difference did not reach statistical significance (15.7% vs 24.4%, p = 0.111).

The postintervention cohort also showed a nonsignificant but clinically important trend toward lower adjusted mortality at 1 year compared with the preintervention cohort (relative risk [RR] = 0.73, 95% confidence interval [CI] = 0.46–1.16, p = 0.18). Predictors of mortality at 1 year included age (RR = 1.05 per 1-year increase in age, 95% CI = 1.02–1.08, p = 0.001), male sex (RR = 1.80, 95% CI 1.28–2.51, p = 0.001), ASA class (RR = 1.70 per 1-point increase, 95% CI = 1.39–2.08, p < 0.0001), and CCI (RR = 1.13 per 1-point increase, 95% CI = 1.06–1.21, p < 0.0001).

The postintervention cohort had significantly higher overall survival than the preintervention cohort (hazard ratio for death = 0.43, 95% CI = 0.25–0.74, p = 0.002; Figure 1). Sensitivity analyses showed that statistical results were robust to different follow-up lengths.

The most common cause of death at 1 year in the study population was dementia (18.2% of the preintervention cohort and 17.6% of the postintervention cohort, respectively), followed by heart disease.

### Table 1. Patient characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Preintervention cohort</th>
<th>Postintervention cohort</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age, y (SD)</td>
<td>81.1 (9.1)</td>
<td>79.5 (7.9)</td>
<td>0.138</td>
</tr>
<tr>
<td>Female sex, no. (%)</td>
<td>95 (70.4)</td>
<td>67 (62.0)</td>
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<tr>
<td>Fracture type, no. (%)</td>
<td></td>
<td></td>
<td>0.218</td>
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<tr>
<td>Femoral neck</td>
<td>62 (45.9)</td>
<td>61 (56.5)</td>
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<tr>
<td>Intertrochanteric</td>
<td>66 (48.9)</td>
<td>42 (38.9)</td>
<td></td>
</tr>
<tr>
<td>Subtrochanteric/other</td>
<td>7 (5.2)</td>
<td>5 (4.6)</td>
<td></td>
</tr>
<tr>
<td>Mean ASA class (SD)</td>
<td>3.0 (0.6)</td>
<td>2.9 (0.6)</td>
<td>0.250</td>
</tr>
<tr>
<td>Mean CCI score (SD)</td>
<td>6.4 (2.5)</td>
<td>6.1 (2.3)</td>
<td>0.451</td>
</tr>
<tr>
<td>Comorbidities, no. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td>32 (23.7)</td>
<td>29 (26.9)</td>
<td></td>
</tr>
<tr>
<td>Liver disease</td>
<td>6 (4.4)</td>
<td>4 (3.7)</td>
<td></td>
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<tr>
<td>Solid tumor</td>
<td>32 (23.7)</td>
<td>18 (16.7)</td>
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<tr>
<td>AIDS</td>
<td>1 (0.7)</td>
<td>0 (0)</td>
<td></td>
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<tr>
<td>Renal disease, moderate to severe</td>
<td>3 (2.2)</td>
<td>8 (7.4)</td>
<td></td>
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<tr>
<td>Congestive heart failure</td>
<td>29 (21.5)</td>
<td>9 (8.3)</td>
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<tr>
<td>Myocardial infarction</td>
<td>31 (23.0)</td>
<td>29 (26.9)</td>
<td></td>
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<tr>
<td>Chronic pulmonary disease</td>
<td>26 (19.3)</td>
<td>30 (27.8)</td>
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<tr>
<td>Peripheral vascular disease</td>
<td>21 (15.6)</td>
<td>14 (13.0)</td>
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<tr>
<td>Cerebrovascular accident or TIA</td>
<td>27 (20.0)</td>
<td>22 (20.4)</td>
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<tr>
<td>Dementia</td>
<td>66 (48.9)</td>
<td>41 (38.0)</td>
<td></td>
</tr>
<tr>
<td>Hemiplegia</td>
<td>1 (0.7)</td>
<td>3 (2.8)</td>
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<tr>
<td>Connective tissue disease</td>
<td>5 (3.7)</td>
<td>8 (7.4)</td>
<td></td>
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<tr>
<td>Leukemia</td>
<td>2 (1.5)</td>
<td>3 (2.8)</td>
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<tr>
<td>Malignant lymphoma</td>
<td>3 (2.2)</td>
<td>1 (0.9)</td>
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<tr>
<td>Peptic ulcer disease</td>
<td>14 (10.4)</td>
<td>5 (4.6)</td>
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<tr>
<td>Mean time to surgery, h (SD)</td>
<td>29.6 (26.2)</td>
<td>27.1 (17.9)</td>
<td>0.389</td>
</tr>
</tbody>
</table>

ASA = American Society of Anesthesiologists; CCI = Charlson Comorbidity Index; SD = standard deviation; TIA = transient ischemic attack.

Figure 1. Overall survival for geriatric patients with hip fractures before and after intervention. CI = confidence interval; HR = hazard ratio (adjusted for age, sex, fracture type, American Society of Anesthesiologists class, Charlson Comorbidity Index, and time to surgery); post = postintervention; pre = preintervention.
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DISCUSSION

A comprehensive geriatric hip fracture program led to significant improvements in overall survival for geriatric patients with hip fractures. A population-based system redesign demonstrates the potential to drive improvements in patient-centric outcomes, in addition to providing inpatient operational efficiencies that decrease health care costs.

Our comprehensive geriatric hip fracture program may have contributed to improved overall survival through several mechanisms. The fragmentation in the inpatient care team decreased after implementation, with a higher percentage of patients on the Orthopedic Surgery Service and on the Orthopedics Unit. Our admission order set included items designed to minimize inpatient complications, such as delirium and urinary tract infections. The reduction in length of stay and improvements in outpatient follow-up may also have played a role. Our program also significantly improved the rate of calcium, vitamin D, and bisphosphonate prescribing at the time of discharge. Although we were unable to determine long-term medication adherence, osteoporosis therapy may be associated with a mortality benefit; the Health Outcomes and Reduced Incidence with Zoledronic Acid Once Yearly (HORIZON) Trial demonstrated a mortality benefit with intravenous zoledronic acid therapy compared with placebo at a median follow-up of only 1.9 years. It is less likely that the survival difference in our study was attributable to baseline differences in the preintervention and postintervention cohorts, given the adjustment for age, sex, fracture type, comorbidities, and time to surgery. In addition, there were no changes in surgical or anesthesia management during the study period.

Our study adds to a growing body of literature that orthogeriatric models of care improve outcomes, including long-term mortality. A meta-analysis by Grigoryan and colleagues showed that routine orthogeriatric collaboration improved 6- to 12-month mortality compared with standard care (ie, geriatric or hospitalist consultation on an as-needed basis), with an odds ratio of 0.83 (95% CI = 0.74-0.94). Another meta-analysis, by Moyet et al, found similar results. Our estimated reduction in 1-year mortality is consistent with findings from these studies, although our finding was not statistically significant, likely because of the modest size of our clinical population. Given the range of clinically important mortality reduction that remains plausible on the basis of this study’s findings, a study of our intervention in a larger patient population may be of value to obtain more precise estimates of the reduction that is possible with this approach to care. Results of our quality improvement initiative also demonstrate that the impact on survival for geriatric patients with hip fractures can extend beyond 12 months. Although the optimal orthogeriatric model (routine geriatric consultation on an orthopedic ward, routine orthopedic consultation on a geriatric ward, or shared comanagement on an orthogeriatric ward) remains unclear in the literature, our study lends further support to the comanagement care delivery system. Unfortunately, the prevalence of any orthogeriatric model of care in the US remains unknown.

Strategies that reduce fragmentation in geriatric hip fracture care are increasingly important. The osteoporosis care gap continues to widen, with declining rates of bone mineral density testing and use of bisphosphonates in patients with osteoporosis. Although the age-adjusted hip fracture rate for women aged 65 years and older steadily declined between 2002 and 2012, it has recently plateaued, resulting in 11,000 more hip fractures than previously projected between 2013 and 2015. The 1-year mortality rate for geriatric patients with hip fractures has also remained near 30% nationally. In 2016, the Centers for Medicare and Medicaid Services proposed the Surgical Hip and Femur Fracture Treatment episode payment model to encourage health systems to redesign care processes and improve quality and care coordination while reducing costs. This Medicare initiative had been slated to go into effect on January 1, 2018, but is now on hold, placing the onus back on clinicians to drive change in their local environments.

This study has some limitations. First, we were not able to include out-of-state residents in our mortality analysis because of the inability to access this data via the state health department or to reliably contact patients and families after discharge. However, this should not have affected the validity of our analysis of in-state residents. Second, we did not perform an a priori power analysis given the fixed size of our original study population; a follow-up study with a larger sample size would be of value. Third, we believe that we adjusted our analyses for the most important independent predictors of mortality but cannot rule out the possibility of confounding from other unmeasured variables. Fourth, because of the relatively small number of deaths, we were not able to draw meaningful conclusions about any differences in cause of death between the 2 cohorts. Fifth, because of multiple concurrent interventions, it was not possible to assess the impact of individual interventions on overall survival. Sixth, we also were not able to determine whether rates of inpatient complications such as delirium or urinary tract infections actually decreased from before to after intervention, because of confounding introduced by variability in evaluation or documentation practices between services and units. Finally, this was a single-center initiative, which limits generalization to other institutions.

CONCLUSION

Our comprehensive geriatric hip fracture program improved overall survival by targeting the fragmented system of care at our institution. Our experience may inform future efforts to improve the quality, safety, and efficiency of care for this vulnerable patient population.

Disclosure Statement

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

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Fixing a Fragmented System: Impact of a Comprehensive Geriatric Hip Fracture Program on Long-Term Mortality

Safety, and Efficiency in Aurora, CO, for their instruction and support. This study was presented in part at the American College of Physicians Internal Medicine Meeting 2018; April 19 to 21, 2018; New Orleans, LA; and at the Western Orthopaedic Association Annual Meeting; August 1 to 4, 2018; Snowmass, CO. Kathleen Louden, ELS, of Louden Health Communications performed a primary copy edit.

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References

The Alternative

Great age is not uniformly a benign experience; however, I am fully persuaded that it is much better than the alternative.

— John Kenneth Galbraith, 1908-2006, Canadian-born economist, public official, and diplomat
This photograph of a young bird was taken in Mr Allencherril’s backyard with a digital camera. Mr Allencherril is a fourth-year medical student at the University of Texas Medical Branch in Galveston. Photography has become a passion of his during the last several years. In college, he majored in film, photography, and chemistry.
ABSTRACT

The time it takes for clinical innovation and evidence-based practices to reach patients remains a major challenge for the health care sector. In 2015, the Veterans Health Administration (VHA) launched the Diffusion of Excellence Initiative aimed at aligning organizational resources with early-stage to midstage promising practices and innovations to replicate, scale, and eventually spread those with greatest potential for impact and positive outcomes. Using a 5-step systematic approach refined over time, frontline VHA staff have submitted more than 1676 practices since the initiative's inception, 47 of which have been selected as high-impact, Gold Status practices. These Gold Status practices have been replicated more than 412 times in Veterans Affairs hospitals across the country, improving care for more than 100,000 veterans and approximately $22.6 million in cost avoidance for the VHA. More importantly, practices such as Project HAPPEN (Hospital-Acquired Pneumonia Prevention by Engaging Nurses to complete oral care) and rapid availability of intranasal naloxone have saved veterans’ lives. Several practices are now being implemented across the country, and the Diffusion of Excellence Initiative is playing a pivotal role as the VHA works to modernize its health care system. This initiative serves as a promising model for other health care systems seeking to accelerate the spread and adoption of clinical innovation and evidence-based practices.

INTRODUCTION

The US health care environment is rapidly changing. Health care systems of all sizes struggle to balance consumerism with value-based care. Organizations that promote and facilitate a culture of learning alongside continuous improvement have emerged as leaders across this evolving landscape, but fostering continuous improvement is only part of the answer. Evidence-based best practices can take years to reach patients.1–4 Innovative solutions for everyday challenges are needed, and innovative approaches are also required to replicate and spread these solutions once they are identified.

Multiple factors contribute to a slow, widespread adoption of evidence-based clinical practices, including the complexity of the innovation, opportunity cost of change, limited resources, and lack of influential leadership or champions.3–6 In 2015, the Veterans Health Administration (VHA) launched the Diffusion of Excellence Initiative (hereafter referred to as Diffusion) to tackle these challenges and accelerate the spread and adoption of clinical innovation and promising practices across the VHA.

Steps of the Diffusion Process

Diffusion uses a 5-step, systematic process to identify, replicate, and eventually scale and spread practices with the greatest potential for positive impact (Figure 1).

Step 1: Identify Promising Practices

As summarized in Figure 2, the VHA hosts an annual, system-wide competition to identify promising administrative and clinical practices that have been previously implemented in 1 or more Department of Veterans Affairs (VA) locations. The competition invites all employees to submit innovations or practices that have demonstrated improvement in health care delivery or operational processes across priorities defined by VHA senior leadership.

As part of the application process, applicants report on key aspects of their practice, including evidence demonstrating their

Figure 1. Diffusion of Excellence Initiative’s Five-Step Process for Diffusing Promising Practices
practice's effectiveness against prior baseline data. Applications are reviewed by Diffusion staff to ensure they align with the competition's eligibility requirements. Subject matter experts (ie, frontline clinical and administrative staff with relevant experience) from across the VHA are then engaged in evaluating applications. Review criteria include factors such as the demonstrated value of the practice, replication feasibility, and alignment to VHA priorities (Table 1).

The review results in the selection of approximately 100 semi-finalists whose applications undergo evaluation by VHA program office leadership and, in the most recent competition, researchers from the VA Quality Enhancement Research Initiative (QUERI). The QUERI researchers rated the semifinalists on a scale of 1 to 5 using a standardized assessment tool based on clinical soundness, potential for impact, and feasibility of implementation in the VHA. On the basis of the rankings and evaluation responses from program office leadership, VHA leaders select approximately 20 finalist practices to advance in the competition.

**Step 2: Find the Champions: Selecting Gold Status Practices**

Finalists pitch their practices during a live, virtual “Shark Tank”-style competition. VA Medical Center (VAMC) and Veterans Integrated Service Network “sharks” bid resources and compete for a chance to have a select practice replicated at their site through 6 months of facilitated implementation. To prepare their bids, “sharks” reference 90-second pitch videos, a summary grid comparing key practice attributes, practice applications, and 90-second, live-competition presentations. Bids might include staff, funding for equipment, capital investments, or facility space. Additionally, “sharks” must demonstrate their facilities' need for the practice through quality or operational data. For instance, a facility whose heart failure readmission rate is 1 standard deviation higher (ie, worse) than the national average would describe this when bidding 2 full-time equivalents to assist with implementing a practice aimed at reducing the readmission rate for patients with heart failure.

After the “Shark Tank”-style competition, a governance board composed of national VHA leaders, including the VA Under Secretary for Health, Deputy Under Secretaries for Health, and senior representatives of operational, quality, and research offices, select practices and “sharks” as winners of the competition. Practices selected for further implementation through the “Shark Tank” are termed Gold Status practices. Each Gold Status practice is paired with 1 to 3 sites, referred to as implementing facilities, which are the sites with winning bids. The selection of implementing facilities is based on the strength of the “shark’s” bid and the demonstrated need for the practice, aiming to optimize the alignment of organizational resources with the hope of achieving maximum return on investment.

**Step 3: Adapt and Replicate Gold Status Practices**

Diffusion provides extensive facilitated support for the implementation of Gold Status practices whereas the implementing facilities ensure executive-level buy-in and resource support. Creators of the Gold Status practices, referred to as Gold Status fellows, serve as the de facto quarterback for the spread of their practice. They assist the implementing facilities by describing the history of the practice, lessons learned, and components of the practice that might be different at new facilities (eg, the type of staff members involved). Most importantly, Gold Status fellows help define core components of their practice. Implementing sites select an implementing facility fellow to oversee the replication at their site. Either VAMC or Veterans Integrated Service Network's Directors are given guidance on the selection of implementing facility fellows, including their professional expertise in the relevant practice topic, passion for the practice, and tenure at the facility.
The Gold Status and implementing facility fellows come together during a 3-day face-to-face workshop aimed at introducing employees to the constructs of implementation science, quality improvement, practical guidance on leadership principles, and marketing and communications. The workshop is referred to as the Diffusion Base Camp.

Additionally, each practice is paired with program management support leaders and an implementation scientist to complete the implementation team. The Program Management Leader receives support from an external consulting team. The support team arranges weekly implementation meetings (including additional members from implementing facilities), helps track project milestones, identifies individuals in the VA Central Office who can help address barriers to implementation, and helps develop materials to encourage implementations (eg, handbooks with practice procedures and promotional materials).

The implementation scientists represent 1 of 8 implementation hubs sponsored by the VA QUERI, which is a nationwide office for connecting implementation researchers with VA operations. In addition to an Evidence Synthesis Program, QUERI consists of 15 large programs that develop and test strategies for implementation, 15 highly partnered evaluation initiatives that use implementation science to address high-priority programmatic needs of the VHA, and 2 resource centers that offer expertise in evaluation methods and use of VA data resources. The QUERI Implementation hubs offer the Diffusion teams expertise on evidence-based strategies for implementing new programs and for direct measurement of the impact of Gold Status practice replication.

Implementation teams spend most of the 2 and a half days at Base Camp discussing and learning practice components, outlining goals for implementing the practice in new facilities, and creating initial implementation plans. The teams carefully consider how to adapt a practice at a new site without losing the practice’s core components. Implementation plans consist of a timeline and milestones for implementation, stakeholders to involve in the implementation, specific practice components that must be in place, strategies for implementation, measures of success, and

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<th>Table 1. “Shark Tank” evaluation criteria</th>
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<td><strong>Criteria</strong></td>
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<td>VHA “Shark Tank” priority impact</td>
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<td>Alignment to VHA policies and processes</td>
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<td>Alignment to VHA priorities</td>
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VHA = Veterans Health Administration.
mitigation strategies for potential risks. Teams conclude the Diffusion Base Camp by presenting their practice implementation plan to a panel of subject matter experts and former Gold Status fellows. After the presentation, practices proceed with a 6-month facilitated implementation. During implementation, teams are guided by these implementation plans, with a strong emphasis placed on ensuring local adaptation and customization while maintaining the original practice’s fidelity.

Step 4: Measure Real-World Impact

The 6-month facilitated replication period provides a valuable opportunity for real-time evaluation and assessment of practice replication while providing support to the implementation teams to optimize success. During the 6 months, project management support leads document barriers and assist in developing risk mitigation strategies during weekly implementation team huddles and project status calls. This information is used to develop a sense of a practice’s ease of replication. Cost of implementation is also assessed throughout the replication phase, for instance, assessing whether the proposed “bid” from a winning facility (ie, 2 full-time equivalents) is the optimal allocation of resources to replicate a select practice. Implementation teams often find that improvements in workflows or leveraging technology can aid in the replication of a practice while reducing required resources.

Implementation teams may also identify lacking health system protocols, clear policies, directives, or standard operating procedures for a specific practice. This information often informs senior leadership about challenges and opportunities to scale larger efforts across the enterprise. In turn, new policies or directives can clear the way for further replication of a practice. The QUERI representatives offer expertise to implementation teams in evaluation measurement and use of key data sources to track potential success. This, perhaps, is one of the most essential aspects to conducting a well-facilitated replication phase because it ensures sound measurement of a practice’s impact and the ability to determine future impact. For example, Project VIONE (Vital, Important, Optional, Not indicated, and Every medication has a specific indication for use), a medication management optimization practice, is leveraging structured query language and other advanced analytics to communicate with the VA’s corporate data warehouse to pull structured data files to develop cost avoidance and impact metrics (eg, costs of medications, number of medications used). This method ensures a unified and consistent approach from site to site and allows for sound estimates of the real-world impact should this practice be implemented at each VA site.

Step 5: Scale and Spread High-Impact, Gold Status Practices

After practices are adapted and replicated at additional sites, practices fall into 4 potential categories for implementation: 1) being packaged for potential organic implementation by other VA facilities; 2) partnering with VA program offices that take the operational lead on implementation in partnership with Diffusion; 3) nationwide implementation and standardization with support of Diffusion; or 4) a decision to discontinue implementation. Practices are selected for inclusion in these groups on the basis of factors such as availability of outcome metrics, the degree of enterprise-wide need, complexity of implementation, and projected impact.

Given limitations to provide staff and programmatic support to diffuse each Gold Status practice, Diffusion works to make information about these practices available to VA facilities that may wish to adopt the practices to address similar challenges without specific assistance from centralized resources (termed “organic implementation”). Projects are packaged for potential grassroots implementation by other VA facilities and include an implementation guide, clinician- and patient-facing information and marketing materials (eg, brochures), and contact information for new sites to access practice support networks. Examples of projects targeted for organic diffusion include Chaplain Groups for Veterans with Moral Injury, a practice that helps veterans embrace the concept of forgiveness of self and others, and Unit Tracking Board, a practice that uses a physical poster board in inpatient units to present clinical outcome data to staff and veterans. To date, projects have been promoted by traditional means, such as email newsletters, national call forums, and word of mouth. Diffusion is currently developing a Diffusion Marketplace that will provide a digital forum similar to Amazon to enable search and discovery of innovative clinical practices. The Marketplace is scheduled to launch internally to all VA employees in summer 2019, and subsequently implement new capabilities and enhancements of user experiences after the launch.

A subset of projects cooperates with a specific VA program office in the VA Central Office. The VA program offices provide subject matter expertise, develop policy, lead innovative efforts, spread best practices, and provide operational oversight of specific clinical and administrative aspects of the VHA. The program offices might decide to partner with Diffusion to spread key aspects of Gold Status practices that align with their respective goals. For example, the VA Mental Health and Chaplaincy Program (part of the VA Office of Mental Health and Suicide Prevention) is partnering with Diffusion to help spread key aspects of 2 former Gold Status practices: Treatment groups focused on addressing the needs of veterans facing challenges relating to feelings of guilt or life purpose (termed moral injury) and partnering with community faith-based organizations to spread awareness of VA suicide prevention efforts. As part of the evolution of this partnership, these program offices are partnering with Diffusion and VA health services researchers to hold a summit that initiates a Dynamic Diffusion Network that will allow for rapid evolution of the Gold Status practice components while measuring and reporting on the impact of the evaluation.

A small subset of practices is selected for nationwide implementation. After each cycle of facilitated implementation (generally annually), the full Gold Status practice portfolio is reviewed and scored on the basis of veteran and health system impact, level of national stakeholder endorsement, ease of implementation, cost-effectiveness, and alignment with departmental priorities. Final endorsement of a practice for national diffusion is determined by VHA leadership. The Diffusion team works to develop national implementation plans that detail the appropriate natural
market within the VA for the practice and the steps needed to more widely roll out the practice to those sites. Similar to the initial facilitated replication, local practice champions are identified at each facility to be accountable for the successful implementation of the practice and to work with their teams to adapt the practice as needed to fit the unique needs of the veterans and/or facility staff.

The decision is sometimes made to discontinue implementation efforts for a select practice for a myriad of reasons. One Gold Status practice used a computer macro to optimize ordering and processing of home oxygen. However, during the replication phase it was discovered that updates to the Veterans Information Systems and Technology Architecture resulted in the need to update the macro code at each site. Considering electronic health record modernization efforts, the level of effort required to maintain this practice was not believed to be practical.

**CURRENT STATUS AND ONGOING EVALUATION**

Since its launch in 2015, the Diffusion has received 1676 submissions of employee-designed promising practices across 4 rounds of competition. Forty-seven practices have been selected as high-impact, Gold Status practices. Table 2 provides a

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<tr>
<th>Practice name</th>
<th>Practice summary</th>
<th>Gold Status VISN/facility</th>
<th>Brief description</th>
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<tr>
<td>Hospital-Acquired Pneumonia Prevention by Engaging Nurses to complete oral care (Project HAPPEN)</td>
<td>This program trains clergy and their congregations to identify and refer at-risk veterans and service members to VA care. Trainees can refer by way of the Veterans Crisis Line and related resources, including local community-based outpatient clinics and other VA facilities.</td>
<td>Gold Status VISN/facility: VISN 2, Albany VAMC: Samuel S Stratton (Albany, NY)</td>
<td>Practice summary: This practice displays a physical poster board on inpatient care units to present clinical outcome data to staff and veterans. It is an easy-to-read, low-cost, customizable tool that drives transparency and performance improvement.</td>
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<td>Chaplain Groups for Veterans with Moral Injury</td>
<td>Chaplains use 2 types of group visits for veterans diagnosed with posttraumatic stress disorder and those struggling with service-connected moral injury. The first group is spiritually based and accessible without an appointment. The second group is a closed group with a higher level of commitment for veterans to engage in spiritual and psychological interventions to combat lingering guilt and shame.</td>
<td>Gold Status facility: South Texas VHCS (San Antonio, TX)</td>
<td>Implementing facility: W G (Bill) Hefner VAMC (Salisbury, NC)</td>
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<td>Unit Tracking Board</td>
<td>The use of multiple medications may be appropriate and necessary in some cases to optimize medical conditions or quality of life. However, polypharmacy can potentially expose patients to the risk of serious consequences because of age-related changes in pharmacokinetics and pharmacodynamics. VIONE (Vital, Important, Optional, Not indicated, and Every medication has a specific indication for use) is a model for clinical pharmacists to review each patient’s medication profile to identify appropriate medications to deprescribe. VIONE’s focus is on reducing drug cost waste while avoiding any adverse events. Polyprescription elimination also reduces health risks and mental impairment for veterans.</td>
<td>Gold Status VISN/facility: VISN 16, Central Arkansas Veterans HCS Eugene J Towbin Healthcare Center (Little Rock, AR)</td>
<td>Practice summary: The use of multiple medications may be appropriate and necessary in some cases to optimize medical conditions or quality of life. However, polypharmacy can potentially expose patients to the risk of serious consequences because of age-related changes in pharmacokinetics and pharmacodynamics. VIONE (Vital, Important, Optional, Not indicated, and Every medication has a specific indication for use) is a model for clinical pharmacists to review each patient’s medication profile to identify appropriate medications to deprescribe. VIONE’s focus is on reducing drug cost waste while avoiding any adverse events. Polyprescription elimination also reduces health risks and mental impairment for veterans.</td>
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<tr>
<td>VIONE—An innovative deprescribing approach to medication management</td>
<td>Prosthetic and Sensory Aids Service’s workload outpaces VHA growth every year by 5% or more. An analysis of 8 sites’ workload and staffing during the past 5 years identified a 40% increase in administrative workload, but only a 9% increase in staff. Approximately 37% of the workload consists of repetitive tasks. The average home oxygen bill is 200 pages long and contains 1500 line items. Iowa City VA HCS automated the home oxygen billing process by integrating Microsoft Excel (Redmond, WA) and VistA. Staff no longer need to print the bill and complete lengthy reviews to uncover incorrect entries when using this macro workbook. This eliminates a significant part of repetitive administrative tasks and allows employees to improve access elsewhere in prosthetics.</td>
<td>Gold Status VISN/facility: VISN 23, Iowa City VA HCS (Iowa City, IA)</td>
<td>Practice summary: Prosthetic and Sensory Aids Service’s workload outpaces VHA growth every year by 5% or more. An analysis of 8 sites’ workload and staffing during the past 5 years identified a 40% increase in administrative workload, but only a 9% increase in staff. Approximately 37% of the workload consists of repetitive tasks. The average home oxygen bill is 200 pages long and contains 1500 line items. Iowa City VA HCS automated the home oxygen billing process by integrating Microsoft Excel (Redmond, WA) and VistA. Staff no longer need to print the bill and complete lengthy reviews to uncover incorrect entries when using this macro workbook. This eliminates a significant part of repetitive administrative tasks and allows employees to improve access elsewhere in prosthetics.</td>
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HCS = Health Care System; VA = Veterans Administration; VAMC = Veterans Administration Medical Center; VHA = Veterans Health Administration; VHCS = Veterans Health Care System; VISN = Veterans Integrated Service Network; VistA = Veterans Information Systems and Technology Architecture; VON = Veterans Integrated Service Network; VSON = Veterans Information Systems and Technology Architecture.
summary of 6 sample Gold Status practices identified through or supported by Diffusion.

Gold Status practices have been replicated 412 times in VHA facilities across the country, affecting more than 100,000 veterans and producing more than $22.6 million in cost avoidance for VHA. These figures were calculated on the basis of locally collected data on metrics relating to the number of veterans and/or employees affected and projected cost avoidance. Because the nature of practices varied, not all practices reported on each metric.

Several practices are spreading nationally on the basis of projected impact across the health system. For example, Project HAPPEN, a practice encouraging the use of oral care to reduce pneumonia, facilitated a decreased incidence rate of nonventilator, hospital-acquired pneumonia (NV-HP) from 105 cases to 8.3 cases per 1000 patient-days, as of October 2018, resulting in an estimated 13 lives saved and $2.8 million in cost avoidance (assuming each avoided case of NV-HAP saves VA approximately $40,000). In addition, Project HAPPEN continues to grow and impact more veterans.

In the spirit of continuous quality improvement, Diffusion has partnered with a multidisciplinary team of QUERI investigators to carry out a mixed-methods evaluation of Diffusion, anchored by implementation science theory and frameworks. Resulting from the VA’s rigorous peer-reviewed grant process, the evaluation is titled, Spreading Healthcare Access, Activities, Research, and Knowledge (SHAARK) QUERI Partnered Evaluation Initiative (PEI).

The SHAARK PEI seeks to better understand 1) the process used by VA facilities and individual staff members to make decisions about participation in Diffusion; 2) criteria used by facilities when deciding whether to adopt promising practices and interventions (eg, bid on a potential Gold Status practice); 3) barriers and facilitators to implementing practices in new settings; and 4) factors that influence the adoption of practices across the VHA. Guided by implementation science frameworks and theories including the Consolidated Framework for Implementation Research, and the Theory of Organizational Readiness for Change, the Theory of Organizational Readiness for Change, and the Theory of Diffusion of Innovation, this ongoing evaluation uses a variety of methods to assess the diffusion process, including interviews, virtual focus groups, structured event observations of Diffusion Summits, surveys of “sharks,” and secondary data analysis (eg, practice spread, VA organizational characteristics).

To date, the SHAARK team has conducted 110 semistructured interviews with Gold Status fellows, implementing fellows, additional implementation team members working with the implementing fellows, and individuals who facilitate implementation. These interviews have provided insight into the reasons for developing Gold Status practices, the process of taking a practice though the Diffusion “Shark Tank” competition and facilitated implementation, and how and why facilities decided to bid on the practice and subsequently implement it. The evaluation also provides an in-depth understanding of practice features that might affect initial implementation and spread. For example, Diffusion was designed to identify potential best practices developed by frontline leaders and staff who are intrinsically motivated by a desire to improve care and/or stakeholder experience to implement promising practices in their facility. However, intrinsic motivation for developing new best practices might not transfer from the Gold Status fellows to those implementing the innovation/practice in new settings. It is important for key staff members to recognize the need to implement a practice. Furthermore, the practice must be compatible with existing workflows and have enough resources (eg, dedicated time and space).

In facilities attempting to replicate Gold Status practices where leaders do not engage staff early in their bidding process, resistance to implementation might be introduced. Implementation might be completed through the persistence and hard work of implementing facility fellows, with extrinsic motivation supplied by highly publicized national Diffusion events, and with the aid of strong, external facilitation; however, sustainability might be undermined in these instances, underscoring the importance of early engagement of all key stakeholders.

Finally, early observations indicate that practices with the widest spread have had longer exposure to Diffusion, a concretely defined tool, a clear national VA leadership expectation for implementation, and/or high-priority VA goals. Upcoming in-depth evaluations of Gold Status practices selected for national rollout will offer a deeper look at implementation challenges as well as outcomes (eg, clinical, cost).

**DISCUSSION**

In the largest, fully integrated delivery system in the US, VA frontline employees at more than 1000 sites of care regularly identify opportunities for improvement and develop solutions to address challenges. Diffusion raises awareness of successful innovations across VA facilities and allows for enhanced organizational learning concerning how to improve clinical and administrative processes. It serves as a promising model for other health care systems seeking to accelerate the spread and adoption of clinical innovation and evidenced-based practices. Although not every process or step outlined in the methods will be applicable or relevant, there are foundational concepts that have been vital in our success. These concepts are discussed here.

**Empower and Invest in the Front Line**

Diffusion takes the approach that frontline employees are the most familiar with the VHAs challenges and thus best positioned to solve them. Diffusion empowers and invests in frontline staff to drive the spread and adoption from the bottom up through customized training, financial support, and a collaborative network of peers. This approach is in stark contrast to top-down strategies, which often force adoption yet rarely succeed in achieving sustained utilization. Focusing on scaling innovation and promising practices from the bottom up also allows necessary adaptation and customization of practices and innovations. This, in turn, improves compatibility of innovations and practices from service line to service line or hospital to hospital, increasing rates of adoption.

**Stay Agile**

Hospitals and health systems are complex organizations composed of diverse groups and teams of professionals from various disciplines. Continuously evolving to meet the needs of
the organization, leadership, and frontline staff has been vital to ongoing support and participation in Diffusion. To continuously adapt and refine the Diffusion model, we have relied on rapid assessments of qualitative research to inform programmatic changes and improvements. Additionally, the Diffusion model remains “objective” to the types of innovations or practices that move through the process. This flexibility enables the initiative to support continuous innovation and progress at the VHA while maintaining a focus on helping the agency serve veterans.

**Mission-Driven Innovation**

New leadership and evolving priorities require hospitals and networks to quickly shift focus from 1 issue to the next. This constant cycle of change can lead to fatigue, resistance to new ideas, and a survival mentality that promotes adherence to the status quo. Additionally, frontline staff’s commitment to innovation efforts are often collateral, with little short-term gain or realization of their efforts. Diffusion focuses on the reasoning behind innovation in the VHA, creating a narrative that frontline innovation and best practices are changing and saving the lives of veterans across the country. In turn, the program challenges everyone to question why they are innovators and who they innovate for—the veteran. Diffusion’s mission is to improve the lives of veterans by positioning and empowering the frontline to advance the agency’s larger mission of serving and caring for our nation’s veterans. Participants in Diffusion have taken hold of this mission and created their own narratives, telling their personal stories of why they innovate in the VHA and the impact it is having on them and the veterans they serve.

**Be Strategic in Diffusion**

The matchmaking that occurs between Gold Status practices and implementing facilities has several important applications. The organization can provide outside, intensive facilitated support for the replication of promising practices at sites where there is a clear need for improvement. Concurrently, the commitment of resources upfront by leadership at implementing medical centers or networks provides leadership support, buy-in, and an eventual expectation for a return on investment. The facilitated implementation cycle allows for detailed evaluation of practices as they are replicated in settings other than their original environment to determine the best next step for these practices. Organizations must commit to the idea that not all best practices and innovations are created equal and thus not all should be scaled. Additionally, understanding challenges and barriers during guided replication helps the organization define a natural market for practice scale, following Rogers’ diffusion curve.11

**Foster a Culture of Innovation**

Diffusion provides a sustainable, established platform and process for engaging groups at all levels. Increasing opportunities for VHA employees to drive continuous improvement at the facility level is resulting in increased employee empowerment and engagement to solve challenges facing the VHA, demonstrated by the outpouring of participation in the Diffusion programs. This buy-in from employees at all levels is a key element to making any innovation successful, and Diffusion provides a pathway to foster multilevel stakeholder engagement across individual facilities and the VHA system.1113 Generating solutions internally from frontline employees has the 2-fold benefit of engaging key stakeholder groups across the VA enterprise, including executive leadership and onsite employees, and ensuring that the VA remains competitive and current in its practices and care offered to veterans. Finally, the organization generates excitement through the “Shark Tank” competition, raising awareness on the importance of innovation, and celebrates small wins that have the potential for major impact. Acknowledging the attempt by employees to solve a challenge is as important as celebrating those whose practices are selected for national diffusion.

**Limitations, Challenges, and Opportunities for Diffusion**

During the course of Diffusion, the program has evolved to address observed challenges including balancing needed evidence with the need to quickly move innovation into the field. The extensive evaluation of Diffusion is designed in large part to help us learn more about this balance. We have also added new tools to help the VA facility and region directors work with their teams to make decisions about the adoption of practices. Innovation and implementation often require multiple people with complementary skill sets; there is a need to clarify roles and skills within this process. Finally, there is a need to build implementation and evaluation skills. Diffusion and the QUERI, which focuses on implementation science and evaluation, have partnered to infuse the concepts of implementation science into the selection of promising practices, evaluation of the VAs Innovation Ecosystem, and moving practices into the health care system.

**CONCLUSION**

To help foster a culture of learning and innovation, the VHA is using the Diffusion framework to identify promising grassroots solutions and then scale and spread them systemwide. By engaging frontline VHA personnel, Diffusion is empowering employees and harnessing their ingenuity to generate ideas that can be easily implemented, replicated, and evaluated with actionable outcomes at facilities across the nation. Diffusion is thus providing invaluable benefits to veterans and ultimately transforming the health care system.

**Disclosure Statement**

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

**Acknowledgments**

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**How to Cite this Article**

References


Influential Obstacle

Psychology is now able to tell us with reasonable assurance that the most influential obstacle to freedom of thought and its new ideas is fear; and fear which can with inimitable art disguise itself as caution, or sanity, or reasoned skepticism, or on occasion even as courage.

— Wilfred Batten Lewis Trotter, FRS, 1872-1939,
English surgeon and pioneer in neurosurgery
Association of Type and Frequency of Postsurgery Care with Revision Surgery after Total Joint Replacement

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ABSTRACT

Context: Postmarket surveillance is limited in the ability to detect medical device problems. Electronic health records can provide real-time information that might help with device surveillance. Specifically, the frequency of postsurgery care might indicate early problems and determine high-risk patients requiring more active surveillance.

Objective: To evaluate whether intensity of postsurgery care is associated with revision risk after total joint arthroplasty (TJA).

Design: Using an integrated health care system’s TJA registry, we identified primary TJA performed between April 2001 and July 2013 (22,953 knees and 9904 hips). Survival analyses evaluated the frequency of specific types of outpatient and inpatient utilization 0 to 90 days postoperatively and revision risk.

Main Outcome Measures: Revision surgery occurring at least 6 months after primary TJA.

Results: Knee arthroplasty recipients with 3 or more outpatient orthopedic allied health/nurse visits within 90 days had a 2.2 times (95% confidence interval [CI] = 1.6-2.9) higher risk of revision within the first 2 years postoperatively and 10.1 times higher risk (95% CI = 7.6-13.3) after 2 years. Compared with hip arthroplasty recipients who had 0 to 3 visits, patients with 6 or more outpatient orthopedic office visits within 90 days had a 15.7 times (95% CI = 5.7-42.9) higher risk of revision. Similar results were observed for 91-day to 180-day visits.

Conclusion: Future studies are needed to determine if more specific data on reasons for the higher frequency of outpatient visits can refine these findings and elicit more specific recommendations for TJA devices.

INTRODUCTION

More than 600 orthopedic implantable medical devices are approved by the US Food and Drug Administration (FDA) for use each year.1,2 Most total joint arthroplasty (TJA) devices are released into the market through the 510(k) process, which typically relies on the substantial equivalence of the device to an existing approved medical device or predicate.3 As a result, new devices can be approved on the basis of “substantial equivalence” as opposed to safety and effectiveness. The Depuy ASR hip replacement recall (DepuySynthes, Warsaw, IN)4,5 demonstrates the potential impact of devices approved on the basis of being substantially equivalent as opposed to new clinical evidence of safety and effectiveness. A minority of devices are evaluated through the FDA Pre-Market Approval process.6 However, clinical data are not routinely required, and those applications requiring a clinical trial are often limited because of strict patient inclusion and exclusion criteria, limited surgeon and center exposure, and lack of longitudinal follow-up. The FDA uses a number of postmarket tools to continue monitoring medical devices, including passive adverse event reporting, mandated postapproval studies, and postmarket surveillance studies.7 These, too, have limited value in detection of medical device problems.8 Recognizing the need for more evidence of medical device performance for evaluation of safety and effectiveness and for decision making, the FDA has spearheaded the development of the National Evaluation System for health Technology (NEST) and promoted the use of real-world evidence from registries and other electronic health information collected as part of routine clinical care.9,10 Part of this includes efficient and coordinated collection of robust data using existing infrastructure to promote medical device safety, effectiveness, and quality.9,10

National TJA registries provide a method for postmarket surveillance using real-world data and have played a critical role in the detection of medical device failures such as the ASR.11 Still, owing to the lag that can occur with data capture and validation, registries are better suited for evaluation of long-term outcomes rather than contemporary surveillance. Instead, the electronic health record (EHR) has been proposed as a tool for public health surveillance.12 The EHR can provide a wide range of real-time electronic health information, which might also allow for more timely surveillance of failures after TJA.

An EHR has the capability of collecting patient health care utilization information, including postsurgical care. Identification of postoperative service utilization is a potentially new area of early identification of TJA failures. The frequency of postsurgery care might be an indicator of early problems after the procedure that could be used as a real-time proxy indicator to help screen high-risk patients who require more active surveillance. Therefore, in a proof-of-concept study, we sought to determine whether the intensity of postsurgery care, as identified through inpatient and outpatient visits during the first 6-month postoperative period, is associated with a higher risk of TJA revision surgery.

METHODS

Study Design, Data Sources, and Study Sample

A cohort study was conducted using Kaiser Permanente’s (KP) Total Joint Replacement Registry (TJRR). KP covers 12.3 million patients in 8 geographical Regions,13 and all TJA procedures

Keywords: inpatient visit, outpatient visit, revision surgery, surveillance, total hip arthroplasty, total knee arthroplasty

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Association of Type and Frequency of Postsurgery Care with Revision Surgery after Total Joint Replacement

Exposure of Interest

Frequency and type of postsurgery care in the health care system during the first 6 months after the TJA was the exposure of interest in this study. There are 2 main categories of utilization recorded in the integrated health care system’s EHR: Outpatient and inpatient-related admissions and visits. Outpatient utilization occurs outside the hospital, whereas inpatient (inpatient) utilization was hospital related. Eight specific types of outpatient care tracked by the EHR were evaluated: Office visit, orthopedic allied health/nurse visit, orthopedic office visit, family practice visit, internal medicine visit, urgent care, occupational medicine/physical therapy, and hospital encounter. Orthopedic office visits are scheduled with orthopedic specialty practitioners, whereas office visits are with nonorthopedic specialty practitioners such as family medicine, primary care, and pain management. Nine specific types of inpatient care tracked by the EHR were evaluated, including hospital admission with surgery, hospital ambulatory surgery, charge router-automated hospital accounting records, Emergency Department (ED) visit, home health, inpatient, observation, outpatient procedure, and outpatient in the hospital. Information about inpatient utilization was first introduced to the registry data collection algorithm in late 2005, then reached full coverage in late 2006; to minimize selection bias and the impact of missing data, inpatient postsurgery care evaluation included primary TJA performed from January 2007 onward. To determine whether the timing of postsurgery care was also important to detect early failures, we evaluated utilization within 1 to 90 days and 91 to 180 days postoperatively separately.

The frequency of postsurgical care was first evaluated as intervals of varying length determined by sample quintiles and histograms of their frequencies. For each postsurgery care type, the decision to evaluate the variable categorically or continuously was based on log-likelihood ratio test, convergence of the model, and proportional hazards property in a crude Cox proportional hazards model. For TKA, categorical variables were chosen for office visits and orthopedic allied health/nurse visits, with the categories of 0 to 2 and 3 or more; for occupational medicine/physiological therapy visits, 0 to 3 and 4 or more; hospital encounter and urgent care, yes or no; family practice visits, 0 to 1 and 2 or more; internal medicine visits, 0 to 1, 2 to 3, and 4 or more. The remaining postsurgery care types were evaluated as continuous variables.

For THA, categorical variables were chosen for office visits and orthopedic office visits, and the categories used were 0 to 3, 4 to 5, and 6 or more; for occupational medicine/physical therapy, 0 to 2, 3 to 8, and 9 or more; hospital encounter, urgent care, internal medicine visits, ED visits, and inpatient, yes or no; family practice visits, 0 to 2, 3 to 6, and 7 or more; and orthopedic allied health/nurse visits, 0 to 2 and 3 or more. The remaining postsurgery care type were evaluated as continuous variables. For categorical variables, the reference level was the interval that included 0.

Outcome of Interest

Revision surgery occurring at least 6 months after the primary TJA was the outcome of interest in this study. Revisions occurring before 6 months (180 days) were excluded. Revision was defined as any reoperation after the index procedure in which an implant was exchanged. Revision operations were prospectively captured and adjudicated by the TJRR.

Covariates

Patient covariates included in our analyses were sex (men vs women), age (≥ 55 vs < 55 years), race (white vs other), and body mass index (BMI; kg/m²). Statistical methods included descriptive analysis, bivariate analysis, multivariable analyses using Cox proportional hazards regression, and sensitivity analysis. Cox regression was appropriate for survival analysis of time to revision surgery (right-censored) and had the advantage of adjusting for time-varying covariates. Bivariate and multivariable analyses were conducted separately by procedure (THA or TKA). Table 1. Characteristics of patients undergoing primary total joint arthroplasty for encounter analysis, 2001-2013

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Knee replacement</th>
<th>Hip replacement</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Revised (n = 9904)</td>
<td>Total (N = 22,953)</td>
</tr>
<tr>
<td>Men</td>
<td>4073 (14.1)</td>
<td>8384 (36.4)</td>
</tr>
<tr>
<td>Age ≥ 55 y</td>
<td>20,979 (91.4)</td>
<td>30-34</td>
</tr>
<tr>
<td>White race</td>
<td>13,603 (59.3)</td>
<td>283 (57.4)</td>
</tr>
<tr>
<td>Body mass index, kg/m²</td>
<td>10,130 (44.1)</td>
<td>&lt; 30</td>
</tr>
<tr>
<td></td>
<td>7035 (30.6)</td>
<td>30-34</td>
</tr>
<tr>
<td></td>
<td>5676 (24.7)</td>
<td>≥ 35</td>
</tr>
</tbody>
</table>

*Data are number (%). Missing data are as follows: Knee: Race (n = 102, 0.4%), body mass index (n = 112, 0.5%); Hip: Race (n = 41, 0.4%), body mass index (n = 46, 0.5%).
body mass index (BMI, 30–34 or ≥ 35 vs < 30 kg/m²), and comorbidities. Diabetes was identified by linking the TJRR to the KP diabetes registry; all other comorbidities were identified using the Elixhauser Comorbidity Index.²⁷

**Statistical Analysis**

All analyses were procedure specific (THA and TKA). Means, standard deviations, frequencies, medians, and interquartile ranges were used to describe the study sample. Cox proportional hazards models were used to evaluate the association between different postsurgical care types and revision after the primary procedure. Proportional hazards assumptions were tested using log(-log) curves and a Kolmogorov–Smirnov test. If proportional hazards assumptions were not met, a time-dependent covariate created by an interaction between a predictor and a function of the study time was included in the model. All models adjusted for covariates. Hazard ratios (HR) and 95% confidence intervals (CI) are presented, as are p values according to the Wald χ² test. Follow-up time was defined as the difference between the primary TJA date and the date of the revision, membership termination from the integrated health care system, death, or the end date of the study period (December 31, 2013), whichever came first. Patients with membership termination or death were censored from our analysis using their date of last follow-up. An α of 0.05 was used as the threshold for statistical significance for individual tests. Postsurgery care data were analyzed using R version 3.1.2 software (R Foundation).

**RESULTS**

There were 22,953 TKA and 9904 THA procedures conducted during our study timeframe (Table 1). The TKA cohort consisted of 8348 men (36.4%); 20,979 patients (91.4%) were age 55 years or older; 13,603 (59.3%) were white; and 10,130 (44.1%) had a BMI less than 30 kg/m². The crude overall incidence of revision after TKA during the study period was 2.1% (n = 493). The THA cohort consisted of 4073 men (41.1%), 8269 patients (83.5%) were age 55 years or older, 6925 (69.9%) were white, and 5839 (59.0%) had a BMI less than 30 kg/m². The crude incidence of revision was 1.3% (n = 133) in the THA recipients.

The 4 most frequent outpatient utilization types after TKA were orthopedic office visit, occupational medicine/physical therapy, office visit, and family practice visit in the first 180 postoperative days. Orthopedic office visit, office visit, and family practice visit were the most common outpatient utilization after THA. Table 2 provides details of outpatient

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### Table 2. Number of outpatient encounters by total joint arthroplasty postoperative time period and revision status, April 2001 to July 2013

<table>
<thead>
<tr>
<th>Encounter type†</th>
<th>Quarter 1 (1-90 d)</th>
<th>Quarter 2 (91-180 d)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number (%)</td>
<td>Total visits</td>
</tr>
<tr>
<td>Knee</td>
<td>Not revised (n = 22,460)</td>
<td>Revised (n = 493)</td>
</tr>
<tr>
<td>Family practice</td>
<td>16,399 (73.0)</td>
<td>126,480</td>
</tr>
<tr>
<td>Hospital encounter</td>
<td>7114 (31.7)</td>
<td>10,128</td>
</tr>
<tr>
<td>Internal medicine</td>
<td>11,856 (52.8)</td>
<td>71,156</td>
</tr>
<tr>
<td>Occupational M/T, PT</td>
<td>19,797 (88.1)</td>
<td>306,033</td>
</tr>
<tr>
<td>Office visit</td>
<td>18,928 (84.3)</td>
<td>94,008</td>
</tr>
<tr>
<td>Orthopedic AH/ NV/OV</td>
<td>9554 (42.5)</td>
<td>28,190</td>
</tr>
<tr>
<td>Orthopedics, medicine</td>
<td>22,403 (99.7)</td>
<td>181,951</td>
</tr>
<tr>
<td>Urgent care</td>
<td>6119 (27.2)</td>
<td>12,750</td>
</tr>
<tr>
<td>Hip</td>
<td>Not revised (n = 9771)</td>
<td>Revised (n = 133)</td>
</tr>
<tr>
<td>Family practice</td>
<td>6984 (71.5)</td>
<td>50,755</td>
</tr>
<tr>
<td>Hospital encounter</td>
<td>2966 (30.4)</td>
<td>4219</td>
</tr>
<tr>
<td>Internal medicine</td>
<td>4987 (51.0)</td>
<td>28,454</td>
</tr>
<tr>
<td>Occupational M/T, PT</td>
<td>5756 (58.9)</td>
<td>54,550</td>
</tr>
<tr>
<td>Office visit</td>
<td>8173 (83.6)</td>
<td>38,243</td>
</tr>
<tr>
<td>Orthopedic AH/ NV/OV</td>
<td>4232 (43.3)</td>
<td>11,519</td>
</tr>
<tr>
<td>Orthopedics, medicine</td>
<td>9732 (99.6)</td>
<td>71,807</td>
</tr>
<tr>
<td>Urgent care</td>
<td>2451 (25.1)</td>
<td>5012</td>
</tr>
</tbody>
</table>

* Encounter types were specified by our integrated health care system’s electronic health record (Epic, Epic Systems, Verona, WI).

† Expressed as median and interquartile range of total visits per patient for the encounter of interest.

AH = allied health; IQR = interquartile range; M/T = medicine/therapy; NV = nurse visit; OV = office visit; PT = physical therapy.
utilization per postoperative timeframe. The 4 most common types of inpatient (hospital-related) utilization for both THA and TKA were outpatient in the hospital, ED visit, charge router-auto hospital accounting record, and inpatient (Table 3).

For TKA, a greater frequency of outpatient utilization in both days 1 to 90 and 91 to 180 intervals were associated with higher revision surgery after adjusting for age, sex, race, and BMI (Table 4). Specifically, during postoperative days 1 to 90, patients with at least 2 family practice visits were 1.8 times (95% CI = 1.5-2.3) more likely to experience a revision surgery than those who had 0 or 1 visit. Patients with any hospital encounter had 2.1 times (95% CI = 1.6-2.7) higher risk of revision in the first 5 years after the index procedure, and 5.0 times (95% CI = 2.8-8.7) higher risk of revision thereafter. Compared with those with 0 or 1 internal medicine visit, patients with at least 4 visits were 1.6 times (95% CI = 1.3-2.0) more likely to experience revision surgery. Patients with at least 4 occupational medicine/physical therapy visits were 3.0 times (95% CI = 2.2-4.0) more likely to experience a revision surgery than those with 0 to 3 visits. Compared with those with 0 to 2 office visits, patients with at least 3 visits were 4.7 times (95% CI = 3.6-6.2) more likely to experience a revision surgery. Patients with at least 3 orthopedic allied health/nurse visits had a 2.2 times (95% CI = 1.6-2.9) higher risk of revision in the first 2.1 postoperative years and 10.1 times (95% CI = 7.6-13.3) higher risk thereafter compared with those with 0 to 2 visits. For every 1 additional orthopedic office visit, there was a 10% higher risk of revision surgery (HR = 1.1, 95% CI = 1.1-1.1). Finally, patients who received an urgent care had a 2.1 times (95% CI = 1.7-2.6) higher risk of revision than patients who did not. Similar results were found for the second postoperative quarter (Table 4). No associations between inpatient utilization and revision surgery were observed for TKA.

For THA, we also found significant associations between postoperative outpatient utilization types and revision surgery, adjusting for age, sex, race, and BMI (Table 5). Patients with at least 7 family practice visits had a 2.6 times (95% CI = 1.7-4.0) higher risk of revision compared with those who had 0 to 2 visits. Patients who had any hospital encounter in the first postoperative quarter were 3.1 times (95% CI = 2.2-4.4) more likely to experience a revision surgery, and those who had any internal medicine visit in the same period were 2.7 times (95% CI = 1.8-4.1) more likely to experience a revision surgery. Compared with those who had 0 to 2 occupational medicine/physical therapy visits, patients with at least 2 visits were 2.8 times (95% CI = 2.2-3.5) more likely to experience revision.

### Table 3. Number of inpatient encounters by total joint arthroplasty postoperative time period and revision status, January 2007 to July 2013

<table>
<thead>
<tr>
<th>Encounter type</th>
<th>Quarter 1 (1-90 d)</th>
<th>Quarter 2 (91-180 d)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number (%)</td>
<td>Total visits (IQR)</td>
</tr>
<tr>
<td>Admit with surgery</td>
<td>1 (0)</td>
<td>1 (0-0)</td>
</tr>
<tr>
<td>Emergency Department</td>
<td>2245 (12.5)</td>
<td>4151 (0-0)</td>
</tr>
<tr>
<td>Home health</td>
<td>3520 (19.6)</td>
<td>5479 (0-0)</td>
</tr>
<tr>
<td>Hospital ambulatory surgery</td>
<td>115 (0.6)</td>
<td>164 (0-0)</td>
</tr>
<tr>
<td>Inpatient</td>
<td>301 (5.8)</td>
<td>345 (0-0)</td>
</tr>
<tr>
<td>Observation</td>
<td>1495 (8.3)</td>
<td>2475 (0-0)</td>
</tr>
<tr>
<td>Outpatient procedure</td>
<td>127 (0.7)</td>
<td>186 (0-0)</td>
</tr>
<tr>
<td>Outpatient in hospital</td>
<td>5515 (30.7)</td>
<td>11,175 (0-1)</td>
</tr>
<tr>
<td>Admit with surgery</td>
<td>2 (0)</td>
<td>2 (0-0)</td>
</tr>
<tr>
<td>Emergency Department</td>
<td>1027 (13.3)</td>
<td>1699 (0-0)</td>
</tr>
<tr>
<td>Home health</td>
<td>1509 (19.5)</td>
<td>2166 (0-0)</td>
</tr>
<tr>
<td>Hospital ambulatory surgery</td>
<td>50 (0.6)</td>
<td>65 (0-0)</td>
</tr>
<tr>
<td>Inpatient</td>
<td>82 (1.1)</td>
<td>111 (0-0)</td>
</tr>
<tr>
<td>Observation</td>
<td>597 (7.7)</td>
<td>847 (0-0)</td>
</tr>
<tr>
<td>Outpatient procedure</td>
<td>146 (1.9)</td>
<td>167 (0-0)</td>
</tr>
<tr>
<td>Outpatient in hospital</td>
<td>30 (0.4)</td>
<td>39 (0-0)</td>
</tr>
</tbody>
</table>

* Hospital encounter information available from January 2007 onward.

* Encounter types were specified by our integrated health care system’s electronic health record (Epic, Verona, Wisconsin, USA).

* Expressed as the median and interquartile range of total visits per patient for the encounter of interest.
physical therapy visits, patients had a 1.7 times (95% CI = 1.1-2.6) and 2.5 times (95% CI = 1.6-3.8) higher risk of revision when they had 3 to 8 visits and at least 9 visits in the first postoperative quarter, respectively. During the same first postoperative quarter, patients with at least 6 office visits had a 4.1 times (95% CI = 2.8-6.2) higher risk of revision compared with those who had 0 to 3 visits. Patients who had at least 3 orthopedic allied health/nurse visits were more likely to experience a revision surgery, with a 5.0 times (95% CI = 3.1-8.1) risk in the first 3.5 postoperative years and a 10.4 times (95% CI = 5.7-18.7) risk thereafter. Patients with at least 6 orthopedic office visits had a 15.7 times (95% CI = 5.7-42.9) higher risk of revision compared with those who had 0 to 3 visits. Patients who received any urgent care had a 2.4 times (95% CI = 1.6-3.6) higher risk of revision than patients who did not have urgent care. Similar results were found for the second postoperative quarter. Revision surgery was also associated with any ED utilization in the first postoperative quarter (HR = 1.9, 95% CI = 1.2-3.0) but not in the second postoperative quarter (HR = 1.8, 95% CI = 1.0-3.5).

**DISCUSSION**

Using a TJA population from a large integrated health care system, we found postsurgical care to be associated with risk of revision surgery after primary TJA. A higher frequency of outpatient care utilization was associated with revision risk for TJA recipients, but thresholds were different for TKA and THA. Three or more orthopedic allied health/nurse visits throughout the first 180 days postoperatively had the strongest association with revision risk after TKA. Meanwhile, 6 or more orthopedic office visits in the first 90 days and 3 or more orthopedic allied health/nurse visits in the 91-day to 180-day window had the strongest associations after THA. The THA recipients with more emergency (inpatient) care utilization were also at higher risk of revision.

To our knowledge, this is the first study to use the EHR to evaluate postsurgical care and revision risk after TJA. Our study lacks granular clinical details of specific reasons for the encounters. Furthermore, planned visits were not discerned from unplanned visits—patient initiated or surgeon directed—nor whether visits were related or unrelated to the primary procedure. Our purpose was to determine whether the intensity of postsurgical care was associated with revision risk, regardless of the nature of the care. This is the most general information available that can be readily extracted from the EHR, allowing for expedited screening and intervention for patients who might be at higher risk of failure.

### Table 4. Adjusted models for associations of outpatient encounters and revision (181 days after surgery) of total knee arthroplasty recipients

<table>
<thead>
<tr>
<th>Encounter type</th>
<th>Visit level</th>
<th>Cumulative revision rate, quarter 1</th>
<th>Adjusted multivariable model, quarter 1</th>
<th>Cumulative revision rate, quarter 2</th>
<th>Adjusted multivariable model, quarter 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Family practice</td>
<td>0-1</td>
<td>0.9 (95% CI = 1.7-2.8)</td>
<td>Reference</td>
<td>1.0 (95% CI = 1.5-2.2)</td>
<td>Reference</td>
</tr>
<tr>
<td></td>
<td>≥ 2</td>
<td>1.5 (95% CI = 1.8-2.5)</td>
<td>Reference</td>
<td>1.9 (95% CI = 3.4-4.9)</td>
<td>2.1 (95% CI = 1.9-2.8)</td>
</tr>
<tr>
<td>Hospital encounter</td>
<td>No</td>
<td>1.1 (95% CI = 1.7-2.2)</td>
<td>Reference</td>
<td>1.0 (95% CI = 1.7-2.4)</td>
<td>Reference</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>1.7 (95% CI = 2.1-2.7)</td>
<td>&lt; 0.001</td>
<td>2.6 (95% CI = 4.3-6.3)</td>
<td>2.6 (95% CI = 2.2-3.2)</td>
</tr>
<tr>
<td>Internal medicine</td>
<td>0-1</td>
<td>1.1 (95% CI = 1.9-2.7)</td>
<td>Reference</td>
<td>1.1 (95% CI = 1.9-2.7)</td>
<td>Reference</td>
</tr>
<tr>
<td></td>
<td>2-3</td>
<td>1.5 (95% CI = 2.2-2.8)</td>
<td>1.3 (95% CI = 0.9-1.7)</td>
<td>0.120</td>
<td>1.4 (95% CI = 2.5-3.7)</td>
</tr>
<tr>
<td></td>
<td>≥ 4</td>
<td>1.6 (95% CI = 2.6-3.8)</td>
<td>1.6 (95% CI = 1.3-2.0)</td>
<td>&lt; 0.001</td>
<td>2.9 (95% CI = 4.8-7.1)</td>
</tr>
<tr>
<td></td>
<td>≥ 4</td>
<td>1.5 (95% CI = 2.5-3.6)</td>
<td>3.0 (95% CI = 2.2-4.0)</td>
<td>&lt; 0.001</td>
<td>2.4 (95% CI = 4.2-6.0)</td>
</tr>
<tr>
<td></td>
<td>≥ 4</td>
<td>1.7 (95% CI = 2.4-3.6)</td>
<td>4.7 (95% CI = 3.6-6.2)</td>
<td>&lt; 0.001</td>
<td>1.9 (95% CI = 3.3-4.6)</td>
</tr>
<tr>
<td></td>
<td>≥ 3</td>
<td>2.1 (95% CI = 2.6-3.2)</td>
<td>2.2 (95% CI = 2.6-3.2)</td>
<td>&lt; 0.001</td>
<td>3.9 (95% CI = 8.7-16.4)</td>
</tr>
<tr>
<td></td>
<td>≥ 3</td>
<td>0.0 (95% CI = 0.0-0.1)</td>
<td>10.1 (95% CI = 7.8-13.3)</td>
<td>&lt; 0.001</td>
<td>4.6 (95% CI = 3.6-5.9)</td>
</tr>
<tr>
<td>Orthopedic AH/NV/OV</td>
<td>No</td>
<td>1.1 (95% CI = 1.7-2.2)</td>
<td>Reference</td>
<td>1.1 (95% CI = 1.9-2.6)</td>
<td>Reference</td>
</tr>
<tr>
<td></td>
<td>≥ 3</td>
<td>2.1 (95% CI = 2.6-3.2)</td>
<td>&lt; 0.001</td>
<td>3.9 (95% CI = 8.7-16.4)</td>
<td>4.6 (95% CI = 3.6-5.9)</td>
</tr>
<tr>
<td>Orthopedics, medicine</td>
<td>0-3</td>
<td>0.0 (95% CI = 0.0-0.1)</td>
<td>—</td>
<td>0.7 (95% CI = 1.3-1.9)</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>≥ 4</td>
<td>1.6 (95% CI = 2.7-3.8)</td>
<td>1.1 (95% CI = 1.1-1.1) per 1 increment</td>
<td>&lt; 0.001</td>
<td>4.8 (95% CI = 7.7-10.3)</td>
</tr>
<tr>
<td>Urgent care</td>
<td>No</td>
<td>1.1 (95% CI = 1.7-2.4)</td>
<td>Reference</td>
<td>1.2 (95% CI = 2.0-2.8)</td>
<td>Reference</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>1.8 (95% CI = 2.4-4.8)</td>
<td>2.1 (95% CI = 1.7-2.6)</td>
<td>&lt; 0.001</td>
<td>2.3 (95% CI = 4.0-5.2)</td>
</tr>
</tbody>
</table>

* No significant associations were observed for inpatient encounters and risk of revision in patients undergoing total knee replacement. Encounter types were specified by our integrated health care system’s electronic health record (Epic, Epic Systems, Verona, WI). Multivariable models were adjusted for age, sex, race, and body mass index; 0.5% of data (n = 112) were excluded in the model because of missing data in covariates.

+ Quarter 1 was 1-90 d; quarter 2 was 91-180 d.

+ Stratification for time dependence; effect of “yes” visits within and after 5 years postoperatively compared with no visits.

+ Stratification for time dependence; effect of ≥ 3 visits within and after 2 years postoperatively compared with 0-2 visits.

AH = allied health; CI = confidence interval; HR = hazard ratio; M/T = medicine/therapy; NV = nurse visit; OV = office visit; PT = physical therapy.
Inacio et al. reported on health care utilization after anterior cruciate ligament reconstruction and found an increased number of orthopedic office visits within the first 90 days postoperatively to be associated with revision surgery, similar to their THA findings. This study hypothesized that the higher frequency of orthopedic office visits was an indication of short-term clinical failure. A number of studies have also used the EHR to evaluate postoperative opioid use, finding a higher number of medications to be associated with arthroplasty revision risk.

The FDA recognizes the current limitations of postmarket surveillance and the need for a more rigorous system in the US; a national strategy for medical device evaluation using real-world evidence from existing electronic data sources and clinical registries has been proposed. Although the need for surveillance is recognized, the rising volume of TJA challenges the ability to postoperatively monitor large populations of patients. Patient-reported outcome measures, and simpler patient-questionnaire evaluations, may identify early patients at risk of failure, but time and labor costs are prohibitive. In contrast, frequency and type of postsurgery care utilization can readily be identified using existing data sources and may potentially be a novel indicator for orthopedic surgeons to monitor patients at higher risk of failure after TJA. Surveillance and early detection of failures is critical for patient safety and quality. Readmissions are used as a standard indicator for safety and quality nationally; however, with the exception of certain planned inpatient readmissions (eg, dialysis, scheduled operative procedures), TJA recipients are not expected to be hospitalized after the procedure. More studies are emphasizing the importance of additional types of postsurgical care, such as ED visits, in the measurement of quality after TJA.

The EHR is capable of collecting all patient contacts in the health care system, not just limited to utilization related to the surgical procedure. The encounter types identified here might be a possible early indicator for health care practitioners in the identification of high-risk patients who require more active surveillance. Health care organizations with a comprehensive EHR may have

### Table 5. Adjusted models for associations of outpatient/inpatient encounters and revision (181 days after surgery) of total hip arthroplasty recipients

<table>
<thead>
<tr>
<th>Encounter type</th>
<th>Visit level</th>
<th>Cumulative revision rate, quarter 1</th>
<th>Adjusted multivariable model, quarter 1</th>
<th>Cumulative revision rate, quarter 2</th>
<th>Adjusted multivariable model, quarter 2</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Outpatient encounters (N = 9855)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Family practice</td>
<td>0-2</td>
<td>0.5</td>
<td>0.9</td>
<td>1.6</td>
<td>Reference</td>
<td>0.5</td>
</tr>
<tr>
<td></td>
<td>3-6</td>
<td>0.4</td>
<td>0.7</td>
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<td>≥ 7</td>
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<td>3.6</td>
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<td>0.8</td>
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</tr>
<tr>
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<td>Yes</td>
<td>1.2</td>
<td>2.3</td>
<td>4.1</td>
<td>3.1 (2.2-4.4)</td>
<td>&lt; 0.001</td>
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<tr>
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<td>No</td>
<td>0.4</td>
<td>0.8</td>
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<tr>
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<td>0.9</td>
<td>1.6</td>
<td>2.9</td>
<td>2.7 (1.8-4.1)</td>
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<td>0.9</td>
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<td></td>
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<td>0.8</td>
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<tr>
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<td>2.4</td>
<td>1.9 (1.2-3.0)</td>
<td>0.009</td>
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</table>

*Encounter types were specified by our integrated health care system’s electronic health record (Epic, Epic Systems, Verona, WI). Multivariable models were adjusted for age, sex, race, and body mass index; 0.5% of data (n = 47) were excluded in the model because of missing data in covariates.

1. Quarter 1 was 1-90 d; quarter 2 was 91-180 d.
2. Stratification for time dependence; effect of “≥ 3” visits within and after 3.5 years postoperatively compared with no visits.
3. AH = allied health; CI = confidence interval; HR = hazard ratio; M/T = medicine/therapy; NV = nurse visit; OV = office visit; PT = physical therapy.
an alternative method to monitor large populations of TJA recipients. Although revisions caused by implant failure mostly showed up after 6 months, early detection through inpatient and outpatient encounters was warranted even in the early latent period, as found in this study. Our study is not without limitations. First, our objective was to determine whether any postsurgery care was associated with a higher risk of revision surgery, not to create a prediction model for revision. Our intent was not to identify specific devices at higher risk of revision caused by certain modes of failure, but rather a proof of concept to determine whether readily extractable information from the EHR could be used to screen patients at higher risk of revision who may require more active surveillance. Future studies are needed to determine whether this information can be used for surveillance of high-risk medical devices. Second, there is also potential for missing data or misclassified encounter types, along with the other inherent limitations of using EHR data. Third, our study excluded patients with complications or revisions within the first 6 months of the primary procedure, which were mostly caused by infections and fractures of the bone. Although our study findings may not be applied to short-term failures, we believe these findings may be useful as a safety indicator for later failures after the primary procedure. Finally, because we were limited to the health care utilization types available through the current EHR platform (Epic), these results may not be generalizable to other institutions using different EHR platforms.

Study strengths included the patient population in the integrated health care system from which the sample was obtained, which is socioeconomically and demographically representative of the geographical regions it covers.10,32 Our study included a cohort of patients with validated outcomes through a total joint replacement registry and full postsurgical care information from our system's EHR.

CONCLUSION

Using postsurgical care identified through the EHR, we found increased outpatient care utilization to be associated with revision surgery after TJA, although the thresholds for revision risk differed between TKA and THA. Health care practitioners might benefit from more active surveillance and intervention for patients with a higher frequency of these types of postsurgical care. Future investigations should determine if more specific data on reasons for seeking postsurgical care can help refine these findings and whether this type of EHR information can be used in prospective surveillance for high-risk medical devices.

Disclosure Statement

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

Acknowledgments

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The Art of Flying

The application of the principles of science to the diagnosis and treatment of disease is only one limited aspect of medical practice. The practice of medicine … includes the whole relationship of the physician to his patient. It is an art, based to an increasing extent on the medical sciences, but comprising much that still remains outside the realm of any science. The art of medicine and the science of medicine are not antagonistic but supplementary to each other. There is no more contradiction between the science of medicine and the art of medicine than between the science of aeronautics and the art of flying.

— Francis W Peabody, 1881-1927, American physician famous for his extensive research into poliomyelitis and typhoid
Clinical Use Cases for a Tool to Assess Risk in Superficial Bladder Cancer

Carmit K McMullen, PhD; Maureen O’Keeffe Rosetti, MS; Sheila Weinmann, PhD; Michael C Leo, PhD; Matthew E Nielsen, MD, MS, FACS

ABSTRACT

Background: Among the approximately 53,000 patients newly diagnosed with early-stage (superficial) bladder cancer each year, there is substantial variability in the progression to muscle-invasive disease. Enhancing risk stratification and risk-stratified surveillance could minimize risks and harms to patients, as well as unnecessary costs to health systems.

Objectives: As a preliminary step in developing and validating a risk assessment tool for superficial bladder cancer in a population-based clinical cohort, we interviewed urologists who might use such a tool to assess need, determine potential use cases, and identify key features to include.

Methods: Using an opportunistic and purposeful sampling design, we invited 13 urologists from a variety of practice settings and with a wide range of clinical experience to take part in qualitative interviews; 9 (5 urologic oncologists and 4 general urologists) participated.

Results: All urologists reported using some form of risk stratification to determine surveillance schedules for patients with bladder cancer. The following use cases were endorsed by 4 or more interviewees: 1) provide evidence to guide clinical management in specific situations, 2) generate patient-facing communication aids, 3) improve documentation about recurrence/progression risk, and 4) create scheduling and callback supports to improve the quality of follow-up care.

Conclusion: Our findings demonstrated several potential clinical-use cases for a risk calculator and clinical decision-support tool for patients with superficial bladder cancer. Clinicians stressed the potential utility of such a tool to improve patient communication, scheduling, and tracking in general urology practice.

INTRODUCTION

Follow-up care for cancer is personally and financially costly.1 In the setting of superficial bladder cancer, cystoscopy is uncomfortable and anxiety-producing for patients2 and is expensive for health systems.3-5 Among the approximately 53,000 patients with bladder cancer per year who present with early-stage disease—superficial (nonmuscle invasive) tumors (stage < T2), there is substantial variability in the progression to muscle-invasive disease (stage ≥ T2).6-8 Five-year risk of progression ranges from less than 1% in the majority—patients with low-grade noninvasive papillary (Ta) carcinoma—to 30% to 70% in patients with stage T1 disease or carcinoma in situ.7 Enhancing risk stratification and risk-stratified surveillance could minimize risks and harms to patients, as well as unnecessary costs to health systems.

Accurately assessing and communicating risk of recurrence and progression is critical to providing appropriate and cost-effective follow-up care. The European Association of Urology (EAU) has recommended risk-stratified surveillance schedules for patients with nonmuscle invasive bladder cancer (NMIBC) for more than a decade,9 with low-risk patients receiving only 3 cystoscopies in the first 2 years (assuming negative results). The National Institute for Care Excellence in the UK has promulgated an even less intensive approach than the EAU for low-risk patients, recommending discharge to primary care if recurrence-free at 1 year.10 The American Urological Association (AUA) recently adopted a more risk-adapted approach11 similar to the EAU guideline. An expert panel representing the AUA has called for population-based data and better predictive tools for bladder cancer surveillance.12 Patients and health systems would benefit from a risk-stratified approach to monitoring that focuses resources on those patients who are most at risk.

One tool for calculating the risk of recurrence and progression in bladder cancer comes from the European Organisation for Research and Treatment of Cancer (EORTC). This tool uses an algorithm developed from a pooled analysis of European clinical trials of NMIBC13 to predict the risks of recurrence and progression to muscle-invasive bladder cancer. This tool forms the basis of current EAU practice guidelines. However, the calculator has faced limited adoption in the US. This may be in part because it relies on aggregate data from clinical trial populations, and it has until recently14 not been validated in a contemporary American population-based cohort. Emerging data from real-world practice settings in the US suggest limitations in the generalizability of the EORTC trial data to observed outcomes in contemporary US practice.15 Additionally, the risk calculator lacks features that apply directly to clinical context, such as decision support, patient communication aids, or documentation and tracking aids.

As a preliminary step in developing and validating a risk-assessment tool for superficial bladder cancer in a population-based clinical cohort, we interviewed urologists who might use such a tool to assess need, determine potential use cases, and identify key features to include.
Interviews were audio recorded and transcribed. Interview transcripts were coded by the co-principal investigator (CM), a medical anthropologist and qualitative researcher, using a template coding approach. This included reviewing all transcripts to identify and summarize text associated with the following codes: Current practice, use of EORTC risk calculator, clinical decision support and health information technology use, conversations with patients about follow-up care, implementation issues, care improvement opportunities, and use cases. “Use case” codes provided specific examples of ways that participants imagined the tool could be used. Co-Principal Investigator CM then reviewed data coded under “use cases,” as well as data across other codes. She consolidated a list of all risk calculator use cases that were mentioned as having utility, as well as concerns about why the risk calculator may not be useful. The other study co-principal investigator (MN), a urologic oncologist, independently reviewed interviews, confirmed the use cases, and helped to clarify descriptions of use cases and their utility.

RESULTS

Current Clinical Practice

All urologists reported using some kind of formal or informal risk stratification to determine surveillance schedules for patients with bladder cancer. One interviewee said he typically followed the AUA guidelines, although he noted that he sometimes recommends longer intervals for some patients. Six urologists specifically mentioned using the EORTC risk categories and/or guidelines, which recommend risk-stratified follow-up schedules, although only 2 reported using the EORTC risk calculator itself. A few outlined specific schedules for patients at low risk of recurrence and progression that involved increasing intervals between cystoscopies after negative results. Several noted that they used “reduced” or “relaxed” surveillance for low-risk patients without providing specific intervals or while noting that their recommendations would depend on the details of a patient’s case. For cases at high risk of recurrence or progression, urologists more uniformly recommended cystoscopy every 3 months for at least 2 years, with some variation in use of bacille Calmette-Guérin treatment.

Potential Use Cases

The following use cases were endorsed by 4 or more interviewees (Table 2):

1. **Provide Evidence to Guide Clinical Management in Specific Situations:** When asked about use cases for a decision-support tool providing personalized risk calculations of recurrence and progression, 4 of the 9 urologists indicated that such a tool would have minimal impact on their clinical management and decision making, because they saw risk stratification in bladder cancer as relatively straightforward. However, there were some specific circumstances in which 4 interviewees believed that decision support in clinical management could be helpful. Interviewees thought that it would be valuable to be able to calculate the risk of recurrence and progression after each negative cystoscopy result, each maintenance bacille Calmette-Guérin treatment, and potential barriers and facilitators to changing practice.

2. **Decision Support and Health Information Technology Use:** Urologists were asked to complete a brief follow-up survey that included questions asking them to rate (on a 5-point Likert scale) how important each of 6 clinical decision-support characteristics would be for a risk-assessment tool. Previous research has identified 9 key criteria for successful clinical decision-support implementation. Our survey questions were based on a subset of 6 of these criteria that we considered most in need of stakeholder input for developing a risk calculator: 1) integration with charting and order entry; 2) minimization of clinician data entry; 3) promotion of action vs inaction; 4) local user involvement in the development process; 5) provision of best evidence for practice change; and 6) demonstration of a care recommendation (not just a risk assessment). Seven of the 9 interviewed urologists completed this survey. Urologists were not compensated for their participation in the interviews or survey.
dose, or after failure of bacille Calmette-Guérin therapy, as well as the risk of recurrence or progression with or without intravesical chemotherapy. They also felt that risk calculators could help determine when to stop surveillance. Tailoring such a tool to general urology practice was seen as important because most superficial bladder cancers are treated in a general urology practice setting, and these general urologists may be most in need of decision support.

*Generate Scheduling and Callback Supports to Improve Quality of Follow-up Care, Especially for Patients with High-Risk Disease:* Noting the challenge of ensuring adherence with follow-up care and the limitations of their existing scheduling systems, 4 interviewees saw great value in a risk management tool that could trigger risk-stratified management protocols. Uses could include automatically setting appointments for follow-up care, providing information to schedulers about who is due or overdue for a cystoscopy or which patients are at highest risk, and sending automatic appointment reminder letters to patients. This type of “tracking system” was endorsed by 1 urologic oncologist and 3 of the 4 general urologists we interviewed. However, 2 of the 5 urologists explicitly said that they did not need a tool to enhance follow-up completion.

### Key Features of Risk Assessment Tools (Survey Ratings)

Urologists were asked in the follow-up survey (n = 7) whether various characteristics of a risk-stratification clinical decision support tool were important. Although all characteristics were rated as valuable, minimizing data entry was rated as the most important feature of a tool (mean rating of 4.6 on a 5-point scale). This was followed in perceived value by providing the best evidence for practice change (mean = 4.4), integration with charting and computerized physician order entry (4.1), promoting action (4.0), the ability to adapt the tool locally (3.9), and the inclusion of a specific recommendation for care (3.9).

### DISCUSSION

Through interviews about the management of NMIBC with urologists from a variety of practice backgrounds, we identified a range of use cases for a personalized risk calculator of recurrence and progression. Participants highlighted the potential of risk assessment tools to improve adherence to follow-up care and to facilitate conversations between patients and urologists regarding appropriate surveillance schedules.

Participants differed in whether they believed that a risk calculator would inform their clinical management. Several reported that risk stratification and follow-up care protocols were simple enough that they did not need a risk calculator. However, others perceived that a risk calculator could help with specific clinical management scenarios, including deciding when to stop surveillance and whether to provide intravesical chemotherapy. Despite the relatively limited clinical management potential of a risk-stratification tool, clinicians were nonetheless enthusiastic about such a tool, particularly

<table>
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<th>Use case</th>
<th>Urologic oncologists</th>
<th>General urologists</th>
<th>Quotes</th>
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<td>Provide evidence to guide clinical management in specific situations</td>
<td>2</td>
<td>2</td>
<td>“Ninety percent of superficial bladder cancer is probably in the general urologist practice. So I think that there’s an enormous need for [a risk calculator]. And I think it should be tailored to them, as much as possible.”</td>
</tr>
<tr>
<td>Generate patient-facing communication aids</td>
<td>3</td>
<td>2</td>
<td>“I think that would really … bring the seriousness of the condition that much closer to home for the patients.”</td>
</tr>
<tr>
<td>Improve documentation about recurrence/progression risk</td>
<td>3</td>
<td>2</td>
<td>“Ideally, I’d have a prepopulated clinical note when I walk into the examination room, a functional version of a SmartPhrase … for my surveillance patients … [that] generates their risk category and risk of recurrence and progression.”</td>
</tr>
<tr>
<td>Create scheduling and callback supports to improve the quality of follow-up care</td>
<td>1</td>
<td>3</td>
<td>“[A tracking system] would seem to be a no-brainer.”</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>“I’ll send myself a future email to make sure they get x, y, z done, at a certain date. And then the email comes back to me, and I open up their chart. I review if they’ve done it. If it’s not done, then I [set up] a telephone encounter for the nursing staff to call them. That’s a lot of work for me.”</td>
</tr>
</tbody>
</table>

SmartPhrase = Epic SmartPhrase, Epic Systems Corp, Verona, WI.
as a means of improving patient communication and ensuring adherence to surveillance.

Both general urologists and urologic oncologists stressed the importance of tailoring risk-stratification tools for the general urology setting. Nearly all patients with superficial bladder cancer receive care in general urology practice, and general urologists expressed greater need for clinical guidance and for management protocols to facilitate scheduling and tracking of follow-up care. Several general urologists reported challenges with scheduling cystoscopy appointments and ensuring that patients receive care on schedule. Tools that automate or facilitate tracking and scheduling could reduce the burden on clinicians and staff while increasing care adherence.

Risk calculators and decision-support tools are available for a wide range of conditions, including prostate, colorectal, and breast cancer; cardiovascular disease; fractures; and diabetes. Consistent with the data presented here, focus group research has found that primary care clinicians use such tools primarily as patient communication aids, although tools are also sometimes used in clinicians’ decision making. Clinicians are more likely to adopt tools that are perceived as well validated, referred to in clinical practice guidelines, easy to use, and integrated into the electronic health record system. The urologists who participated in our study echo the findings from other clinical contexts. Although they did not anticipate that a risk calculator would have much impact on their clinical management of NMIBC, they anticipated uses for communication and documentation. Similar to primary care clinicians, they highly valued user-friendly, integrated, and evidence-based tools.

Although the clinicians we interviewed represented a range of clinical experiences and practice environments, it is possible that these views may not generalize to the broader population of urologists. We interviewed a small number of clinical stakeholders, and they were not randomly selected. However, they were intentionally chosen to represent a variety of perspectives and practice contexts, and there was broad consensus across this diverse group of participants about the most promising use cases for a risk-assessment tool and the ideal characteristics for such a tool. It is also worth noting that these interviews occurred before the recent changes in AUA guidelines for managing superficial bladder cancer surveillance. We would anticipate that there would be more support in the urology community for the use cases suggested in this article than there would have been before the guideline change.

Although we acknowledge the limitations inherent to this initial developmental stage of work, our study nonetheless provides, to our knowledge, the first documentation of clinician insights into potential use cases and applications of clinical decision-support tools for bladder cancer surveillance. Future efforts could include enrollment of a larger sample of urologists and use of the Delphi method or other approaches to further assess the applicability of such approaches to clinical care. Additionally, crowdsourcing perspectives from a larger sample of clinicians, for instance, through email surveys of urologic professional societies, could further inform future efforts. Principles of user-centered design hold great promise for the development of clinically consequential applications of health information technology to oncology care.

CONCLUSION

Our findings demonstrate several potential clinical use cases for a risk calculator and clinical decision-support tool for patients with superficial bladder cancer. In particular, clinicians stressed the potential utility of such a tool to improve patient communication, scheduling, and tracking in general urology practice.

Disclosure Statement

The author(s) have no conflict of interest to report.

Acknowledgments

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Clinical Use Cases for a Tool to Assess Risk in Superficial Bladder Cancer


Mark E Gasparini, MD; Toby W Chang, PharmD; Mark St Lezin, MD; John E Skerry, MD; Andy Chan, PharmD; Krishna A Ramaswamy, MD

ABSTRACT

Introduction: Despite guidelines for prevention of recurrent renal calculi, routine dietary modification and metabolic evaluation are often not performed.

Objective: To determine feasibility of a multicenter, pharmacist-staffed program to enroll patients at high risk of recurrent kidney stones and provide dietary instruction, metabolic evaluation, and medical therapy via telemedicine.

Methods: A total of 536 consecutive adult patients were referred from 3 Northern California Kaiser Permanente facilities. We determined the proportion of patients who enrolled, received dietary counseling, and completed metabolic evaluation at 12 months. The program was staffed by a clinical pharmacist and supervised by urologists following a protocol based on the American Urological Association guidelines. Patients were contacted entirely via telemedicine. Cystine or struvite kidney stones, renal tubular acidosis, and primary hyperoxaluria were exclusion criteria.

Results: Of the 536 patients, 500 agreed to enrollment. Among patients enrolled for 3 months, 99% self-reported compliance with at least 3 of 5 aspects of dietary advice. A complete metabolic evaluation including 24-hour urine collection was performed in 80% of patients by 12 months. A significant improvement in all urinary parameters occurred in 52 patients with calcium stones who repeated 24-hour urine testing. The 12-month dropout rate was 12.4%.

Conclusion: A telemedicine-administered, pharmacist-staffed, protocol-driven program can provide dietary advice and obtain compliance with metabolic testing for patients at high risk of recurrent kidney stones. Rates of metabolic testing and dropout compare favorably with previously reported rates. This report represents, to our knowledge, the first telemedicine-administered, pharmacist-staffed, kidney stone prevention program published in the literature.

INTRODUCTION

Kidney stone disease is extremely common, recurrent, and costly. The lifetime prevalence of kidney stones is about 10%.^{1-4} Kidney stones are likely to recur, with a recurrence rate of at least 50% within 10 years in first-time stone-forming patients.^{4-6} Recurrent stone formers have a much higher rate of subsequent recurrence, reported to be 50% at 1 to 5 years.^{7,8} The cost to care for patients with renal calculi was estimated at $5 billion annually in the US in 2013.^{9}

Dietary modifications, metabolic evaluation, and medical treatment have been shown to dramatically lower recurrence rates. The American Urological Association^{4} both currently recommend dietary modification in all kidney stone formers and metabolic evaluation and medical treatment for high-risk or recurrent stone formers.

Despite these recommendations, routine dietary modification and metabolic evaluation are often not performed. Several studies have shown that compliance with current best practice guidelines is less than ideal.^{10} Patients are often unaware of the correct dietary interventions, suggesting that dietary instruction is inadequate. Often, 24-hour urine testing is not performed, with completion rates as low as 7%.^{11,12} Even in those patients receiving care to prevent stones, compliance can be difficult to maintain despite the proven benefits, and the dropout rate is substantial.^{13,14} Compliance with metabolic testing and dietary modification can be challenging and time consuming, and community-based urologists may not have the time or interest to deal with this problem.

Patient compliance with diet and medical regimens is challenging for many other chronic medical conditions, and care models have been developed to improve compliance and clinical outcomes. Several studies have shown that clinical teams using standardized evidence-based protocols aided by the addition of nonphysicians, such as medical assistants, registered nurses, and clinical pharmacists, can result in improved compliance and improved clinical outcomes.^{15-17} Clinical pharmacists, who are well trained in dietary modification and medication compliance, have proved beneficial in achieving guideline-based care in many chronic medical conditions.^{18-21} Clinical pharmacist–administered dietary education, lifestyle modification, and management of drug therapy have been shown to be effective at improving diabetic control, hypertension, and other clinical outcomes. There is even a report of the successful use of telepharmacy consultations in a chronic care management program.^{22}

In our organization, we have the additional challenge of trying to follow a single best practice guideline in 21 separate facilities with more than 100 urologists. A single program following 1 best practice guideline administered via telemedicine across multiple facilities could possibly address this challenge. For these reasons, we piloted a telemedicine-administered, pharmacist-staffed,

**METHODS**

Adult patients at high risk of recurrent kidney stone disease (defined as recurrent stone formers or first-time urate stone formers) were eligible for referral to the program. Patients with cystine, xanthine, or struvite stones were excluded. Patients with known renal tubular acidosis (RTA) or primary hyperoxaluria were also excluded. Referrals were accepted from 3 Kaiser Permanente (KP) Northern California facilities (South San Francisco, Oakland, and Richmond). Referral was at the discretion of the primary urologist after an initial evaluation. Referred patients received a telephone consultation with a pharmacist who introduced the program, provided dietary education, and proceeded with metabolic evaluation and medical treatment according to our stone prevention protocol.

The protocol was based on the American Urological Association and European Association of Urology guidelines and was reviewed and approved by a group of urologists, nephrologists, endocrinologists, and rheumatologists. The protocol and the clinical pharmacist’s scope of practice were reviewed and approved by the KP South San Francisco Pharmacy and Therapeutics Committee. Our clinical pharmacist had received 1 year of postgraduate training in the areas of telemedicine and diet and medication compliance in addition to the normal areas of practice. The pharmacist was supervised by a urologist and an endourologist.

Telephone follow-up occurred at a minimum of 6-week, 3-month, 6-month, and 12-month intervals the first year; more frequent follow-up occurred if laboratory, medication, or compliance issues arose. After the first year, telephone follow-up occurred annually, or sooner if the patient experienced a new stone event. All patients were requested to repeat a 24-hour urine test yearly. Patients who experienced a new stone event were requested to repeat serum testing as well as a 24-hour urine collection.

Dietary recommendations followed the clinical practice guidelines and were approved by clinical experts as well as dietitians. These diet recommendations were then scripted and delivered at every telephone encounter and included a detailed discussion on 1) fluid intake, 2) salt intake, 3) protein intake, 4) calcium consumption, and 5) oxalate consumption. Written materials were provided by secure email messaging or postal mail. Results of the initial 24-hour urine collection guided future more detailed and specific dietary instructions. Compliance with the diet was defined as the self-reported adherence to at least 3 of 5 aspects of dietary advice listed earlier and was obtained at every follow-up interval.

Metabolic evaluation included a baseline basic metabolic panel (CHEM-7), calcium, and uric acid measurements as well as a 24-hour urine collection. The 24-hour urine collection included assessment of volume, creatinine, calcium, oxalate, uric acid, citrate, sodium, potassium, phosphate, and pH. Urine abnormalities were corrected 1 to 2 abnormalities at a time. Patients with abnormal initial results of the 24-hour urine test were asked to repeat a second urine test 6 months later.

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**Figure 1. Schematic diagram representing an overview of the protocol.**

- Presence of risk factors for renal tubular acidosis: see Methods section.
- BID = twice a day; GU = genitourinary; HCTZ = hydrochlorothiazide; K = potassium; QID = 4 times a day; TID = 3 times a day; UCaNa = urinary calcium/urinary sodium.

---
Dietary changes were emphasized for all stone formers. Medications were limited to specific indications only, and correction was made on only 1 to 2 urinary abnormalities at a time. A repeated 24-hour urine collection was recommended at 6-month follow-up for all patients with a nonvolume abnormality on initial collection; abnormal was defined as any deviation from the normal laboratory range for that constituent. Mixed stones were treated as calcium stones unless urate was 80% or higher. Patients who were noted to have certain extreme values in the initial workup were referred to a specialist (endourologist) as noted in Figure 1. Patients with high or high-normal serum calcium levels obtained a repeated serum calcium test along with a serum parathyroid hormone measurement and if the test results were abnormal, they were referred to an endocrinologist. Patients with major risk factors for RTA were referred to a nephrologist. Risk factors for RTA were defined as urinary citrate excretion below 50 mg/d alone, or urinary citrate excretion of 50 mg/d to 150 mg/d with low serum potassium, high chloride, or low CO₂ level, more than 50% brushite or hydroxyapatite stones, or nephrocalcinosis (on the basis of the 2016 consensus statement\(^\text{33}\)). Patients who noted a recurrent stone were referred to their primary urologist for reevaluation. Patients deemed at risk of RTA on the basis of the inability to correct urinary citrate levels to above 150 mg/d despite compliance with the protocol also were referred to a nephrologist.

Patients who were referred to the program but declined to participate were defined as those who verbally declined on initial contact or who did not respond to the 6-week follow-up phone call. The dropout rate was defined as the number of patients who were unable to be reached after 5 attempts, who declined to continue in the program, or who died of unrelated issues divided by the total number enrolled for that time period.

Statistical analysis involved use of the Student 2-tailed t-test. Results were expressed as the mean and standard deviation.

**RESULTS**

A total of 536 patients were referred to the kidney stone prevention program during a 17-month period. Five hundred patients were enrolled, as defined by agreeing to receive the initial consultation as well as completing the 6-week follow-up phone call; 36 patients declined enrollment.

Patient demographics are listed in Table 1. Of the 500 patients enrolled, 100% completed dietary counseling and 266 of the 268 patients (99%) enrolled for at least 6 months in the program self-reported compliance with at least 3 of 5 aspects of dietary advice.

Overall, 288 of the 500 patients completed a 24-hour urine test. Of the 268 patients in the program at least 6 months, 183 (68%) completed both serum and 24-hour urine testing. Of the 120 patients in the program at least 12 months, 96 (80%) completed both serum and 24-hour urine testing (Figure 2).

Abnormal results of the 24-hour urine test were found in 251 of the 288 patients (87%). Of these 251 patients, 92 (37%) had solitary abnormalities, whereas 159 patients (63%) had multiple abnormalities; 56 of 251 patients (22%) had 3 or more abnormalities. Hyperoxaluria was the most common abnormality at 24%, followed by hyperuricosuria at 21% and low volume at 17% (Table 2).

When we separated out the 446 calcium oxalate stone formers, 248 completed an initial 24-hour urine test, of which 212 had abnormal results. Of these 212 abnormalities, 178 were nonvolume abnormalities. Fifty-two of these 178 patients (29%) were in the program long enough to repeat a second collection

### Table 1. Demographic Characteristics of Patients Enrolled in Program (N = 500)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (median); range, y</td>
<td>55 (57); 23-88</td>
</tr>
<tr>
<td>Sex, % women/men</td>
<td>34/66</td>
</tr>
<tr>
<td>Previous stone composition,(^*) no. of patients</td>
<td>2.8</td>
</tr>
<tr>
<td>Calcium oxalate</td>
<td>315</td>
</tr>
<tr>
<td>Unknown composition</td>
<td>102</td>
</tr>
<tr>
<td>Urate</td>
<td>54</td>
</tr>
<tr>
<td>Calcium phosphate</td>
<td>25</td>
</tr>
<tr>
<td>Pure apatite</td>
<td>2</td>
</tr>
<tr>
<td>Pure brushite</td>
<td>2</td>
</tr>
<tr>
<td>Average no. of previous stone events</td>
<td>2.8</td>
</tr>
<tr>
<td>Enrollment period, mo</td>
<td>17</td>
</tr>
<tr>
<td>Mean follow-up, d</td>
<td>267</td>
</tr>
</tbody>
</table>

\(^*\) Stone analysis data obtained from Quest Diagnostics (San Juan Capistrano, CA).

### Table 2. Type of abnormalities on initial 24-hour urine test (N = 438)\(^*\)

<table>
<thead>
<tr>
<th>Abnormality</th>
<th>Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypercalciuria</td>
<td>49 (11.19)</td>
</tr>
<tr>
<td>Hyperuricosuria</td>
<td>91 (20.78)</td>
</tr>
<tr>
<td>Hyperoxaluria</td>
<td>107 (24.43)</td>
</tr>
<tr>
<td>Hypocitraturia</td>
<td>64 (14.61)</td>
</tr>
<tr>
<td>Low volume</td>
<td>74 (16.89)</td>
</tr>
<tr>
<td>Hypermaturia</td>
<td>53 (12.10)</td>
</tr>
</tbody>
</table>

\(^*\) N = total number of abnormalities. Please note 159 of 251 patients had multiple abnormalities.
and were found to have a statistically significant improvement in the averages of all listed urinary parameters (Table 3).

Seventeen hypernaturic patients repeated a 24-hour urine test by 17 months, and 14 (92%) of the test results normalized. Additionally, 25 hyperoxaluric patients repeated a 24-hour urine test and 12 (48%) had results that normalized. For the 16 hypocitraturic patients who repeated a 24-hour urine test, 5 (31%) results normalized. Among hypercalciuric patients who repeated a 24-hour urine test, 4 (24%) of 17 results normalized. Finally, 24 hyperuricosuric patients repeated a 24-hour urine test and 13 test results (54%) normalized.

A total of 114 patients (23%) were receiving medical therapy on the basis of the protocol. Three patients were found to have primary hyperparathyroidism. Five patients were found to be receiving the carbonic anhydrase inhibitor acetazolamide or topiramate. Of the 500 patients who enrolled in the program, the overall dropout rate was 11.8% (59/500); 57 patients could not be contacted for follow-up, and 2 patients died of unrelated causes. The dropout rate was 12.4% (17/137) for those in the program longer than 12 months.

**DISCUSSION**

Kidney stone disease is extremely common, recurrent, and costly. Diet and lifestyle changes as well as medical treatment of underlying metabolic abnormalities can greatly affect a patient’s risk of recurrence, and this provides a compelling reason to counsel, evaluate, and treat these individuals. The American Urological Association and European Association of Urology both currently recommend dietary modification in all stone formers with metabolic evaluation and medical treatment for high-risk or recurrent stone formers or those who are interested.

Despite these recommendations, routine dietary modification and metabolic evaluation are often not being performed with compliance; 24-hour urine testing has been reported to be as low as 7.4% in high-risk patients and 16.8% in recurrent stone formers. Although patients and urologists are often extremely motivated to treat the initial painful stone episode, interest in long-term dietary changes or onerous metabolic evaluations is often very low. Even in those patients getting dietary instruction, metabolic evaluation, and medical treatment, compliance can be difficult to maintain despite the proven benefits. Dauw et al reported dismal low compliance rates with pharmacologic therapy for patients with kidney stones, including an adherence rate of only 13.4% for citrate therapy.

Dropout rates of 20% per year have been reported by Parks and colleagues. There is also difficulty in obtaining and interpreting 24-hour urine results, and the benefit has been called into question by some authors.

In addition, medical prevention must be cost effective. Cost-effectiveness depends on recurrence rate, intervention rate, and cost of care. Recurrence rates vary widely from less than 0.1 stones per year for first-time stone formers to greater than 1.0 stones per year for certain recurrent stone formers. The percentage of patients who require urologic intervention varies widely from 23% to 60%, as does the cost of care. Cost estimates from Europe in the late 1990s suggest that the recurrence rate must be more than 0.2 episodes per year to be cost effective and that metabolic evaluation in first-time stone formers is unlikely to be cost effective. For these reasons, we selected 2 high-risk groups for evaluation: Recurrent stone formers and urate stone formers.

Like hypertension, diabetes mellitus, and cardiovascular disease, kidney stone disease is dramatically affected by simple compliance with dietary and lifestyle changes. A team approach involving the addition of nurses and pharmacists to the delivery of standardized protocols can result in improved compliance and improved clinical outcomes compared with usual care. Clinical pharmacists are specifically trained in dietary modification, lifestyle modification, medication compliance, and telemedicine, and transferring many of these activities to a clinical pharmacist has proved beneficial in other chronic medical conditions.

Hyperoxaluria was the most common nonvolume urinary abnormality identified in our study, which is consistent with the recent rising trend of hyperoxaluria in the US. We could show early postintervention improvement in both urinary oxalate and urinary sodium excretion, unlike in other studies.

**CONCLUSION**

Our pilot study shows that it is feasible to enroll patients in a telemedicine-administered, pharmacist-staffed, protocol-driven, multicenter program for kidney stone prevention in a large integrated health care system: Results of a pilot program.

<table>
<thead>
<tr>
<th>Urine abnormality</th>
<th>Mean value (standard deviation)</th>
<th>Baseline</th>
<th>After intervention</th>
<th>Percentage difference</th>
<th>p value</th>
<th>Percentage normalized</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypercalciuria (250 mg/d)</td>
<td>17</td>
<td>388.4 (83.6)</td>
<td>292.2 (71.9)</td>
<td>25</td>
<td>0.001</td>
<td>24</td>
</tr>
<tr>
<td>Hypernatriuria (&gt; 200 mg/d)</td>
<td>17</td>
<td>220.2 (63.7)</td>
<td>166.5 (60.6)</td>
<td>22</td>
<td>0.005</td>
<td>52</td>
</tr>
<tr>
<td>Hyperuricosuria (&gt; 700 mg/d)</td>
<td>24</td>
<td>847.3 (227.5)</td>
<td>694.8 (258.9)</td>
<td>21</td>
<td>0.014</td>
<td>54</td>
</tr>
<tr>
<td>Hyperoxaluria (&gt; 45 mg/d)</td>
<td>25</td>
<td>60.6 (14.4)</td>
<td>49.1 (19.1)</td>
<td>19</td>
<td>0.022</td>
<td>48</td>
</tr>
<tr>
<td>Hypocitraturia (&lt; 320 mg/d)</td>
<td>16</td>
<td>156.7 (88.2)</td>
<td>297.1 (177.7)</td>
<td>90</td>
<td>0.006</td>
<td>31</td>
</tr>
</tbody>
</table>


Energetic Work

The kidneys are like the officials who do energetic work, and they ebb through their ability and cleverness.

— The Yellow Emperor’s Classic of Internal Medicine, Bk 3 Sect 9, Huang Ti Nei Ching Su Wen (Huangdi), c 2704 BC-2598 BC, known as the Yellow Emperor, a legendary Chinese sovereign and culture hero
The Power of Plants: Is a Whole-Foods, Plant-Based Diet the Answer to Health, Health Care, and Physician Wellness?

Benjamin Ha, MD

ABSTRACT

The exponential rise in the cost of health care since the 1980s in the US is unsustainable. It is estimated that more than 70% of health care dollars are spent addressing the result of unhealthy lifestyles that are increasing the rates of obesity, diabetes, and cardiovascular disease. There is also a severe and worsening epidemic of physician burnout in the US, which threatens the health of physicians and patients alike. In this article, I share why I believe a whole-foods, plant-based diet is a powerful prescription for optimal health and the answer to health, health care, and physician wellness.

“No disease that can be treated by diet should be treated with any other means.”
—Maimonides

INTRODUCTION

In spring 2013, I coauthored an article titled “Plant-Based Diets: A Nutritional Update for Physicians.” Widely read and shared by many people interested in plant-based nutrition, the article helped to ignite a plant-based movement within Kaiser Permanente (KP). In retrospect, what I now realize is that if not for one of my patients, that article may never have been written. The goal of this article is to share my personal journey to embracing a whole-foods, plant-based diet and why I believe it is the answer to health, health care, and physician wellness.

PERSONAL JOURNEY TO A WHOLE-FOODS, PLANT-BASED DIET

Robert and Rose Anne Park were 2 of my very first patients after I joined KP in 2003. They met at a United Service Organizations (USO) dance in Oceanside, CA, and after getting married and living in many cities across the US, they settled in Bakersfield, CA, to raise their family. Active in their church, Mr Park became Pastor Robert. He often led workshops for newly married couples and volunteered to teach Sunday school. Like many people whose life work is to serve others, Mr Park did not make his own health his highest priority. He received multiple medications for high blood pressure and diabetes, including insulin, and he struggled to control his weight.

In spring 2012, I received an email from Mr Park telling me he noticed blood in his urine, asking if he should be concerned. I ordered a computed tomography scan of his kidneys and assured him we would diagnose the problem. The scan showed no findings of concern in his kidneys. However, it did show multiple lesions in his liver and pancreas. On further testing and biopsies, Mr Park received a diagnosis of metastatic pancreatic cancer. After meeting with an oncologist, he understood that his prognosis was poor, and he decided to forgo all treatment. He enrolled in hospice and lived the final days of his life without fear, comforted by his faith in Jesus Christ. He died at home several weeks later, surrounded by his beloved family.

A few weeks after his death, his wife came to see me for a visit. The first thing I noticed was that Mrs Park had lost a considerable amount of weight. I assumed it was because of the stress of her husband’s illness and grief over his death. At the end of our visit, she asked if I would promise to do something for her; she asked that I read the book Eat to Live by Joel Fuhrman, MD. She explained that after her husband’s diagnosis, their son began searching for answers as to why his father’s pancreatic cancer had developed and how he could reduce his own risk. On the basis of his research, their family embraced a plant-based diet and saw benefits to their overall health, including weight loss. Before leaving the visit, she said to me, “I know it’s too late for Robert, but maybe this information can help someone else.”

Although I was skeptical of the idea that diet could affect cancer risk, I had to admit to myself that I had been taught very little about nutrition in medical school and residency. In the first few years after joining KP, I had gained more than 6.75 kg (15 lb) and was struggling with my own weight along with having episodic attacks of gout. After reading Eat to Live along with The China Study and other books outlining the research supporting the benefits of a whole-foods, plant-based diet, I faced a crucial decision. Do I ignore all the scientific evidence and research I now knew regarding the health benefits of a plant-based diet? Or, was I willing to challenge my ego and current mindset about health and nutrition? To answer that question, I begrudgingly decided to try a plant-based diet.

Unwilling to go all-in overnight, I initially eliminated all dairy and animal products except for eggs and fish. After a month, I had lost 4.5 kg (10 lb), felt healthier, was sleeping better, and had more energy. Given the results, I challenged myself to eat a completely plant-based diet without any animal products for a month. By the end of the month, I was below my high school weight and no longer experienced gout attacks.

As I personally experienced the benefits, I incorporated this concept into my medical practice and encouraged my patients to consider trying a whole-foods, plant-based diet. A whole-foods, plant-based diet aims to maximize consumption...
of nutrient-dense plant foods while minimizing processed foods, oils, and animal foods (including dairy products and eggs). It encourages lots of vegetables (cooked or raw), fruits, beans, peas, lentils, soybeans, seeds, and nuts (in smaller amounts) and is generally low fat. Although many whole-foods, plant-based diet advocates are vegan and consume no animal products, a popular variation is to be “flexitarian” and occasionally consume small amounts of dairy and animal protein. Many of my patients were willing to try a predominately plant-based diet after I shared with them my own experience along with the knowledge that I would monitor them closely.

The results astonished me. Within weeks, many patients were able to reduce or eliminate the hypertension and diabetes medications they had been taking for years. They told me that if they had known they could stop taking their medications by simply changing their diet, they would have done so long ago. However, many had never been told this was a possibility, so they believed that medication was the only way to control these conditions. For me, “deprescribing” medications was more professionally satisfying than prescribing multiple medications for my patients with chronic conditions.

HEALTH BENEFITS OF A PLANT-BASED DIET RECOGNIZED

There is growing acknowledgment and recognition of the health benefits of a plant-based diet for disease prevention, treatment, and reversal. For example, in KP Southern California, Sean Hashmi, MD, MS, FASN, the Regional Physician Director for Weight Management and Clinical Nutrition, hosts a monthly webinar, during which he reviews the latest nutritional science and research and provides evidence-based recommendations for medical practice. He often concludes his presentations with author Michael Pollan’s quotation “Eat food, not too much, mostly plants.” The nonprofit Plantrician Project’s Sixth Annual International Plant-Based Nutrition Healthcare Conference and the American College of Lifestyle Medicine’s annual conference Lifestyle Medicine 2018 saw more than 1000 health professionals in attendance. David Katz, MD, MPH, Founding Director of the Yale-Griffin Prevention Research Center in Derby, CT, leads the True Health Initiative, a global movement to make the fundamental truths about healthy, sustainable living and eating common knowledge. And, Rosane Oliveira, DVM, PhD, Founding Director of University of California, Davis Integrative Medicine, acknowledges that their “strongest focus is in the area of nutrition and plant-based diets which we believe is the number one way to successfully prevent, halt or reverse serious health conditions such as obesity, hypertension, type 2 diabetes and cardiovascular disease.”

Along with the article I coauthored on plant-based nutrition, The Permanente Journal has published additional articles on this topic, including the article by dietitian Julieanna Hever, “Plant-Based Diets: A Physician’s Guide,” and the article by Tuos et al., “A Plant-Based Diet, Atherosclerosis, and Coronary Artery Disease Prevention.” This past spring, Bodai and coworkers published an article in The Permanente Journal titled “Lifestyle Medicine: A Brief Review of its Dramatic Impact on Health and Survival,” which serves as both a comprehensive literature review and call to action for the entire medical community.

RECOMMENDATIONS FOR PATIENTS

Last year, after a decade as an Assistant Area Medical Director for KP in Bakersfield, CA, I decided to return to a full-time family medicine practice to spend more time working directly with patients. Speaking from the front lines, what I have found is that patients are hungry for information on ways to improve their health through lifestyle changes instead of medications.

I have streamlined my talking points about the benefits of a whole-foods, plant-based diet so that I can quickly cover the basics using my “Rule of 4.” I hold up 4 fingers on my left hand and tell patients to focus on eating more of 4 foods: Fruits, vegetables, whole grains, and beans. I then hold up 4 fingers on my right hand and tell patients to focus on eating less of 4 foods: Animal protein, dairy, processed foods, and oil/fried foods. I recommend they gradually shift their diet, with the goal of eating at least a 90% whole-foods, plant-based diet. I then provide them with handouts that further explain the benefits of a whole-foods, plant-based diet; provide links to additional resources; and offer an in-person or virtual follow-up visit.

I clarify with patients that my intention is not to convince them to become a vegan or vegetarian, but to encourage them to focus on eating more unprocessed plant-based foods. What has surprised me is that I cannot predict which patients will embrace and act on my recommendations. For those who have, many have lost weight, reversed their type 2 diabetes and high blood pressure, and dramatically reduced their need for prescription medications. I am convinced that a whole-foods, plant-based diet is an effective and evidence-based intervention that physicians should recommend to all patients to improve health and wellness.

CHALLENGES IN CHANGING THE CULTURE OF MEDICINE

Although many of my patients have been receptive to my advice about nutrition, when I share my newfound perspective with my colleagues, I typically hear the following responses: “I don’t have the time to talk to patients about nutrition,” “I don’t feel I have the knowledge to counsel patients on lifestyle,” “Nutrition has little to no impact on health and chronic disease,” or simply “I could never give up eating meat.” Their responses reflect the tremendous challenges in changing the culture of medicine to one that emphasizes lifestyle medicine and a “nutrition first” approach to disease prevention and treatment.

There are a growing number of resources now available for physicians to learn about the role of nutrition in disease prevention and treatment. You may attend a nutrition conference, complete an online certification program such as the eCornell certificate in Plant-Based Nutrition (www.ecornell.com/certificates/nutrition/plant-based-nutrition), become board certified by the American College of Lifestyle Medicine (www.lifestylemedicine.org/Board-Certification), or review online resources such as the Web site of Michael Greger, MD.
Disillusionment of an American Physician,
productivity and only for the face-to-face
you “eat what you kill,” meaning that
approach. Physicians in fee-for-service
service reimbursement model in health
care offers little or no financial incentive
our current health care delivery system.
health care, will continue to struggle in
ited financial resources and access to
many people, especially those with lim
overall cost of health care. Meanwhile,
will not decrease, but likely increase, the
and the field of personalized medicine
advances in medical research, technology,
to slow the cost escalation. Although ad
lates with the increased rates of diabetes,
The rising rates of obesity directly corre
in the US are now overweight or obese. The
clinical outcomes and life expectancy are
not the best in the world. According to the
CDC, more than 70% of people in the US are now overweight or obese. The
The power of plants is a whole-foods, plant-based diet the answer to health, health care, and physician wellness?
for care:” he said. “It’s common sense that when people are healthy, they typically require minimal
health care. Therefore, in a fee-for-service model, physicians receive no compensation when healthy patients do not seek care.
In a health care system like KP in which physicians are partners of a medical group
and receive a salary, compensation is no longer tied directly to productivity. Therefore,
the focus shifts to providing patients with high-quality, cost-effective care with
an emphasis on disease prevention. There is an overarching organizational incentive in KP to help patients live healthy lives and thrive. When patients do not seek care other than for preventive services, attention and resources can be focused on the patients who do require medical care.
However, even in KP, physicians are challenged with incorporating effective lifestyle and nutritional counseling into their practice. In my 2 decades as a family
physician, there has been a shift in medicine from providing mostly acute, episodic care to the long-term management of chronic diseases such as hypertension, diabetes, and obesity. Despite our best efforts, physicians can often feel as though nothing we do for patients actually makes
them better or healthier, leading to a diminished sense of personal accomplishment. Furthermore, quality metrics for chronic disease care indirectly encourage physicians to aggressively prescribe multiple medications for conditions such as hypertension and diabetes, with little incentive or reward for taking the time to counsel, educate, or assist patients in embracing a healthier lifestyle. These challenges, along with increasing administrative and clerical tasks, are affecting physician wellness and contributing to the emotional exhaustion and depersonalization characteristic of burnout.
Recently, I realized that I had a critical decision to make to help address my
own sense of burnout. I asked myself this question: For the rest of my career, do I want to be a healer or a drug “dealer”? I choose to be a healer. There is no greater joy in medicine than when you heal patients and restore their health rather than simply treating their chronic illness with medication. The gratitude I receive from patients who transform their lives reminds me why I chose to become a physician. On the basis of my clinical experience, I am convinced that no pill or medical procedure exists today or will ever exist that can help patients to improve their health as effectively as a prescription for a whole-foods, plant-based diet and healthy lifestyle.

CONCLUSION
Physicians still hold a trusted place in society. We must strive each day to continue to earn and deserve this trust. My day-to-day practice as a family physician is by no means perfect. Not all patients are interested in making changes to their lifestyle and nutrition. However, embracing lifestyle medicine, especially a plant-based diet, has greatly improved the health of my patients, my own wellness, and sense of satisfaction and fulfillment as a physician. I now finish each day in the clinic confident that I tried my best to empower my patients to take control of their health.
Looking back, I owe a tremendous debt of gratitude to Mr. Robert Park and his family. If not for them, I may have never realized that a whole-foods, plant-based diet is a powerful prescription for optimal health and wellness and plays a crucial role in the answer to health, health care, and physician wellness. Mr. Park’s life and death influenced my own life in ways he could never have imagined, and his legacy lives on with every patient I have the privilege to serve.
References

No Single Chemical

Everything in food works together to create health or disease. The more we think that a single chemical characterizes a whole food, the more we stray into idiocy.

— T Colin Campbell, b 1934, American biochemist
This photograph was taken while hiking down from Cadillac Mountain in Acadia National Park, ME, shortly after sunrise. Standing at 1530 feet tall, Cadillac Mountain is the highest peak on the eastern coastline, and from October to mid-March, it offers the first sight of sunrise in the US.

Dr Ramirez is the Family Medicine Chief at the Downey Medical Center in Southern California.
ABSTRACT

Introduction: Abdominal aortic aneurysms (AAA) more commonly affect men than women and are estimated to affect 4% to 8% of men older than age 60 years. Mortality because of a ruptured AAA is high, but elective repair is an effective and relatively safe intervention.

Case Presentation: A 79-year-old man came to the Emergency Department because of worsening back pain. Workup revealed a previously unknown, 10-cm aneurysm that had ruptured. Unfortunately, the patient died during emergency surgery.

Discussion: A literature review of proper screening, referral timeframe, the most common surgical techniques, potential complications, and postoperative surveillance was conducted. Early detection, referral to vascular surgery, and possible open or endovascular repair are key to limiting the morbidity and mortality associated with AAA.

INTRODUCTION

Ruptured abdominal aortic aneurysms (AAA) represent the 13th leading cause of mortality in the US. An arterial aneurysm is a weakening of the arterial wall with subsequent dilation to 150% or greater of its normal diameter. The most common type of arterial aneurysms, AAA, becomes clinically significant at diameters greater than 3 cm. Most commonly, AAA are located inferior to the renal arteries. However, they can extend proximally above the celiac trunk and distally beyond the aortic bifurcation. We report the case of an elderly man who was found to have a previously unknown, 10-cm AAA that had ruptured. Informed consent could not be obtained. An effort has been made to anonymize patient information so as to not cause harm to the patient or his family.

CASE PRESENTATION

Presenting Concerns

A 79-year-old man presented to the Emergency Department reporting the acute onset of low back pain radiating to the left side of his chest. The pain started the same day, had become progressively worse, and was not relieved by changes in position. The patient denied hematuria, dysuria, constipation, diarrhea, or any recent trauma.

His medical history was remarkable for known cardiovascular disease, including coronary artery disease with previous myocardial infarction and 4-vessel coronary artery bypass graft; a 31-pack-year history of tobacco use; paroxysmal atrial fibrillation treated with warfarin anticoagulation; and hypertension. Other comorbidities included stage 3 chronic renal insufficiency and hyperlipidemia. He had no known history of aortic aneurysm. On presentation, the patient’s vital signs were stable; however, he appeared in obvious discomfort. His blood pressure was 104/66 mmHg, pulse was 64/min, respiratory rate was 16/min, oxygen saturation was 97% on room air, temperature was 36.5 °C, and body mass index was 28.62 kg/m². Results of his physical examination included clear lungs; a regular heart rate and rhythm; and an obese abdomen that was soft and had mild distention. No AAA or hepatosplenomegaly were palpated. The patient had considerable discomfort on light palpation of the abdomen, with pain radiating to his flank and back bilaterally.

Laboratory results were overall unremarkable and included a normal troponin I level of 0.01 ng/mL (normal value = 0.00-0.09 ng/mL), white blood cell count of 13.9 × 10⁹/L, and hematocrit of 41%. Of note, the patient’s anticoagulation was subtherapeutic with an international normalized ratio of 1.7 (goal range = 2.0-3.0). The results of an electrocardiogram demonstrated normal sinus rhythm without acute ST changes. The results of an emergent computed tomography angiography (CTA) scan of his abdomen and pelvis demonstrated a 10-cm AAA with a large retroperitoneal hematoma consistent with a contained aortic rupture (Figure 1).

Figure 1. Axial computed tomography angiography scan shows ruptured abdominal aortic aneurysm (AAA). Triangle = center of a 10-cm AAA; star = the building retroperitoneal hematoma.

Keywords: AAA, abdominal aortic aneurysm, arterial aneurysm, endovascular aneurysm repair, open aortic repair, ruptured AAA
Therapeutic Intervention and Treatment

Establishment of appropriate intravenous access with judicious intravenous fluid administration and narcotic pain control was initiated. Blood typing and crossmatching were initiated while the patient received fresh frozen plasma and vitamin K for reversal of warfarin therapy. An emergent vascular surgical consultation was obtained, and open surgical exploration was recommended to the patient. He subsequently underwent an attempted open aortic repair (OAR). Unfortunately, blood loss was extensive, and the patient suffered a myocardial infarction intraoperatively.

Follow-up and Outcomes

Despite extensive resuscitation efforts, the patient died in the operating room. Figure 2 shows the timeline of the case.

DISCUSSION

Reported mortality rates for patients with a ruptured AAA are as high as 90%. In contrast, mortality rates for patients undergoing elective AAA repair are typically less than 10%. Accordingly, it is imperative to diagnose AAA before rupture. The risk factors for AAA include male sex, age greater than 65 years, a history of tobacco use, and a family history of AAA in first-degree relatives. It is estimated that 4% to 8% of men and 0.5% to 2% of women older than age 60 years have AAA. If left untreated, the natural progression of AAA is to continue to enlarge. Larger aneurysms have an associated higher risk of rupture. In addition, larger aneurysms expand at a faster rate than smaller aneurysms. A 5-cm aneurysm has an estimated 20% annual risk of rupture, whereas a 6-cm aneurysm has an estimated 40% annual risk of rupture. Aneurysm repair is a relatively safe and effective way to minimize the risk of death associated with rupture. Along with ordering appropriate AAA screening, primary care physicians should be knowledgeable about when to refer a patient to a vascular surgeon, how to optimize a patient’s comorbid conditions before surgery, the potential complications, and the necessary postrepair surveillance.

Screening

Dedicated ultrasonography is the gold standard for AAA screening. However, AAA can also be detected by physical examination. According to the Society for Vascular Surgery, all men and women older than age 65 years who have smoked more than 100 cigarettes in their lifetime, as well as those with a family history of AAA in a first-degree relative should undergo 1-time abdominal aortic ultrasonography. An aortic width of greater than 3 cm is considered clinically significant, and details of when to refer to a vascular surgeon will be addressed later in this article.

Cursory evaluation for AAA can also be done during the annual physical examination. To appropriately evaluate for AAA, the patient should lie supine with knees bent, allowing relaxation of the abdominal wall. The physician should palpate the epigastric region for an abdominal pulse. Then the physician can determine the width of the aorta by placing his or her index fingers on either side of the pulsating aorta. AAA will demonstrate an expansile pulsation that is appreciable anterolaterally. An experienced practitioner will recognize the characteristic feel of an expanded aorta. Patients with less abdominal girth, as well as those with larger aneurysms, are more likely to have an aneurysm discernable on physical examination.

Many practitioners are not aware of the effectiveness of the physical examination at identifying AAA. In a study by Fink et al, blinded physicians were asked to examine patients with or without known AAA. The physical examination was 82% specific for aneurysms larger than 5 cm, 69% for aneurysms 4 to 4.9 cm, and 61% for aneurysms from 3 to 3.9 cm. Their study demonstrates that the physical examination can be very useful for detecting moderate-sized to larger aneurysms. This may be of particular use in patients who would not otherwise qualify for screening according to the current guidelines.

Patients suspected of having AAA on the basis of the physical examination findings, and all patients meeting the screening criteria, should undergo an abdominal aortic ultrasonogram evaluation to confirm the presence of AAA.

For any stable patient suspected of having a symptomatic or ruptured AAA, CTA of the abdomen and pelvis should be ordered. Classic symptoms of a ruptured AAA are hypotension, acute severe back or flank pain, and a pulsatile abdominal mass.

When to Refer

An abdominal aorta with a width larger than 3 cm is considered aneurysmal, but the risk of rupture at 3 cm is minimal. Any patient found to have an AAA greater than 4 cm should be

<table>
<thead>
<tr>
<th>Aneurysm diameter, cm</th>
<th>Ultrasonography frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.0-3.9</td>
<td>Every 3 y</td>
</tr>
<tr>
<td>4.0-4.9</td>
<td>Annually</td>
</tr>
<tr>
<td>5.0-5.4</td>
<td>Every 6 mo</td>
</tr>
</tbody>
</table>

Table 1. Recommended aneurysm surveillance

Figure 2. Timeline of the case (in hours).

CTA = computed tomography angiography; ED = Emergency Department.
referred to a vascular surgeon for further evaluation and possible intervention. Typically, women are considered for intervention at an aneurysm size of 5 cm or larger, and men are recommended to undergo repair at 5.5 cm or larger.\(^2\) Serial ultrasonogram evaluations are recommended for patients who have AAA smaller than the threshold for treatment. The frequency of imaging depends on the size of the aneurysm (Table 1). Because larger aneurysms tend to expand at a faster rate, they require a more frequent monitoring schedule.\(^2,3\)

**Optimization for Surgery**

Once a patient is found to be a candidate for elective AAA repair, s/he should undergo a comprehensive cardiac evaluation and be thoroughly counseled about the importance of tobacco cessation. This should include appropriate nicotine replacement therapy in addition to group or individual counseling. Cardiovascular disease, often perpetuated by tobacco use, is one of the leading causes of mortality following aortic aneurysm repair.\(^4\)

Optimization preoperatively should also include consideration of statin therapy. Multiple studies of aneurysm repair have reported that fewer than 50% of participants were taking a statin medication at the time of the procedure.\(^4,5,7,10,11\) Among Medicare patients older than the age of 50 years undergoing aortic repair, Galíñanes et al\(^12\) reported preoperative statin use to be associated with a 26% reduction in 1-year mortality in addition to a decreased overall complication risk. In another study, Pini et al\(^10\) found that patients receiving statins were more likely to have a reduction in type 2 endoleaks at follow-up compared with their counterparts not receiving statins.

Many studies have attempted to identify medications effective at inhibiting the enlargement of AAA, therefore decreasing the need for surgical intervention. Primarily, research efforts have focused on antibiotics and propranolol. Doxycycline has demonstrated a reduction in aneurysm growth in animal models. However, these results have not translated to humans.\(^13\) Studies of the effects of propranolol have not demonstrated statistically significant results and have been further complicated by poor tolerance in patients.\(^13\)

**Methods of Repair**

There are 2 methods of AAA repair: OAR and endovascular aneurysm repair (EVAR). The first OAR was reported in 1951. Since this first-reported OAR, improved surgical technique as well as robust perioperative management have led to excellent morbidity and mortality rates. However, OAR remains a major surgical procedure, particularly in patients with associated comorbidities. As such, EVAR was developed in the early 1990s.

For an OAR, the surgeon will typically approach the aorta through a midline abdominal incision. The AAA is exposed in the retroperitoneum. The aneurysm is then excluded by suturing a prosthetic graft to the proximal and distal end of the diseased aorta. Patients who receive OAR spend, on average, 3.7 days longer in the Intensive Care Unit and 6.5 days longer in the hospital than their counterparts who receive EVAR (p < 0.001 and p < 0.001, respectively).\(^5\) Most patients will feel fully recovered 4 to 6 weeks after surgery. The perioperative risk of mortality from OAR is 4% compared with 1.4% in EVAR.\(^1,2\) Open repairs are higher risk procedures with greater blood loss and typically longer operative duration. Despite these perioperative disadvantages, OAR has lower rates of repeated intervention and lower long-term mortality than EVAR has.\(^3\)

The EVAR technique is performed in an operating room with radiologic capability. Access is typically obtained via the femoral arteries either percutaneously or via a small incision in the groin. Guidewires and catheters are then manipulated under fluoroscopic guidance through the iliac arteries into the aorta. A modular stent graft device is assembled in vivo to exclude the aneurysm. The EVAR devices require patients to meet strict anatomic criteria. In fact, incompatible anatomy accounts for 93% of the patients who are rejected for EVAR.\(^14\) Most patients treated with EVAR are discharged on postoperative day 1 and feel fully recovered 1 to 2 weeks after surgery. In the first 6 months postoperatively, EVAR is associated with lower rates of morbidity and mortality.\(^5,6\) Disadvantages of EVAR include the need for lifelong surveillance with radiologic imaging, a higher rate of reintervention, and a higher rate of aneurysm-related death after 6 months.\(^5\)

**Women and Abdominal Aortic Aneurysm**

Men are more likely to have AAA. However, women have worse outcomes in AAA management than men do, including aneurysm rupture at smaller diameters.\(^15\) Women also have higher rates of perioperative mortality, longer hospital stays, and are more prone to serious intraoperative complications.\(^16\) Although EVAR has become the more frequently performed procedure for AAA repair, many women do not meet the strict anatomical criteria.

**Perioperative Complications**

Perioperative complications are similar between EVAR and OAR, including colonic ischemia, wound complications, renal failure, myocardial infarction, pneumonia, and death. However, the rates at which these complications occur are, overall, higher in patients who receive OAR vs EVAR.\(^2\) Additionally, EVAR is associated with complications not encountered with OAR, including contrast medium reaction, contrast medium-induced renal insufficiency, and radiation injury in the event of a prolonged procedure.

**Colonic Ischemia**

Colonic ischemia occurs because of occlusion of the inferior mesenteric artery during repair of the AAA. This complication is 2.7 times more likely after OAR than EVAR.\(^17\) Colonic ischemia commonly presents within the first 24 hours postoperatively with symptoms of left-sided abdominal pain, cramping, and rectal bleeding.\(^17\)

**Wound Complications**

Groin pain or fever after EVAR is associated with infections at the access site. If a wound infection is not identified early, it can lead to the feared complication of graft infection. After an OAR, it is important to identify wound infections to avoid skin breakdown and abdominal wall dehiscence.
Long-Term Complications

Endoleaks

Endoleaks are the most commonly encountered complication of EVAR. An endoleak is a leakage of blood between the graft and the aneurysm sac. Some types can cause the aneurysm sac to enlarge and, if untreated, to eventually rupture. There are 5 types of endoleaks, and all are asymptomatic until rupture of the aneurysm sac. They may be noted at the end of a procedure or may develop years later. Table 2 details the classification, the timing of presentation relative to the primary intervention, and the next steps in the management of endoleaks.

Graft Infection

Graft infections are a rare complication of both EVAR and OAR. Infection of the graft should be suspected in anyone with history of EVAR or OAR who has sepsis of an unknown etiology or a new pseudoaneurysm juxtaposed to an indwelling aortic graft. As mentioned earlier, infection at the groin access site of an EVAR should also raise suspicion. Treatment of a known graft infection is surgical removal.

Aortoenteric Fistula

Aortoenteric fistula (AEF) is a complication that can occur in isolation or accompany a graft infection. As the name implies, an AEF is a connection between the aorta and the small intestine, most commonly the duodenum, which overflies the proximal AAA repair site. An AEF typically presents with a herald gastrointestinal bleed followed by frank exsanguination. Emergent CTA or endoscopy can confirm the presence of an AEF.

Buttock Claudication and Limb Occlusion

Endograft exclusion of the internal iliac artery can result in the development of buttock claudication. Most of these cases are self-limiting. A much more serious complication is limb occlusion, which is a medical emergency. Patients will typically present with acute symptoms of claudication.

Sexual Dysfunction

Sexual dysfunction is common in patients with arterial disease. Symptoms may worsen postoperatively after OAR. Often this is self-limited. A subset of patients will require a urology referral for further management.

Surveillance and Follow-up

After undergoing EVAR, patients require a surveillance CTA scan at 1 month, 6 months, and 12 months. If the results of the 1-month scan are normal, patients do not require the 6-month scan. Surveillance of the aneurysm does not end there. Yearly abdominal CTA is recommended for the rest of the patient’s life. Long-term follow-up is challenging, and noncompliance with imaging reaches close to 60% approximately 3 to 4 years after EVAR. Lifetime surveillance of these patients is important given the potential for late complications, which may not present until they become life threatening. Patients who receive EVAR are subjected to a greater lifetime burden of ionizing radiation than their counterparts who underwent OAR; however, studies have failed to demonstrate a statistically significant increase in malignancy rates among EVAR populations.

The recommended follow-up after OAR is much less intensive compared with EVAR. Patients should receive a dedicated abdominal aortic ultrasonogram with color Doppler of their aneurysm sac every few years to monitor for endoleaks and para-anastomotic aneurysms. They do not require annual CTA.

CONCLUSION

Our case highlights the importance of appropriate screening for AAA, referral to vascular surgery, and possible lifesaving interventions. Unfortunately, in the case reported here, the patient’s AAA remained undiagnosed until he presented to the Emergency Department with a rupture of his AAA. A screening ultrasonogram would likely have identified his AAA before rupture and allowed him to be evaluated for EVAR or OAR. This case emphasizes the potential role for screening programs, such as registries or notifications in the electronic medical record. Barriers to screening are many, including limited time in each clinic visit and patient ambivalence to screening. We suggest dedicated clinic visits to address preventive care recommendations, which would allow adequate discussion surrounding the patient’s goals and preferences.

Disclosure Statement

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

Table 2. Classification of endoleaks, timing of presentation relative to primary intervention, and next steps in management

<table>
<thead>
<tr>
<th>Type of endoleak</th>
<th>Cause</th>
<th>Timing</th>
<th>Increased risk of rupture</th>
<th>Next steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>1A/1B</td>
<td>Poor aorta-graft seal</td>
<td>Perioperative or late complication</td>
<td>Yes</td>
<td>Immediate intervention</td>
</tr>
<tr>
<td>2</td>
<td>Patent lumbar arteries or IMA</td>
<td>Late complication</td>
<td>Maybe</td>
<td>Monitor with serial imaging (CTA/ultrasonography)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Intervention if aneurysm expansion</td>
</tr>
<tr>
<td>3</td>
<td>Poor seal or separation between graft parts</td>
<td>Late complication</td>
<td>Yes</td>
<td>Immediate intervention</td>
</tr>
<tr>
<td>4</td>
<td>Porous graft</td>
<td>Perioperative complication</td>
<td>No</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Late complication</td>
<td>Yes</td>
<td>Intervention needed</td>
</tr>
<tr>
<td>5 (endotension)</td>
<td>Expansion of the aneurysm sac for unknown reason</td>
<td>Late complication</td>
<td>Maybe</td>
<td>Intervention needed</td>
</tr>
</tbody>
</table>

CTA = computed tomography angiography; IMA = inferior mesenteric artery.
Abdominal Aortic Aneurysm: A Case Report and Literature Review

Acknowledgments
Kathleen Louden, ELS, of Louden Health Communications performed a primary copy edit.

How to Cite this Article

References

Humility
There is no disease more conducive to clinical humility than aneurysm of the aorta.
— William Osler, MD, 1849-1919, physician, pathologist, teacher, diagnostician, bibliophile, historian, classicist, essayist, conservationist, organizer, manager, and author
Roughly 2 years ago I was attending a physician wellness program at Kaiser Permanente (KP), where I work. One of the topics was mindfulness, and as I was sitting in the room, I thought that this was the least helpful topic of the program. Little did I know that it would end up being the complete opposite.

Shortly after attending the program, I was relaxing at home and flipping through an issue of Sports Illustrated magazine, when a picture caught my eye. The image was of National Basketball Association (NBA) basketball player Aaron Gordon doing a spectacular dunk over a spinning Stuff the Magic Dragon mascot at the 2016 Slam Dunk Contest. The title of the accompanying article was "Mind over Mascot." The article talked about mindfulness in sports and mentioned the Lucid mental training app (Lucid Performance Inc; Mill Valley, CA) with Graham Betchart as the mental skills coach. I wanted to improve my golf game, and after being introduced to the concept of mindfulness at my recent session, I decided to get the app.

To me, mindfulness is about being in the present moment, not thinking of the past or the future but of what is happening now. It is letting go of things you can't control. It is a state of nonjudging or accepting the current situation as it is. It's also as George Mumford, author of The Mindful Athlete, calls it—a space between stimulus and response.

The key is to try to be mindful throughout the day. If one meditates regularly, it can become second nature. I discovered, however, that I could benefit almost immediately. First, I learned from the Lucid mental training app to use my breath to get into the present moment. It took only 5 to 15 minutes a day, but I was able to develop the skill of focusing on my breath and not attaching to other thoughts, thus letting them go. Then, I decided to try mindfulness at other times of the day, such as while walking the dogs in the park. I focused only on my breath, and when any other thoughts came into my mind, I observed them rather than attaching to them. What I noticed was how much more observant I was. I noticed the planes flying overhead, the different birds and their calls in the trees, and the train horn blowing in the distance—things that were always there, but because I was preoccupied with other thoughts, I had never noticed. This is a form of what Jon Kabat-Zinn, PhD, in his book Full Catastrophe Living, calls a "walking meditation." I then decided to take it to the golf course. As part of my preshot routine, I would take a few breaths and focus on the things that I could control and not on the things that I couldn't—like the water to the left, the people nearby watching, or the last hole—and it helped. It didn't improve my physical skills, but I was much more frequently able to play to my best of my ability, and it certainly improved my enjoyment of the game.

I then wondered if it would work in the clinic. So, just before entering the examination room, I would take a few breaths to get into the present moment, not thinking of the patient before or the one next but one. The one I was about to see. If I was running behind, I wouldn't worry about it because there was nothing I could do about it. I found that the visits ended up being more satisfying for me and my patient. I was more observant of my patient's words and body language and listened better. More than anything, patients want a doctor who listens, and a mindful doctor does that. It's not easy to see a schedule of 20 or more patients one after the other, but if you are fully present with each visit, it becomes 20 individual human connections, which is the essence of medicine and what makes it so satisfying.

Our breath is always with us, and we can use it to get into the present moment and to focus. As physicians we are constantly being interrupted. It all starts in residency when (in my days) you were handed a pager (now, a cell phone). At first, the pager is a symbol that you have arrived, but you soon realize that it is also a lot harder to focus on what you were in the middle of doing when you got paged. In such a situation, you could use your breath in 2 ways. You could use it to create that space between stimulus and response so you could calmly and intelligently answer the page, and then you could use your breath to refocus, get in the present moment, and resume what you were doing.

Being a physician is a stressful occupation. When we make mistakes—and we will all make them—the consequences sometimes can be devastating for our patients and for ourselves. One of the things taught in the Lucid app for athletes is that we are human beings choosing to play a sport. In our case, we are human beings choosing to make another human being better. We must remember that we are not the white coats that we wear or the successes or failures that happen while wearing the coat, but the person inside who has inherent value for choosing this profession.

Being a mindful physician has other benefits. It helps bring calm to the chaos. After working for 25 years, I can count on 1 hand how many times a patient has yelled at me. But, as we all know, it happens. Recently a young lady came in for her first visit with me after transitioning from pediatrics to adult medicine. She was accompanied by her father. We sat down, and she began telling me about her headaches. Her father suggested that we try some narcotics because he gave her 1 from a family member's prescription and it helped. As I began to explain that perhaps we should try other things first, he stood up, came closer, and with a raised voice said that I cared more about my license than his daughter. I felt my heart rate increase and the urge to respond. So, I took a few breaths and noticed my heart rate slow as I listened to his words, saw his daughter...
crying, and thought of my reply. I let him finish and then calmly and gently said that I cared for his daughter, and that was the reason I didn't think narcotics were a good idea at this time.

We are in the midst of a change in the management approach to chronic pain. I understand why this father was requesting narcotics because that was what he was accustomed to. We need different ways to look at pain, and mindfulness is one.

Roughly 30 years ago, Kabat-Zinn developed the MBSR (mindfulness-based stress reduction) program at the University of Massachusetts Medical Center. Still offered at the university medical school, this 8-week program is not just for stress reduction. Patients are referred to the program for management of stress but also for chronic pain or depression, often after standard medical treatment fails to help them. The program has been shown to significantly reduce anxiety and depression scores for the participants at completion of the program and up to 3 years later. Many other medical centers have modeled clinics after this groundbreaking program, including KP.

I recently saw a patient whom I believe had trigeminal neuralgia. He meditated daily, and as he was giving me his history, he would periodically close his eyes and take deep breaths. He was using his breath to handle the lancinating pain he was having. He was more interested in the cause of the pain than getting a pill to make it go away. Mindfulness can benefit patients if they are willing to try to look at pain, stress, and depression in a nonjudging way, rather than the primary focus being to take medicine to make their symptoms go away.

I used to wake up on Monday morning with the typical blues, thinking of what happened the few days before and what I was planning on doing for the coming weekend. Now, I wake up and look forward to that day and that moment, knowing that the current moment is the most important one and the only one that I can control and that I have the power to make that moment as good as it can be. So, mindfulness can help make every patient encounter, every day, and every moment as good as it can be. If mindfulness can help bring back the joy in medicine and life to a former skeptic and still novice mindful physician, perhaps it can do the same for you and your patients (see references and Sidebar: Suggested Reading for a few resources).

Breathe

Breathe. Let go. And remind yourself that this very moment is one you know you have for sure.

— Oprah Winfrey, b 1964, American media executive, actress, talk show host, television producer, philanthropist

Suggested Reading


Disclosure Statement

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

Acknowledgments

Kathleen Louden, ELS, of Louden Health Communications performed a primary copy edit.

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References

Rule 1: Recognizing the Rules and Patterns to Solve Problems and Puzzles Brings Internal, Fundamental Joy

photographs

Mihal Emberton, MD, MPH, MS

Dr Emberton reports: “I have always been fascinated with human learning and human connectedness. Photography is an amazing tool that allows me to capture these human moments, revisit them, frame them, apply perspective, and better understand them. Wynn Bullock (an acclaimed 20th century American photographer known for his color light abstractions and black-and-white photography of nature) stated, “When I photograph, what I’m really doing is seeking answers to things,” and I completely agree.”

These photographs were taken with an iPhone and the silvered filter was applied in Photoshop Express.

Dr Emberton is a perpetual student, a practicing primary care physician, and a medical educator in San Francisco, CA.
Treating Vitamin D Deficiency and Insufficiency in Chronic Neck and Back Pain and Muscle Spasm: A Case Series

Chunbo Cai, MD, MPH

CLINICAL MEDICINE

ABSTRACT

Introduction: The association between vitamin D deficiency or insufficiency and pain in the musculoskeletal system, especially in the neck and/or back regions, and/or muscle spasm is not well studied. The results of the limited studies have been mixed.

Case Presentation: The goal of this report is to examine the association between vitamin D deficiency and insufficiency and chronic neck and back pain and muscle spasm and the role of correction of vitamin D deficiency and insufficiency in the treatment of chronic pain and muscle spasm, especially in the neck and back regions. This case series reviewed medical records to identify patients with chronic pain (lasting from 6 months to 1 year) in the neck and back regions that improved significantly through the correction of the vitamin D deficiency or insufficiency. Patients were referred to the spine clinic of a tertiary hospital in a major metropolitan area in the Northwest by their primary care physicians after physical therapy and after first-tier pain medications, including nonsteroidal anti-inflammatory drugs, had failed. Some of the patients had epidural steroid injections without significant relief. The blood vitamin D level was tested at the clinical laboratory, and patients were given 50,000 IU of oral vitamin D once a week for 12 weeks. The main outcome measures were patient self-reported visual analog scale score and degree of muscle spasm. The 4 patients included in this series all had more than 70% improvement in their symptoms after taking 50,000 IU of vitamin D once a week for 12 weeks.

Discussion: Vitamin D deficiency and insufficiency can cause or worsen neck and back pain and muscle spasm. The correction of vitamin D deficiency and insufficiency plays an important role in the treatment of chronic neck and back pain and muscle spasm among patients having concurrent vitamin D deficiency and insufficiency because it can be prevented and treated easily. Given the high health care expenditure on the treatment of chronic neck and back pain, prompt and accurate diagnosis and treatment of vitamin D deficiency and insufficiency not only increase the quality of care but also reduce the cost.

INTRODUCTION

Historically, vitamin D deficiency (serum level < 20 ng/mL) and insufficiency (serum level < 30 ng/mL) have been linked with skeletal health and disorders, such as osteoporosis, osteomalacia, or rickets. During the past decades, several reports have been published on the role of vitamin D deficiency or insufficiency in non-skeletal disorders, especially many chronic diseases. The most recognized conditions include various cancers, autoimmune diseases, hypertension, cardiovascular disease, and diabetes. However, the association between vitamin D deficiency or insufficiency and pain in the musculoskeletal system, especially in the neck and/or back regions, and/or muscle spasm is not well studied. The results of the limited studies have been mixed. A few case reports and a small cohort study for certain musculoskeletal conditions have been published in the past few years, reporting a positive effect of vitamin D in treating chronic pain in palliative medicine and chronic low back pain. Recently, Sikora-Klak et al. recommended prompt treatment of vitamin D insufficiency and deficiency in athletes because of the high prevalence of vitamin D deficiency among the athletes, which imposes the risks of stress fracture, illness, and delayed muscle recovery. A quantitative meta-analysis of 19 randomized controlled trials with 3436 participants (1780 receiving vitamin D supplementation and 1656 receiving placebo) reported a significantly greater mean decrease in pain score (primary outcome) with vitamin D supplementation compared with placebo in people with various chronic pain conditions. However, another study conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) included 8 clinical trials and reported that vitamin D supplementation was not more effective than placebo, no intervention, or other conservative or pharmacologic interventions for low back pain. However, that study was limited because the overall quality of evidence was "very low" because of the poor methodologic quality and small sample sizes of the included studies. A retrospective study reported that the severity of pain increased in patients with low back pain as the deficiency of vitamin D increased among 98 patients. However, the study defined the vitamin D deficiency group as those whose vitamin D serum level was lower than 20 ng/mL (84 patients) vs 20 ng/mL and higher in the healthy group (only 14 patients), which did not reflect the vitamin D-insufficient population as those with serum levels of 20 to 30 ng/mL. One study reported that vitamin D and ferritin correlate with chronic neck pain but did not address the role of vitamin D deficiency in neck pain; notably, the studied population was skewed on sex, with 90% of patients being women. This article reports 4 cases of chronic pain (from 6 months to 1 year) in the neck and back regions in patients in whom pain and muscle spasm improved significantly through the correction of the vitamin D deficiency or insufficiency. An effort has been made to anonymize patient information so as to not cause harm to the patients.

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Keywords: chronic back pain, chronic neck pain, patient self-reported visual analog scale score, VAS score, vitamin D deficiency, vitamin D insufficiency
CASE PRESENTATIONS

Presenting Concerns

Case 1
A 46-year-old man with a medical history of AIDS and hepatitis B who had a 6-month history of back pain radiating into the frontal, lateral, and posterior aspects of both thighs with cramps and numbness was referred to the spine clinic. His visual analog scale (VAS) score was 6 to 8 out of 10. He was not anemic. The patient had tried physical therapy and pain medications, including nonsteroidal anti-inflammatory drugs (NSAIDs). The physical examination did not reveal any significant findings except for a limited range of motion in the lumbar spine attributable to the pain. Results of magnetic resonance imaging revealed mild degenerative changes throughout the lumbar spine with L5-S1 grade I anterolisthesis. Radiograph results revealed anterolisthesis of 4- to 4.5-mm slippage at L5 on S1 without evidence of instability on flexion or extension views.

The blood vitamin D level was 23 ng/mL (reference range, 30-100 ng/mL). The patient was prescribed 50,000 IU of oral vitamin D once a week for 12 weeks. After taking vitamin D for 8 weeks, the patient reported 80% improvement in pain. Retesting of vitamin D revealed a level of 31 ng/mL (reference range, 30-100 ng/mL).

Case 2
A 62-year-old man with a greater than 40-year history of T9 complete paraplegia had pain from worsening muscle spasm in the lower body and legs for 1 year, which severely interfered with his sleep. Daily stretching no longer provided relief. He reported a VAS score of 8 to 9 out of 10. He was not anemic. He could not tolerate tizanidine, which was prescribed as a muscle relaxant and pain medication. He had been given baclofen with progressive increasing of the dosage to the point where a baclofen pump was considered. Physical examination findings were consistent with T9 paraplegia. He also had increased muscle tone, suggesting mild spasticity in both the legs and ankles. The muscles in the calves were very tight on deep palpation.

His blood vitamin D level was 15 ng/mL (reference range, 30-100 ng/mL). He was prescribed 50,000 IU of oral vitamin D once a week for 12 weeks. After finishing the regimen, he reported 90% improvement. Retesting of vitamin D revealed a level of 51 ng/mL (reference range, 30-100 ng/mL).

Case 3
A 42-year-old woman with scoliosis had an 8-month history of pain and muscle tightness in the midback and low back. The VAS score was 9 out of 10. She was not anemic. Physical examination revealed no significant findings besides the scoliosis. The patient had tried physical therapy and pain medications, including NSAIDs. Radiograph results of the thoracolumbar spine revealed stable mild degenerative changes and moderate scoliotic curvature.

Her blood vitamin D level was 22 ng/mL (reference range, 30-100 ng/mL). She was prescribed 50,000 IU of oral vitamin D once a week for 12 weeks. After taking the vitamin D for 6 weeks, she reported 80% improvement in her pain level. Retesting of vitamin D revealed a level of 32 ng/mL (reference range, 30-100 ng/mL).

She returned to the clinic 1 year later for a 3-month history of gradual onset of recurrent midback pain and muscle spasm again. She did not continue to take vitamin D at the lower dosage daily as recommended because she was concerned about potential toxic effects. Retesting of vitamin D revealed a level of 14 ng/mL (reference range, 30-100 ng/mL). After taking 50,000 IU of vitamin D twice a week for 3 weeks, she reported 70% improvement of her symptoms. Retesting of vitamin D revealed a level of 29 ng/mL (reference range, 30-100 ng/mL).

Case 4
A 41-year-old man had a 1-year history of neck pain radiating into the shoulders, with muscle tightness in the upper arms and wrists. His VAS score was 8 to 9 out of 10. He was not anemic. The patient had tried physical therapy and pain medications, including NSAIDs. In addition, the patient also occasionally felt weak in the right arm. On physical examination, other than a limited range of motion in the cervical spine and tenderness in the neck and upper back region, there was no other significant finding. Cervical spine magnetic resonance imaging revealed mild spondylotic changes.

His vitamin D level was 27 ng/mL (reference range, 30-100 ng/mL). After taking the 3200 IU of vitamin D daily for 1 week, he reported 70% improvement in his symptoms and 90% improvement at 10 weeks. Retesting of vitamin D revealed a level of 36 ng/mL (reference range, 30-100 ng/mL).

DISCUSSION

All 4 patients in this case series had preexisting spinal conditions. Although the preexisting spinal conditions could be the cause of the pain symptoms, the results observed in this case series provide evidence of the association between the vitamin D deficiency or insufficiency and the concurrent episodes of pain and muscle spasm. Although Goccek et al11 proposed an inverse linear association between vitamin D level and the VAS scores from low back pain, this association only reflected the individuals with vitamin D serum levels below 20 ng/mL because the control group contained patients with vitamin D insufficiency (vitamin D level of 20-30 ng/mL). This study indicates that vitamin D supplementation also plays an important role in the patients with vitamin D serum levels between 20 and 30 ng/mL. It is evident that treating vitamin D deficiency or insufficiency is important in the management of chronic neck and back pain and muscle spasm. The mechanism for this association is not yet clear, which calls for more in-depth research. However, in part, it could be related to the deficiency and/or imbalanced homeostasis of intracellular and/or extracellular electrolytes, including calcium, magnesium, and phosphorus, resulting from the vitamin D deficiency, as reported through the historical research data.12 Recent research has indicated that the vitamin D receptors play important roles in cellular signal transduction and mediation of immune responses.13,14 Vitamin D deficiency is becoming pandemic for various reasons in the modern era and has drawn vast attention from the public.15,16 Recent interventional studies have found promising effects of vitamin D supplementation on cancer pain and muscular pain but only in patients with insufficient levels of vitamin D when...
starting intervention. Possible mechanisms for vitamin D in pain management are the anti-inflammatory effects mediated by reduced cytokine and prostaglandin release and effects on T-cell responses. It is important for practitioners to be aware of and recognize the coexistence of vitamin D deficiency and insufficiency among the population with chronic pain because it can be prevented and treated easily. Turner et al. reported the mean duration of opioid use for the inadequate vitamin D and adequate vitamin D groups were 71.1 and 43.8 months, respectively \( (p = 0.02) \). Given the high health care expenditure on the treatment of chronic neck and back pain, prompt and accurate diagnosis and treatment of vitamin D deficiency and insufficiency not only increase the quality of care but also reduce the cost, considering that the cost of the serum vitamin D test is approximately $25 vs the cost for the second or third tier of pain medications; narcotics especially are much more expensive, yet they have severe potential adverse effects and an adverse social impact.

**CONCLUSION**

On the basis of this small case pool, vitamin D deficiency and insufficiency play an important role in chronic pain and muscle spasm in the musculoskeletal system. However, treatment of vitamin D deficiency and insufficiency improves symptoms in those individuals. Although this series calls for in-depth, large cohort studies to further research relationship, a vitamin D test should be performed in individuals with chronic pain and muscle spasm who have the risk factors for vitamin D deficiency or insufficiency, such as lack of sun exposure because of their lifestyle or certain medical conditions, especially among those who do not respond to the first tier of treatment, including NSAIDs and/or physical therapy.

**Disclosure Statement**

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

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**References**


Novel Antiplatelet Perioperative Bridging Protocol for Lung Lobectomy: A Case Report

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ABSTRACT

Introduction: Some patients with cardiac stents will need thoracic surgery during the dual antiplatelet therapy (DAPT) period. When surgery cannot be safely delayed to allow 1 year of uninterrupted DAPT, appropriate perioperative management of anticoagulation is critical.

Case Presentation: A patient treated with new drug-eluting stents and DAPT was concomitantly diagnosed with lung cancer and required a lobectomy. We describe the novel addition of ticagrelor (a short-acting oral antiplatelet agent) to eptifibatide (a short-acting intravenous antiplatelet agent) to bridge DAPT for surgery.

Discussion: This ticagrelor-eptifibatide perioperative bridge resulted in decreased preoperative hospitalization compared with eptifibatide alone. There were no associated perioperative cardiac or bleeding complications.

INTRODUCTION

In the Medicare population alone, more than 300,000 patients undergo stent placement via percutaneous coronary intervention (PCI) each year.1 It is therefore not surprising that up to 10% of candidates for major lung resection will have had prior coronary artery intervention.2,3 Patients with drug-eluting stents (DESs) placed via PCI are generally maintained on at least 1 year of dual antiplatelet therapy (DAPT), most commonly aspirin and clopidogrel. The most recent American College of Cardiology/American Heart Association (ACC/AHA) guidelines on this topic recommend an absolute minimum of 3 months of uninterrupted DAPT before cessation for elective surgery, and an ideal minimum of 6 months.4 Stent thrombosis and perioperative myocardial infarction are the most feared complications of DAPT interruption and are associated with considerable mortality. The risk of these complications is highest in the first 4 to 6 weeks after PCI, but remains substantial for up to 6 months.4

Evidence-based guidance for the perioperative management of patients who need noncardiac surgery during this high-risk timeframe is extremely limited. Although all major guidelines and standards of practice recommend the continuation of aspirin in most cases, the appropriate management of the second component of DAPT, usually clopidogrel, is much less clear. The ACC/AHA did not find sufficient evidence to recommend a bridging regimen in their guidelines.5 The Society of Thoracic Surgery guidelines for antplatelet drug management suggest that short-acting, reversible, intravenous antiplatelet agents may be used to reduce the amount of time without DAPT when noncardiac surgery must be performed sooner than 6 months after DES placement, but similarly do not describe or recommend a bridging regimen.5 Although the major guidelines do not provide information on specific bridging therapy, a handful of case reports and case series have described the successful use of eptifibatide, a glycoprotein IIb/IIIa-inhibitor with a half-life of 2.5 hours,6 to bridge patients for surgery. Eptifibatide’s inhibition of the glycoprotein IIb/IIIa receptor occurs downstream of clopidogrel’s inhibition of the P2Y12 receptor,7 but still provides an adequate second target of antiplatelet therapy to aspirin’s COX-2 inhibition. Eptifibatide intravenous infusion (“drip”) is generally begun at 72 hours and stopped 4 to 12 hours before a planned procedure2,8-10 because platelet function returns to normal 4 to 6 hours after cessation.6 This timing requires preoperative admission of more than 72 hours in most cases, to begin the eptifibatide drip at the appropriate time after clopidogrel cessation, which usually occurs 5 days before surgery. Eptifibatide drip was not resumed postoperatively in any of the reports; rather, in most cases, clopidogrel was restarted 12 to 72 hours after surgery, often with a loading dose.

To reduce the nontrivial length of preoperative admission as well as the overall duration of DAPT interruption, we developed a new, multidisciplinary plan for management. Our bridging protocol includes an inpatient pre- and postoperative bridge with eptifibatide in addition to an outpatient bridge with ticagrelor, an oral antiplatelet agent with a short half-life of 7 hours.5 Like clopidogrel, ticagrelor is a P2Y12 inhibitor, but they differ in 2 key properties. First, ticagrelor is a direct-acting agent, giving it a faster onset of activity after initial dosing than clopidogrel, which must first be processed from its prodrug to active form. Second, its receptor-binding is reversible, so recovery after the last dose is comparatively rapid—whereas recovery after the last dose of clopidogrel, which acts irreversibly, takes days because new platelet synthesis is required.11,12 Platelet activity after ticagrelor cessation becomes subtherapeutic by 24 hours, and function is only substantially reconstituted after 48 to 72 hours.5,13 Ticagrelor is approved for use in DAPT and may actually provide superior prevention of acute coronary syndrome, with ACC/AHA guidelines recommending its use over clopidogrel in selected patients.4

CASE PRESENTATION

Presenting Concerns

A 72-year-old man with history of hypertension, diabetes, and benign prostatic hypertrophy presented with dyspnea...
on exertion. Coronary artery computed tomography (CT) revealed atherosclerotic disease, and an elective cardiac catheterization later that same month resulted in placement of 2 DESs. He was subsequently prescribed aspirin and clopidogrel according to the standard of care. A small pulmonary nodule had been detected incidentally during the coronary CT, and a dedicated chest CT further characterized it as a 1.8-cm, spiculated, right upper lobe nodule with imaging features highly suggestive of malignancy. Because of the risk of bleeding associated with an interventional radiology biopsy while on DAPT, the nodule was instead further evaluated with positron emission tomography–CT and was found to be strongly tracer-avid, also highly suggestive of malignancy.

**Therapeutic Intervention and Treatment**

The patient was evaluated in our thoracic surgery clinic only 3 weeks after placement of DESs. To avoid a substantial delay in curative surgery for this early-stage cancer, we developed a plan for perioperative management of his DAPT via collaborative decision making among members of a multidisciplinary care team. A detailed discussion of thrombotic risk assessment is beyond the scope of this report, but a number of factors were considered by the team, including the patient’s comorbidities, stent size and length, number of stents, and size of the territory at risk. These were weighed against the risk of interval cancer metastasis, at which point the high chance of cure would be lost. Ultimately, the surgery was postponed for the 6-week period of highest risk after DES placement but not for the usual 3 months. It was believed that the new protocol’s minimization of the patient’s time on antiplatelet monotherapy allowed an acceptable risk-benefit balance to enable a sooner oncologic operation. The surgery was planned at a facility where interventional cardiology would be available in case of perioperative cardiovascular complications.

The timeline and details of his perioperative bridging protocol are shown in Table 1. Consistent with the ACC/AHA guidelines, aspirin therapy was never interrupted. The incision was made less than 8 hours after the eptifibatide drip was stopped. His video-assisted thoracoscopic surgery right upper lobectomy proceeded without complication. The estimated blood loss was 50 mL, and the case duration was 135 minutes. The eptifibatide drip was restarted by 6 hours after surgery. We had intended to restart clopidogrel on postoperative day 1, but this was postponed and the eptifibatide was continued for possible chest tube removal. On postoperative day 2, the decision was made to leave the chest tube in place because of the persistence of a small air leak. Clopidogrel was subsequently restarted, and the eptifibatide drip was discontinued 3 hours later. The loading dose of clopidogrel, which had been part of the planned protocol, was omitted on the basis of the surgeon’s assessment of bleeding risk based on intraoperative findings.

**Follow-up and Outcomes**

The patient’s postoperative course was uneventful, without bleeding or cardiovascular complications. There were no Emergency Department visits or hospital re-admissions after discharge. The patient recovered appropriately, and continued to be well at 24-month follow-up.

**DISCUSSION**

Our protocol resulted in only 17 hours of perioperative antiplatelet monotherapy (vs a usual 22-58 hours). This regimen additionally allowed a decrease in the preoperative hospitalization (1 day vs a usual 3-4 days) and thus in total length of stay. There were no complications in the 2-year follow-up period.

There are several unique features of this novel bridging protocol that may have contributed to its success, both in terms of acceptance by the consulting teams and in terms of its clinical outcomes. Ticagrelor has a rapid onset of action and allows a more rapid reconstitution of platelet function after its withdrawal than does clopidogrel; as such, the surgery team was comfortable with continuing oral antiplatelet therapy until closer to the time of surgery, minimizing the duration of preoperative admission for intravenous therapy. The novel continuation of eptifibatide postoperatively also permitted an earlier return to full DAPT; the rapid onset resulted in a near-immediate therapeutic effect after redosing, and the surgeons were willing to accept the risk because the eptifibatide could be rapidly withdrawn in case of a bleeding event. The combination of the preoperative oral

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**Table 1. Timeline of the case of a 72-year-old man on DAPT (aspirin 81 mg daily + clopidogrel 75 mg daily) with suspicious primary nodule**

<table>
<thead>
<tr>
<th>Day*</th>
<th>Events/Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>−49 (−7 weeks)</td>
<td>Patient underwent cardiac catheterization with placement of 2 DESs.</td>
</tr>
<tr>
<td>−32</td>
<td>PET-CT results confirmed likelihood of lung cancer diagnosis. Thoracic surgery consult was ordered.</td>
</tr>
<tr>
<td>−28</td>
<td>In thoracic surgery consult, the very likely new lung adenocarcinoma with no evidence of metastatic disease was discussed with the patient, as well as treatment options. VATS lobectomy was recommended. Multidisciplinary discussions of timing and DAPT management began.</td>
</tr>
<tr>
<td>−26</td>
<td>Multidisciplinary consensus was reached (protocol as noted below).</td>
</tr>
<tr>
<td>−10</td>
<td>Last dose of clopidogrel 75 mg was taken in the morning (aspirin 81 mg was also taken on this and all mornings, which was unchanged).</td>
</tr>
<tr>
<td>−9</td>
<td>Patient took ticagrelor 85-mg loading dose in the morning and first dose of ticagrelor 90 mg in the evening, which continued twice daily.</td>
</tr>
<tr>
<td>−2</td>
<td>Patient took last dose of ticagrelor 90 mg in the morning.</td>
</tr>
<tr>
<td>−1</td>
<td>Patient was admitted to the hospital and was given eptifibatide 2 μg/kg/min.</td>
</tr>
<tr>
<td>0</td>
<td>Eptifibatide was stopped 6 h before surgery (8 h before incision time). Patient underwent VATS lobectomy. Eptifibatide 2 μg/kg/min was resumed 6 h after surgery.</td>
</tr>
<tr>
<td>+2</td>
<td>Clopidogrel was restarted with the first dose of 75 mg in the morning. Eptifibatide drip was stopped 3 h after the clopidogrel dose. Patient was discharged home in the afternoon.</td>
</tr>
</tbody>
</table>

*Day 0 = day of surgery.*

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Consult = consultation; DAPT = dual antiplatelet therapy; DESs = drug-eluting stents; PET-CT = positron emission tomography–computed tomography; VATS = video-assisted thoracoscopic surgery.
ticagrelor and intravenous eptifibatide bridge with a postoperative eptifibatide bridge reduced the interruption of DAPT and the associated cardiac risk to a level that was acceptable to the cardiology team. Both the ACC/AHA and the Society of Thoracic Surgeons guidelines promote multidisciplinary risk-assessment and decision making individualized for each patient and clinical situation. This measure was crucial in our case, as it ultimately led to the development of this new bridging protocol.

Although this operation would be considered “elective noncardiac surgery” by most guidelines, delays on the order of months are considered clinically significant for the curative resection of lung cancer that is localized on presentation. This bridging protocol could potentially be applied to any patient with DESs and a similar indication for time-sensitive “elective” surgery during the DAPT period. We describe our first experience with this protocol in a single patient; additional studies will be needed to verify the efficacy and safety of this novel bridging protocol in a larger cohort. Future applications of the regimen should attempt to restart clopidogrel with a loading dose, as was originally intended in this case.

CONCLUSION

Necessary thoracic surgery (in this case, a lung cancer operation) during the recommended period of DAPT following DES placement is not an uncommon clinical scenario, and yet there are no well-defined bridging guidelines. A bridging protocol of oral ticagrelor followed by short-duration intravenous eptifibatide preoperatively and intravenous eptifibatide postoperatively may be used in these situations to permit a prompt oncologic resection while minimizing the balanced risks of cardiac and surgical complications. The reduction in length of stay by 2 to 3 days is an important advantage of this protocol over similar eptifibatide-based bridging regimens. Consideration should also be given to application of this protocol to other surgical subspecialty operations necessitated within the DAPT period.

Disclosure Statement

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

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Foundation

The foundations of medicine are reason and observation.

— Giorgio Armeno Baglivi, 1668-1707, Armenio-Italian physician and scientist
Poststreptococcal Reactive Arthritis: Diagnostic Challenges

Colleen Chun, MD; Daniel J Kingsbury, MD

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ABSTRACT

Poststreptococcal reactive arthritis (PSRA) is associated with prior group A β-hemolytic streptococcal (GABHS) infection and has a reported annual incidence of 1 to 2 cases per 100,000 persons, approximately twice that of acute rheumatic fever (ARF) in the US. Children who present with reactive arthritis are not uncommon in a busy general pediatric practice in the US, whereas children who present with ARF are very rare. Distinguishing PSRA from ARF can be challenging because the symptoms and signs are similar, but the diseases differ in long-term therapy, follow-up evaluation, and prognosis. We review the diagnostic criteria for PSRA, the pertinent features of the 2015 ARF diagnostic guideline from the American Heart Association, and the major characteristics that differentiate PSRA from ARF.

INTRODUCTION

Poststreptococcal reactive arthritis (PSRA) is associated with prior group A β-hemolytic streptococcal (GABHS) infection and has a reported annual incidence of 1 to 2 cases per 100,000 persons, approximately twice that of acute rheumatic fever (ARF) in the US. In comparison, the incidence of reactive arthritis from bacterial enteric infections is 0.6 to 3.1 cases per 100,000 persons in Minnesota and Oregon,5 5.4 cases per 100,000 children younger than 16 years in Finland,6 and 9 cases per 100,000 children in Norway.7 Children presenting with reactive arthritis are not uncommon in a busy general pediatrics practice in the US, whereas children presenting with ARF are very rare. Distinguishing PSRA from ARF can be challenging because the symptoms and signs are similar but the diseases differ in long-term therapy, follow-up evaluation, and prognosis. We review the diagnostic criteria for PSRA, the pertinent features of the 2015 ARF diagnostic guideline from the American Heart Association, and the major characteristics that differentiate PSRA from ARF.

DIAGNOSTIC GUIDELINES

Diagnostic criteria for PSRA include persistent, additive, nonmigratory acute arthritis in 1 or more joints, evidence of prior GABHS infection, and the lack of other major criteria for ARF.8 When considering the diagnosis of ARF, it is important to review the incidence–related differences in ARF diagnostic criteria published in 2015 by the American Heart Association.7 In addition to the revised Jones criteria, this update added new information about Doppler echocardiographic findings of carditis and incidence–related differences in diagnostic criteria adopted from the Australian ARF diagnostic guideline.9 The latter recommendation specifies that the Jones criteria for individuals at high risk for ARF differ somewhat from those for individuals at low risk. Individuals are considered at low risk if they live in a community with an annual ARF incidence of fewer than 2 cases per 100,000 school-aged children or an all-age rheumatic heart disease (RHD) prevalence of 1 case or fewer per 1000 persons per year. Individuals are considered at high risk for ARF if they live in a community with an annual ARF incidence of more than 30 cases per 100,000 among 5- to 14-year-olds or an all-age RHD prevalence of more than 2 per 1000 persons per year. Criteria for those at moderate risk are less well defined. For patients from communities at greater than low risk, polyarthritis and aseptic monoarthritis are considered major Jones criteria, and monoarthritis is a minor criterion. These criteria are in contrast to the diagnostic criteria used in the US, where the incidence of ARF is low and polyarthritis remains a minor criterion (Figure 1).

Although ARF incidence is low in the developed countries of Europe and North America, the rates of ARF and RHD in Aboriginal Australians (153-380 cases per 100,000 among 5- to 14-year-olds), Maoris, Pacific Islanders in New Zealand, and Pacific Island nations are some of the highest in the world. The prevalence of RHD is also high in the Indian subcontinent, sub-Saharan Africa, Latin America, the Middle East, and Northern Africa.8

MUSCULOSKELETAL FEATURES

Detailed serial examination of the patient’s joints and history of joint symptoms are essential to distinguishing PSRA from ARF. PSRA joint symptoms include persistent, additive, nonmigratory acute arthritis that lasts for a mean of 2 months (range, 1 week to 8 months) despite nonsteroidal anti-inflammatory drug (NSAID) treatment.8 In contrast, ARF arthritis is typically acute and migratory, improves promptly within 2 days of starting NSAID treatment,4 and has a self-limited course.10 Although it reduces the future risk of streptococcal infection, antibiotic prophylaxis does not affect the course of the arthritis.9 Tenosynovitis has also been reported in 35% of patients with PSRA11 and can present with tender tendon nodules, which should not be confused with the subcutaneous nodules of ARF. The latter, in contrast, are typically painless, located over larger joints, and often associated with RHD.12

CARDITIS

Carditis has been reported in 5.8% of PSRA cases among children8 and can occur without a cardiac murmur.11 The onset of PSRA-related carditis has been reported 1 to 18 months after the arthritis appears.12 In contrast, 50% to 70% of ARF cases have carditis at initial presentation,15 and it is rare for RHD to manifest more than 1 week after arthritis onset.2

There are a few published case series with late echocardiographic follow-up studies of patients with PSRA, and fewer studies include whether patients reported cardiac symptoms of lightheadedness.

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Poststreptococcal Reactive Arthritis: Diagnostic Challenges


Figure 1. Revised Jones Criteria

chest pain, syncope, dyspnea with exertion, palpitations, dizziness, or fatigue. In a report of 52 children in Italy with PSRA, all had normal echocardiography results without clinical evidence of valvular disease at diagnosis, 1 year, and 6 to 10 years later. All patients had received secondary prophylaxis. Among 146 children with PSRA in Israel without cardiac symptoms or murmur on examination, 69 children had echocardiographic follow-up 1 to 6.9 years after diagnosis. Thirty-eight of the 69 patients (55%) were treated with antibiotic prophylaxis, of whom 7 had minimal-to-mild mitral insufficiency and 1 had mild tricuspid insufficiency. Among the remaining 31 patients (45%) who lacked antibiotic prophylaxis, 10 had minimal-to-mild mitral insufficiency, 1 had mild tricuspid insufficiency, and 1 had mild aortic insufficiency. Acute-phase reactant levels at diagnosis and with delayed-onset carditis were not reported. No patient had valve leaflet thickening or restricted motion. These findings did not meet 2012 World Heart Federation criteria for echocardiographic diagnosis of ARF carditis. Among 40 children with PSRA in Jordan, none had carditis at diagnosis; however, 4 patients who were nonadherent with antibiotic prophylaxis developed carditis during the first 2 years of follow-up accompanied by arthritis, elevated acute-phase reactants, and elevated antistreptolysin-O antibody titers. Three of the 4 patients had mitral insufficiency, and the fourth had mitral and aortic insufficiency. One of the 4 patients had silent carditis defined as echocardiographic evidence of valvular involvement without murmur, pericarditis, or heart failure.

An unpublished case of a school-aged patient with suspected PSRA had normal echocardiography results and completed 10 days of penicillin treatment. Findings from the cardiac examination were normal at follow-up visits 12, 39, and 40 days after diagnosis. Sixty-one days after diagnosis, the patient had a new heart murmur, and results of a follow-up echocardiogram showed mild-to-moderate mitral insufficiency with leaflet thickening, mild aortic insufficiency, and mild left ventricular enlargement. The patient did not have cardiac symptoms, and acute-phase reactants were normal. Secondary prophylaxis with penicillin was restarted. Twelve months after diagnosis, the echocardiogram showed mild aortic and mitral insufficiency with complete resolution of the left ventricular enlargement.

Although many children with PSRA and delayed-onset carditis reportedly lacked cardiac symptoms, identifying the proportion of children with ARF and RHD without cardiac symptoms is limited by the literature. Studies of hospitalized patients with RHD tend to omit those without cardiac symptoms. Multiple studies of children in India and Africa diagnosed RHD solely on echocardiographic findings from large-scale screenings of children attending school; however, alternative explanations for the valvular abnormalities were not uniformly sought so the true sensitivity and specificity of the echocardiographic abnormalities to diagnose RHD remained unknown. Therefore, a direct comparison to the children diagnosed with PSRA who subsequently are diagnosed with carditis without cardiac symptoms is not possible.

The risk of carditis among adults diagnosed with PSRA differs from that of children. Two prospective studies from the Netherlands of adults with PSRA evaluated individuals for carditis. The 1999 study of 23 adults treated with antibiotic prophylaxis for 2 years and followed-up for 4 years did not find evidence of carditis. The 2009 study involved 75 adults who were not treated with antibiotic prophylaxis after PSRA diagnosis. After a median of 8.9 years of follow-up, 60 of the 75 individuals had follow-up echocardiographic studies, which did not reveal an increased incidence of valvular abnormalities compared with controls. Possible explanations for the marked difference in carditis among adults include the following: 1) an age-related difference in carditis incidence among patients with PSRA, 2) the alternative diagnosis of reactive arthritis attributable to another bacteria or virus in an individual with unrelated persistently elevated levels of streptococcal antibodies, or 3) the alternative diagnosis of a different seronegative subacute-to-chronic arthritis.

TREATMENT

Patients with PSRA should be followed-up closely for at least 1 year with complete physical examinations. NSAID treatment should continue until the arthritis has resolved and acute-phase reactants become normal. Antibiotic treatment should be
prescribed to eradicate streptococci from the throat followed by secondary antibiotic prophylaxis. Secondary prophylaxis is recommended for 1 year for patients with PSRA with normal initial echocardiography results because of possible delayed onset of carditis. If carditis develops, the patient is typically classified as having ARF and should continue secondary antibiotic prophylaxis according to the current GABHS guideline. However, in contrast to ARF, the effectiveness of secondary prophylactic prophylaxis to prevent the occurrence or recurrence of PSRA carditis is not well studied.\textsuperscript{1,24}

CONCLUSIONS

PSRA should be part of the differential diagnosis for children and adults presenting with acute arthritis in 1 or more joints. On the basis of differences in disease presentation, clinical course, and response to NSAID therapy, PSRA and ARF appear to be separate entities. In addition, different genetic markers have been correlated with each disease: HLA-DRB1*01 with PSRA and HLA-DRB1*16 with ARF.\textsuperscript{9} Because the diagnosis of PSRA relies on sequential clinical findings that may not have occurred before a patient’s first office visit, there is risk of a missed diagnosis without careful follow-up.

There remain many unanswered questions about the usefulness of antibiotic prophylaxis with PSRA. The lack of carditis as a late-onset complication among adults without antibiotic prophylaxis\textsuperscript{22} raises the question of the effectiveness of prophylaxis in preventing late-onset carditis. Studies in children are inconclusive, and there is the additional concern about avoiding unnecessary antibiotic treatment. Until there are more prospective studies to better delineate the optimal treatment for and prognosis of PSRA, treatment recommendations will continue to resemble those for ARF. Additional studies of PSRA are needed that include follow-up echocardiograms and acute-phase reactant measurements at standardized intervals, serial screening for cardiac symptoms, and evaluation for concurrent viral causes with new-onset carditis. Such studies would help determine the optimal frequency of echocardiography surveillance for patients with PSRA.\textsuperscript{5}

Disclosure Statement

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

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CASE PRESENTATION

A 25-year-old woman presented to the Emergency Department with hematemesis and melena. She denied history of jaundice or liver disease. At initial presentation, her blood pressure was 90/50 mmHg with a heart rate of 140/min. Physical examination was remarkable for abdominal distension. Laboratory findings demonstrated hemoglobin of 3.0 g/dL, and platelets were 100,000/mm³. Liver function test findings included total bilirubin, 0.5 mg/dL; aspartate aminotransferase/alanine aminotransferase, 90/70 U/L; alkaline phosphatase, 59 IU/L; total protein, 4.9 g/dL; albumin, 1.7 g/dL; international normalized ratio, 1.6; and normal kidney function test results. The test results for hepatitis B surface antigen, hepatitis B core antibody, and antihepatitis C antibody were negative. The test results for detection of antibodies against nuclear and smooth muscle antigen were positive, with both having a titre of 1:40 and raised total immunoglobulin G level, indicating autoimmune hepatitis as the probable cause of cirrhosis.

The patient was initially resuscitated with isotonic fluids and packed red blood cell transfusions. Results of an upper gastrointestinal endoscopy did not show varices in the esophagus or stomach. The proximal segment of the second part of the duodenum showed multiple varices, and 1 of the varices had a nipple sign (Figure 1). Computed tomography of the abdomen results showed nodular liver, splenomegaly, ascites, and paraduodenal varices with a patent portal vein, splenic vein, and superior mesenteric vein (Figure 2). The afferent vein supplying the duodenal varices was from the superior mesenteric vein, and the efferent vein drained into the inferior vena cava. N-Butyl cyanoacrylate was injected into the varices, leading to obliterations of varices. She received intravenous terlipressin and prophylactic antibiotics injections along with other supportive care. Although the bleeding was controlled, she developed hospital-acquired pneumonia and died from sepsis.

DISCUSSION

Duodenal variceal bleeding is an uncommon complication of portal hypertension with very high mortality rates. Cirrhosis is the most common cause of duodenal varices, and in most cases, it occurs concomitantly with esophageal varices and/or gastric varices. Isolated duodenal varices are less frequently reported. Retroperitoneal portosystemic shunts cause an increase in hepatofugal blood flow through the gastroduodenal veins and superior and/or inferior pancreaticoduodenal veins, which leads to the development of paraduodenal varices. These paraduodenal varices can communicate through perforators with vascular channels in the submucosa of the duodenum, which can gradually enlarge over a period of time to form duodenal varices. The most common site of occurrence is at the duodenal bulb, and the frequency of occurrence decreases the farther away the site is from the duodenal bulb.

Duodenal varices are most frequently diagnosed by endoscopic examination. If the site of bleeding cannot be identified by endoscopic examination, other modalities such as abdominal
computed tomography, mesenteric angiography, and endoscopic ultrasonography can be considered. The optimal treatment modality is not well established because of its rare occurrence. Treatment modalities such as band ligation, sclerotherapy, hemoclips, coil embolization, transjugular intrahepatic portosystemic shunt, balloon-occluded retrograde transvenous obliteration, and shunt surgery have been used in management of bleeding duodenal varices.\textsuperscript{1,2,4-8}

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Gastroscopy
Gastroscopic examination … permits repeated differential diagnosis, which is not possible by other methods, for interpreting pictures of disease conditions, which formerly could not be diagnosed at all. The different forms of chronic gastritis and ventricular polyposis especially belong in this class.

—— Rudolf Schindler, 1888-1968, German physician regarded as the “father of gastroscopy”
HEALTH CARE COMMUNICATION

The Best Physicians Are Destined to Hell

Scott Abramson, MD

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ABSTRACT

Physician burnout is real. But the solution involves courage—the courage to look inside one’s heart and the courage to ask for help.

“The Best Physicians are destined to hell.” This is a famous teaching in the Torah, the Jewish holy book. Now why would the holy book of the Jews make such a statement?

The answer, the rabbis explained, is this is a lesson about arrogance—and this is a lesson about humility. “The Best Physicians,” as we all know, may also be the most prideful. They may not realize they need help treating their patients. And if they do realize it, their hubris, their feeling of self-importance, may prevent them from asking. For this, they fail their patients. And they fail themselves.

In this teaching there may be truth. I think most of us have had moments in our professional lives in which we have not reached out to colleagues for fear of appearing ignorant or of feeling incompetent. Of this, I know I have been guilty.

But this teaching may be true in another way. Sometimes when we, “The Best Physicians,” are suffering from emotional exhaustion, when we have lost the feeling of satisfaction in our daily work, and when we are staring burnout in its charred face, we ourselves, “The Best Physicians,” don’t reach out. We don’t ask for help. For many of us, the story of our professional lives is this: We face overwhelming workloads, long hours in the hospital, and even more hours at home with our portable medical computers (my “Laptop Lover” is what my wife calls mine). We spend countless, frustrating hours doing clerical work that a medical secretary could do. We miss dinnertime with our loved ones. We miss bath time, bedtime, and reading time with our children. We miss their soccer games and their music recitals. But in the face of this overwhelming pressure, what do we do? How do we respond? Most of us, “The Best Physicians,” do what we have always done. We do what our years of training dictate we do—we put our heads down and work harder. We plow through. We suck it up. We tough it out because “when the going gets tough” (you can fill in the ____).

We are made of grit, backbone, pluck, and spunk. We are not quitters. We bite the bullet, swallow the pill, pay the piper. We do all this, but we don’t ask for help. We persevere in silence. And while we may tough it out, our flame gets dimmer. We, “The Best Physicians,” may begin to see (or maybe we don’t see) the beginnings of burnout.

No doubt, the potential solutions to burnout are myriad, from paleo dieting to mindfulness to gratitude journaling to goat yoga (just to name a few). However, this commentary is not about those kinds of solutions. It is instead about a more primal solution: The solution that demands, before all else, we reach deep into our souls, acknowledge our physician angst, overcome our professional pride, and have the courage to accept from others support and guidance.

So, if there is a kernel of truth in this narrative for you, please reach out to someone: Your physician well-being committee, a psychiatrist, a counselor in your faith community, a trusted colleague, a loved one. Someone.

Maybe “The Best Physicians” are “destined to hell.” But if you, “The Best Physicians,” my colleagues, are headed toward this destination, please heed this warning: Do not take this journey alone.

And if you see your fellow physicians heading down this path, think about lending a helping hand, a warm shoulder, or a listening ear.

Remember: Friends don’t let friends become “The Best Physicians.”

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A celebration of death as part of life, the Noche de Altares festival in Santa Ana, CA, is one of the largest Dia de los Muertos festivals in the country. This photograph was taken at the festival in 2018.

Dr Ramirez is the Family Medicine Chief at the Downey Medical Center in Southern California.
COMMENTARY

Creating World-Class Care and Service for Our Nation’s Finest: How Veterans Health Administration Diffusion of Excellence Initiative Is Innovating and Transforming Veterans Affairs Health Care

Carolyn Clancy, MD

E-pub: 09/19/2019

ABSTRACT

As the largest integrated health care system in the US, the Veterans Health Administration is dedicated to continually innovating its systems, technology, and practices to provide high-quality care to US veterans. In this article, I describe the Veterans Health Administration’s Diffusion of Excellence Initiative, which involves an annual, systemwide competition to recognize Department of Veterans Affairs employees and identify promising practices for implementation in other Department of Veterans Affairs facilities or Veterans Integrated Service Networks. To demonstrate the reach and impact of the initiative, I highlight practices that are being implemented in 4 areas: 1) direct scheduling, 2) access to health care in rural areas, 3) access to mental health care, and 4) interactive and patient-centered care. In addition, I outline the primary components of the current transition plan to elevate lessons learned and transform the initiative from a nascent start-up to a sustainable part of the Veterans Health Administration’s culture.

INTRODUCTION

As the Deputy Under Secretary for Health for Discovery, Education, and Affiliate Networks at the Veterans Health Administration (VHA), the largest integrated health care system in the US, my topmost priority has always been to improve the quality and consistency of care delivered to the 9 million veterans that the VHA serves. This supports the agency’s vision for providing veterans a consistent, seamless care experience at any Department of Veterans Affairs (VA) medical facility across the country. To that end, the VA is constantly seeking to innovate its systems, technology, and practices to ensure that our veterans are receiving the highest caliber health care.

Through the Diffusion of Excellence Initiative, the VA has created a culture that is committed to identifying innovative and best practices that are employee driven and creating the pathway to standardize and spread these practices on the basis of proven success and outcomes. The Diffusion of Excellence Initiative is all about identifying, recognizing, and spreading best practices as the engine to drive continuous improvement across the VA and to change veterans’ lives for the better.

DIFFUSION IN ACTION: IMPLEMENTING PRACTICES, CHANGING LIVES

The VHA hosts an annual, systemwide competition to recognize top performers and to identify promising administrative and clinical practices and innovations that have been previously implemented in 1 or more VA locations. Inspired by the reality television series “Shark Tank,” the competition invites all employees via email, social media, and signage to submit innovations or practices on their own time that have demonstrated improvement in care delivery or operational processes across VA priorities. As defined by VHA senior leadership, priorities are access, care coordination, employee engagement, medical-surgical nursing, clinician recruitment and retention for rural facilities, quality and safety, suicide prevention, and veteran experience.

Since late 2015, more than 1600 practices have been submitted during the course of 3 “Shark Tank”-style competitions. For each competition, subject matter experts from the field evaluated submissions using prespecified review criteria (eg, demonstrated impact of the practice, feasibility of replication, and alignment to VHA priorities) and selected semifinalists. The VA program office leaders then evaluated the semifinalist applications on a scale of 1 to 5 using a standardized assessment tool based on the same review criteria. On the basis of the evaluation responses from program office leadership, finalists were selected for advancement in the competition by VHA senior leaders—the “sharks.”

In total, 47 practices have been selected and designated as Gold Status practices for facilitated implementation in other VHA facilities or Veterans Integrated Service Networks (VISNs). Diffusion focuses on spreading evidence-based best practices and innovative promising practices that have demonstrated outcomes. The Gold Status practices are currently at various stages of implementation, ranging from targeted implementation within a VISN to broad implementation at VA Medical Centers throughout the country within multiple VISNs.

Although there are many success stories that speak to the reach and impact of Diffusion of Excellence practices in making a difference every day for veterans, this article highlights 4 different practice areas: 1) direct scheduling, 2) access to health care in rural areas, 3) access to mental health care, and 4) interactive and patient-centered care. From improving radiology and optometry services to delivering mental health services to rural veterans, or engaging veterans in advanced care decisions, the Diffusion of Excellence Initiative is improving and fundamentally changing how the VA delivers care and service to its most important customer, the veteran.
Patient-Driven Direct Scheduling

Perhaps the greatest success story of the Diffusion of Excellence Initiative is the Audiology and Optometry Direct Scheduling Pilot, identified through the VHA “Shark Tank”-style competition as one of the VHA’s top priority groups: veterans in rural areas. One-fourth of all US veterans—more than 5 million veterans—reside in rural communities and experience great difficulties in accessing care and services, stemming from geographic barriers, limited Internet access, and high poverty rates. Several Diffusion of Excellence practices specifically focus on rural veterans. One such practice, TeleWound, uses econsultations, clinical video telehealth, and store-and-forward telehealth, which eliminates travel burden and reduces the risk of infection and hospitalization for the VA’s rural population.

Another practice, the Community Housing Fair, is a 1-day event during which homeless veterans collaborate with landlords, employers, and other community partners who can help provide same-day housing. This housing fair was especially useful for veterans in rural community-based outpatient clinics, where there are numerous barriers to adequate housing.

Improving Veteran Access to Mental Health Care

Identifying veterans at risk of suicide has typically been reactive, with interventions dependent on a veteran self-disclosing suicidal thoughts or intent or a clinician recognizing warning signs. The Suicide Prevention-Addiction Recovery Care group therapy model introduced a group therapy approach to proactively address suicide risk among veterans in the population receiving treatment for substance use disorder. Mental health clinicians provide education and help veterans identify plans and coping strategies during a session that is cofacilitated by a suicide prevention coordinator and a specialist in substance abuse disorders.

Interactive and Patient-Centered Care

Project HAPPEN (Hospital-Acquired Pneumonia Prevention by Engaging Nurses to complete oral care) encourages VA staff to perform oral care for and with veterans to reduce the risk of nonventilator (-associated), hospital-acquired pneumonia (NV-HAP). A lack of oral care causes bacteria to grow on teeth, which can be aspirated into the lungs and cause pneumonia. The practice ensures that inpatient, nonventilator-dependent veterans receive oral care by providing consistent staff training, educating patients on oral care and its association with pneumonia, and standardizing the procurement process for oral care supplies. Within the first 19 months of implementation, the NV-HAP incidence rate has decreased from 105 cases to 8.3 cases per 1000 patient-days, resulting in an estimated 13 lives saved and a cost avoidance of $2.8 million.

These practices show how innovation directly affects and benefits veterans nationwide and are only a few of the many examples of “diffusion in action.” But, the Diffusion of Excellence Initiative focuses on more than just improving systems and processes; it aims to inspire VA employees and leaders as active and valued contributors to the innovation process. The Diffusion model empowers VHA employees to engage in developing creative solutions to some of the agency’s most difficult challenges, which ultimately influences and helps shape the organization’s future.

FROM START-UP TO SUSTAINED

The Diffusion of Excellence Initiative provided the VHA with a framework that leverages the agency’s large scope and scale to deliver demonstrable improvements in the way we care for our nation’s veterans. It is also a framework that any health system can use to maximize innovation in providing high-quality and consistent health care. The initiative empowered employees by harnessing their ingenuity and bright ideas into actionable outcomes that provide invaluable benefits not only to the lives of veterans but also to their caregivers and supporters.

In the nearly 3 years since its inception, the Diffusion of Excellence Initiative diligently followed the innovation mantra, “Think big. Act small. Fail fast. Learn rapidly.” As with any new endeavor, there were missteps, missed opportunities, and flat-out failures, but the team behind the initiative learned ceaselessly, remained agile, and adapted as necessary (eg, using digital survey platforms to streamline the application process, and providing finalists with training on pitching their practices).

The next challenge, however, is elevating such lessons learned to transition the initiative from a nascent start-up to a sustainable part of VHA’s culture. There are 3 primary components of the current transition plan: 1) cultivate the culture, 2) build partnerships and encourage collaboration, and 3) embrace appropriate technology.

Cultivate the Culture

The Diffusion of Excellence Initiative tapped into something powerful: VHA employees are mission-driven. When given the opportunity, they jumped at the chance to improve and overhaul clinical and administrative processes, to adapt best practices from the private sector for VHA use, and to develop new products and practices from the ground up—all with the pure intention of improving the...
veteran experience. It will be important to maintain that energy and drive. To do that, the initiative will increase the amount of opportunities for learning, sharing, and collaboration among VHA employees by hosting virtual grand rounds sessions, offering implementation science training, and developing collaborative learning networks.

Build Partnerships and Encourage Collaboration

The VHA takes pride in providing the best care for veterans, particularly regarding health challenges prevalent in the population (eg, traumatic brain injury, posttraumatic stress disorder, and the need for prosthesis and assistive technology). However, there is much to learn from addressing those challenges in other federal and state agencies and the private sector. In the coming months and years, the team behind the initiative will actively seek opportunities to share what worked and did not work, while simultaneously endeavoring to learn from the successes and failures of colleagues seeking to identify, develop, and spread innovation outside the VHA. The initiative will also develop targeted collaborations with private sector health systems in an effort to educate community partners that provide care for veterans.

Embrace Appropriate Technology

Technology is an important part of the modernization process. It supports collaborative activity, encourages networking and sharing of information; and generally makes data collection, tracking, and analysis a less daunting process. In the next year, the initiative team will develop a centralized digital platform that supports all the promising and best practices in the VHA and creates a community with which to collaborate and share information and data.

Focusing on these 3 major components will enable the VHA to capitalize on the lessons learned over the course of the past 3 years and enable a smooth transition into the next phase of the Diffusion of Excellence Initiative. This evolution will not occur without additional failures and missteps, but I am confident that successes will outweigh these. We look forward to sharing our future learnings!

Disclosure Statement

The author is a general internist and health services researcher who has served as the Veterans Health Administration (VHA) Deputy Under Secretary for Health for Discovery, Education, and Affiliate Networks (DEAN) since July 22, 2018, and has no conflicts of interest to disclose. The views expressed in this paper are those of the author and do not reflect the position or policy of the Department of Veterans Affairs or the United States Government.

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A Noble and Pleasant Profession

The medical profession is a noble and pleasant one, though laborious and often full of anxiety.

— Andrew James Symington, 1826-1898, English poet
ABSTRACT

Tele-intensive care unit (tele-ICU) implementation has been shown to improve clinical and financial outcomes. The expansion of this new care delivery model has outpaced the development of its accompanying regulatory framework. In the first part of this commentary we discussed legal and regulatory issues of telemedicine in general and expanded on tele-ICU implementation in particular. Major legal and regulatory barriers to expansion remain, including uncertainty regarding license portability and reimbursement. In this second part we discuss the effects of telemedicine implementation on the various aspects of medicolegal risk and risk mitigation, with a particular focus on tele-ICU. There is a paucity of legal data regarding the effect of tele-ICU implementation on medicolegal risk. We will therefore systematically discuss the effects of tele-ICU on the various root causes of medical error. Given the substantial capital and operational investment that must be undertaken to build and run a tele-ICU, any reduction in risk adds to the financial return on investment and further decreases barriers to implementation.

INTRODUCTION

In this second part of a 2-part commentary on legal perspectives on telemedicine, we discuss the effects of telemedicine implementation on the various aspects of medicolegal risk and risk mitigation, with a particular focus on tele-intensive care unit (tele-ICU).

Evidence Base on Risk Mitigation

Tele-ICU is the use of an off-site command center in which a team of critical care practitioners participates collaboratively in the care of critically ill patients in remote bedside intensive care units (ICUs) through linked and interfaced health information, electronic medical records, data streams, and audiovisual connections. In addition to cost savings and increased access and clinical care efficiency,1-4 tele-ICUs also have potential to greatly reduce risk through a variety of mechanisms. A recent study by a large multi-state, nonprofit health care system that implemented a tele-ICU program in 2006, covering 450 ICU beds across 5 states, found that the frequency of malpractice claims and incurred costs for critically ill adults were significantly lower at sites with a tele-ICU than at those without a tele-ICU.5 Specifically, in a study looking at 5 years before implementation of a tele-ICU to 1 year after, claims costs dropped from an average of $6 million annually to less than $500,000, and the number of ICU-specific claims dropped to less than 50% of claims in prior years.5

A study of the Physician Insurers Association of America Data Sharing Project, the largest ongoing independent database of Medical Professional Liability claims, found that of the approximately 94,000 claims between 2004 and 2013, a mere 196 cases (0.2%) involved telemedicine, with only 56 (0.05%) of these resulting in payment.6 Most closed claims relating to telemedicine in the Data Sharing Project named diagnostic error or failure to respond as the chief medical factor involved in the allegation.6

Common Root Causes of Medical Error

According to the Agency for Healthcare Research and Quality,7 which is part of the US Department of Health and Human Services, there are 8 common root causes of medical error:

1. Communication problems (the most common cause of medical errors)
2. Inadequate information flow (including problems that prevent the availability of critical information when needed to influence treatment decisions and timely and reliable communication of critical test results)
3. Human problems (relating to how standards of care, policies, or procedures are followed and may include suboptimal documentation)
4. Patient-related issues (including incomplete patient assessment)
5. Deficient organizational transfer of knowledge (relating to the level of knowledge needed by individuals to perform the tasks they are assigned)
6. Staffing patterns and workflow (can cause errors when health care practitioners are too busy because of inadequate staffing or when supervision is inadequate)
7. Technical failures (including device or equipment failure)
8. Inadequate policies (poorly documented, nonexistent, or clinically inadequate procedures).

In the context of an ICU, problems in communication, particularly between physicians and nurses, are frequent causes of human error. The demanding, dynamic, and complex environment of the ICU can also pose challenges relating to distraction, burnout, and fatigue. Furthermore, in many ICUs, the nature of the
physician's contact with each patient is intermittent, and as the number of patients that the intensivist is responsible for supervising increases, further reducing the frequency of patient-provider contact, so does the risk of error. The key to reducing the risk of medical error in the ICU is “good communication and transfer of information … a complete, coherent, and updated knowledge base of the patient status requires a 2-way information flow among team members.”

TELE-INTENSIVE CARE UNIT AND RISK MITIGATION

A tele-ICU is uniquely equipped in at least 5 ways to greatly reduce the risk of medical error in all of the above-described areas. First, the tele-ICU provides for constant, continuous exchange of patient information between the tele-ICU and the local caregivers. The tele-ICU’s 2-way audio and video connections allow staff to speak directly with bedside physicians and nurses as well as patients and their family members. Because most tele-ICUs operate in a 24-hour, 7-day/week environment they are very useful in filling in gaps in which bedside providers may not be available to communicate with families, patients, or other health care practitioners. The enhanced level of communication and continuous flow of information provided by the tele-ICU are important factors in reducing the risk of medical error.

Second, the tele-ICU’s sophisticated alerting and monitoring mechanisms integrate and prioritize multiple data points and various levels of clinical information to enable rapid treatment decisions. For example, the tele-ICU software, eICU program, developed by VISICU Inc, Baltimore, MD, and Philips, Amsterdam, The Netherlands, is able to identify any trending pattern and alert the tele-ICU when the likelihood of an adverse event or deterioration of the patient’s condition increases. Because the alerts go directly to the tele-ICU, its staff can streamline workload for the bedside staff and enhance safety for the patient by identifying and filtering out false alarms. In this way, the focused, undistracted environment of the tele-ICU, combined with its technologically advanced software, can substantially reduce the risk of medical error from inadequate information flow, organizational transfer of knowledge, staffing patterns and workflow, and technical failures.

The third way that tele-ICUs can reduce the risk of medical error is by providing a built-in second opinion, which reinforces the capabilities of the bedside caregivers. Most tele-ICU operations perform comprehensive evaluations on all new patients admitted to their monitored ICUs, which usually includes an audiovisual evaluation, review of the medical record, and frequently a discussion with members of the bedside team. The tele-ICU practitioners will document their overall assessment in an admission note, which is entered into the permanent medical record. This feature is fairly unique in clinical critical care delivery, which usually operates with 1 critical care specialist documenting the critical care and added consultants documenting their specific issues. In this way, the addition of a second critical care expert’s documentation can serve as a powerful “automatic” second opinion, allowing an opportunity for medical team opinions to be confirmed by a second expert when reflecting consensus on the clinical care being provided. In a study published earlier this year, the Mayo Clinic in Rochester, MN, demonstrated the value of second opinions. The study found that as many as 88% of patients who sought a second opinion obtained a new or refined diagnosis. Second opinions can lead to quicker access to lifesaving treatment, stop unnecessary treatments, reduce stress for patients and their loved ones, and prevent diagnostic error. Misdagnosis or delayed diagnosis is a common basis for medical malpractice actions.

It is important to note that the current evidence has clearly established that the value of tele-ICU services depends vitally on their implementation and ongoing support. Bedside practitioners buy-in and acceptance of the provided collaborative tele-ICU services along with clear and effective communication pathways between the tele-ICU and bedside teams are essential to maximize value in patient management, supervision, and monitoring. After evaluating a new ICU patient admission, the tele-ICU practitioner must discuss any active additional patient management feedback and suggestions with the bedside provider team in a collegial and timely fashion, similar to any consultant providing recommendations. Documentation of the initial assessment and subsequent interactions should be professional and nonconfrontational. The tele-ICU admission note is entered into the medical record, and it, along with any subsequent interactions, also taking on the character of consultation notes, should establish the consensus and discuss any additional or differing recommendations by the tele-ICU practitioner, just like between all multidisciplinary bedside teams caring for a given patient, complete consensus is not always expected, but a discussion of why a particular pathway was chosen is helpful.

The fourth way that tele-ICUs can reduce the risk of medical error is through the surveillance and support provided by the tele-ICU to the bedside physicians. This surveillance not only reduces risk of an adverse outcome but also strengthens the ability of health care providers to establish that the standard of care has been met should a malpractice action be brought. For example, in a case against a hospital alleging failure to adequately monitor an ICU patient’s condition, where the hospital includes teleradiology in patient care, practitioners will be able to bolster their defense by showing that the local physician acted properly and that teleradiology was in place to continuously monitor the patient. Currently, there is a dearth of reported malpractice cases involving tele-ICU care. One case involved an alleged failure to adequately remotely monitor and assess an ICU patient and to summon in a timely manner an intensivist for a more thorough bedside evaluation. Again, communication among practitioners is a critical factor in the success of a tele-ICU in reducing medical risk. With a well–implemented, well-supported tele-ICU in place, defendants in malpractice litigation can argue that the plaintiff must overcome an additional hurdle to prove departures from the standard of care. The promulgation of specific standards of care related to the practice of telemedicine, still mostly limited to teleradiology, would also assist practitioners in establishing that the standard of care has been met. As such, hospitals and health care practitioners with telemedicine embedded in patient care would therefore be less vulnerable to the success of frivolous malpractice cases, and malpractice carriers may reduce collective and individual insurance rates where telehealth solutions are in place.
The last way that tele-ICUs can reduce the risk of medical error is that tele-ICU expert staff can aid in the organizational transfer of knowledge through standardization and support of bedside practitioners as well as in the buffering of workload surges. As a recent important study on the financial impact of tele-ICU implementation with enhanced care standardization and logistics support features has shown, a centralized tele-ICU can serve well to harmonize and standardize clinical care practices and procedures, thereby indirectly reducing risk in a meaningful way.

CONCLUSION

Tele-ICUs can greatly reduce the risk of medical error in many ways: From providing constant, continuous exchange of patient information with local caregivers to enabling rapid treatment decisions by integrating and prioritizing multiple data points, providing an automatic second opinion, and facilitating the or decisions by integrating and prioritizing multiple data points, providing an automatic second opinion, and facilitating the organizational transfer of knowledge. Going forward, the key to its continued success and growth will include implementation and ongoing support, as well as buy-in and acceptance from bedside providers. Moreover, adoption by state legislatures of a uniform standard of care for providers with telemedicine in place would both assist with proper implementation and reduce medicolegal risk.

Disclosure Statement

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Anticipation

One of the unique characteristics of man is that he does not live only in the present; at his best, he has a deep sense of continuity with the past and is concerned with the future. … Adaptability must incorporate the needs of day-to-day existence subject to limitations and requirements created by the desire to preserve the past and modified by anticipations for the future.

COMMENTARY

Maintaining our Humanity in the Digital Age of Medicine

Jeffrey Siegel, MD

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ABSTRACT
This critique on the changes in health care delivery is from a physician's viewpoint. I believe that modifying these changes, with humanistic values in mind, will benefit both patients and clinicians going forward.

INTRODUCTION
I've been thinking about the changes in medicine and how the Generation X physicians like me have a role in transmitting what we saw and learned at the tail end of the prior iteration of medicine in the 20th century. What we learned can, and should, have an impact on medicine now and on the tsunami of change heading our way.

HOW MEDICINE USED TO BE
I can remember my uncle practicing internal medicine from the basement office of his home in Bayonne, NJ. He saw patients at home and rounded in the hospital. It was very inefficient and very hard. What he did not have to do was document everything he said or did, but we know now that the lack of detail was a problem. Information asymmetry was absolute, the doctor knew everything, and patients were in the dark, making physicians authorities but keeping people in a fearful fog of medical arcana. This could never have been considered an efficient way to do a job, and medicine was clearly trailing other professions that were leveling the playing field between the customer/client/patient and the professional/practitioner.

There was a good reason for this asymmetry and lag. Until recently, medicine has been finding its way, with practitioners, not just academicians, keenly involved in discovering diseases, testing methods, and treatments. The delivery of new discoveries in health care is not usually as simple as it is in other endeavors delivering a new product or service. The addition of new and treatments with their implications has made the conversations that must occur between patients and clinicians all the more complicated. Humans are not widgets, and making the process into widget production was not something to occur without a fight, for good reason.

HOW MEDICINE IS NOW
Disassembling the process of medical care was bound to happen, as the study of health services and the encroachment of business processes have been thoroughly. Simple processes made inordinately complex continue to be untangled to their elements. Much of that is good, such as a move away from antiseptic, monolithic medical environs back into people's lives and homes. Yet, while these many good changes are occurring, we are in danger of disenfranchising humans—practitioners and patients—from seemingly innately human interactions. It is then reasonable to ask: What is the value of human relations in health care if patients are just interested in getting services as efficiently as possible, and we are asked to deliver them with the most minimal of human contact? Is that the only goal for health care? Isn't health care a medium of disassembling the process of medical care? Isn't health care a medium in which our humanity and relations—2-sided relations—should be of primacy? If we streamline everything to the point of obviating human interactions, are we contributing to the health of our society or are we participating in the creation of an efficient and insensate society?

Electronic medical records (EMRs) have been growing in fits and starts for decades. The challenges have been numerous and herculean, with the basic issues of integration of legacy systems and syntax being hard enough to overcome. Lost in the mix of these challenges was the primacy of the human interactions occurring on a daily basis over and over again. The computerized machine brings fields to fill, and the competition for the physician's attention between the computer and the patient began in earnest. At this point, the computers have won, hands down. This does not make physicians happy; it makes us burned out. The data entry has taken us out of our primary role. We can't think too broadly or inquisitively about issues when we are scribes. That's why the future iterations of EMR development must have the machine working for the patient and the physician, and not the inverse. The toxic effect of the reversal of these roles is felt every day by practitioners and patients. The bar was set too low, or not even at all, for how an EMR in the room with 2 people would affect that relationship. This is a primary imperative for future systems development; new systems must be rooted with the value of human interaction as a core priority of design.

HOW MEDICINE SHOULD BE
So where does this leave us in medicine, and what can we do to specifically change things going forward? The good news is that the dynamics of the primary care system as it presently exists are reaching a breaking point. In the large medical system that I work in, we have been using our present EMR, a national standard bearer, since 2007. I have been involved in multiple innovation projects and practicing internal medicine this whole time, yet I have not once met a person of any job title from our EMR vendor. That is an astounding intimation of a disconnect between the end users and designers of a system that is ripe for massive disruption. If a system is not responsive to its customers, hacks will be developed to improve function. That has occurred in our system internally, but it is inevitable that those flaws will be appropriately seen as a massive opportunity for external businesses to help what is now the dire state of primary care delivery. Just as the personal computer industry and the Massive Software Company Whose Name Cannot be Spoken were

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so dominant in the 1990s, the world has changed dramatically since that time. The technology companies that will survive and thrive will be those whose leaders and systems designers recognize that some of the primary values in deciding on system design were flawed and must be changed. End users, such as physicians, nurse practitioners, physician assistants, and patients, must be involved on the design end of EMR systems in addition to information technology executives and insurers. That involvement will be dismissed as innately leading to analysis paralysis, and it may take a lot of time, but the alternative is our present unsustainable dynamic. Computer clicks, time, and the effect on interactions between patient and practitioner are not trivial asides; they are primary issues that must be of utmost value. The leviathans who thought end users had to suffer with what was brought to them can easily end up themselves being dinosaurs, unable to adapt, if they do not rethink their flawed value ecosystem.

As we seek to naturalize the medical record, we should get back to human interactions at the center of health care. As much as convenience is critical for the delivery of care, it behooves us in medicine to realize there is an innate role of teaching and guidance that must be at the core of the patient-physician relationship. The rebalancing of information asymmetry does not replace human experience. Even as artificial intelligence (AI) programs doing deep learning can outwit a diagnostician, a key here is that the genius of much of AI is based on experiences of humans to build the information pool being used to build algorithms and even create observations. Just as we have made a poor decision to have our information used by social media with, what we know now, are scant or unintended returns, we should be wary of how information will be used in medicine. The machines and the systems should work for us. What is at stake is our humanity. The machines will be better at much of what we now do. Should we work for them or have them work for us? The key will be in the systems and guideposts we put into place. It will be great to have bots (Internet robots) do a lot of work for patients and physicians, but a world where we talk to bots instead of each other and have AI algorithms making decisions for us is a future that we should avoid.

In the same way that EMRs need to have end users involved in design, it will be imperative to have human values inculcated into the AI algorithms that will be increasingly used in the electronic record. As much as we know that values have evolved and mostly progressed over time, we are at risk of placing limits on AI systems with values that may be considered archaic to a fully evolved humanity. This will include decisions to pursue care for conditions on the basis of cold hard calculations. These decisions and many others must be made by human arbiters. AI can be used only as a guide. For instance, pursuits of treatment in oncology that may have seemed futile on the basis of extant calculations in the past were integral to the human will to survive that would not necessarily be in the interests of an algorithm. This continued pursuit most likely led to the sparks of creativity that have bent the arc of oncologic care outcomes now. Placing human survival at a premium in this setting might impede the progress of an absolutely rational entity, but it is a risk we must take. There are values to set as guideposts, such as the primacy of human life, that will need to limit the supposed progress of AI. Our technical capacity has outstripped our sociologic sophistication, and we must place limits on technical overreach until society can (or may never!) be in sync with an absolutely rational entity.

CONCLUSION
There was a lot wrong with the Golden Age of medicine when physicians were gods and the public was in the dark. It is just as important to realize that we have much work to do to avoid making the machines our new gods.

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How to Cite this Article

A Very Precious Commodity
But by the neglect of the study of the humanities, which has been far too general, the profession loses a very precious commodity.

— William Osler, MD, 1849-1919, physician, pathologist, teacher, diagnostician, bibliophile, historian, classicist, essayist, conservationist, organizer, manager, and author
Time to Revamp Nutrition Education for Physicians

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ABSTRACT

Obesity is a national and global epidemic and is usually the result of a poor diet and lifestyle. Obesity is a strong risk factor for type 2 diabetes and cardiovascular disease, which are leading causes of morbidity and mortality. Ample scientific evidence supports that nutritional interventions involving plant-based diets can be effective in the prevention and treatment of obesity, diabetes, and cardiovascular disease. Many patients are interested in improving their eating habits and frequently look to physicians for dietary advice. However, most physicians are unable to provide meaningful guidance because of a lack of nutrition education. We launched programs to educate our physicians and patients about the benefits of plant-based diets, with an overwhelmingly positive response. Because physicians are at the forefront of fighting the obesity epidemic, it is imperative to emphasize nutrition education for current and future physicians.

INTRODUCTION

It was a typical day in the clinic, and I was seeing a 19-year-old female patient. We had addressed multiple problems, and just as we were wrapping up the visit, she asked if I could recommend a weight loss program. She was morbidly obese and had tried various diets without success. She had read about bariatric surgery online and was wondering if I could refer her to a bariatric surgeon. She was frustrated and despondent, and bariatric surgery was her last hope. I wanted to help her, but we were out of time. As an internal medicine physician with a particular interest in nutrition and lifestyle, I wanted to educate her about the benefits of a whole-food, plant-based diet. However, it is nearly impossible to offer meaningful dietary guidance in a short office visit. Sadly, it would have been easier for me to refer her for a major surgery than to properly discuss a low-cost, low-risk lifestyle intervention. I gave her the best dietary advice I could in the brief time we had, knowing that it may not be enough to set her on the right path. A 19-year-old turning to bariatric surgery—how did we get to this point?

I have seen innumerable patients in the same situation, struggling with obesity and related complications and feeling increasingly hopeless about their health. Despite our best intentions and state-of-the-art medical care, their chronic conditions often progress because we are not addressing the underlying root of the problem: An unhealthy diet and lifestyle. Ample research has shown that a whole-food, plant-based diet can prevent and possibly reverse many of the chronic conditions commonly encountered in clinical practice. Such a diet is composed primarily of whole grains, legumes, fruits, and vegetables; limits the intake of fat to less than 10% of calories; and restricts the intake of any animal-based foods (including dairy, poultry, seafood, and red meat). Despite the well-known benefits of plant-based foods, the average American diet is deficient in fruits, vegetables, legumes, whole grains, and fiber, while high in saturated fat, added sugars, and sodium.1 In 2012, an estimated 318,356 American deaths owing to heart disease, stroke, and diabetes were associated with a suboptimal diet—defined as a diet low in fruits, vegetables, whole grains, nuts, and seeds, and high in processed meats, sugar-sweetened beverages, and sodium.2

After caring for patients with lifestyle-related diseases for more than 15 years, I realized that we were losing the battle against obesity and obesity-related conditions. A change was needed in how we approach the prevention and treatment of some of our most common chronic diseases.

A DIFFERENT KIND OF WEIGHT-LOSS PROGRAM

I wanted to launch a whole-food, plant-based, weight loss program for our patients, and I was fortunate enough to work with an organization that had the resources and vision to support me in this endeavor. We established a 12-week program that involved a weekly 60-minute session led by a physician and a nutritionist. The session included weigh-ins, education, recipe exchange, and support. We taught our patients about the expected benefits of changing their diet and gave them weekly guidance to help them gradually transition from their current diet to a whole-food, plant-based diet. Each week, the participants were advised to replace an unhealthy food with a healthier option, for example, replacing sugar-sweetened beverages with fresh fruits. Although changing lifelong eating habits can seem overwhelming, the support from their peers and the teaching staff motivated our patients to persist.

EDUCATING THE PHYSICIAN EDUCATORS

At the same time, we implemented a regionwide program to educate our physicians about nutrition. We hosted a weekly lunchtime seminar at each of our medical centers that reviewed the research regarding nutrition and chronic disease and that was accredited for continuing medical education (CME) credit. The seminar also included a specially catered, plant-based lunch for the medical staff. Taking nutrition education to busy clinicians at their place of practice while providing a warm and nutritious lunch facilitated attendance and interest in the program.

The response was overwhelmingly positive from both patients and health care practitioners. Time-constrained physicians were happy to refer patients to a program that was based on solid scientific evidence. Patients were thrilled to learn that there was...
a lifestyle that would not only help them lose weight but also keep it off long term while improving their health. They reported that they felt empowered and emboldened in a way they hadn’t before. The fact that they did not have to count calories and carbohydrates—an onerous and impractical task—was an added bonus. Soon, patients who had not previously eaten tofu or legumes were happily exchanging their favorite healthy recipes. Additionally, they were excited because they felt better; even before the weight loss was evident on the scale, their joint aches and blood glucose and blood pressure levels started to improve. The patients felt that they were regaining control of their health. They wished that their physicians had shared this knowledge earlier with them. But, the reason they had not was simple—their physicians did not discuss the benefits of plant-based diets because they did not know about them.

THE EVIDENCE

Obesity is a national and global epidemic that is almost always caused by lifestyle and diet. According to the Centers for Disease Control and Prevention, more than 93 million Americans adults are obese, or nearly 40% of the US population. Obesity costs the US an estimated $147 billion annually in medical costs. Clinicians are at the forefront of this epidemic but are poorly trained to tackle it because medical education includes very little training in nutrition. Most medical schools offer 19.6 hours of education in the field of nutrition, or less than 1% of total lecture time. Furthermore, most of this education is in the form of biochemistry rather than practical aspects of food selection and consumption. Nutrition education is similarly insufficient in postgraduate education programs. As Devries and colleagues noted in their recent article, most residency training programs incorporate little if any nutrition education.

Obesity is a strong risk factor for type 2 diabetes. The Centers for Disease Control and Prevention estimates that more than 30 million and 84 million Americans have diabetes and prediabetes, respectively. Diabetes costs Americans $327 billion per year. Although randomized clinical trials have shown that a whole-food, plant-based diet can improve glycemic control in patients with type 2 diabetes more than standard treatment does, very few physicians in training are taught this information.

Obesity and diabetes are leading risk factors for cardiovascular disease, the number 1 killer in the US. Almost 800,000 Americans die of cardiovascular disease each year, which costs the US nearly $1 billion daily. Most physicians are well versed with these statistics, but many are unaware that multiple research studies have shown that healthy lifestyle and dietary changes can reverse cardiovascular disease. Most of these studies used a low-fat vegetarian diet limiting fat to 10% of daily calories. Adopting such a diet can seem challenging, but we and others have noted that with the correct guidance and education, patients are motivated and able to make meaningful changes. It is important to note that the DASH and Mediterranean diets, which are associated with a lower risk of cardiovascular disease, are also rich in plant-based foods, such as fruits, vegetables, and legumes, with limited intake of fat and animal products. It is likely that the benefits of such diets are because of an increased emphasis on plant-based foods.

THE NEED TO ADD NUTRITION TO MEDICAL EDUCATION

Clearly, we need to bridge the gap in our medical training, and an increasing number of physicians and health care organizations recognize this need. The American Medical Association’s public health policy statement prioritizes nutrition and physical activity.

Most patients consider physicians the utmost experts in health and nutrition and frequently turn to them for dietary advice. Our patients are entrusting us with their most valuable commodity: Their health. Do we not owe it to them to educate current and future physicians adequately? For future physicians, this means incorporating meaningful nutrition education into medical school and residency curricula. Just as students and residents are required to rotate through primary care wards, they should be required to rotate through clinic- or hospital-based programs that incorporate nutrition into disease management. Many programs around the country use nutrition as an integral part of disease prevention and treatment. By spending time in such programs and learning firsthand how nutrition can prevent and treat chronic disease, future physicians will be more adept at guiding their own patients. For practicing physicians, ongoing CME requirements by state licensing boards should incorporate a certain number of hours in nutrition, just as they do for HIV care or pain management. The CME requirements can be easily satisfied through online courses, national conferences, or on-site seminars similar to ours.

Busy clinicians need not provide in-depth nutrition counseling to their patients. Clinicians may guide their patients to various online resources, such as Kaiser Permanente’s “Plant-Based Diet” booklet and the “Plant-Based Healthy Plate.” They may also refer patients to other health care professionals who specialize in nutrition-based prevention and treatment. However, physicians do need to have a basic working knowledge of nutrition in order to refer their patients to the appropriate resources and clinicians, just as they do with other specialty care.

A team-based approach to nutrition counseling is highly effective and economical. Such teams—composed of physicians, nutritionists, and nurses—can provide ongoing support, education, guidance, and cooking demonstrations. For patients with limited financial means, who often have limited access to healthy foods and bear a disproportionate burden of chronic disease, it may be helpful to include social workers on the team. Because there is a common concern that plant-based diets will cost more, it is important to educate patients that the converse is true. For example, legumes are a substantial source of protein and fiber and are much cheaper than a comparable quantity of red meat, poultry, or seafood. In addition to providing comprehensive nutrition counseling, a multidisciplinary team can monitor meaningful patient outcomes and provide feedback to all clinicians involved in the patient’s health.

Our medical education system must change because the current system that emphasizes medication and procedures over diet and lifestyle is simply not sustainable. We are getting fatter, sicker, and poorer treating diseases that could have been prevented with sensible and low-risk lifestyle and dietary changes. The time for change is now.
COMMENTARY

Teaching

Learning is an active process and each of us learns more when we teach than when we are taught.

— Eugene A Stead, Jr, MD, 1908-2005, American medical educator, researcher, and founder of the physician assistant profession
EDITORIAL

Assessing Impact of Biomedical Scholarship in the Information Age: Observations on the Evolution of Biomedical Publishing and a Proposal for a New Metric

Robert Hogan, MD

ABSTRACT
This editorial contains a discussion on the state of the art of biomedical publication and the history and development of indexing, its evolution, and complexity. A traditional method of journal assessment is in use—the journal impact factor—but it is compromised by well-documented deficiencies. Present-day alternatives to the journal impact factor are listed, and a proposal to develop a novel metric of merit in publication, the influence factor, is described.

INTRODUCTION
Scholarship is near and dear to the profession of medicine. As medical professionals, we are scientists first. We study, we learn, we observe, we theorize, we ponder; perhaps we involve ourselves in ethical scientific experiments (eg, clinical trials). When we have something to say deserving of a broad audience, we write. We weather peer review. We publish. With luck and a bit of fortitude, interesting feedback arrives from near and far, and knowledge is advanced. In the end, not only do we invest our time in what we produce but also much potentially rests on successful authorship. Career advancement, professional recognition, reputation, and expertise manifest—all potentialities won or lost in the drive to produce important high-quality work and to have our work published in the right places. Every physician is in some sense an author. The clinician writes notes on every patient encounter, the consultant forms itself. A superb article buried in an arcane publication might never obtain the recognition rightfully due. At worst, a young researcher might be seen as failing a vital test, lose a promotion to a higher academic standing, fail to attract grants, be seen as irrelevant, or miss the awarding of tenure. What then is the “right” publication? Well-known, long-established, prestigious journals such as the New England Journal of Medicine, the Journal of the American Medical Association, and the Annals of Internal Medicine have massive publication histories, deep resources, distinguished contributors, and enviable reputations. Passing peer review in those venues is daunting, to say the least, particularly early in career development. However, there are virtually thousands of titles of lesser recognition to choose from, depending on the intended audience, specialty orientation style, and content of a given work.

Somehow there is a matchup between authors and publications; authors find a satisfactory publication, editors find suitable authors, and publications and content flow. Thoughts move about on paper or electronically on the Internet, blogs, and as of late on social media. The speed with which ideas move is vastly different from earlier eras, as is the scope and scale of the movement of information. Curious observers should query not only the details of what moves where when, but ultimately what all the changes amount to.

For authors and editors alike, at the end of the day, surely the inevitable questions arise: What effect has our work had? Who has heard us, and who has incorporated our thoughts and conclusions into their own thinking? How good is our work, and how do we know? What influence have we had by publishing? How much does our scholarly scientific work matter, and how do we know that it does? One widely accepted historic indicator of the value of a published work is the journal impact factor, which is a rank of the average frequency that a journal’s articles are cited in other literature. Publishing work in high-impact-factor journals is traditional evidence of scholarly excellence.

For editors, manuscript selection—the drawing in, receiving, editorial processing, sorting, weeding out, facilitating improvement, and ultimately influencing the development of interesting, thought-provoking, genuinely useful manuscripts—may make or break a publication. Thus, the influence of authors and the influence of publications are inextricably intertwined; authors wishing to maximize the clout of their work wish to seek out prominent journals to submit to; journals wish to draw in good authors producing high-quality articles. This tidy interwoven system was unassailable for decades, until the world of information and how it moves transformed itself.

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HISTORY OF THE STATE OF THE ART OF PUBLICATION

As an article is being developed, credibility demands that the author or authors place their work in context. For context, one must be familiar with other work germane to the topic, and to be familiar, one must have searched for and read other work in the field. Thus, to produce high-quality scholarly manuscripts, one must cite the literature. The process by which scholars have determined who has written what and where their writings may be found is changing. For my generation, trained in the 1970s, Index Medicus was the huge, encyclopedic go-to reference work. This massive print work was a catalog of the publications of the biomedical scholar's world. As the volume of material in print grew, it became clear that production of larger and larger compendiums of printed matter was becoming unwieldy. At the same time, the biomedical scholar wishing to assemble a personal collection of important materials had few options. One could keep collections of journals bound or unbound, leading to massive shelves of paper, and strive to recall where important works were found within, or, more economically, one could tear out articles of individual interest and file them in some systematic way in hopes of locating them on demand. Keeping a personal file card system was another alternative.

Later, the National Library of Medicine began to produce MEDLINE, a computer-based storage cataloging and retrieval system to replace Index Medicus. Regarding what essentially was an enormous electronic file card system, I recall being dazzled to learn in the late 1970s that 6 million citations were contained in MEDLINE versions, which were directly available then only to librarians. A medical student in the 1970s could present a request for a literature search to the biomedical library staff, and in hours or days (depending on librarian workload), receive a dot matrix fanfold printout. In that now obsolete manner, one could, with a modest effort and some professional help, determine who had written what on a particular topic of interest theoretically drawn accurately from any of millions of citations. Today, MEDLINE’s descendant PubMed (www.pubmed.gov) lists more than 29 million citations, and the body of data is open to the Internet—using public.

But, who wrote what was not the only question of the day. When scholars wrote on important topics, they referred to others’ work. So also evolved the need to keep track of who cited whom. Being widely cited not only warms the heart of an author but suggests on its face that the author has clout, and in this respect, little has changed over the decades. What has changed are the rapidity with which an article is disseminated, the breadth of potential recognition and commentary that it may generate, and a vast expansion of venues for citation.

Current Contents was the tally sheet of the earlier day: A publication of publications, carrying copies of the title pages of many major biomedical journals. This, in turn, was intimately linked to an Author Citation Index—in other words, the quantification of “who published what where” and “who cited whom where?” For measurement we must have descriptors, organization, classification, and so on. Enter the somewhat arcane fields of journalology and scientometrics. These disciplines foster understanding about what journals do in the course of their work and how we quantify certain goings-on in the literature of the scientific world.

Thoughtful observers began early on to visualize the utility of some kind of organized methodical citation tracking system. In this environment arose the venerable journal impact factor. Conceptually described by Garfield in 1955, as originally conceived, the journal impact factor was a practical way of sorting citations according to their point of origin. The journal impact factor was conceived of as a means of helping librarians. In an elegant article, a mathematical model for calculating journal impact factor was described. This proprietary measurement method has been much discussed and over time came to be something other than what it was conceived as; it came to be seen as an indicator for journal quality. Garfield developed the Institute for Scientific Information in 1960, which also developed the highly useful and then well-respected Current Contents. Publishing in high-impact-factor journals became a surrogate marker of academic excellence.

To place all this in context, in 1955, one might mimeograph typewritten pages and hand distribute perhaps 100 copies, but there were no faxes, no copiers, no email, no blogs, and of course no Web sites because the Internet did not exist. At the same moment in history, slide rules were necessary for rapid calculations, sextants were used to determine position in unknown territory, and all telephones were hardwired and the lowest-cost connection plans involved party lines (in which a human operator made manual switches and connections among users). Book publishers and newspapers were a pathway for the distribution of material, but formidable barriers existed to both the simple reproduction of the printed word and its distribution. A successful scientific textbook might have reached tens of thousands of readers over its lifetime. At the time of impact factor initiation, email had not been invented; Web sites were where arachnids hung out; blogs weren’t even a science fiction, pie-in-the-sky dream; and tweeting is what winged creatures of the air did. Not every information system developed in the 1950s has become obsolete in the Information Age, but one must ponder whether the original concept remains as important and legitimate 60 years later as it was in its heyday.

When the impact factor was conceived, the pathways to the recognition of an individual’s work were limited. Furthermore, the movement of scholarly information was via a slow, narrow, concisely defined path: Completion of a work, submission to 1 or more of a small number of publications for consideration, peer review, and publication. A strength of the journal impact factor, however, is the simplicity with which Garfield originally defined it. As is so often the case, strengths can also be weaknesses. Implicit in the journal impact factor and in the whole notion of citations is an unstated idea. By counting citations, one creates a closed loop. This metric is about how often published scholars are referred to by other published scholars.

THE STATE OF THE ART IS EVOLVING

Today, the complete audience for a biomedical scholar publishing a manuscript and the audience for a biomedical publication is not as clear. There was a day when scholars “spoke” with their publications to scholars, and there was some process—a wag would call it education—a kind of

Assessing Impact of Biomedical Scholarship in the Information Age: Observations on the Evolution of Biomedical Publishing and a Proposal for a New Metric
trickle-out effect that resulted in scientific information reaching the public at large.

Today, I would argue that we in biomedical scientific fields have not just one audience but many. How could our audience possibly continue to just be our peers of other scientists/clinicians/scholars or trainees given the way that electronic media disseminate information? There is the broader world of trained professionals such as nurse practitioners, physician assistants, nurses, clinical assistants, psychologists, podiatrists, and chiropractors. Additionally, your readership may contain the literate population who have little or no education in science (yet plenty of opinions) but have a robust appetite for knowledge about their own health and that of their friends, family, and community.

Our most earnest wish as scholars, authors, and professionals in the biomedical journalism field is that efforts to promote high-quality publications will result in a better-informed world, and that those who seek to be well informed, to be educated, and to strive for wisdom will be edified. We may also hope and wish that the production of forthright, honest, high-quality biomedical information will readily translate to opportunities to benevolently affect clinical decision making.

At some point, the availability and utilization of a published article by an enormous international universe of readers stopped looking like heresy. Before Gutenberg's printing press, a tiny class of citizens had access to the printed word, paper was costly, and payment was required to view influential thoughts written down, so barriers existed to the movement of knowledge. Arguably, the past 50 years of paper-based publication was like the pre-Gutenberg era. Articles were in journals, journals were available to elite audiences who paid for subscriptions, and the public remained uninformed unless experts were consulted. Of late, some publications offer open access, meaning virtually anyone with an electronic device, an Internet connection, and a free search engine installed has a reasonable chance of locating, viewing, and potentially downloading for storage all open-access scientific information, thus eliminating some of the barriers previously in place. We have witnessed the democratization of information and knowledge.

Since the first iteration of the impact factor (in the 1960s), much has changed in how information moves. As news outlets provide coverage (air time) to important medical developments, the printing press is steadily diminishing as the prime technical means of information dissemination. One does not know the qualifications of visitors to an article published in cyberspace. Laypersons, students, trainees, and professionals alike all leave the same cyber footprints by indistinguishable browsing behavior. Cybermetrics do, however, give us clues as to whether articles are being downloaded and how long browsers linger.

In today's transformed world of information movement, I and others are questioning how germane the journal impact factor is.

The journal impact factor, although in broad use to this day, has been extensively criticized. It has been rejected as a basis for evaluating research, criticized as unreliable, and there have been calls for its abandonment and replacement. A recent blistering critique called out major issues with the journal impact factor, calling it "highly misleading" and "meaningless as a predictive measure." Yet, the journal impact factor persists, perhaps because of institutional inertia, tradition, or lack of materially improved alternatives.

**COMPLEXITY OF THE STATE OF THE ART**

If the journal impact factor is outdated, aging, flawed, dated, or otherwise doubtful, one might expect that there are newer, better, more sophisticated methods by which biomedical scholars may reckon the way their work is attended to. Perhaps most disturbing of all is the likelihood that the impact factor has been important enough that it is now of diminishing, if not dubious, value because unscrupulous individuals, hell-bent on getting great numbers, subvert it by gaming. As examples, some publications demand that prospective authors cite other works previously published by them as a condition of acceptance. This may be the Information Age, but with electronic publishing came not only the opportunity for a revolution in how scientific information is propagated but, regrettably, the moment for substantial subversion. Junk science has begotten junk journals.

Rapacious desire for scientific recognition and advancement has spawned abominations such as predatory journals, a sort of tabloid pseudojournalism, the twisted sister of legitimate science and scientific publication. In this perverse scheme, authors pay to publish and are required to cite the publication they are involved with (one gaming strategy), a pay-to-pass scheme designed to bump up impact factor scores. This strategy has led to the development of a list that one observer (a librarian) proposed as a catalog of dubious publications, but the list is no longer actively supported. If a new comprehensive metric of merit does gain wide acceptance, one can anticipate that gaming the system would grow more difficult.

**TOWARD DEFINING AN IDEAL INDEXING METHOD**

As mentioned, the old publishing world has been upended by the Information Age or, more specifically, transformed from a closed system to a vastly open system. As indexing methods have proliferated, and with the passing of a half century since the inception of the journal impact factor, a robust discussion about generating an ideal indexing method is due.

The following are a few ideas about potential dimensions of a publication's scientific value, in the abstract as I see it, on the basis of decades in medicine as a clinician, author, and editor:

- **Novelty:** Genuine discovery is a core component of science.
- **Applicability:** Widely useful insights are of greater consequence than narrower ones.
- **Appreciability:** Most readers—certainly the author's peers—should be able to appreciate the value of a work. If no one understands a discovery, it may still be important, but it is destined to languish in obscurity.
- **Sustainability:** Deep science ought not to be based on transient blips but rather on milestones and trend makers.
- **Game-resistant merit:** Good science has no room for trickery, sophistry, and the foolishness of dressing up mediocre work in elegant guise.
- **Indexing of important work:** Scientific work that is important should be indexed within and outside traditional publishing channels, including doctoral
PROPOSAL FOR NEW UNIFIED MEASURE OF SCHOLARLY ACTIVITY: THE INFLUENCE FACTOR

Suppose one were to leap ahead conceptually to a moment when indexing becomes more inclusive. Rather than focusing exclusively on how often scholars cited a particular published work, let’s consider measuring the value of that work more broadly. How many people know about a published work (perhaps obtained through surveys) could be a measure. Another could be how many people are influenced by what an author has written. If some discovery is reported, how widely is the discovery discussed? Is it tweeted or cited in Facebook, and if tweeted, how often retweeted; if seen in Facebook, how often liked and shared? Does the material reach other media, such as radio or television? What markets and what size audience does each subsequent transfer to other media involve? There have long been commercial “clipping services” (focused on newspapers) and also media extraction services (focusing on television and radio activity). It is not too much of a leap of imagination to visualize an electronic indexing method in which all social media—Facebook, Twitter, and so on—as well as all print media and virtually all electronic media references to one’s work somehow were melded together into a comprehensive, huge index, combining literally every important mention of a work. Perhaps then one would begin to grasp the true outlines of how broad and how deep the meaning of a work is moving through the world. But, then another layer would need to be obtained for yet deeper importance. We might determine which works influence policy development or which works trigger legislation? Perhaps it would be important to know how many languages the new information enters. Another layer could be how durable the influence of the material is. For instance, does it trigger the formation of study groups or the development of derivative research, and perhaps most importantly of all, how durable is the core concept? Another thought to ponder is whether 1 small fact triggers a cascade of investigation. Or does 1 large study of necessity lead to something more fundamental than 1 small study, even if well done?

I suggest that in this Information Age, adding new, broad, current-day variables to the calculus of merit will more exactly allow measurement of the value of both individual manuscripts and the journals that offer them to the reading community. The development of a modern tool will reflect the reality of extremely broad audiences. If need be, each element might be weighted, and conceivably, institutions pondering scholarly merit might tune the weighting to local priorities.

Some acknowledgment of Web page views (“hits”) would be a start. Because some journals are paperless and exist virtually in cyberspace, their staff must know not only their “subscriber” base but also how often articles are viewed. Similarly, print journals that have a parallel Web-based version, know information about visitors to their articles. Although there are several methods for analyzing metrics on the Internet, an entire science could arguably be developed about patterns of medical article utilization on the Web. These patterns could include how quickly an article is recognized by, say, the first 100 readers (or the first 100,000, 1 million, etc); how sustained interest is in the article, how rapidly interest falls off, and ultimately how durable interest is in a particular piece. These and other parameters are readily observed, measured, and recorded. How to interpret such data will make for an interesting discussion.

In today’s Internet world, an item that “goes viral” might reach millions overnight. In this context of nearly unlimited distribution of the written word in electronic form, is this not clearly the right moment to ponder what lies beyond impact factors? Surely authors wish to be well cited by

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other scholars as always. And, as has been the case for many decades, some of what finds its way past peer review and into the scientific literature will be picked up by the avid science monitoring and reporting industry and passed along to the enormous audience of science watchers. One need not hope for an individual article to go viral and reach tens of millions of viewers as an indicator of value. It seems apparent, however, that something that draws large numbers of views has tapped a reservoir of interest, thus establishing a new dimension of value.

In addition to cybermetrics, other elements are worthy of consideration. For instance, movement between media might be of interest—whether one’s work gets mentioned in newspapers, magazines, radio or television talk shows, or blogs. Most importantly, a metric should include evidence that one’s work begins to reach into policy decisions within universities, health organizations, the government, or the courts.

The time has come to move the useful concepts behind the journal impact factor into the Information Age. The technology exists to develop bold new methods. We as scholars in biomedicine write not only to inform the relatively small universe of fellow scholars. We write knowing that well-crafted research may also more or less easily reach biomedical trainees, policy makers, other media, and ultimately citizens across the globe. Accordingly, a new measure of the value of a publication (and of an author’s work) must incorporate a broader metric of the reach it spans than how often a work is cited. Such a measure also must include how many hits the publication generates among Web browsers, whether it generates discussion in blogs or reaches into other media, and if it influences policy making.

I propose a new concept that I will call the influence factor. An influence factor might be defined as the sum of scholarly citations plus some derivative of how many times the work is actually viewed (e.g., hits on the online publishing site) plus a reflection of how widely the article moves to other media (e.g., mass media, social media), and even ultimately how much influence it has on philosophical, conceptual, or policy matters.

For those fond of mathematical precision, influence factor could be defined thus:

$$\text{INF} = (a + b + c + d/1000 + P)$$

where INF = influence factor, $a =$ number of scholarly citations, $b =$ number of print media citations, $c =$ number of non-print citations (television, radio, podcasts), $d =$ number of hits recorded in Google metrics for electronic-only or Web-reproduced publications, and $P =$ substantive policy changes definitively linked to the work.

**HOW TO GET FROM HERE TO THERE**

Replacement of journal impact factor will not happen easily, automatically, or overnight. It is entrenched, is traditional, and has withstood prior calls for replacement. When it becomes increasingly clear that deficiencies are glaring and persistent, the time to reach for alternatives has begun, as I believe it has. The development by stakeholders of a vision of a better system would be a start. This might occur in government agencies (the National Institutes of Health, Department of Health and Human Services, and Centers for Medicare and Medicaid Services come to mind), or perhaps in the private sector or academia. There are surely forums in the health information technology sector where high-level policy issues can be addressed. The vision should incorporate a new and substantially better approach to credibly, fairly, and consistently evaluating the value of scholarly work. As described, an influence factor can be broader in scope, deeper in reach, fairer, and more credible than existing and historic methods. Once a vision is established and the opportunity for development opens, calls for submissions, such as requests for proposals, would bring into play productive and competitive forces in the health information technology sector and broader academic communities. The industry has failed to produce a definitive replacement to date, and, in fact, multiple competing services may make replacement of journal impact factor less likely rather than more likely.

The slide rule is an antiquate, the microcograph machine is obsolete, the rotary dial phone is fading in the mists of time. It is time for the journal impact factor—a product of time past—to fade from the stage and make way for new, more robust means of assessing scholarly works.

Improved indexing methods may serve to emphasize genuine scholarly scientific merit.

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**How to Cite this Article**

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My journey toward mindfulness began with a burst appendix. At the time, I didn't realize it was appendicitis. I was just relaxing after work (I'm the part-time maintenance man at the Myrtle Beach Art Museum). So, I'm watching TV, enjoying a snack and a cold beverage when I suddenly get a sharp, stabbing pain in my stomach.

“Enough already with the cold pizza,” I'm thinking. A couple of hours later, the pain has not let up, but it hasn't increased either. And so to bed. But it turns out that it's tough to get into a comfortable position. I toss and turn and finally manage to get some sleep, but the next morning, the pain has increased, just moderately, mind you. Being manly and exceptionally stubborn, I choose to ignore it. Not my smartest decision, but I soldier through the day and that night.

However, by day 3, it's readily apparent that this is not indigestion. I decide that I'd better get to a walk-in clinic, but when I slide into my car, I realize that I can't drive—I'm too weak and somewhat disoriented. Fortunately, my neighbor is leaving for work just then and she takes me to the walk-in clinic. The helpful doctor there takes one look and says, “We need to get you to the nearest Emergency Room (ER) right now!”

With that pronouncement, they call for an ambulance. One arrives within minutes. The EMS guys on board are very knowledgeable, thorough and reassuring, but they warn me that the ride to the hospital may be very uncomfortable. An understatement to be sure! I think my stomach felt every pothole and bump in the road. By the time I arrive at the hospital, I am in excruciating pain.

As luck would have it, there are no ER rooms available, so I end up moaning and groaning in the hall. Can't get warm, can't stand the pain, can't imagine how I'm going to get through the next minute. Then, like a deus ex machina in some ancient Greek drama, the surgeon on call appears. He's a tall, good-looking, muscular guy who happens to be Lithuanian. He takes one look at my stomach, gives it a poke, which nearly sends me into agony orbit and pronounces, “Busted, Da. Busted!” With that, I'm wheeled off to the OR.

The procedure is a success, but in the recovery room, I'm informed that my recovery may be somewhat painful and lengthy because my appendix had burst. “You had a close call,” is how my surgeon describes it.

A month later, the pain has subsided to a certain degree, as long as I'm careful how I move around, but I've noticed that my belly button, which was always an “inzy” has become an “outzy.” In fact, after 3 months have passed, it looks like half a golf ball is trying to break out of my navel. I can still push it back in without any pain, but it stubbornly returns to its “outzy” configuration shortly thereafter.

Naturally, being manly and stubborn (Did I mention that before?), I choose to ignore it for as long as possible. However, a year later, exactly to the date of my original operation, I'm back in the surgeon's office. He tells me that I really should undergo an umbilical hernia repair and that he can handle the procedure laparoscopically. According to him, performing the operation this way will result in a shorter and less painful recovery.

If my recovery was less painful, I'd hate to see what a more painful recovery would be like. One year later, I find out.

My “outzy” navel condition has returned in spades. My surgeon tells me that might occur about 5% of the time. He proposes that this time, if I agree, he will perform the repair surgically. Again I am assured that my recovery will be less painful and shorter.
I have to pause here to say that throughout this entire episode, I have grown to like and trust the surgeon and his staff. Although they have been entirely professional, I’ve established a first name “phone friend” relationship with several staff members.

That said, my recovery proves to be extremely painful and lengthy. Finally, after 3 months of diminishing pain, I feel that I’m entirely healed and am now ready to get back in the gym.

But wait. One day at work, I start to feel kind of odd. I decide to take a break and talk with my coworkers. I go into the lobby, take a seat and realize that despite having worked with the receptionist for more than 2 years, I can’t remember her name. She asks me the name of the current US President. I don’t know. In fact, although I know where I am, I can’t remember the names of any of my fellow employees. She insists that we call 911.

Long story short, the EMS crew that arrives tells me that I may have suffered a TIA (which I learn is shorthand for a transient ischemic attack). I’m rushed to yet another hospital where I’m thoroughly tested, held overnight for observation, and then released with no apparent damage.

Two days later, I start experiencing a tightness in my chest and have difficulty breathing. I call 911. Back to the ER. All the tests for a heart attack or heart condition prove to be negative. Two days later, the symptoms return. I call 911 yet again. Another trip to the hospital. Another round of testing proves to be negative.

I consult with my regular doc. She wants me to see a cardiologist. Her physicians’ assistant calls one and fortunately, the cardiologist has an opening that afternoon. I agree to the appointment and on my way into his office, I am suddenly very dizzy and experience severe tightness in my chest and neck. I’m put in a wheelchair and wheeled into one of their exam rooms where I’m once again carefully checked over.

At this point, I’m convinced that I have some sort of serious heart condition. And why not? I had rheumatic fever as a child and every other member of my family has or had been diagnosed with congestive heart failure. How could I think that I could beat the odds?

The cardio doc comes in, takes one look at the latest test results and my recent medical history and thenpronounces, “You’re fine, it’s all in your head! I’ve got something I want you to do!”

With that, he rushes from the room.

My reaction is electric. I feel like a huge weight has been removed from my shoulders. Am I suddenly taller? I feel like it. It’s all in my head? Just panic attacks? Eureka, I’m saved!

The doctor returns with what turns out to be a lengthy excerpt from Eckhart Tolle’s remarkable best seller, The Power of Now. “I want you to get this book, read it, and report back to me. It’s your homework. Don’t argue, just do it!” he growls at me. Who knew that a cardiologist could also be a psychiatrist?

Tolle’s book is packed with all kinds of useful ideas, breathing exercises, and tips about how to “Be in the moment. Be right here, right now.”

Now to be completely honest, I’ve been aware of mindful thinking for years, and have been a rather casual follower of that practice as well. If all of this sounds like some kind of instant wrinkle removal or hair restoration remedy, it isn’t. It’s a whole lot harder. However, after the latest rounds of hospital and doctor visits, I’ve finally decided that I really do have to walk the walk instead of just talking the talk. By being in the moment, every moment that I can, I can deal with any difficulties I might encounter when they need to be encountered, not in the middle of the night or any other nonproductive time.

So, I’m on the road to mindful thinking and mindful living. Which means, in addition to mindful thought, it’s adios to margaritas with rocks and salt. How about no salt at all? (Well mostly.) I’ve also cut down on my coffee consumption. I eat more fruits and veggies, hit the gym regularly, and practice the Buddhist edict to think not-thinking. I’ve also found that in my case, some advice from Alcoholics Anonymous is very helpful: You can’t think your way into a new way of living … you have to live your way into a new way of thinking.

Will all these mental exercises and lifestyle changes work? Well, since my latest blood pressure reading was 110 over 70, I’ve got a feeling they just might.

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Find the Blessing
Every experience, no matter how bad it seems, holds within it a blessing of some kind. The goal is to find it.

— Siddhartha Gautama, the Buddha, 567-484 BC, ascetic and sage
Nelson Armour and Ted Glasoe’s traveling art exhibit, *Surface Tension: Beauty and Fragility in Lake Michigan,* was recently open at the local center for the arts. I was in town for my uncle’s unexpected death caused by a car accident, and I needed to take a break from the devastation of the moment.

Glasoe’s poignant and exhilarating photos of Lake Michigan highlighted its grandeur and unparalleled, assertive beauty. Each image portrayed a different aspect of this Great Lake’s alluring and even sometimes stupendous power. Armour altered the same images and unpacked each scene into vulnerable, unsettling tableaus of devastation. He intricately reconstructed each milieu into what would happen as a result of pollution and global climate change.

The juxtaposition of power and disaster struck me because it made evident the fragility of even the most monumental of scenes. It reminded me of how powerful and influential a figure my uncle was for my family, yet how transient and tenuous his life could be. Despite the anguish I was feeling over the loss of someone so close to me, this exhibit helped me cherish my relationship with my uncle.

My uncle was one of the strongest people I knew. He was the first person in my extended family to go to high school, and he worked extremely hard to make sure his 5 younger siblings had the resources to make it all the way through graduate school. He was the financial and emotional pillar of support that made it possible for my family to succeed. Glasoe’s images of the sheer might of nature reminded me of my uncle’s role as a pillar of strength for my family.

Armour’s images, however, also reminded me of my uncle. Six years earlier, he sustained a massive cardiac arrest, and he was in the intensive care unit for more than a week. The situation was as ugly and devastating as the altered images that Armour so intricately fabricated. However, my uncle made a full recovery, and since that shattering health crisis, my uncle’s vulnerability in that moment made him see the beauty in life, despite life’s delicate propensity for tragedy. Subsequently, he got a law degree in his 70s, traveled around the world, and wrote a biography of my grandfather. So, when I saw Armour’s images, I chose to see the beauty in them, rather than their ugliness. I saw how the images’ vulnerability, just as in my uncle’s case, gave the scenes purpose and motivation for the betterment of nature.

This art exhibit helped me appreciate and celebrate my uncle’s life, and it helped me learn more about myself. I understandably am still sad that he is gone, but I’m happy that I was able to celebrate his life. I better understand the need to be strong for myself, my family, and my community. I also understand that being vulnerable isn’t always necessarily a negative trait. It can help open one’s mind to new possibilities. In my case, my newfound strength and appreciation of my vulnerability as a human has allowed me to gain more humble confidence in accomplishing my life goals.

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I look forward to Lucy's appointments. Lucy is friendly, full of life and energy, and endlessly enthusiastic. She used to be a chef but now teaches cooking at a community college. I ask her about her class: How she goes about her work, and why she loves it so much. Her stories are endless. The only other thing she likes to talk about as much are her young children and her annual summer gig as a chef at the Canyon resort—a get-away spa for the rich and famous near Phoenix.

It happens that another patient once told me he had been a student at the community college where he learned how to run a restaurant. He now owns a successful food truck. As I asked more and more about his background it, became clear that he had been one of Lucy's students. He clearly adored Lucy as much as I.

Lucy has cancer. A slow-growing cancer. One that we have never had to treat but one that one day will get worse.

I always look forward to seeing Lucy though I dread the day I have to tell her that things have changed.

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The Check-in People at the Hospital Make Me Cry

Jimmy Unger, MD

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https://doi.org/10.7812/TPP/18.312

ABSTRACT

A Somali immigrant describes the painful process of checking in at a medical office in terms that evoke an even more intense emotional response than the traumatic events he experienced in his homeland.

Aden, my son; Ismail, the translator; and I had been waiting in line for a long time. There are some computer check-in machines that nobody is using. I never use those because they’re in English. Even with Ismail helping me, they are hard to use. He’s always a nice guy, like a friend. While we’re waiting, he’s busy on his iPad doing I don’t know what.

“I can help whoever’s (I hear the word) ‘necks’,” says the Check-in Lady at her computer, not looking at me. I think I know what she wants, but I’m hearing something about “necks,” so I take a second to think about what is going on. I have no idea what she’s talking about. In the 8 years I’ve lived in America, I have worked hard at learning English. No way I can figure out why she’s talking about “necks.” We’re here for Aden’s check-up, nothing to do with his neck.

I look back to Ismail for help, but he’s still busy with his iPad. A lady standing in line behind us with her 4 kids understands what the Check-in Lady is saying, because she walks around us in a hurry and goes right to the desk to check in.

I have been bringing my kids to this hospital for check-ups and sicknesses for 5 years. The Check-in People know me. I know what they will want: My Kaiser Permanente card, my driver’s license, and my Oregon Health Card. (The Oregon Health Card is the insurance card they give poor people here.) I am ready. I have seen that almost everybody at this hospital has Oregon Health Cards, but there are some people who don’t have them. They either have their Visa cards or lots of dollars that they pay with. I don’t pay anything when I come here. It seems like the people that pay are always treated better. The Check-in Person smiles at them, calls them by their names, and asks how they’re doing. Me—they don’t smile, they don’t look at me, they look at the translator, always in a hurry. Kind of reminds me of how, in my country, if you bribe the guys with money, they treat you nice. Even if I had the money, I’m not gonna bribe the Check-in People.

The doctors and nurses here—they are nice. They seem to understand me; they listen. They make it so the kids don’t get too scared or cry too much at the doctor. The doctors are like magic sometimes. A couple of years ago, Aden was losing his hair—almost like an old man. I thought maybe spirits were making him lose his hair. The doctor gave us this medicine to drink, and the hair came back!

What I don’t like is the check-in part. I know I’m a grown man. They don’t seem to know that; they treat me like a kid. I’m not stupid, but they treat me like I’m dumb. I’m not deaf, but they talk extra loud, almost yelling at me. I know why; they know I’m not from here. I look different. I’m black, not black like American blacks—I’m really dark. My English is funny. A lot of my clothes are old and come from Somalia. They must think I don’t belong here.

I owned a small store in my country and made enough money. My wife, kids, and I moved to America because it wasn’t safe back there. I took care of my wife and 8 kids, prayed 5 times a day, went to the mosque whenever I could. I come here, and they treat me like a kid. They know I need a translator; my English isn’t that good yet. I know how much I have learned in a short time. I have heard Americans try to speak Somali. People like me learn a lot faster, let me tell you. Maybe if Americans talked slow and listened to me, I wouldn’t use a translator, but that doesn’t happen.

Finally, it’s our turn. I’ve been practicing in my head, “I’m Mr Mohammed. This is my son, Aden Mohammed, here for his 13-year check-up with Dr __.”

The Check-in Lady knows me and Ismail; we’ve seen her many times. Ismail, the translator; Aden, my son; and I walk up together; I’m ready to speak. She looks up from her computer and looks at Ismail, the translator, and asks him, “What’s he here for today?” Like I’m invisible or deaf or stupid or a little kid. Ismail and she talk quickly, and we get checked in.

While we’re waiting for the doctor to come in the doctor’s room, I start talking to Ismail about how the Check-in Lady made me sad, mad, and feel like a stupid kid. He said maybe I should talk to Dr __ about it, so I stop talking about it.

The check-up is fine. The doctor says Aden’s healthy, we’re doing a great job, but we need to make sure he sees the dentist soon. He needs a flu shot; that’s it.

The doctor asks, “Is there something else you want to talk about?” I say “no” because I don’t want to bother the doctor with the Check-in People problem. Ismail reminds me that maybe I should bring it up.

I talk to the doctor, telling him the same thing I’m telling you. I’m a little afraid I’m wasting his time. I know he’s a busy guy. Maybe he doesn’t have time to mess with my hurt feelings. He looks kinda mad and stops me after a while. Ismail tells me that he’s saying stuff like, “This is not OK… Your family is always welcome at this office… The people here should always make you feel welcome.” He asks if I will talk to one of the bosses of the office. I don’t really want to; I’m starting to want to go home (in Portland, not back to Somalia). I don’t want to talk to some fancy white lady who probably will say the Check-in People didn’t do anything wrong. I look at Aden—he wants to go home. I also know that he wants me not to be a “wimp.” He always is telling me,
“Don’t be a wimp, Aabbe” (that means “Papa” in our language.) I say I’ll stay and talk to the office boss. I start crying—hard; it’s hard to stop. Crying like a kid, in front of my son.

I have seen my brothers killed, babies starved, girls raped—never cried with any of that stuff. I don’t know why the Check-in People are making me cry, when all the terrible stuff I lived with in my country didn’t make me cry. I have seen cruelty and many deaths that never made me cry. Came all the way to America, and the Check-in People make me cry.

The boss is not a white lady, but a black guy who seems cool. He listens. I see he’s mad … but not at me. He’s mad at the Check-in People. He asks who checked me in and who talked to me that way. He asks if it happened just this one time or does it happen all the time. I tell him, “Almost every time.” I don’t want to get anyone in trouble, so I tell him, “I can’t remember who did it.” He says he’ll talk to the Check-in People and make sure that I get treated right next time.

As we’re leaving, Dr ___ sees us, thanks us, tells us goodbye. Ismail, the translator, is gone, and Dr ___ says something to Aden. I don’t hear all of what he said, but I hear him say “Dad” and “brave” with a big smile. I ask Aden what the doctor said. “Whatever…. Can we go home now? I’m starved.”

He, too, had a smile—you know, the kind teenage boys never want their Aabbe to see.

Disclosure Statement

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

Acknowledgments

“The Check-in People at the Hospital Make Me Cry” is a slightly fictionalized account of an office visit of one of my patients. The names used here have been changed. The author wishes to express his admiration and gratitude to immigrant families who every day demonstrate courage that allows them to begin to overcome both the trauma from which they have escaped and the new hardships they face in the US. He also thanks the “front-office” and “back-office” staff who take the extra time to help care for these patients daily—often not receiving the praise that they so richly deserve.

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Be Just

I did by all persons as I would they should do by me. I was always just in my practice …

— Nicholas Culpeper, 1616-1654, English botanist, herbalist, physician, and astrologer
She came in overdressed, over perfumed, and 30 minutes late to the last appointment of an evening clinic, which was scheduled to close at 9 pm.

“The perfect ending to a 14-hour day,” I thought as I listened to her tell my nurse that she couldn’t get off work early and she had to be seen. She had a “cough.”

“Oh well, easy enough,” I thought.

I introduced myself and took a brief history: 2 weeks of a cough, she didn’t smoke, no blood with her cough, no fever, no weight loss—looking good. A perfunctory physical was normal. I was just starting my “watchful-waiting-with-reassurance” speech when she interrupted.

“I know my body,” she said. “I need a chest x-ray.”

Fatigue and the obstinate set of her jaw made me take the path of least resistance.

“Sure,” I said.

Waiting for her to return from x-ray, I spent the next 30 minutes flipping through a journal I wasn’t interested in and wondering if I should eat a full meal when I got home or defer to my heartburn. When I heard my nurse greet her in the hallway, I hurried out to intercept, tell her the obvious, and slip out while the nurse finished her discharge.

I took the envelope (before digital days) and slammed the film onto the view box so that we could look at the film shoulder to shoulder, only to see a constellation of metastatic stars covering the dark sky of her lung fields.

“What are those?” she asked, pointing at the film.

I was suddenly ashamed of my self-pity over a 14-hour day, ashamed of my cursory exam, ashamed of my rote diagnostic assumptions, and ashamed of my selfish hurry. What could I say to a woman at 10 o’clock on the night before she was supposed to travel to her daughter’s wedding?

The seconds were ticking away as I tried to find the right words to start with, when I felt the gentle touch of her hand on my arm and her words, which were spoken with more empathy and understanding of me than I’d ever shown her: “Don’t worry, Doctor. It will be okay.”

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

How to Cite this Article
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Animals often have an innate sense of their surroundings. We’ve seen this in studies showing how birds migrate early when large storms are imminent. There have been studies of dogs who can “sniff” out urine that has malignant cells. And we know for a fact that certain ocean predators, such as sharks, can sense fear in prey.

When I was an intern in the CCU, a pilot pet therapy program was started that entailed bringing animals to patient rooms. My first thought was that these animals would bring their own bacteria from room to room, despite the fact that infectious disease seemed okay with it. I later saw how patients responded and felt more “alive” with these companions. From even the lonely fish in a tank to the hyper canine, patients spoke only good things about the program.

One such pet who made a lasting imprint was a dog named Snowball. He was a large, almost bear-like, white dog that had the fluffiest coat of hair I had ever seen on a dog. His presence was definitely known in the room as he weighed probably as much as I did. The pet therapists would tell us that he had a way with patients but was also peculiar in that he was very picky about whom he interacted with.

As time went by, we noticed a strange pattern. Snowball would be very engaging with specific patients—jumping up on the bed, playful and interactive—and with other patients he would remain distant. There was no obvious pattern, disorder, or common denominator among patients except one: Each patient he played with would have a life-threatening event in the next 24 hours. There was Mr S, who came in with ventricular tachycardia and improved, but one day from discharge he coded unexpectedly and passed that night. There was Ms B, who was admitted for diabetic ketoacidosis and easily treated only to end up dying from an unknown pulmonary embolism the next day. Lastly, there was the young cancer patient, Mr P, whom we saw that day actually play with Snowball and incidentally he suffered a septic event and ended up in the ICU. We started referring to Snowball, as the “death dog” and the “grim reaper.”

As time has gone by, I often wonder if that was truly a fair assessment of this well-meaning creature. As physicians, we also encounter our patients and establish a good rapport with them, only to have them decline, sometimes shortly after meeting them—but that does not make us a harbinger of death. Perhaps Snowball was merely meaning to give these kind souls a caring goodbye and not acting as a messenger of morbidity.

How to Cite This Article

The story “The Death Dog” was originally published in leaflet, 2017;5(2). Available from: http://leaflet-ejournal.org/archives-index/item/the-death-dog

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BOOK REVIEW

Promoting Biodiversity in Food Systems
Edited by Irana W Hawkins

Sarah Delcourt, MS, RD
E-pub: 09/20/2019

Poor health status, population growth, pollution, and climate change are major topics of discussion worldwide. The questions asked by a variety of laypeople and professionals on these topics include: How can health status improve among all populations? and what impact does the environment have on human health? Researchers are taking a closer look at what affects human and environmental health. New and old approaches are being implemented to address these concerns within the realm of farming, food production, and health care. Irana Hawkins, editor of Promoting Biodiversity in Food Systems, presents a compelling collection of research about biodiversity at all levels, from microscopic to global, and its vital role in improving the health status of life on earth in a sustainable manner. The purpose of the book is to convey how important it is to conserve and promote biodiversity, with food systems emphasized as the most critical component of this mission. The information presented within Promoting Biodiversity in Food Systems is organized, well-researched, and emphasizes the importance and necessity of using an interdisciplinary approach to enable healthful eating while supporting people and planetary health.

The chapters in Promoting Biodiversity in Food Systems are written by various authors with an assortment of credentials and expertise. Each chapter presents current, evidenced-based research from reliable sources. Helpful and appropriate diagrams, tables, pictures, and other visuals are used in most chapters. In addition, each chapter builds on the next, and collectively they present a strong argument for how and why biodiversity is a key component in achieving health for all life on earth. Specific, realistic solutions are provided by each author for achieving sustainable biodiversity and better health for humans and the planet. The book is unique in that it makes a strong recommendation not only to choose plant-based foods (sustainable, environmental-friendly, and cost-efficient), but also to choose and support organic produce and farming practices (more sustainable and environmental-friendly than conventionally grown food, encourages/utilizes biodiversity). Opportunities to improve this book in future editions include an in-depth analysis of agrochemicals and their effect on human health and nutrient composition of foods.

As a whole, Promoting Biodiversity in Food Systems promotes an interdisciplinary approach for achieving planetary health. It makes clear that everyone—from farmers to consumers to food processors and producers to the professionals in the health care sector—has an important role in his/her health and no one can be left out. Overall, the common theme found in Promoting Biodiversity in Food Systems is that both individuals and communities can help “restore biodiversity, stability, and resilience in local ecosystems and beyond.”

The book emphasizes that we all make a difference, and we can make little and big changes in our lifestyle patterns to support planetary health. By taking a closer look at the research regarding poor health, population growth, environmental pollution, and climate change, Promoting Biodiversity in Food Systems presents a variety of thoughts, ideas, and solutions to address what can be done today, and what should be implemented in the near future. In addition, it suggests further scientific research that should be conducted to better understand and deal with current and future environmental changes, and the inseparable needs of both people and the planet.

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

How to Cite this Article

References

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Keywords: biodiversity, food systems, planetary health, promoting biodiversity, sustainable biodiversity
**BOOK REVIEW**

**Picture of Health: Transform your self-care and health care through Ayurvedic and Integrative Medicine**

Written by Charles R Elder, MD, MPH, FACP, & Leslie D Elder, MD

Sanford Nidich, EdD

**Perm J 2019;23:19.179**

E-pub: 11/01/2019

**Portland, OR:** The Permanente Press, 2019

ISBN: 978-0-9770463-8-6

Paperback: 181 pages; $29.95

*Picture of Health* is a practical and user-friendly guide for patients and clinicians to promote health and wellness through a complementary and integrative approach. It aims for coordinated care between conventional and ayurvedic systems that is patient-centered and treats the whole person. Using diet, herbs, meditation and other behavioral modalities, along with conventional medicine, *Picture of Health* offers a natural and effective option for prevention and treatment of chronic illness.

Ayurvedic health care has been continuously practiced in India and other parts of the world, and "is likely the oldest practiced tradition of health care, dating back to 500 BCE" (the oral tradition is much older). Part I of the book takes the reader through the basics of this system of health care, emphasizing the importance of prevention through daily routine, diet, exercise, and stress-reduction techniques.

Health, from the platform of ayurveda, is a state of balance and disease a state of imbalance, based on 3 fundamental "psychometabolic principles": "doshas." The 3 doshas are "vata," "pitta," and "kapha."

The dosha vata governs all the movement—mind, body, and spirit: Movement of thoughts through the mind, food through the digestive tract, blood through the blood stream. Pitta governs digestion, metabolism, and transformation. Kapha governs structure, the physical structure of the body.¹

The balance/imbalance state of each dosha can be detected through the ancient technique of pulse diagnosis of 3 fingers (index, middle, and ring) placed on the pulse of the patient to determine the degree to which the qualities, functioning, and structure of different aspects of the physiology are in a state of balance. A self-report questionnaire is also used to determine mental and physical conditions and health behaviors.

There are 10 constitutional types based on the 3 doshas. A central feature of the book is the presentation of dietary menus based on constitutional type. The book has recipes to help in adjusting and adhering to one’s prescribed diet.

The discussion of daily routine and healthy eating habits can benefit everyone, irrespective of constitutional type. According to ayurveda, good health and digestion go hand-in-hand. Because good digestion is so critical, we are advised to eat our main meal during lunch, in the middle of the day around noon, when the digestive fire (agni) is greatest. The Elders cite research linking the secretion of digestive fluids, and other biochemical processes, to the time of day and suggest that these studies reinforce the ancient ayurvedic principle of eating the main meal during the midday to aid proper digestion.

For good health and wellness, many simple recommendations are included such as eating a lighter dinner at night, avoiding cold drinks, eating fresh and cooked food in a settled environment, sleeping by 10:00 pm, rising by 6:00 am, and exercising between 6:00 am and 10:00 am. The Elders, with extensive experience as both practitioners and researchers, recommend the daily practice of Transcendental Meditation (TM) in one’s daily routine morning and evening. Research studies on the benefits of TM for chronic conditions, such as high blood pressure and cardiovascular disease, are described. They also discuss how neurophysiologic functioning during TM practice is different compared with other relaxation and meditation programs.

The important discussion of the use of herbs in prevention such as turmeric for its anti-inflammatory properties, brahmi for optimizing mental functioning and reducing emotional stress, and ashwagandha for improving overall well-being takes place in Part II. Ashwagandha is a particularly good herb for balancing vata.

Part III provides many case histories and testimonials from patients who have gained benefit from using the ayurvedic system of medicine. These case studies include benefits for pain and hormonal changes, and recommendations for diabetes.

*Picture of Health* achieves its goal of providing an easy-to-read guide for health and wellness based on ayurveda and integrative medicine. I highly recommend its adoption in medical schools and continuing medical education programs for physicians.

**How to Cite this Article**

Nidich S. *Picture of health: Transform your self-care and health care through ayurvedic and integrative medicine* written by Charles R Elder, MD, MPH, FACP, & Leslie D Elder, MD. *Perm J* 2019;23:19.179. DOI: https://doi.org/10.7812/TPP/19.179

**Reference**


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Keywords: alternative modalities to enhance allopathic care, ayurvedic medicine, daily routine, doshas, holistic medicine, integrative medicine in traditional health systems, mind-body techniques
Section A.

Article 1 (page 4) A 10-Year Analysis of 3693 Craniotomies During a Transition to Multidisciplinary Teams, Protocols, and Pathways

The successful transition to a multidisciplinary team approach for craniotomy patients involved all of the following except:

- a. on-site and off-site team building to restore collegially, build trust, and improve communication between neurosurgeons, neurocritical care doctors, hospitalists, and mid-level practitioners
- b. collaboration with nurses and pharmacists to roll out and revise craniotomy order sets and care pathways
- c. data collection to monitor for improved care efficiencies such as case volume, complications, and length of stay
- d. design and implementation of a standardized, searchable craniotomy discharge summary with drop-down lists
- e. the creation, testing, revision, and approval of standardized craniotomy care protocols was a quick and painless process

The long-term commitment to transforming the inpatient neurosurgery service to a multidisciplinary team model lead to the following outcomes except:

- a. improved communications between colleagues, patients, and families
- b. smoother transitions across the continuum of care
- c. increased medical and surgical complication rates after implementing protocols and pathways
- d. improved care efficiency allowed absorption of a 73% increase in craniotomy case volume over 10 years without an increase in hospital days or operating rooms backlog

Patients with kidney stones are typically compliant with:

- a. 24-hour urine testing
- b. pharmacologic therapy
- c. long-term dietary modification
- d. treatment of a painful stone episode
- e. follow-up after a stone episode


Which statement below is NOT correct concerning the metabolic evaluation of high-risk kidney stone formers?

- a. It has been shown to decrease recurrence rates
- b. It is endorsed by the American Urology Association (AUA) and the European Association of Urology (EAU)
- c. It is universally performed with excellent completion rates
- d. Compliance has historically been challenging

Patients with kidney stones are typically compliant with:

- a. 24-hour urine testing
- b. Pharmacologic therapy
- c. Long-term dietary modification
- d. Treatment of a painful stone episode
- e. Follow-up after a stone episode

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?

<table>
<thead>
<tr>
<th>Objective</th>
<th>5 = highly likely</th>
<th>4 = likely</th>
<th>3 = unsure</th>
<th>2 = unlikely</th>
<th>1 = already did this</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objective 1</td>
<td>Integrate learned knowledge and increase competence/confidence to support improvement and change in specific practices, behaviors, and performance.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Objective 2</td>
<td>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.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Objective 3</td>
<td>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.</td>
<td>5</td>
<td>4</td>
<td>3</td>
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Fall 2019

CME Evaluation Program

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

Email

Address

Signature

Date
California Lisbon ink, watercolor Latifah Apatira, MD

From Dr Apatira: “Nature painting” is a centuries-old printmaking technique used to create detailed, illustrated images of natural objects such as plants for study and art. Image transfer occurs by directly applying ink to a freshly picked plant, sandwiching the plant between 2 sheets of paper, and rubbing the surface of the plant by hand, capturing a precise and clear print, an impression of life.

Dr Apatira is a plant enthusiast, mixed-media artist, nature photographer, and Occupational Medicine Physician at the Kaiser Permanente Southern San Francisco Medical Center in CA. More of Dr Apatira’s work can be seen at www.tillayola.com.

TABLE OF CONTENTS

ORIGINAL RESEARCH & CONTRIBUTIONS

1 10-Year Analysis of 3680 Cranioectomies During a Transition to Multidisciplinary Teams, Protocols, and Pathways Paul T. Atkins, MD, PhD, Ami Banerjee, MD, Ken Guppy, MD, PhD, James Sirlin, DO, John Flaggby, MD, Yoganand NANDAN, MD, Elaine O. Yu, Luis Pacheco, Adrienne Rozance, MD, Rob Avasthi, MD, James Chang, MD, Mark T. Hua, MD

The observational study involved sequential implementation of a multidisciplinary team, protocols, and a mandatory pathway. Retrospective review of admissions (2005-2017) revealed reduced craniotomy complication rates, case volume increased 77%, and hospital length of stay improved by 63%, as well as increased professional collegiality and satisfaction. A successful craniotomy discharge summary is an important tool for contemporaneous monitoring of quality and efficiency of care. The authors present outcomes data, including complication indices, operating time, complications, functional outcomes, delays in discharge, and discharge destinations using the craniotomy discharge summary.

11 Predictive Factors for Early Relapse in Multiple Myeloma after Autologous Hematopoietic Stem Cell Transplant. Andrew Mayer Poomsunthan, MD, Ricardo Schellekens, MD, Allan Carter, MD, Odale Khoshtail, OMD, Leonardo Farol, MD, Thai Cao, MD, Pisoon Sethawat, MD

A total of 141 patients were included in this retrospective analysis. Factors found to be associated with inferior progression-free survival were disease status less than complete response at the time of hematopoietic stem cell transplant (HSCT), no use of maintenance therapy after HSCT, International Staging System stage III, and high Freiburg Comorbidity Index. Disease status less than complete response, stage III, and Freiburg Comorbidity Index were associated with inferior maintenance therapy, and male sex were the most predictive factors for early relapse (< 18 months). These results highlight the need for consideration of alternative therapy at such instances.

16 Lifestyle interventions and Cortisol Plaque Barrier: A Comparative Analysis of Two Lifelihood Intervention Programs in Patients with Coronary Artery Disease. Rachael E. Keesul, MD, MPH, Omer M. Alish, MD, Columbus D. Babula, MD, Adina Meier, MD, Maria Robinson, MD, Darlene Newton, EHPH, Raoul Bartucca, MA, MS, Cynthia Cortes, RN,off, Field Patterson, MPH, Mohamed Ibraimal, MPH, MPH

In a randomized, single-center, double blind study in 120 patients with established coronary artery disease (CAD), neither the Complete Health Improvement Program (CHIP) nor an ad hoc, nonsequential combination of various healthy-living classes was effective in inducing plaque regression in patients with established CAD after a 6-month period. However, patients in improving several CAD risk factors, which shows that the nonsequential offering of the healthy-living programs can lead to similar outcomes as a formal, sequential, established program (CHIP) in many aspects.

23 Spontaneous Coronary Artery Dissection: Clinical Characteristics, Management, and Outcomes in a Racially and Ethnically Diverse Community-Based Cohort. Stephanie Chen, MD, Nalakshita Merchant, MD, MI, Kenneth N. Maher, MD, Robert J. Lundstad, MD, Sahan Nakar, Anna J.r. Guin, MD, MPH

Anastomotic-coronary dissection of patients (median age 46, 65% women, 49.5% nonwhite) with spontaneous coronary artery dissection (SCAD) at Kaiser Permanente Northern California during a 10-year period compared 311 SCAD cases with 333 healthy, matched controls. Pregnancy and hypertension were associated with SCAD compared with controls. Fifty-five patients (17%) were successfully treated with nesiritide; of which, in 54 SCAD cases, major adverse cardiovascular events occurred in 8.1%, and race did not influence outcomes.

28 Failing a Formalized Impact: System of a Comprehensive Geriatric Hip Fracture Program on Long-Term Morality. Mary Anderson Wallace, MD, Andrew Harner, MD, Michael E.fatley, MD, Anastasia A-Trono, Christine D. Jones, MD, NEC, Ethel D. Ward, RN, RN, NCS, Michelle C. Canaan, MD, RN, PhD

In a retrospective cohort study of patients (age 65 years and older) admitted to an academic medical center with an acute fragility hip fracture (1/1/2013-12/31/16), the authors identified 243 hip fracture admissions, including 135 before and 108 after a comprehensive geriatric hip fracture program implementation (12/1/16). The postintervention cohort trended toward a lower unadjusted 1-year mortality rate (15.7% vs 24.4%), and had a significantly higher overall survival rate than did the preintervention cohort.

Picture of Health is a practical guide to improve their health by integrating conventional and holistic medicine. It offers disease guidelines, specific and holistic advice, recipes, and many practical tips for those who are ready to take the next step toward ideal health.

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Charles R. Eber, MD; FACP; APC; Leslie D. Edler, MD

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