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No known published study has focused on a plant-based diet in the treatment of ulcerative colitis (UC). In a prospective study of 60 patients with mild UC or UC in remission who did not need immediate treatment (29 initial episodic cases and 31 relapse cases), the cumulative relapse rates at 1, 3, 5 and 6 years of follow-up were 2%, 4%, 7%, 18%, and 19%, respectively. Relapse rates after educational hospitalization providing a plant-based diet were far lower than those reported with medication. Educational hospitalization is effective in inducing halting relapsing diseases.

13 Marijuana’s Influence on Pain, Initial Weight Loss, and Other Bariatric Surgical Outcomes. Frank R. Dauer, MD, William D. Doshay, MD, Harris W. Feldman, MD, Adam O. Tait, MD, Brian J. Potter, MD, Jason M. Johnson, DO, Loren J. Silvis, PhD, Farhad A. Haider, MD.

Pain management can be challenging following bariatric surgery; and obese patients tend to increase opioid use after undergoing surgery. Data were collected for 434 consecutive patients undergoing weight reduction surgeries (5/2014-7/2015) among whom 36 (8.3%) reported marijuana (MJ) use. Perioperative opioid requirements were significantly higher in the MJ user group despite lower subjective pain scores (3.0 ± 4.24). The difference in opioid requirements suggests an interaction between MJ use and opioid tolerance or pain threshold. The percentage of total body weight loss, improvement in medical comorbidity, and incidence of postoperative complications at 30-day follow-up were not affected by MJ use in this cohort analysis.

Potentially Preventable Hospital and Emergency Department Events: Lessons from a Large Innovation Project. Lail S. Gobhaya, MD, Masie A. Ongley, RN, MPH, Emily D. Parker, PhD, MPH, Robert Ferguson, Sidney Magurn, PhD, PhD, Robin R. Whelan, PhD, Claire Neely, MD, Emily Brandtleser, MD, MS, Mark O. Williams, MD, Mark Ochsenhirt, MD, Todd Hennenkamp, RN, Jeanette Y Ziegler, PhD.

There are few proven strategies to reduce the frequency of potentially preventable hospitalizations and Emergency Department visits. Of the studied events, 15% were consumed to be potentially preventable (39% of Emergency Department visits and 14% of hospitalizations) and 4% of patients had 40% of events. Only type of insurance coverage; patient’s level of resources, particularly for understanding of care; and inability to access clinic care were more frequent in those with preventable events. Neither disease control nor ambulatory care-sensitive conditions were associated with potentially preventable events.

26 Understanding Waste in Health Care: Perceptions of Forensic Physicians Regarding Time Use and Appropriateness of Care They Refer and Others Provide. John P. Carneyhaus, PhD, Michael H. Hunter, MD, Nicole R. Veen, MPH, Chong A. Yen, PhD, Helen K Kanabar, MD, MPH, Sandra H Barry, MA, Robert H Black, MD, BS.

In a cross-sectional online survey of all Southern California Permanente Medical Group physicians primarily employed in primary care-based care (3148), 61% of respondents indicated that 15% of their time spent on direct patient care could be shifted to nonphysicians, and between 10% and 16% of care provided was equitable or inapplicable. That apparent at least that at one primary care system, the opportunity to increase value through task shifting and avoiding inappropriate care is more narrow than commonly perceived on a national level.

34 Impact of Body Mass Index on Postconceptional Depression in Teenagers Aged 13 to 18 Years. Nancy Stanley, OD, Katherine F. Reilly, MD, Ronald Williams, MD, Michelle M. Lewis, MD, Lan Kong, PhD, Matthew Silvis, MD.

In a retrospective chart review at a regional concussion program located at an academic medical center, medical records of all patients aged 13 to 18 years treated from 2005-2012 were reviewed with 252 patients meeting the inclusion criteria of sports-related concussion and having body mass index data. There was no statistically significant difference in recovery time between obese and overweight patients and others. After concussion, incidence, and impulsivity may be more likely than headaches in overweight and obese patients.

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Sarah Beekley, MD, is a Pediatric Hospitalist in Redwood City, CA. More of her artwork is available at www.beekleywatercolor.com.

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THE COMPLETE GUIDE TO SELF-MANAGEMENT OF DEPRESSION: PRACTICAL AND PROVEN METHODS
Harriet S. Dugall, MD, FAPA
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Bloomingon, IN: Archway Publishing; 2016
Paperback: 338 pages $34.99

For information and/or rates for placing an announcement here, please contact amy.r.eakin@kp.org.
Efficacy of Bilateral Transcutaneous Posterior Tibial Nerve Stimulation for Fecal Incontinence. Georgia Dedemadi, MD, PhD, FACVS, Shota Takano, MD, PhD

Bilateral transcutaneous posterior tibial nerve stimulation (BTPNS) is a new second-line treatment for refractory fecal incontinence. Twenty-two patients (median 64 years, range 26-81) with a male:female ratio of 9:13 completed BTPNS. Mean episodes of fecal incontinence were significantly reduced from 4.7 to 1.5. An improvement of 50% or better in episodes of fecal incontinence was achieved in 77.2% of patients. The median Wexner score significantly decreased from 10.2 to 6.9. The median Wexner score significantly reduced from 4.7 to 1.5. Significant improvement was seen in the embarrassment domain (2.2 vs 2.8). Resting and squeezing anal pressures revealed no significant changes.

Comparative Effectiveness of Surgical Options for Patients with Ductal Carcinoma in Situ: An Instrumental Variable Approach. Lewei Duan, MS; Aniket A Kawatkar, PhD

Many patients with ductal carcinoma in situ (DCIS) receive treatment that is too extensive for qualified subjects. 72.2% underwent breast-conserving surgery and 27.8% underwent mastectomy. No significant benefit was observed with a more aggressive surgical procedure in preventing DCIS recurrence or cancer progression in a diverse population. Many patients with DCIS could benefit from breast-conserving surgery with preservation of their body image. Breast conservation followed-up with cancer surveillance is a rational approach to ensure effective care for patients with DCIS.

Listening Beyond Auscultating: A Quality Improvement Initiative to Improve Communication Scores in the Hospital Consumer Assessment of Health Care Practitioners and Systems Survey. Nardine Saad Riegels, MD, Emily Asher, MD, MS, MPH, MPA; Joseph R Cartwright, MD, MEd; Jessica L Chow, MD, MPH; Elaine D Lee, MD; Aniket A Kawatkar, PhD; Bradford Tropea, MD; Allen Chang, MD; Joseph R Cartwright, MD; Jessica L Chow, MD, MPH; Elaine D Lee, MD; Aniket A Kawatkar, PhD; Bradford Tropea, MD; Allen Chang, MD;

Integration of sound communication practice with clinical workflows has proven difficult. In this quality improvement initiative, medical students used the rapid improvement model to test interventions. Literature review and process analysis yielded 42 potential interventions by medical students. The final intervention used a structured reminder embedded in the electronic health record to direct physicians to begin interventions by eliciting patient concerns, which included pain symptoms (28%), disease or treatment course (16%), and discharge planning (10%). In the Hospital Consumer Assessment of Healthcare Providers and Systems survey, physician listening scores rose from 73.6% (2014) to 77% (2015).

The Effect of Abnormal Vitamin D Levels in Athletes. Jakub Sikora-Klak, MD; Steven J Nary, MD; Justin Yang, MD; Eric Makhni, MD; F Daniel Khanraz, MD; Nima Mehran, MD

Vitamin D is a lipophilic prohormone integral to musculoskeletal, autoimmune, oncologic, cardiovascular, and mental health. Most American adults have inadequate levels of vitamin D. Even among athletes, there is a high prevalence of vitamin D deficiency, which may place competitors at risk of stress fractures, illness, and delayed muscle recovery. This review is to describe the epidemiology of vitamin D deficiency and its effects on athletic performance and musculoskeletal health.

Obstructive Uropathy and Sepsis Caused by an Inguinoscrotal Bladder Hernia: A Case Report. Seena Safavy, MD; Emmanuel Mitsinikos, MD; Bradford Tropea, MD; Allen Chang, MD; Hetal Patel, MD

Inguinoscrotal bladder hernia is a very rare pathology, occurring in up to 4% of all inguinal hernias in the general population. We present a case of an inguinoscrotal bladder hernia causing obstructive uropathy and sepsis in a 59-year-old obese man who presented with left-sided flank and abdominal pain that radiated to his left groin. It is prudent to first stabilize the patient via decompression of the upper urinary tract and antibiotics before herniorrhaphy.

Metastatic Angiosarcoma of the Scalp Presenting with Cystic Lung Lesions: A Case Report and Review of Cystic Lung Diseases. Antonette A Ajayi, MD, MPH; Stephanie V Commis, MThChL; David E Clarke, MD, FCCP

An 83-year-old woman presented with a scalp lesion that was initially thought to be caused by scalp trauma but was later found to be an angiosarcoma. The authors discuss the common presentation of cutaneous angiosarcomas and their tendency to metastasize to the lung and to present as cystic lesions. They review the common conditions that can cause cystic changes in the lungs.

Endogenous Group A Streptococcal Endophthalmitis in a Healthy 42-Year-Old Man: A Case Report. Tan Duong, MD; Shahin Shahbaz, MD; Sung Lee, MD

Endogenous endophthalmitis is a rare condition that is caused by hematogenous spread of bacteria or fungi and is usually seen in patients with predisposed medical conditions. The authors report an unusual case of group A streptococcal infection causing endogenous endophthalmitis and septic arthritis in a healthy 42-year-old man.

The Unmet Challenge of Medication Nonadherence. Fred Kleininger, MD

Medication nonadherence for patients with chronic diseases is extremely common, affecting as many as 40% to 50% of patients who are prescribed medications for management of chronic conditions such as diabetes or hypertension. A Cochrane review shows that multifactorial interventions are more effective. In at least one integrated health care system, Kaiser Permanente Northern California, a combination of approaches centered on the electronic health record has improved medication adherence rates to above 80%. Effective change will not happen until key players decide to take on this challenge and reimbursement systems are changed to reward health systems that improve medication adherence and chronic disease control.

How a “Nothingoma” Can Bring Joy to a Physician. Scott Abramson, MD

During our visit, I talked with Joanne and examined her. Everything was perfectly fine. I reviewed the MRI. It clearly showed an incidential, harmless finding, a “nothingoma.” As I reassured her and was making my exit, Joanne grasped my hand between hers.

Exploring Empathy in the Face of Patient Anonymity and Professional Challenges and Barriers. Carina Mendoza, MD

This is a reflective short story addressing empathy through the eyes of Maria (fictitious patient), confronted with negotiating her first encounter at a medical facility, and through the actions of Dr Jones (fictitious physician) who, at a critical juncture, fails to engage empathically with her patient, donning the ubiquitous hospital gown. Maria’s story is a collage of multiple clerkship experiences of a fourth-year medical student, and of shared anecdotal accounts from patients and medical practitioners.
COMMENTARY

91 From Principles to Practice: Real-World Patient and Stakeholder Engagement in Breast Cancer Research.
Sarah M Greene, MPH; Susan Brandzel, MPH; Karen J Wemli, PhD, MS
Kaiser Permanente Washington Health Research Institute (KPWHRI) developed a set of eight principles to guide how research teams should work with patients and other stakeholders to simultaneously achieve research aims and embrace this new paradigm in how research teams collaborate. With a goal of assisting other research teams, this article describes the genesis of the KPWHRI principles, their relevance to patient- and stakeholder-engaged research, and how these principles were brought to life in the context of a specific Patient-Centered Outcome Research Institute-funded project on surveillance imaging in women after a breast cancer diagnosis.

NARRATIVE MEDICINE

95 Pigments and Medicine.
Sarah Beekley, MD
A physician’s work is challenging, complicated, and sometimes even daunting. We heal, but we are also witnesses to tragedy and loss. Maintaining grace in this setting requires an active investment in community, self, and beliefs. And so, when I am not working, I paint.

96 Home-Based Palliative Care Program Relieves Chronic Pain in Kerala, India: Success Realized Through Patient, Family Narratives.
Apama Sai Ajajaran; Ann Brodnerick, MD, MS
The current project features the pain stories of six patients who received treatment from Pallium India, one of the most sophisticated palliative care programs in India that emphasizes holistic pain treatment. A Pallium India staff member asked questions about each patient’s pain experience. Pain narratives (with photographs) illustrate the substantial impact of Pallium India’s home visit program and the role of total pain assessment in delivering high-quality palliative care.

100 Cathartic Poetry: Healing Through Narrative.
Richard Bruce Hovey, MA; PhD; Valerie Curro Khayat, MA; Eugene Feig
“Most people are completely afraid of silence.” —EE Cummings
This article explores the efficacy of writing and reading poetry as a means to help people living with chronic pain to explore and express their narratives in their own unique way. One of the authors’ poetry is sent out almost weekly to the members of our pain support group as a method of sharing his own experiences of living with pain, as well as to support and to inspire hope in others. This article is a philosophical hermeneutic conversation about pain and poetry.

BOOK REVIEW

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Shobana Kubendran, MBBS, MS; GCC; Jennifer Duong, MPH; Fanglong Dong, PhD; Amy Lueking, MD; Darren Farley, M

CASE REPORTS

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Sara Dawoud, MBMS; Rachie J Solomon, MPH; Stephanie A Eyerly-Webb, PhD; Neil A Abrahams, MD; Fernando Pedraza, MD; Juan D Arenas, MD, MBA; FACS; Tjasa Hranjec, MD, MS-CR

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Invasive Baxal Cell Carcinoma of the Skin Treated Successfully with Vismodegib: A Case Report.
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Lindsay C Shipley, MD; S Trevor Taylor; Christina Grimley; Kevin Stoffer; Jack Goldstein, MD

IMAGE DIAGNOSIS

Image Diagnosis: Plummer-Vinson Syndrome: An Unusual Cause of Dysphagia.
Puneet Chhabra, MD, DM; Hunny Khurana, MD

Image Diagnosis: Allergic Fungal Sinusitis.
Satvinder S Bakshi, MS, DNB
**ABSTRACT**

**Context:** No known published study has focused on a plant-based diet (PBD) in the treatment of ulcerative colitis (UC).

**Objective:** To investigate relapse prevention in UC after consumption of a PBD during educational hospitalization in Japan.

**Design:** Prospective study of patients with mild UC or UC in remission who did not need immediate treatment. A PBD and dietary guidance were provided during a two-week hospitalization.

**Main Outcome Measures:** The primary end point was relapse (a flare-up that required more aggressive treatment) during the follow-up period. Kaplan-Meier analysis was used to calculate the cumulative relapse rate. Secondary end points were immediate improvement in symptoms or laboratory data during hospitalization and a chronologic change in the PBD score, which evaluated adherence to the PBD.

**Results:** Sixty cases were studied: 29 initial episode cases and 31 relapse cases. Of these, 31 involved proctitis; 7, left-sided colitis; and 22, extensive colitis. Thirty-seven patients were receiving medication; 23 were not. The median age was 34 years; median follow-up was 3 years 6 months. Eight cases relapsed during follow-up. The cumulative relapse rates at 1, 2, 3, 4, and 5 years of follow-up were 2%, 4%, 7%, 19%, and 19%, respectively. Most patients (77%) experienced some improvement such as disappearance or decrease of bloody stool during hospitalization. The short- and long-term PBD scores after the hospitalization were higher than baseline PBD scores.

**Conclusion:** Relapse rates after educational hospitalization providing a PBD were far lower than those reported with medication; 23 were not. Educational hospitalization is effective at inducing habitual adherence to the PBD.

**INTRODUCTION**

Ulcerative colitis (UC) and Crohn disease have a common etiopathogenesis and features, and they fall under the collective term inflammatory bowel disease (IBD). No longer a disease mainly seen in Europe and North America, IBD is now a global disease. Despite the recognition of westernization of lifestyle as a major driver of the growing incidence of IBD, countermeasures against such lifestyle changes have been recommended, except that patients with Crohn disease should not smoke. Dysbiosis (imbalance) of the gut microflora has been observed in IBD, and it is apparent now that gut microflora is influenced by our diet. Thus, it seems critical to maintain gut symbiosis for the suppression of gut inflammation by consuming a suitable diet. With a suitable diet, substantial improvement in the prognosis of IBD can be expected. We consider that the lack of a suitable diet is the biggest issue faced in current treatment of IBD.

We regard IBD as a lifestyle disease caused mainly by our omnivorous (Western) diet. We have been providing a plant-based diet (PBD) to all patients with IBD since 2003. By incorporating a PBD in treatment, we have achieved and published far better outcomes in both the active stage and quiescent stage in Crohn disease than those reported previously.

If IBD is accepted to be a lifestyle disease mainly caused by a westernized diet, then current practice must change. Current practice recommends lifelong medication for relapse prevention in IBD. Diet, however, is critically important. Although medication is needed in the active phase of IBD, diet is generally more important than medication to maintain remission in the quiescent phase. If a suitable diet is established as part of a changing lifestyle, medication ultimately may not be needed to maintain remission.

The Japanese diet has become westernized and is now far from an omnivorous (Western) diet. We regard IBD as a lifestyle disease caused mainly by our omnivorous (Western) diet. We have been providing a plant-based diet (PBD) to all patients with IBD since 2003. By incorporating a PBD in treatment, we have achieved and published far better outcomes in both the active stage and quiescent stage in Crohn disease than those reported previously.

The Japanese diet has become westernized and is now far from a PBD. With increasing affluence in Japan, replacement of our diet with a PBD is not easy. This replacement can, however, be achieved by a short period of educational hospitalization. We started educational hospitalizations in 2003. The percentage of patients with UC admitted for educational hospitalization was 30% of all admitted patients with UC.

Our goal is the prevention of a relapse during the follow-up period after educational hospitalization. We hypothesized that educational hospitalization will decrease the relapse rate, and, eventually, remission will be maintained in most UC-affected patients not with medication but with a PBD.
METHODS

Design, Settings, and Patients

We designed a single-group trial (study number UMIN000019061), which was conducted at 2 tertiary care hospitals in Akita in northern Japan: Nakadori General Hospital and Akita City Hospital. The first author (MC) worked for Nakadori General Hospital between 2003 and 2012 and has been working for Akita City Hospital since 2013. This study was approved by the ethical committees of Nakadori General Hospital and Akita City Hospital (Protocol Numbers 19-2003 and 15-2015). Written informed consent was obtained from all patients.

Patients with UC who did not need immediate treatment and were able and willing to be admitted for about two weeks were included in the study. Cases comprised both initial episodes of UC and cases of disease relapse. Patients who received a diagnosis of UC through a health checkup but never had symptoms were excluded.

Educational Hospitalization

A lacto-ovo vegetarian diet (about 30 kcal/kg of standard body weight) with fish once a week and meat once every 2 weeks (ie, a semivegetarian diet) was provided during hospitalization. Details of the semivegetarian diet have been described previously.9 During hospitalization, food other than the meal service was discouraged. The plant-based diet score (PBDS), which evaluated adherence to the PBD, was 35 during hospitalization.10

On the first day of admission, for a patient who did not have bloody stool, a fecal occult blood test (OC-Auto III Latex Reagent, Eiken Chemical Co Ltd, Tokyo, Japan; normal range ≤ 50 ng/mL)16 was performed. Patients were provided with educational material on lifestyle diseases, healthy lifestyle habits,17 pathogenesis of IBD, and information on the PBD. During hospitalization, patients were provided with answers to any questions they had. A registered dietitian also visited the patients.

<table>
<thead>
<tr>
<th>Habit</th>
<th>Frequency, amount, or type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smoking (no. of cigarettes/d)</td>
<td>(more than 20) (6-19) (1-5) Rare None</td>
</tr>
<tr>
<td>Regular exercise*a</td>
<td>Every day 3-5 d/wk 1-2 d/wk Rare None</td>
</tr>
<tr>
<td>Alcohol*b</td>
<td>Every day 3-5 d/wk 1-2 d/wk Rare None</td>
</tr>
<tr>
<td>Eating between meals*a</td>
<td>Every day 3-5 d/wk 1-2 d/wk Rare None</td>
</tr>
<tr>
<td>Sugar in tea or coffee*b</td>
<td>Large amount Average amount Small amount Rare None</td>
</tr>
<tr>
<td>Type of diet:</td>
<td>Semivegetarian Japanese Pro-Japanese Standard/mixed Pro-Western</td>
</tr>
</tbody>
</table>

*a Gray shading represents your present habit (style). Black shading indicates habits that need to change and represents the recommended habit (style); lack of a black-shaded box in a row indicates that no change is needed.

*b Item in boldface represents recommendation for drastic alteration in habit.

<table>
<thead>
<tr>
<th>Food</th>
<th>Daily 3-5 servings/wk 1-2 servings/wk Rarely None</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rice</td>
<td></td>
</tr>
<tr>
<td>Miso soup</td>
<td></td>
</tr>
<tr>
<td>Pulses (beans, soybeans, peas, etc)</td>
<td></td>
</tr>
<tr>
<td>Vegetables</td>
<td></td>
</tr>
<tr>
<td>Udon/soba (Japanese noodles)</td>
<td></td>
</tr>
<tr>
<td>Ramen (Chinese noodles)</td>
<td></td>
</tr>
<tr>
<td>Bread</td>
<td></td>
</tr>
<tr>
<td>Tea, coffee</td>
<td></td>
</tr>
<tr>
<td>Juice</td>
<td></td>
</tr>
<tr>
<td>Cola/soda</td>
<td></td>
</tr>
<tr>
<td>Beef:</td>
<td></td>
</tr>
<tr>
<td>Pork/chicken</td>
<td></td>
</tr>
<tr>
<td>Minced or processed meat</td>
<td></td>
</tr>
<tr>
<td>Fish</td>
<td></td>
</tr>
<tr>
<td>Cheese/butter/margarine</td>
<td></td>
</tr>
<tr>
<td>Sweets</td>
<td></td>
</tr>
<tr>
<td>Ice cream/milk shake</td>
<td></td>
</tr>
<tr>
<td>Yogurt (plain)c</td>
<td></td>
</tr>
<tr>
<td>Green tea</td>
<td></td>
</tr>
<tr>
<td>Potatoes/starches:</td>
<td></td>
</tr>
<tr>
<td>Fruits:c</td>
<td></td>
</tr>
</tbody>
</table>

*c Gray shading represents your present habit (style). Black shading indicates habits that need to change and represents the recommended habit (style); lack of a black-shaded box in a row indicates that no change is needed.

*c Servings are spread over a week.

c Item in boldface represents recommendation for drastic alteration in habit.
and talked to them about the PBD and helped them get used to it. At the end of the hospitalization, a qualified dietician gave dietary guidance to the patients and the person who prepared the patient’s meals.9 Laboratory tests, including any with previously abnormal results, were repeated. Patients were advised to continue consuming the PBD after discharge.

**Medication before and during Educational Hospitalization**

Medication already prescribed by a physician was maintained before and during hospitalization irrespective of whether it was an initial case or a relapse case. When a patient was referred without a prescription of medication, no medication was administered before and during hospitalization. However, when there was no improvement observed during the first seven to ten days after hospitalization, medication was initiated according to guidelines.18

**Food-Frequency Questionnaire and Plant-based Diet Score**

A questionnaire of dietary habits and lifestyle behaviors before onset or relapse of the disease was given to patients when the educational hospitalization was scheduled. This food-frequency questionnaire included 45 questions that covered almost all foods or food groups in Japan.9 The questionnaire was obtained immediately after admission, before the patient received information about the PBD. On the basis of the questionnaire, a table was created that summarized a patient’s current and future recommended lifestyle and dietary habits.9 A representative table for a 22-year-old patient experiencing an initial episode of UC is shown in Tables 1a and 1b. The recommended dietary habits in Tables 1a and 1b are consistent with the PBD. These tables were given to the patient during hospitalization and was used by the dietician when giving dietary guidance.

A PBDS was calculated from the questionnaire responses. The method for how the PBDS was calculated has been described previously.10 In brief summary, 8 items considered to be preventive factors for IBD had a positive score, and 8 items considered to be IBD risk factors had a negative score. The PBDS was calculated as the sum of the positive scores (PBDS+) and negative scores (PBDS-). A higher PBDS indicated greater adherence to the PBD.10 The PBDS for the same 22-year-old patient in Tables 1a and 1b is presented in Table 2.

**Follow-up**

Follow-up was continued as long as possible. The interval between the educational hospitalization and initial follow-up visit to the Outpatient Department after discharge varied depending on the stability of the patient’s condition. For a patient who started receiving medication at the end of hospitalization, the interval to initial follow-up was three to four weeks. For a patient who was in unstable remission, the interval was four to six weeks. For a patient who was in stable remission, the interval was eight weeks. For a patient who was in remission for more than a few years without medication, the interval was three to six months.

| **Table 2. Plant-based diet score (PBDS) for a 22-year-old Japanese patient with inflammatory bowel disease** |
|-------------------------------------------------|-----------------|-----------------|-----------------|-----------------|
| **Food group** | **Scoring by frequency of consumption** | **Example: 22-year-old at initial episode of ulcerative colitis** | **Baseline (before hospitalization)** | **PBDS during educational hospitalization** | **19 mo after discharge** |
| | **Daily** | **3-5 servings/wk** | **1-2 servings/wk** | **Rarely** | **Baseline (before hospitalization)** | **PBDS during educational hospitalization** | **19 mo after discharge** |
| Positive score | | | | | | | |
| Vegetables | 5 | 3 | 1 | 0 | 3 | 5 | 3 |
| Fruits | 5 | 3 | 1 | 0 | 0 | 5 | 3 |
| Pulses (beans, soybeans, peas, etc) | 5 | 3 | 1 | 0 | 0 | 5 | 5 |
| Potatoes/starches | 5 | 3 | 1 | 0 | 0 | 5 | 1 |
| Rice | 5 | 3 | 1 | 0 | 0 | 5 | 5 |
| Miso soup | 5 | 3 | 1 | 0 | 0 | 5 | 5 |
| Green tea* | 5 | 3 | 1 | 0 | 0 | 5 | 5 |
| Yogurt (plain) | 5 | 3 | 1 | 0 | 0 | 5 | 5 |
| Negative score | | | | | | | |
| Meat | -5 | -3 | -1 | 0 | -3 | 0 | -3 |
| Minced or processed meat | -5 | -3 | -1 | 0 | -3 | 0 | -3 |
| Cheese/butter/margarine | -5 | -3 | -1 | 0 | 0 | 0 | 0 |
| Sweets/ice cream/milk shake | -5 | -3 | -1 | 0 | 0 | 0 | 0 |
| Soft drinks (cola/carbonated beverages/juice) | -5 | -3 | -1 | 0 | 0 | 0 | 0 |
| Alcohol | -5 | -3 | -1 | 0 | -5 | 0 | 0 |
| Bread | -5 | -3 | -1 | 0 | 0 | 0 | 0 |
| Fish | -2 | -1 | 0 | 0 | -1 | 0 | -1 |
| **PBDS** | | | | | **11** | **35** | **25** |

* Servings are spread over a week.
* Green tea is recommended to drink at home but is not provided at the hospital.

PBD = plant-based diet.
Assessment of Efficacy

The primary end point was relapse during the follow-up period after educational hospitalization. Relapse was defined as a change in the clinical status of the patient that required more aggressive medical treatment. 15,19-22 Reappearance of streaks of blood, a small volume of blood, or bloody stool was not counted as relapse if blood disappeared or was controlled with previous medication and/or with modification of the diet or a lifestyle behavior.

The secondary end point was immediate improvement during educational hospitalization. Patients with UC recruited for educational admission comprised 3 groups: mild (disease) activity 23; remission 23 with abnormal laboratory test results, including fecal occult blood tests; and remission with normal laboratory test results. For the first 2 groups, improvement was defined as the disappearance of bloody stool (clinical remission), 24 a decrease in the volume of blood, normalization of the fecal occult blood

### Table 3. Demographics of study patients with ulcerative colitis

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Total (N = 60)</th>
<th>Initial episode cases (n = 29)</th>
<th>Relapse cases (n = 31)</th>
<th>p value&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male/female (%)</td>
<td>35/25 (58/42)</td>
<td>18/11 (62/38)</td>
<td>17/14 (55/45)</td>
<td>0.5700</td>
</tr>
<tr>
<td>Age (years), range</td>
<td>16-79</td>
<td>16-79</td>
<td>17-79</td>
<td>0.4053</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>39 (18)</td>
<td>38 (3)</td>
<td>41 (3)</td>
<td></td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>34 (22-54)</td>
<td>34 (22-51)</td>
<td>34 (25-58)</td>
<td></td>
</tr>
<tr>
<td>Extent of ulcerative colitis, no. (%)</td>
<td></td>
<td></td>
<td></td>
<td>0.9470</td>
</tr>
<tr>
<td>E1: Proctitis</td>
<td>31 (52)</td>
<td>15 (52)</td>
<td>16 (52)</td>
<td></td>
</tr>
<tr>
<td>E2: Left-sided colitis</td>
<td>7 (12)</td>
<td>3 (10)</td>
<td>4 (13)</td>
<td></td>
</tr>
<tr>
<td>E3: Extensive colitis</td>
<td>22 (37)</td>
<td>11 (38)</td>
<td>11 (35)</td>
<td></td>
</tr>
<tr>
<td>Severity: maximum, no. (%)</td>
<td></td>
<td></td>
<td></td>
<td>0.4968</td>
</tr>
<tr>
<td>S1: Mild</td>
<td>48 (80)</td>
<td>24 (83)</td>
<td>26 (84)</td>
<td></td>
</tr>
<tr>
<td>S2: Moderate</td>
<td>11 (18)</td>
<td>5 (17)</td>
<td>4 (13)</td>
<td></td>
</tr>
<tr>
<td>S3: Severe</td>
<td>1 (2)</td>
<td>0 (0)</td>
<td>1 (3)</td>
<td></td>
</tr>
<tr>
<td>Severity on educational admission, no. (%)</td>
<td></td>
<td></td>
<td></td>
<td>0.2000</td>
</tr>
<tr>
<td>S0: Remission with normal FOB</td>
<td>20 (33)</td>
<td>12 (41)</td>
<td>8 (26)</td>
<td></td>
</tr>
<tr>
<td>S1: Mild or S0 Remission with abnormal FOB</td>
<td>40 (67)</td>
<td>17 (59)</td>
<td>23 (74)</td>
<td></td>
</tr>
<tr>
<td>Disease duration: range (months)</td>
<td>1-204</td>
<td>1-60</td>
<td>2-204</td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>31 (45)</td>
<td>7 (12)</td>
<td>53 (53)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>8 (2-40)</td>
<td>3 (1-6)</td>
<td>33 (11-72)</td>
<td></td>
</tr>
<tr>
<td>Case referral status, no. (%)</td>
<td></td>
<td></td>
<td></td>
<td>0.7341</td>
</tr>
<tr>
<td>Referred</td>
<td>38 (63)</td>
<td>19 (66)</td>
<td>19 (61)</td>
<td></td>
</tr>
<tr>
<td>Nonreferred</td>
<td>22 (37)</td>
<td>10 (34)</td>
<td>12 (39)</td>
<td></td>
</tr>
<tr>
<td>Medication during hospitalization, no. (%)</td>
<td></td>
<td></td>
<td></td>
<td>0.1066</td>
</tr>
<tr>
<td>None</td>
<td>23 (38)</td>
<td>13 (45)</td>
<td>10 (32)</td>
<td></td>
</tr>
<tr>
<td>Local (suppository, enema): 5-ASA and/or SH</td>
<td>9 (15)</td>
<td>6 (21)</td>
<td>3 (10)</td>
<td></td>
</tr>
<tr>
<td>Oral 5-ASA</td>
<td>16 (27)</td>
<td>8 (27)</td>
<td>8 (26)</td>
<td></td>
</tr>
<tr>
<td>Both local medication and oral 5-ASA</td>
<td>5 (8)</td>
<td>0 (0)</td>
<td>5 (16)</td>
<td></td>
</tr>
<tr>
<td>Immunomodulator</td>
<td>7 (12)</td>
<td>2 (7)</td>
<td>5 (16)</td>
<td></td>
</tr>
<tr>
<td>Oral PS and oral 5-ASA</td>
<td>3 (5)</td>
<td>1 (3)</td>
<td>2 (6)</td>
<td></td>
</tr>
<tr>
<td>PS, AZA, and local medication or oral 5-ASA</td>
<td>3 (5)</td>
<td>1 (3)</td>
<td>2 (6)</td>
<td></td>
</tr>
<tr>
<td>AZA, local medication, and oral 5-ASA</td>
<td>1 (2)</td>
<td>0 (0)</td>
<td>1 (3)</td>
<td></td>
</tr>
<tr>
<td>Corticosteroid dependent</td>
<td>2 (3)</td>
<td>0 (0)</td>
<td>2 (6)</td>
<td></td>
</tr>
<tr>
<td>Previous proctocolectomy</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Days of hospitalization, range</td>
<td>5-30</td>
<td>5-23</td>
<td>7-30</td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>14 (5)</td>
<td>13 (1)</td>
<td>14 (1)</td>
<td>0.4184</td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>13 (11-16)</td>
<td>13 (11-16)</td>
<td>14 (11-16)</td>
<td></td>
</tr>
<tr>
<td>F/U after educational hospitalization&lt;sup&gt;b&lt;/sup&gt;</td>
<td>(n = 57)</td>
<td>(n = 28)</td>
<td>(n = 29)</td>
<td>0.8146</td>
</tr>
<tr>
<td>Mean (SD), months</td>
<td>46 (39)</td>
<td>45 (35)</td>
<td>47 (44)</td>
<td></td>
</tr>
<tr>
<td>Median (IQR), months</td>
<td>36 (17-59)</td>
<td>38 (14-65)</td>
<td>36 (18-58)</td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup> Comparison between initial episode cases and relapse cases ($\chi^2$ test).

<sup>b</sup> This section has different n values than the main column headers for this table.

5-ASA = 5-aminosalicylic acid; AZA = azathioprine; FOB, fecal occult blood test result; F/U = follow-up; IQR = interquartile range; PS = prednisolone; SD = standard deviation; SH = steroid hormone.
test result or a decreased volume of fecal occult blood, and other improvements. Otherwise, the immediate outcome was defined as unchanged. Short-term (≤ 2 years) and long-term (> 2 years) chronicologic changes in the PBDS were also studied.

Safety Evaluations

Safety assessments included vital signs, patient complaints, findings during daily practitioner rounds, and physical examinations.

Statistical Analysis

Demographic parameters are expressed as mean and standard deviation (SD) and/or median (interquartile range), as appropriate. The frequency of categorical variables between initial episode cases and relapse cases was assessed using the χ² test. Chronicologic changes in PBDS+, PBDS-, and total scores in identical patients were compared using the paired t-test or Wilcoxon test. Kaplan-Meier survival analysis was used to calculate the cumulative proportion of patients who had a relapse. Comparison of cumulative relapse rates between patients with an initial episode and those with a relapse, or between patients on and without a medication regimen, was tested using the log-rank test. All directional tests were 2-tailed. A p value ≤ 0.05 was considered statistically significant. Statistical analyses were performed using JMP 8 software (SAS Institute Inc, Cary, NC).

RESULTS

Patient Characteristics

By extent of disease, E1 (proctitis) was most frequent (31 cases, 52%), followed by E3 (extensive colitis; 22 cases, 37%), and E2 (left-sided colitis; 7 cases, 12%). Of 60 cases, 48 (80%) were mild; 11 (18%) were moderate, and 1 (2%) was severe by maximum severity (Table 3). The difference between mean disease duration (7 months) for initial episode cases compared with mean disease duration (53 months) for relapse cases was statistically significant (p < 0.0001; Table 3). Medication was not provided during the hospitalization in 23 cases (38%). There were 2 cases in which immunomodulators (systemic prednisolone or azathioprine, or both) were used for initial episode cases and 5 for relapse cases. There were 2 relapse cases with steroid dependence. None of the 60 cases had previous surgical resection of the large bowel (Table 3). All patients ingested the PBD during the hospitalization.

Twenty-two of 60 cases were admitted during their school or company’s seasonal holidays. Although a 2-week period was recommended for educational hospitalization, the period differed among patients. Most ranged between 11 and 16 days, with a peak at 14 days. One patient had a psychiatric illness and was discharged earlier than planned, on Day 5, because of anxiety. In this case, dietary guidance was provided at the Outpatient Department.

Three of 60 patients were transferred to physicians immediately after discharge from the educational hospitalization for unavoidable reasons. Of the remaining 57 patients, 34 were followed-up while they received medication, whereas 23 cases received no medication during follow-up. All patients who did not achieve clinical remission during educational hospitalization achieved remission soon after discharge to the Outpatient Department. During the follow-up period, 17 patients moved out of Akita and were transferred to other physicians. Ten patients stopped attending follow-up sessions. The remaining 30 patients attended follow-up sessions to the end of July 2017. The mean follow-up period after educational hospitalization was 3 years 10 months (median = 3 years; Table 3).

Efficacy

Primary End Point: Relapse Rate

Of 57 cases, 8 (4 of 28 initial episode cases and 4 of 29 relapse cases; 4 cases each on and without a medication regimen) relapsed during the follow-up period (Table 4). Cumulative relapse rates at 1, 2, 3, 4, and 5 years were 2%, 4%, 7%, 19%, and 19%, respectively (Figure 1). There were no differences in cumulative relapse rates between initial episode cases and relapse cases (p = 0.9651; Figure 1). Mean time to relapse was 7 years 3 months (6 years 7 months for initial episode cases and 7 years 6 months for relapse cases). Similarly, there were no differences in cumulative relapse rates between cases on (n = 34) and without (n = 23) a medication regimen (p = 0.9644). In 2 of 8 relapse cases, a colectomy was eventually performed because of corticosteroid dependency (Table 4). Biologic agents were not administered for these 2 cases because of unavailability at the time.

Secondary End Points

Twenty of 60 patients had no symptoms, and their fecal occult blood tests were negative. However, the remaining 40 patients had either mild activity with symptoms or were in remission with some abnormality in fecal occult blood tests or serum C-reactive protein concentration (Table 3). In these 40 cases, the immediate effects of hospitalization were assessed. Disappearance of bloody stool (clinical remission) occurred in 11 cases (27%); 4 of these patients were not receiving medication. A decrease in the volume of blood was observed in 10 cases (25%). Normalization of fecal occult blood or a decrease in the volume of fecal occult blood was observed in 4 cases (10%). Other improvements, such as in serum C-reactive protein concentration, bowel movements, or
body temperature, were observed in 6 cases (15%). No improve-
mant was observed in 9 cases (23%; Figure 2). In 2 of these 9
cases, some medication was added.

One patient was mistakenly not asked to respond to the food-
frequency questionnaire. Therefore, baseline PBDS was deter-
mined from 59 patients. Mean (SD) baseline PBDS+, PBDS−,
and PBDS were 23.2 (8.4), 13.2 (5.8), and 9.8 (9.8), respectively
(Table 5). For 23 patients, at a median follow-up period of 1 year
2 months, respective scores were 28.4 (8.0), 6.8 (5.9), and 21.6
(10.6). These 3 values were significantly better than those at base-
line (p < 0.0001 or p = 0.0001; Table 5). In the other 16 patients,
at a median follow-up period of 3 years 11 months, respective
scores were 27.5 (6.8), 8.8 (7.3), and 18.7 (9.8). These 3 values
were better than those at baseline: The last 2 were statistically
significant (p = 0.0461, p = 0.0340; Table 5).

Safety
All patients ate the PBD, and none experienced an adverse
effect. There was no serious adverse event because of 5-amino-
salicylic acid or local use of corticosteroid hormone.

DISCUSSION
To our knowledge, this is the first published study of
prevention of relapse of UC by means of a PBD in patients
guided through a short educational hospitalization. Cumula-
tive relapse rates at 1, 2, 3, 4, and 5 years during follow-up
after educational hospitalization were 2%, 4%, 7%, 19%, and
19%, respectively. These relapse rates are far better than those
previously reported.15,19-22,25-27

The definitions of relapse and remission for UC vary accord-
ing to the perspective of clinical trials, guidelines, clinical prac-
tice, and patients.28-30 The symptom, streaks of blood in the stool,
is determined as relapse by Mayo scoring 28 and Montreal clas-
sification,23 but not by a simple clinical colitis activity index. 29
The definition of these terms influences relapse and remission
rates.31,32 In the current study, we followed the Inflammatory

Table 4. Relapsed and surgically treated cases in the follow-up after educational hospitalization

<table>
<thead>
<tr>
<th>No.</th>
<th>Sex</th>
<th>Age, y</th>
<th>Extent*</th>
<th>Clinical case</th>
<th>Disease duration</th>
<th>Medication</th>
<th>Efficacy</th>
<th>Medication</th>
<th>Duration after EH</th>
<th>Treatment</th>
<th>Indication</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>M</td>
<td>16</td>
<td>E2</td>
<td>IE</td>
<td>1 mo</td>
<td>5-ASA, PS</td>
<td>NA</td>
<td>5-ASA</td>
<td>3.5 mo</td>
<td>Addition of PS, AZA</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>F</td>
<td>28</td>
<td>E3</td>
<td>IE</td>
<td>3 mo</td>
<td>None</td>
<td>NA</td>
<td>5-ASA</td>
<td>2 y 2 mo</td>
<td>Addition of PS</td>
<td>3 y 5 mo</td>
<td>Steroid dependency</td>
</tr>
<tr>
<td>3</td>
<td>M</td>
<td>59</td>
<td>E3</td>
<td>IE</td>
<td>3 mo</td>
<td>None</td>
<td>Unchanged</td>
<td>None</td>
<td>3 y 11 mo</td>
<td>Local</td>
<td>None</td>
<td>Erythema nodosum on relapse</td>
</tr>
<tr>
<td>4</td>
<td>M</td>
<td>18</td>
<td>E3</td>
<td>IE</td>
<td>1 mo</td>
<td>None</td>
<td>Improved</td>
<td>None</td>
<td>6 y 6 mo</td>
<td>PS, IFX, AZA</td>
<td>None</td>
<td>CRMO of left tibia preceded 18 mo before relapse</td>
</tr>
<tr>
<td>5</td>
<td>M</td>
<td>20</td>
<td>E3</td>
<td>Relapse</td>
<td>6 y</td>
<td>Local, 5-ASA, PS, AZA</td>
<td>NA</td>
<td>5-ASA, AZA</td>
<td>1 y 5 mo</td>
<td>Addition of PS</td>
<td>2 y 12 mo</td>
<td>Steroid dependency</td>
</tr>
<tr>
<td>6</td>
<td>F</td>
<td>19</td>
<td>E1</td>
<td>Relapse</td>
<td>9 mo</td>
<td>Local</td>
<td>Improved</td>
<td>None</td>
<td>3 y 4 mo</td>
<td>IFX</td>
<td>None</td>
<td>Extension of lesion: E1 to E3</td>
</tr>
<tr>
<td>7</td>
<td>M</td>
<td>61</td>
<td>E3</td>
<td>Relapse</td>
<td>10 y</td>
<td>Local</td>
<td>Improved</td>
<td>Local as per occasional demands</td>
<td>3 y 11 mo</td>
<td>PS</td>
<td>None</td>
<td>Distress with 5-ASA</td>
</tr>
<tr>
<td>8</td>
<td>F</td>
<td>34</td>
<td>E3</td>
<td>Relapse</td>
<td>6 y</td>
<td>Local</td>
<td>Improved</td>
<td>None</td>
<td>8 y 9 mo</td>
<td>5-ASA</td>
<td>None</td>
<td></td>
</tr>
</tbody>
</table>

*E1 = proctitis; E2 = left-sided colitis; and E3 = extensive colitis.
5-ASA = 5-aminosalicylic acids (orally); AZA = azathioprine; BMI = body mass index; CRMO = chronic recurrent multifocal osteomyelitis; EH = educational hospitalization; F = female;
IE = initial episode of ulcerative colitis; IFX = infliximab; local = suppository, enema; M = male; mo = months; NA = not applicable; PS = prednisolone (orally); y = years.
Bowel Southeastern Norway (IBSEN) Study Group’s definition of relapse: A change in clinical status of the patient that requires more aggressive medical treatment.19-22 This definition seems adequate for clinical practice.

On the basis of inception cohort studies, it has been determined that extensive colitis or severe systemic symptoms at diagnosis are not associated with increased relapse rates.19-22,33,34 This means that relapse occurs irrespective of the extent of the disease and the severity. Few articles have described relapse rates at 1 year for initial episode cases.19,21,27 The rate is reported as 50% by the IBSEN Study Group,19 and estimated to be 28% from a Kaplan-Meier plot provided by the European Collaborative Study Group of Inflammatory Bowel Disease.21 It is 68.1% according to a Japanese study in which the definition of relapse was based on a Disease Activity Index29 of 2 or greater.27 After the first year, disease activity decreases over time.19,26,34

Cumulative relapse rates are 57% to 78% at 5 years and 67% to 83% at 10 years.20-22,26 The participants in the current study comprised almost half each of initial episode cases and relapse cases. Although the median disease duration was short for initial episode cases compared with relapse cases (3 months vs 33 months; Table 3), a higher relapse rate was not observed for initial episode cases compared with relapse cases (Figure 1).

To date, adherence to 5-aminosalicylic acid in the quiescent stage has been advocated to prevent a relapse.15-17,18 Kawakami et al11 used the same definition of relapse that we did in a study of Japanese patients who were in remission for more than 6 months, and they reported a relapse rate at 1 year of 41% for nonmedication-adherent patients and 16% for medication-adherent patients. Reports of this kind have been the basis for lifelong maintenance medication in UC.13-15

Our relapse rate of 2% at 1 year is far better than that previously reported.15,19,21,26,27,35 Whether a similar low relapse rate is found in ordinary patients with UC who have not undergone educational hospitalization needs to be elucidated. Our educational protocol resulted in patients voluntarily moderating their meat, processed meat, and alcohol intake, which are reported to be dietary risk factors for relapse in UC.35 We believe that IBD is a lifestyle disease mediated mainly by a westernized diet. It is suggested that patients can stop medication when they feel confident after a few years of remission using the PBD. This may go some way to relieving a patient’s fear about the disease, especially compared with being told that they may need to receive medication for life.13-15

In the current study, the majority (77%) of patients experienced improvements in symptoms and/or laboratory data during hospitalization (Figure 2). We can attribute this to some extent to the patients’ appreciation of the importance of diet. The mean baseline PBDS (9.8 [SD = 9.8] from 59 patients) in this study was comparable with the score (10.9 [9.5] from 159 patients with UC) in a previous study.10 The significantly high PBDS at the short-term follow-up (median = 14.0 months) compared with the baseline score (p < 0.0001; Table 5) indicated that patients altered their dietary habits in favor of the PBD. Dietary adherence to the PBD for more than 1 year might change gut microbial enterotypes,8 resulting in relapse prevention. In this study, a high relapse rate in initial episode cases compared with relapse cases29,26,34 was not observed. This indicates that the high relapse rate in the first year for initial episode cases might be suppressed with dietary intervention.

Although sustained dietary change is desired, a decrease in PBDS was observed during the long term (median duration = 3 years and 11 months). Most patients tended to lose their determination to adhere to the PBD once they had been in remission for a few years. However, they still consumed more of the recommended food and consumed less of the food that was discouraged compared with baseline (Table 5). Consequently, the PBDS was higher compared with baseline (p = 0.0340; Table 5). Patients appeared to manage the level of PBD by themselves according to their condition, suggesting that educational hospitalization enhanced their self-management skills.

A PBD was previously shown to be effective in both the active and quiescent stages of Crohn disease.9,11 The current study has shown that a PBD is effective in both the active and quiescent stages of UC as well. Of note, four patients with mild activity of UC achieved remission without medication during the educational hospitalization. Except for our case report,36 this is the first reported successful induction of remission by dietary manipulation without medication among published dietary trials.37-40 A reduction in the incidence of relapse by

| Table 5. Chronologic change of plant-based diet score (PBDS) |
|---|---|---|---|---|---|---|
| | Follow-up period (months) | PBDS+ | PBDS- | PBDS |
| | n | Mean (SD) | Median (IQR) | Mean (SD) | Median (IQR) | Mean (SD) | Median (IQR) |
| Base | 59 | 23.2 (6.4) | 23.0 (17.0-31.0) | 13.2 (5.8) | 12.0 (9.0-19.0) | 9.8 (9.6) | 12.0 (3.0-15.0) |
| | 23 | 20.9 (8.3) | 19.0 (16.0-27.0) | 13.6 (6.3) | 13.0 (9.0-19.0) | 7.3 (9.7) | 12.0 (0-15.0) |
| | 16 | 25.1 (9.1) | 24.0 (18.3-33.5) | 12.8 (5.4) | 12.5 (9.0-17.8) | 12.3 (8.9) | 15.0 (3.8-17.0) |

<table>
<thead>
<tr>
<th>Follow-up (F/U)</th>
<th>Base vs short-term F/U</th>
<th>Base vs long-term F/U</th>
</tr>
</thead>
<tbody>
<tr>
<td>Short-term</td>
<td>23</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Long-term</td>
<td>16</td>
<td>0.1307</td>
</tr>
</tbody>
</table>

* Wilcoxon test.

IQR = interquartile range; PBDS+ = sum of positive scores on questionnaire (see Table 2); PBDS- = sum of negative scores on questionnaire (see Table 2); SD = standard deviation.
means of educational hospitalization will contribute not only to personal benefits to the patients themselves but also to health care savings.

Research on gut microflora has advanced our understanding about the key role of the gut microflora in health and disease.\textsuperscript{[6-8, 41-46]} It is not limited to gut homeostasis but extends to individual health.\textsuperscript{[41, 43, 44]} Microbial diversity plays an important role in gut homeostasis.\textsuperscript{[6-41, 46]} Reduced microbial diversity (dysbiosis) is commonly observed in a variety of chronic diseases.\textsuperscript{[31, 44]} Recently, the relationship between diet and microbial diversity has been elucidated.\textsuperscript{[6-41, 46]} A diet that is high in fat and sugar and low in dietary fiber tends to reduce microbial diversity, resulting in poor production of microbial metabolites such as short-chain fatty acids, which have diverse effects in maintaining homeostasis. In contrast, a PBD rich in dietary fiber increases microbial diversity and produces beneficial microbial metabolites.\textsuperscript{[6, 41-46]} This observation might partly explain why a PBD prevents a variety of chronic diseases.\textsuperscript{[47, 48]} Indeed, the same explanation applies to IBD,\textsuperscript{[6, 41, 43-45]} indicating that replacing an omnivorous diet with a PBD in IBD is the right approach.

Comprehensive lifestyle changes are fundamental for treating chronic diseases.\textsuperscript{[31, 52]} However, changes in lifestyle, including dietary habits, are not easy.\textsuperscript{[53]} Our study indicates that educational hospitalization is an effective method for the replacement of an omnivorous diet with a PBD. Educational hospitalization is seldom seen in the literature,\textsuperscript{[53]} but it is common for diabetes mellitus in Japan.\textsuperscript{[34]} It is suggested that this modality will be effective for a variety of chronic diseases.

Our study had some limitations. The PBDS was developed at the late stage of the study.\textsuperscript{[15]} Therefore, short- and long-term chronic changes in PBDS were not obtained from the same patients. Patients with short-term PBDS (n = 23) and those with long-term PBDS (n = 16) were different: They did not overlap (Table 5). Comparison of PBDS at 3 time points (ie, baseline, short-term, and long-term) from the same patients would have been more appropriate. Our study was also limited in that there was no control group and the sample size was small. Larger controlled studies are needed to validate the results. Additionally, further studies are needed to elucidate how educational hospitalization can alter the natural history of UC.

CONCLUSION
Relapse rates after educational hospitalization providing a PBD experience are far lower than those reported with medication. Educational hospitalization is effective at inducing habitual dietary changes.

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

Acknowledgments
We thank Marcin J Schroeder, PhD, Professor of Mathematics at Akita International University, for the statistical review. Kathleen Louden, ELS, of Louden Health Communications provided editorial assistance.
Good Advice

We [now] devote more attention to the patient’s diet and habits, and more often send him away with good advice than with hastily written prescriptions.

— Robert Hall Babcock, MD, LL.D, 1851-1930, blind American physician
ABSTRACT

Introduction: Pain management can be challenging following bariatric surgery, and patients with obesity tend to increase opioid use after undergoing surgery. This report quantifies marijuana (MJ) use and its relationship to pain and other surgery-related outcomes in a population from a state that has legalized MJ.

Methods: Data were collected for consecutive patients undergoing weight reduction surgeries between May 1, 2014 and July 31, 2015. Demographics, preoperative comorbidities, medications, and perioperative opioid use were analyzed. The primary outcome evaluated was inpatient opioid pain medication use quantified using natural log morphine equivalents. Secondary outcomes included percentage of total body weight loss after three months, postoperative complications, and changes in medical comorbidities.

Results: A total of 434 patients, among whom 36 (8.3%) reported MJ use, comprised the study population. Perioperative opioid requirements were significantly higher in the MJ-user group (natural log morphine equivalents of 3.92 vs 3.52, p = 0.0015) despite lower subjective pain scores (3.70 vs 4.24, p = 0.07). MJ use did not affect percentage of 90-day total body weight loss, development of postoperative complications, or improvement in medical comorbidities.

Conclusion: Perioperative opioid use was significantly higher in the MJ-user group despite lower subjective pain scores. The difference in opioid requirements suggests an interaction between MJ use and opioid tolerance or pain threshold. The percentage of total body weight loss, improvement in medical comorbidity, and incidence of postoperative complications at 90-day follow-up were not affected by MJ use in this cohort analysis.

INTRODUCTION

It is a challenge to optimize pain management and weight loss outcomes following bariatric surgery. Preoperative opioid use is associated with increased costs and health care utilization and poorer outcomes following nonemergent or elective abdominal surgeries. In the bariatric surgical population, rates of opioid use during the year following surgery (excluding the 30-day postoperative period) increase substantially among those who use opioids chronically or intermittently before their surgery. In light of the US opioid epidemic, understanding and managing this issue is an urgent challenge.

Patients who undergo bariatric surgery may be especially vulnerable to substance abuse. Their predisposition to obesity and increased use of opioids or other substances such as marijuana (MJ) are mediated by overlapping gene environment interactions. The pathways associated with substance-use disorders vary by substance and are not uniform. Additionally, psychological “symptom substitution” theories suggest that when patients who undergo bariatric surgery are no longer able to consume food compulsively, alternative substance abuse behaviors emerge. From a biological perspective, dopamine-based reward pathways are activated after consuming both highly palatable foods and drugs of abuse, although individual drug activation pathways may differ. Anatomical changes to the gut after bariatric surgery, particularly following Roux-en-Y gastric bypass (RYGB), accelerate alcohol absorption and lengthen elimination times. The most common reasons for substance use cited by inpatients undergoing bariatric surgery are addiction transfer (83%), “psychological problems” (75%), and stronger effects/faster onset (58%); these reasons point to the complex interaction of biopsychosocial factors associated with addiction onset after surgery. Consequently, understanding MJ’s role in the complex interaction between weight, food, and other substances of abuse following bariatric surgery is critical.

MJ’s effects on substance-use disorders, pain management, and other bariatric surgery-specific outcomes, including weight loss, comorbidity changes, and surgical adverse events, are not known. MJ is simultaneously recognized as a drug of abuse, a potential therapeutic agent, and a recreational substance. Commonly used forms of the drug have...
multiple active metabolites with various pharmacologic effects. Delta-9-tetrahydrocannabinol (THC) is the most active ingredient and is known to trigger the endogenous cannabinoid system. Two primary receptors, cannabinoid-1 (CB-1) and cannabinoid-2, have been identified. CB-1 receptors, located centrally in the nervous system, cause well-recognized psychotropic and euphoric effects. CB-1 receptors also can be found in adipose tissue, the liver, and skeletal muscle and are partial regulators of various metabolic functions. Cannabinoid-2 receptors primarily are located peripherally in immune cells. The endogenous cannabinoid system has been implicated in pathways regulating energy homeostasis, appetite, inflammation, and pain.

CB-1-receptor activation in hypothalamic nuclei may increase caloric intake. Activation in the neurons of the mesolimbic system increases the desire for food. These receptors also are found in peripheral adipose tissue, and their activation stimulates lipogenesis.

Animal models of obesity demonstrate that increased, long-lasting activation of CB-1 receptors of the endocannabinoid system results in obesity maintenance. Dysregulation of the endocannabinoid system is thought to lead to visceral obesity and contribute to diabetes.

Medical MJ use has been approved primarily for treatment of chronic pain, spasticity in multiple sclerosis, and for nausea or loss of appetite for patients receiving chemotherapy to treat cancer. Early investigational use of cannabinoids in the treatment of refractory pediatric epilepsy is ongoing; however, there currently is no accepted indication for use in surgical patients. Furthermore, when compared with opioid analgesia for acute pain, MJ is inferior to opioids primarily because of known central nervous system adverse effects. To date, our knowledge only one case report has been published that demonstrates the successful use of THC extract to control protracted nausea and vomiting in a bariatric patient. Increased postoperative pain and requirements for opioid rescue analgesia in MJ users were reported in a Jamaican study. The lack of empiric data and concern for inferior weight loss and possible risk for substance-use disorders has prompted some practitioners to question whether MJ use should be a contraindication to bariatric surgery.

This study's primary hypothesis was that MJ use was unlikely to affect initial outcomes following laparoscopic bariatric surgeries. The secondary hypothesis was that side effects of MJ use such as increased appetite would adversely affect initial weight loss.

**METHODS**

This review analyzed MJ use in a cohort of 434 consecutive patients undergoing primary bariatric operations (RYGB, sleeve gastrectomy, or gastric banding) between May 1, 2014 and July 31, 2015. During the study period, 517 bariatric operations were performed in a Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program-accredited weight-loss surgery center after institutional review board approval. Eighty-three patients were excluded from this analysis for various reasons (Figure 1). Exclusion criteria included prior bariatric surgery, nonmetabolic surgery, surgical revision of any type, and incomplete chart data. Of the 434 patients included, 197 (45.4%) were treated with laparoscopic sleeve gastrectomy or other laparoscopic procedures, 212 (48.8%) were treated with laparoscopic RYGB or 120 cm antecolic–antegastric Roux limb, a 50-cm bilipancreatic limb, and a 30 cc gastric pouch. Sleeve gastrectomy was performed over a 36Fr bougie. All procedures involved a completion endoscopy as a leak test to ensure appropriate and secure reconstruction.

Standardized pain management included 30-mg intravenous ketorolac every 8 hours for 24 hours if no chronic kidney disease, bleeding complications, or other contraindication existed. All patients received 1-g intravenous acetaminophen before surgery and 1–2 doses of 1-g intravenous acetaminophen after surgery. Liquid pain medication was offered immediately after surgery; however, most patients used intravenous morphine sulfate or hydromorphone as needed during the early postoperative period (initial 12 hours). All patients were offered heating pads and ice packs and were prescribed a 5-mg hydrocodone/325-mg acetaminophen per 240-mL solution elixir. Patients who could not tolerate the elixir were prescribed oxycodone tablets 5 mg to 15 mg every 4 hours as needed for pain. Each patient was prospectively questioned about cannabis use during routine preoperative visits. Patients were asked if they considered themselves to be a regular user (at least 1 use per month). We chose to not subcategorize the route or type of administration (inhaled, edible, hashish, etc) because of limited statistical power to evaluate the association of MJ use subtype with outcomes of interest. Charts were reviewed to obtain data on demographics and preoperative comorbidities (Table 1). All patients received 3 standardized doses of ketorolac after surgery regardless of procedure type. No patient received oral nonsteroidal anti-inflammatory drugs.
Marijuana’s Influence on Pain Scores, Initial Weight Loss, and Other Bariatric Surgical Outcomes

The primary study outcome was to quantify perioperative use of opioid pain medication using natural log morphine equivalents correlated with postoperative subjective pain scores (Table 2). Data regarding preoperative use of prescription opioids were not collected. Preoperative opioid use could be viewed as a proxy for burden of presurgical medical illness (severity of knee/hip arthritis, etc).

Secondary study outcomes included initial (90-day) percentage of total body weight loss after 3 months, which is quantified in Table 3. We also examined a secondary hypothesis that MJ use would negatively influence weight loss because of increased postoperative appetite.

Surgical outcomes data included 30-day postoperative complications, Emergency Department (ED) visits, and readmissions (Table 4). Improvement in medical comorbidities was measured through analysis of pre- and postmedication dose requirements for treatment of hypertension, diabetes mellitus, psychiatric illness, and pulmonary disease.

Continuous demographic variables were compared using Student’s t-tests, and categorical data were compared using Pearson χ² tests between the MJ-use and nonuser groups. Continuous outcome variables were modeled using linear regression, and MJ use was entered as an independent variable along with other variables possibly associated with the outcome. Outcome variables were modeled using Poisson regression. All calculations were performed with R-3.3.2. Variables modeled included demographics; comorbidities; preoperative and postoperative weight; American Society of Anesthesiology class; oxygen dependence; continuous positive airway pressure use; preexisting chronic pain syndromes; history of tobacco use; and psychiatric diagnoses of depression, anxiety, and bipolar disorder. All postoperative weights were recorded at a 3-month postoperative visit (± 30 days). Medication data for the treatment of comorbidities that qualify patients for bariatric surgery were extracted from the pre- and posthospital medication reconciliation list. Perioperative opioid use was quantified by the pharmacy using natural log morphine equivalents. A logarithmic transformation was necessary to correct for the nonconstant variability of the morphine equivalent outcome data. Institutional standardized subjective pain scores (0-10 scale) were analyzed to quantify patient perception of pain levels.

### RESULTS

The prevalence of regular MJ use in the study cohort was 8.3% (36/434). The MJ cohort was younger (41.7 years vs 48.8 years, p = 0.003) and healthier when comparing average number of comorbidities (1.8 vs. 2.5, p = 0.003) with the nonuser cohort (Table 1). The two cohorts were similar with respect to sex, American Society of Anesthesiology classification, and preoperative body mass index. The MJ-user cohort had a higher prevalence of chronic pain, but this was not statistically significant in

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### Table 1. Preoperative demographics and comorbidities of study population

<table>
<thead>
<tr>
<th>Variable</th>
<th>Marijuana users (n = 36)</th>
<th>Nonusers (n = 395)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years, mean (SD)</td>
<td>41.7 (13.1)</td>
<td>48.8 (12)</td>
<td>0.003*</td>
</tr>
<tr>
<td>Men, no. (%)</td>
<td>9 (25.0)</td>
<td>94 (23.7)</td>
<td>1.0</td>
</tr>
<tr>
<td>Preoperative weight, lbs, mean (SD)</td>
<td>281.8 (49.9)</td>
<td>278.5 (52.8)</td>
<td>0.71</td>
</tr>
<tr>
<td>LOS, days, mean (SD)</td>
<td>1.97 (1.5)</td>
<td>1.82 (1.9)</td>
<td>0.59</td>
</tr>
<tr>
<td>BMI, kg/m², mean (SD)</td>
<td>44.7 (6.1)</td>
<td>45.1 (6.5)</td>
<td>0.68</td>
</tr>
<tr>
<td>Number of comorbidities, mean (SD)</td>
<td>1.8 (1.3)</td>
<td>2.5 (1.5)</td>
<td>0.003*</td>
</tr>
<tr>
<td>Chronic pain present, no. (%)</td>
<td>18 (50)</td>
<td>142 (35.8)</td>
<td>0.13</td>
</tr>
<tr>
<td>Tobacco use history, no. (%)</td>
<td>20 (55.6)</td>
<td>152 (38.3)</td>
<td>0.064</td>
</tr>
<tr>
<td>CPAP with oxygen use, no. (%)</td>
<td>8 (22.2)</td>
<td>123 (31)</td>
<td>0.365</td>
</tr>
<tr>
<td>Inhalers required, no. (%)</td>
<td>9 (25)</td>
<td>117 (29.5)</td>
<td>0.71</td>
</tr>
</tbody>
</table>

* Statistically significant (p < 0.05).

BMI = body mass index; CPAP = continuous positive airway pressure; LOS = length of stay; SD = standard deviation.

### Table 2. Perioperative opioid use and daily average pain score in study population

<table>
<thead>
<tr>
<th>Variable</th>
<th>Marijuana users (n = 36)</th>
<th>Nonusers (n = 395)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>LN total morphine unit equivalents, mean (SD)</td>
<td>3.92 (0.67)</td>
<td>3.52 (0.75)</td>
<td>0.002*</td>
</tr>
<tr>
<td>Daily average pain score (0-10 scale), mean (SD)</td>
<td>3.70 (1.3)</td>
<td>4.24 (1.7)</td>
<td>0.07</td>
</tr>
<tr>
<td>Chronic pain diagnosis present, no (%)</td>
<td>18 (50)</td>
<td>142 (36)</td>
<td>0.13</td>
</tr>
</tbody>
</table>

* Statistically significant (p < 0.05).

LN = natural log; SD = standard deviation.

### Table 3. Univariate analysis of total body weight loss percentage

<table>
<thead>
<tr>
<th>Variable</th>
<th>Marijuana users (n = 36)</th>
<th>Nonusers (n = 395)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percentage total body weight loss, mean (SD)</td>
<td>-0.18 (0.06)</td>
<td>-0.18 (0.06)</td>
<td>0.89</td>
</tr>
</tbody>
</table>

SD = standard deviation.

### Table 4. 30-day outcomes for marijuana users and nonusers after bariatric surgery

<table>
<thead>
<tr>
<th>Outcome variable</th>
<th>Marijuana users (n = 35)*</th>
<th>Nonusers (n = 395)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical site infection, no. (%)</td>
<td>1 (2.8)</td>
<td>6 (1.5)</td>
<td>0.55</td>
</tr>
<tr>
<td>Readmissions, no. (%)</td>
<td>3 (2.9)</td>
<td>28 (7.1)</td>
<td>0.69</td>
</tr>
<tr>
<td>Postoperative Emergency Department visits, no. (%)</td>
<td>6 (17.1)</td>
<td>54 (13.7)</td>
<td>0.57</td>
</tr>
</tbody>
</table>

* A low incidence of pneumonia and urinary tract infection precluded analysis.

* One patient died before 30-day follow-up analysis.
compared to the nonuser cohort (50% vs 36%, \( p = 0.13 \)). There was a higher incidence of tobacco use in the MJ-user cohort (smoking with a 1+ pack/y history), which also was not significantly different between groups (36% vs 38%, \( p = 0.064 \)). Although the MJ-user population had a lower recorded prevalence of home oxygen use, continuous positive airway pressure use, and use of maintenance inhalers, these data were not significant between groups. The MJ cohort had a lower prevalence of hypertension and diabetes. There was a high prevalence of the aforementioned psychiatric diagnoses in both populations.

A secondary multivariate analysis was performed, and no association between MJ use and weight loss was noted. Surgical outcome variables at 30 days were similar with respect to surgical site infection, 30-day readmission, and 30-day ED visits (2.8% vs 1.5%, \( p = 0.59 \); 2.9% vs 7.1%, \( p = 0.69 \); 17.1% vs 13.7%, \( p = 0.064 \)). There was a high prevalence of substance abuse in both populations.

Poisson regression was used to analyze the effect of MJ use on pre- and postoperative prescription requirements for the most common comorbidities affecting bariatric patients: Hypertension, type 2 diabetes mellitus, and psychiatric diagnoses. There were no statistically significant differences between preoperative and postoperative prescription requirements to treat hypertension or psychiatric conditions (\( p = 0.845 \) and \( p = 0.842 \), respectively). A clear trend was observed for lowering doses of diabetes medications, but this trend did not reach statistical significance (\( p = 0.0731 \)).

Pain scores were obtained 3 times daily during hospitalization. Our institution uses a standardized assessment in which 0 equals no pain and 10 equals maximum pain. These scores were then averaged to obtain a daily pain score (Table 2). There was a significant difference in total opioid use between groups; 47 mg for MJ users vs 37 mg for nonusers (natural log total morphine equivalents 3.92 vs 3.52, \( p = 0.0015 \); Figure 2). Despite higher opiate use, MJ users reported lower average pain scores (3.70 vs 4.24, \( p = 0.07 \)), although this difference did not reach statistical significance.

**DISCUSSION**

MJ remains an illegal substance according to federal law. However, as states legalize MJ, its use has increased for both recreational and medical purposes. Medical indications stem from the limited published evidence and from data supporting the ways in which MJ and THC affect the endocannabinoid system. The primary hypothesis of this study, “Marijuana use is unlikely to affect initial outcomes following bariatric operations,” is supported by these data. The secondary hypothesis, “Marijuana use may adversely affect initial weight loss,” however, was refuted. We specified a low threshold with which to define MJ use (at least one use of any MJ preparation within 30 days of surgery). Urinary drug screening was not performed to validate or refute recent cannabis intake, which introduced potential for underreporting. Voluntary participation in the study could have been adversely affected if patients undergone preoperative and postoperative urinary drug screening.

An unanticipated consequence of MJ use was discovered in this cohort analysis. Postoperative opioid analgesic use was statistically increased among MJ users vs nonusers. Jefferson et al’s 2013 study\(^{27}\) is the only publication in the medical literature to corroborate this finding. This finding is paradoxical because THC alters the endocannabinoid pathway to enhance antinociceptive effects rather than produce increased pain.\(^{29}\)

In this study, preoperative opioid use was not quantified because there was no reliable way to confirm exact use patterns. This was a potential weakness because several patients entering the study with substantial opioid dependence could skew the results from a chronic-use perspective. Urinary drug screening could have detected such dependence but was not used in this cohort analysis. Studies on the long-term effects of MJ use and abuse demonstrate an MJ withdrawal syndrome that is characterized by a constellation of symptoms including irritability, weight loss, anorexia, insomnia, restlessness, and abdominal pain.\(^{30}\) Withdrawal occurs shortly after cessation and lasts 2 to 6 days on average.\(^{30}\) It is possible that patients with higher than average postoperative opioid use were experiencing a combination of intensifying pain stimuli and simultaneous MJ withdrawal. We did not have the capability to measure cannabinoid levels to validate withdrawal symptoms in the MJ-user cohort. Pain associated with MJ withdrawal may have contributed to the increased opioid requirement noted in our MJ-user data set. The increased perioperative opioid requirement also may reflect a decreased pain threshold in the MJ cohort, but this cannot be precisely determined because pain was a subjective variable in this study.

The secondary hypothesis that MJ use would adversely affect weight loss was rejected. This cohort analysis suggests that the combination of gastric restriction...
Marijuana’s Influence on Pain Scores, Initial Weight Loss, and Other Bariatric Surgical Outcomes

How to Cite this Article

References
17. Atakan Z. Cannabis, a complex plant: Different compounds and different effects on individuals.
Marijuana’s Influence on Pain Scores, Initial Weight Loss, and Other Bariatric Surgical Outcomes


Outside Influences

The truth is that medicine, professedly founded on observation, is as sensitive to outside influences, political, religious, philosophical, imaginative, as is the barometer to the changes of atmospheric density. Theoretically it ought to go on its own straightforward inductive path, without regard to changes of government or to fluctuations of public opinion. [But, there is] a closer relation between the Medical Sciences and the conditions of Society and the general thought of the time, than would at first be suspected.

— Oliver Wendell Holmes, 1809-1894, American physician, poet, and polymath
Potentially Preventable Hospital and Emergency Department Events: Lessons from a Large Innovation Project

Leif I Solberg, MD; Kris A Ohnsorg, RN, MPH; Emily D Parker, PhD, MPH; Robert Ferguson; Sanne Magnan, MD, PhD; Robin R Whitebird, PhD; Claire Neely, MD; Emily Brandenfels, MD, MS; Mark D Williams, MD; Mark Dreskin, MD; Todd Hinnenkamp, RN; Jeanette Y Ziegenfuss, PhD

ABSTRACT

Introduction: There are few proven strategies to reduce the frequency of potentially preventable hospitalizations and Emergency Department (ED) visits. To facilitate strategy development, we documented these events among complex patients and the factors that contribute to them in a large care-improvement initiative.

Methods: Observational study with retrospective audits and selective interviews by the patients’ care managers among 12 diverse medical groups in California, Minnesota, Pennsylvania, and Washington that participated in an initiative to implement collaborative care for patients with both depression and either uncontrolled diabetes, uncontrolled hypertension, or both. We reviewed information about 373 adult patients with the required conditions who belonged to these medical groups and had experienced 389 hospitalizations or ED visits during the 12-month study period from March 30, 2014, through March 29, 2015. The main outcome measures were potentially preventable hospitalizations or ED visit events.

Results: Of the studied events, 28% were considered to be potentially preventable (39% of ED visits and 14% of hospitalizations) and 4.6% of patients had 40% of events. Only type of insurance coverage; patient lack of resources, caretakers, or understanding of care; and inability to access clinic care were more frequent in those with potentially preventable events. Neither disease control nor ambulatory care-sensitive conditions were associated with potentially preventable events.

Conclusion: Among these complex patients, patient characteristics, disease control, and the presence of ambulatory care-sensitive conditions were not associated with likelihood of ED visits or hospital admissions, including those considered to be potentially preventable. The current focus on using ambulatory care-sensitive conditions as a proxy for potentially preventable events needs further evaluation.

INTRODUCTION

As concern grows in most countries over increasing health care costs, more attention is focused on reducing waste and unnecessary services.1 Eddy and Shah2 have demonstrated that increasing quality of care alone will not have significant cost-saving potential. Emanuel3 has highlighted the need to focus cost-reduction efforts on the areas with the most potential for both cost savings and quality improvement (unnecessary hospitalizations, Emergency Department [ED] visits, and specialist services).

In the US, the Centers for Medicare & Medicaid Services has implemented the first financial penalties on hospitals for excessive readmissions.4 Attention likely will be increasingly directed to all hospitalizations because readmissions represent only approximately 9% of hospital admissions, and to avoidable ED visits because of the expense of providing care in this setting and its tendency to lead to unscheduled hospital admissions.5,6

There are three problems preventing effective action to reduce potentially preventable events (PPEs): 1) there are no validated methods for identifying patients most likely to have PPEs, 2) there is little evidence for effective prevention strategies, and 3) nearly all the studies of potentially avoidable hospital admissions are misleading because they have used an unproven methodology for measuring these events. This unproven methodology was based on the assumption that most avoidable admissions are caused by conditions believed by expert panels to be prevented by better ambulatory care (therefore called ambulatory care-sensitive conditions [ACSCs]).7 These conditions were originally identified in the early 1990s by an expert panel of six academic physicians but without any study of those situations. The Agency for Healthcare Research and Quality later labeled these conditions as a measure of quality for access to care (called Prevention Quality Indicators) and provided an updated expert panel review in 2009.8 The conditions include ...

[Further text and references are omitted for brevity.]
diabetes with complications or hypoglycemia/acidosis, chronic obstructive lung disease, asthma, hypertension, heart failure, dehydration, bacterial pneumonia, urinary tract infections, angina without procedures, lower extremity amputations in diabetes patients, and perforated appendix.

For two decades, admissions for these conditions have been used as the main measure of PPEs. However, to our knowledge there have been no published studies of actual cases to confirm either the proportion of hospitalizations attributed to these conditions that are preventable or the proportion of PPE hospitalizations represented by these diagnoses. This observational quality improvement study sought to learn the frequency of PPEs among the complex patients cared for in a large nationwide initiative to spread collaborative care for patients with uncontrolled depression and diabetes and/or cardiovascular disease and whether any characteristics of patients, conditions, or events are of value in predicting which patients are most likely to experience PPEs.

METHODS
Setting
This study was conducted within a large government-funded innovation award to spread an evidence-based model of collaborative care for patients with both active depression and uncontrolled diabetes, cardiovascular disease, or both in 18 diverse medical groups in 8 states in the US. Diabetes was considered uncontrolled if the most recent hemoglobin A1c (HbA1c) level was ≥ 8.0%, and cardiovascular disease was uncontrolled if the systolic blood pressure was ≥ 145 mmHg. A central group defined the care model and then trained facilitators in each medical group on ways to implement it in their care systems. However, as a quality improvement initiative, there were no research staff involved in supporting these efforts (www.icsi.org/supporting_systems_change/compass/). Required components of this care model included use of an electronic registry and tracking system, close follow-up by care managers (most of whom were registered nurses), frequent measurement of condition control, and weekly systematic case reviews with specialty consultants of all patients not improving. Twelve of these 18 medical groups agreed to participate in this review of ED and hospital events among their patients enrolled in the initiative.

Study Patients
Patients were eligible for inclusion in this study if they received care from one of the 12 participating groups, were enrolled in the care model throughout the period being studied (March 30, 2014, through March 29, 2015), and had one or more ED visits or hospitalizations in that period.

Data Sources
As part of the initiative, data were collected on patient characteristics through a practice-based electronic registry that was used for care of both individual patients and panels of patients as well as evaluation of the impact of the initiative. These data included patient age, sex, presence of depression, diabetes, cardiovascular disease, race/ethnicity, and insurance product (commercial, Medicaid, Medicare, or none). They also included Patient Health Questionnaire-9 scores (a survey-based measure of depression severity), blood pressure, HbA1c (a blood test measuring level of blood sugar over long periods), and contact notes as well as date and reason for all known ED visits and hospitalizations.

Audit Procedures
Medical groups that had ≤ 100 patients meeting the audit criteria described above had all qualifying patients included in the audit process; those with < 100 patients had a randomly selected group of 100 patients included to avoid auditor burden and overweighting the sample with patients from a few large medical groups. Avoiding auditor burden and sample overweighting also led to selecting the most recent event of each type (ED or hospital). When available, the second most recent event was also identified in case the first was not auditable owing to missing documentation, a hospitalization for planned surgery, or an ED visit followed by a hospitalization within 24 hours (treated as a hospitalization). Thus, up to 2 of each event type were identified so that up to 1 per type of each event person would be audited.

A chart audit database tool (REDCap [Research Electronic Data Capture], Vanderbilt University, Nashville, TN) contained patient demographic and clinical data to be verified by the auditor as well as questions about the patient, the event, and its preventability. Chart auditors had separate access to discharge summaries and these, as well as the care manager’s personal knowledge of the patient’s circumstances, were used to quantify and describe the following:

• Admission and discharge diagnoses
• Medical and nonmedical reasons for the event (lack of money, lack of caretaker, lack of patient understanding, inability to access clinic, mental illness, substance abuse, or other)
• Degree of control of depression, diabetes, and hypertension
• Patient treatment adherence
• Contacts with the care manager in the two weeks before the event
• Systematic case review in the two weeks before the event
• Whether the event was caused by any ACSCs

On the basis of these data and their own knowledge of the patient, care managers determined potential preventability using this definition: A problem that might not have occurred or might have been managed at home or in clinic if the care manager had been aware of it in the prior two weeks.

The audits were performed by the care managers of these patients because they had implicit knowledge of their patients that would facilitate identification of both medical and nonmedical causes. A consulting physician was available if there was need for additional input on the medical preventability of the event. Auditors were provided with a protocol and training to standardize the audit process, but testing of interrater reliability was not feasible because judgments were influenced by the care manager’s implicit knowledge of the patient.

Analysis
Demographic and clinical characteristics were described for all patients as well as those with events using means and
standard deviations for continuous variables and percent for categorical variables. The frequencies and rates of events, care manager contacts, and systematic case reviews were determined per patient per month from data in the registry. The χ² test was used to test for homogeneity in the distribution of categorical variables, and the t-test was used for continuous variables. Logistic regression was used to calculate odds ratios (ORs) and 95% confidence intervals (CIs) for the probability of a PPE in relation to patient characteristics, event characteristics, and ACSCs separately and collectively (ie, any ACSC). Models examining the relationship between the number of care manager contacts or systematic case reviews were adjusted for length of enrollment during the study period; otherwise all models were unadjusted. In a post hoc analysis, a single physician (LS) used the discharge diagnosis to group the medical reason for events by condition and to estimate the medical severity of each case as major (requiring in-person medical attention), minor (not requiring that), or intermediate/indeterminate. Logistic regression was used to examine levels of severity in the probability of PPEs.

This study was conducted from September 1, 2014, through June 30, 2015, and was reviewed by the institutional review boards at all participating groups and approved as exempt as a quality improvement study.

RESULTS

The numbers of patients and events (hospital admissions or ED visits) for each stage in the development of the audited sample are listed in Table 1. Of the 2620 patients enrolled in this initiative during the study year, 978 (37.3%) had 2286 events during the study year, an average of 1.4 ED visits and 1.0 hospitalizations each. The frequency of events per patient varied widely, with 18% having 1 and 1% having 10 or more. Those 1% had a total of 20% of all events, and 4.6% of the patients had 40% of total events.

After applying the exclusion rules below to the 522 patients with 954 events selected for possible audit, only 406 patients and 456 events were eligible for audit, and 373 patients (92% of those eligible) and 389 events (85%) had complete audits. The reasons that 498 events were not audited were as follows:

- One event type already audited for a patient: 118 or 23.7%
- Coincident ED visit and hospitalization: 39 or 7.8%
- Discharge information not available: 134 or 26.9%
- Planned admission: 43 or 8.6%
- Other: 74 or 14.9%
- Not able to be audited within the study time limits: 90 or 18.1%

The audited sample resembled the unaudited population of all enrolled patients with events except for small differences in racial distribution (8.3% vs 10.6% black) and Hispanic ethnicity (13.3% vs 15.3%), and larger differences in insurance coverage (17.8% vs 24.8% commercial and 55.8% vs 46.5% Medicare).

Table 2 shows the distribution of characteristics of all patients who were enrolled in participating medical groups during the study period. Although these bivariate analyses suggest that some characteristics of patients or their care were significantly associated with either overall events or ED visits and hospitalizations separately, none of these associations was large enough to be clinically significant. Unadjusted logistic regression models predicting the probability of events were also conducted (data not shown in the Table). The main factors associated with both total events and ED/hospital events separately were having Medicaid or Medicare insurance (OR = 1.5, CI = 1.2-1.9) compared with commercial insurance, and patients with both diabetes and cardiovascular disease in addition to depression (OR = 2.2, CI = 1.3-3.6) compared with depression only. Additional patient characteristics were associated with greater likelihood of ED or hospital stays, but none of these associations was large. Degree of control of any of the 3 conditions had no relation to the likelihood of events (data not shown). Two features of the care model were significantly associated with a greater likelihood of events: The number of care manager contacts/month and the number of systematic case reviews/month.

Similar investigation of the relationship between patient characteristics and the presence of PPEs found even fewer statistically significant relationships. The only significant associations were that Hispanic patients were less likely to have PPEs (OR = 0.4, CI = 0.4-0.6) compared with whites, and patients on Medicaid are more likely to have PPEs (OR = 3.6, CI = 1.7-7.8) compared with those on commercial insurance. The likelihood of having audited PPE event was unrelated to the number of events a patient had (as long as they had any). This is based on calculated ORs for having a PPE of 0.28 for those with a history of 1-2 events/y, 0.27 if 3-4, 0.55 if 5-6, 0.31 if 7-9, and 0.32 if 10 or more, all with overlapping 95% CIs.

In Table 3, the focus is on events rather than patients. Of the 389 events audited, 109 (28.0%) were considered to be PPEs (39% of the ED visits and 14% of the hospitalizations). PPEs were not associated with any of the conditions included in the ACSCs list, either individually or collectively, but they were associated with nonmedical factors considered by the care

### Table 1. Numbers of patients and events in study of potentially preventable hospital and Emergency Department events

<table>
<thead>
<tr>
<th>Group</th>
<th>Patients</th>
<th>N (%)</th>
<th>Events</th>
<th>Total</th>
<th>ED visit</th>
<th>Hospitalization</th>
</tr>
</thead>
<tbody>
<tr>
<td>At participating medical groups</td>
<td>2620</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Patients with events in the study period</td>
<td>978</td>
<td>(37.3)</td>
<td>2286</td>
<td>1366</td>
<td>920</td>
<td></td>
</tr>
<tr>
<td>Selected for audit</td>
<td>522</td>
<td>(53.4)</td>
<td>954</td>
<td>504</td>
<td>450</td>
<td>(48.9)</td>
</tr>
<tr>
<td>With events eligible for audit</td>
<td>406</td>
<td>(77.8)</td>
<td>456</td>
<td>247</td>
<td>209</td>
<td>(46.4)</td>
</tr>
<tr>
<td>Completely audited</td>
<td>373</td>
<td>(91.8)</td>
<td>389</td>
<td>214</td>
<td>175</td>
<td>(83.7)</td>
</tr>
<tr>
<td>With PPE</td>
<td>107</td>
<td>(28.7)</td>
<td>109</td>
<td>84</td>
<td>25</td>
<td>(14.3)</td>
</tr>
</tbody>
</table>

*Each percentage is in relation to the row above.

ED = Emergency Department; PPE = potentially preventable event—a problem that might not have occurred or might have been managed at home or in clinic if the care manager had been aware of it in the prior two weeks.
managers to have contributed to the event. The ORs (95% CIs) for these factors compared with those without these factors were as follows: Lack of money or other resources, 2.9 (1.4–5.8); lack of caretaker, 3.5 (1.9–6.4); lack of patient understanding, 5.5 (3.4–8.9); and inability to access clinic for care, 1.9 (1.05–3.4).

Of the ED events considered to be PPEs, 75 (89%) were considered able to be cared for in the clinic instead of the ED or hospital within the next week. That was also true for 20 (80%) of the 25 hospital admissions considered potentially preventable.

Table 4 summarizes the discharge diagnoses for audited events. For the ED, the most frequent conditions were traumatic, gastrointestinal, and orthopedic; these conditions also had the highest proportion of events rated as PPEs. In contrast, the most frequent problems leading to hospitalization were cardiovascular, infections, neurologic, gastrointestinal, and psychiatric, whereas cardiovascular and pulmonary problems had the greatest likelihood of being PPEs. Conditions considered major relative to minor severity were much less likely to be PPEs (OR = 0.28, CI = 0.14–0.58), whereas those rated intermediate in severity were also intermediate in the likelihood of being PPEs (OR = 0.49, CI = 0.29–0.84) (data not shown in tables).

**DISCUSSION**

These results suggest that even among a medically complex set of patients with major mental and physical problems, a sizable proportion of hospitalizations and (especially) ED visits were believed by their care managers to have been preventable. Surprisingly, the level of control of an individual’s depression, diabetes, or hypertension had no relation to the likelihood either

<p>| Table 2. Bivariate analysis of patient characteristics and care factors in relation to events* |
|---------------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|</p>
<table>
<thead>
<tr>
<th>Characteristicb</th>
<th>All Events</th>
<th>ED visit</th>
<th>Hospitalization</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total patients</td>
<td>Patients with no events</td>
<td>Patients with events</td>
</tr>
<tr>
<td>N</td>
<td>2620</td>
<td>1642</td>
<td>978</td>
</tr>
<tr>
<td>Male sex</td>
<td>37.9</td>
<td>38.8</td>
<td>36.3</td>
</tr>
<tr>
<td>Age, y</td>
<td>46.0</td>
<td>48.4</td>
<td>42.9</td>
</tr>
<tr>
<td>Racec</td>
<td>75.6</td>
<td>73.8</td>
<td>78.6</td>
</tr>
<tr>
<td>White</td>
<td>9.2</td>
<td>8.8</td>
<td>9.7</td>
</tr>
<tr>
<td>Black</td>
<td>46.0</td>
<td>43.6</td>
<td>50.0</td>
</tr>
<tr>
<td>Hispanic ethnicity</td>
<td>1.9</td>
<td>1.9</td>
<td>1.8</td>
</tr>
<tr>
<td>Insurance</td>
<td>27.3</td>
<td>30.4</td>
<td>22.1</td>
</tr>
<tr>
<td>Commercial</td>
<td>24.8</td>
<td>24.0</td>
<td>26.1</td>
</tr>
<tr>
<td>Medicaid</td>
<td>46.0</td>
<td>43.6</td>
<td>50.0</td>
</tr>
<tr>
<td>Medicare</td>
<td>3.5</td>
<td>4.1</td>
<td>2.5</td>
</tr>
<tr>
<td>None</td>
<td>47.7</td>
<td>51.4</td>
<td>41.4</td>
</tr>
<tr>
<td>Conditions</td>
<td>11.5</td>
<td>11.4</td>
<td>11.5</td>
</tr>
<tr>
<td>Dep only</td>
<td>37.4</td>
<td>33.1</td>
<td>44.6</td>
</tr>
<tr>
<td>Dep + Diab</td>
<td>9.1</td>
<td>8.9</td>
<td>9.4</td>
</tr>
<tr>
<td>Dep + CV</td>
<td>126.6</td>
<td>126.5</td>
<td>126.6</td>
</tr>
<tr>
<td>Dep + Diab + CV</td>
<td>73.2</td>
<td>73.6</td>
<td>72.7</td>
</tr>
<tr>
<td>Disease control, mean</td>
<td>8.5</td>
<td>8.5</td>
<td>8.6</td>
</tr>
<tr>
<td>PHQ-9 score</td>
<td>8.5</td>
<td>8.5</td>
<td>8.6</td>
</tr>
<tr>
<td>SBP, mmHg</td>
<td>126.6</td>
<td>126.5</td>
<td>126.6</td>
</tr>
<tr>
<td>DBP, mmHg</td>
<td>73.2</td>
<td>73.6</td>
<td>72.7</td>
</tr>
<tr>
<td>HbA1c, %</td>
<td>6.5</td>
<td>8.3</td>
<td>7.3</td>
</tr>
<tr>
<td>Care manager contacts/mo, mean</td>
<td>1.0</td>
<td>0.9</td>
<td>1.2</td>
</tr>
<tr>
<td>Systematic case reviews/mo, mean</td>
<td>0.4</td>
<td>0.3</td>
<td>0.5</td>
</tr>
<tr>
<td>Months enrolled in COMPASS, mean</td>
<td>11.1</td>
<td>11.1</td>
<td>11.2</td>
</tr>
</tbody>
</table>

* All data are presented as percentages unless otherwise noted.
** χ² test was used to test for nonrandom distribution across categorical variables.
† Some responses to the race questionnaire are not included (Pacific Islander, Native American, Other, Unreported/Refused to answer) so answers do not add to 100%.
CV = cardiovascular disease; DBP = diastolic blood pressure; Dep = depression; Diab = diabetes; ED = Emergency Department; HbA1c = hemoglobin A1c; PHQ-9 = Patient Health Questionnaire; SBP = systolic blood pressure.
of having events or of having events that were considered potentially preventable. It does not appear that any combination of typical medical characteristics would be of much clinical value in identifying patients who are more likely to have PPEs. The largest associations were with nonmedical factors like patient lack of resources, caretakers, understanding, and access to the clinic. Although history of frequent ED visits or hospitalizations does not identify patients at greater risk of preventable events, it seems useful to pay extra attention to the 5% of complex patients who have 5 or more events in a year, since they account for fully 40% of all events and because their audited events were just as likely to be PPEs as those with fewer events.

One of the more interesting findings from these audits was the lack of any association between PPEs and events caused by ACSCs. That was true overall as well as for each of the ACSCs individually, even in patients with two or three ACSCs contributing to their event. That lack of association was especially notable since most of this patient population had four of the ten ACSCs as a reason for enrollment in this program. This may be an important preliminary indication of potential problems with the ACSC list, which was created by expert opinion and, as far as we can tell, has never been validated by actual audit of events. Nei-

The largest associations were with nonmedical factors like patient lack of resources, caretakers, understanding, and access to the clinic.

Table 3. Event characteristics in relation to potentially preventable events (PPEs)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>All events</th>
<th>ED visit</th>
<th>Hospitalization</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Not PPE</td>
<td>PPE</td>
<td>Total</td>
</tr>
<tr>
<td>N</td>
<td>280</td>
<td>109</td>
<td>389</td>
</tr>
<tr>
<td>Patient insurance</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Commercial</td>
<td>21.4</td>
<td>9.4</td>
<td>18.1</td>
</tr>
<tr>
<td>Medicaid</td>
<td>23.5</td>
<td>37.3</td>
<td>27.4</td>
</tr>
<tr>
<td>Medicare</td>
<td>54.3</td>
<td>51.4</td>
<td>53.5</td>
</tr>
<tr>
<td>Event because of ambulatory care sensitive conditions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall (any)</td>
<td>56.1</td>
<td>56.0</td>
<td>56.0</td>
</tr>
<tr>
<td>Diabetes</td>
<td>32.5</td>
<td>26.6</td>
<td>30.9</td>
</tr>
<tr>
<td>Hypertension</td>
<td>18.2</td>
<td>1.5</td>
<td>16.7</td>
</tr>
<tr>
<td>CHF</td>
<td>16.4</td>
<td>11.0</td>
<td>14.9</td>
</tr>
<tr>
<td>Angina</td>
<td>2.9</td>
<td>4.6</td>
<td>3.3</td>
</tr>
<tr>
<td>Could have been managed in</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinic next week</td>
<td>0.7</td>
<td>9.3</td>
<td>3.1</td>
</tr>
<tr>
<td>Clinic following day</td>
<td>5.4</td>
<td>36.1</td>
<td>13.5</td>
</tr>
<tr>
<td>Clinic the same day</td>
<td>13.7</td>
<td>34.3</td>
<td>20.0</td>
</tr>
<tr>
<td>Only in ED/hospital</td>
<td>72.2</td>
<td>10.2</td>
<td>54.8</td>
</tr>
<tr>
<td>Uncertain</td>
<td>7.9</td>
<td>10.2</td>
<td>8.6</td>
</tr>
<tr>
<td>Event was avoidable for</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical reasons</td>
<td>3.2</td>
<td>37.6</td>
<td>12.9</td>
</tr>
<tr>
<td>Nonmedical reasons</td>
<td>5.4</td>
<td>40.4</td>
<td>15.2</td>
</tr>
<tr>
<td>Nonmedical reasons for event</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lack of money or other resources</td>
<td>6.4</td>
<td>16.5</td>
<td>9.3</td>
</tr>
<tr>
<td>Lack of caretaker</td>
<td>8.6</td>
<td>22.8</td>
<td>13.1</td>
</tr>
<tr>
<td>Lack of patient understanding</td>
<td>25.4</td>
<td>65.1</td>
<td>36.5</td>
</tr>
<tr>
<td>Inability to access clinic</td>
<td>12.5</td>
<td>21.1</td>
<td>14.9</td>
</tr>
<tr>
<td>Mental illness</td>
<td>15.4</td>
<td>24.8</td>
<td>18.0</td>
</tr>
<tr>
<td>Substance abuse</td>
<td>5.7</td>
<td>6.4</td>
<td>5.9</td>
</tr>
<tr>
<td>Other</td>
<td>12.1</td>
<td>9.2</td>
<td>11.3</td>
</tr>
</tbody>
</table>

* All data are presented as percentages unless otherwise noted.
* χ² test was used to test for nonrandom distribution across categorical variables.
* CHF = congestive heart failure; ED = Emergency Department; NA = not applicable (cells too small to test).
a marker for overuse. But what if this rate turned out to be unrelated to preventability of admissions?

In the mid-1980s, peer review organizations sought to make medical record reviews more efficient by focusing on events more likely to have quality problems. The Minnesota Project studied the value of using 15 sentinel hospital admission conditions widely thought to reflect poor ambulatory care (similar to the ACSC list). Review of 673 cases in that project found that only 10% of these cases suggested possible care quality problems. Although that rate made peer review more efficient than random case selection, it is hardly high enough to warrant use as a proxy for poor care or preventable admissions. However, expert panels concluded (without case review) that 50% to 70% of admissions for poor care or preventable admissions. However, expert panels concluded (without case review) that 50% to 70% of admissions for 96 of 174 conditions (including most of the ACSCs) should be preventable.

The finding that patients with limited resources and lack of care are more likely to have PPEs is not surprising. However, it does suggest the importance of developing and testing strategies to address these factors. Nagasaka et al have demonstrated that adjusting for low socioeconomic status greatly reduced hospital readmission rates for each of the conditions currently penalized by the Centers for Medicare & Medicaid Services. This suggests a need to ensure that nonmedical factors are addressed by coordinated and proactive provision of social services and education in addition to medical and behavioral health care.

The association of events with the number of care manager contacts and systematic case reviews probably reflects the greater attention provided to patients who were experiencing difficulties that later led to events. However, it also suggests that these extra contacts might have provided an opportunity to prevent the events. Preventing unnecessary events is a new perspective for most health care professionals, who are trained to provide care, not to control costs.

**CONCLUSION**

The main purpose of this quality improvement study was to learn enough about PPEs to inform strategies to reduce them. Each medical group participating in this study used its own data and knowledge of local conditions to identify and implement actions that might reduce PPEs. Despite being preliminary, these findings suggest the need for much more information about the actual preventability of expensive events like hospitalizations and ED visits before we continue to assume that certain diagnoses are preventable.

**Disclosure Statement**

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

**Acknowledgments**

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Mary Corrado, ELS, provided editorial assistance.

**References**


**How to Cite this Article**


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**Table 4. Condition type and severity relationship to discharge diagnosis for events**

<table>
<thead>
<tr>
<th>Type</th>
<th>ED visits (N = 214)</th>
<th>Hospitals (N = 175)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%)</td>
<td>PPE, n (%)</td>
</tr>
<tr>
<td>Traumatic</td>
<td>37 (19.2)</td>
<td>8 (11.1)</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>23 (11.9)</td>
<td>12 (16.7)</td>
</tr>
<tr>
<td>Orthopedic</td>
<td>17 (8.8)</td>
<td>11 (15.3)</td>
</tr>
<tr>
<td>Pain</td>
<td>15 (7.8)</td>
<td>1 (1.4)</td>
</tr>
<tr>
<td>Ear, nose, throat</td>
<td>15 (7.8)</td>
<td>7 (9.7)</td>
</tr>
<tr>
<td>Endocrine</td>
<td>14 (7.3)</td>
<td>4 (5.6)</td>
</tr>
<tr>
<td>Infection</td>
<td>13 (6.7)</td>
<td>4 (5.6)</td>
</tr>
<tr>
<td>Neurologic</td>
<td>12 (6.2)</td>
<td>4 (5.6)</td>
</tr>
<tr>
<td>Pulmonary</td>
<td>8 (4.2)</td>
<td>3 (4.2)</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>5 (2.6)</td>
<td>3 (4.2)</td>
</tr>
<tr>
<td>Psychiatric</td>
<td>4 (2.1)</td>
<td>1 (0)</td>
</tr>
<tr>
<td>Other</td>
<td>30 (15.6)</td>
<td>21 (23.7)</td>
</tr>
<tr>
<td>Total</td>
<td>193</td>
<td>72</td>
</tr>
</tbody>
</table>

* Does not add to 214 and 175 because there were 21 ED visits and 7 hospitalizations with no data for disease category.

Ignorance

The superior physician helps before the early budding of the disease . . . .
The inferior physician begins to help when [the disease] has already developed;
he helps when destruction has already set in. And since his help comes when
the disease has already developed it is said of him that he is ignorant.

— 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
ORIGINAL RESEARCH & CONTRIBUTIONS

Understanding Waste in Health Care: Perceptions of Frontline Physicians Regarding Time Use and Appropriateness of Care They and Others Provide

John P Caloyeras, PhD; Michael H Kanter, MD; Nicole R Ives, MHA; Chong Y Kim, PhD; Hemal K Kanzaria, MD, MSHPM; Sandra H Berry, MA; Robert H Brook, MD, ScD

ABSTRACT

Background: Approximately 30% of total US health care spending is thought to be "wasted" on activities like unnecessary and inefficiently delivered services.

Objectives: To assess the perceptions of clinic-based physicians regarding their use of time and appropriateness of care provided.

Design: Cross-sectional online survey of all Southern California Permanente Medical Group partner and associate physicians (N = 1034) who were primarily providing clinic-based care in 1 of 4 geographically and operationally distinct Kaiser Permanente Southern California Medical Centers.

Main Outcome Measures: The proportion of time spent on direct patient care tasks perceived to require the respondent’s clinical/specialty training as a physician or another physician who has similar years of clinical training (vs physicians with fewer years of clinical training, nonphysicians, or automated or computerized systems), and the proportion of care provided by the respondent and by other physicians with whom they are familiar that is perceived to be appropriate (vs equivocal or inappropriate).

Results: More than 61% of respondents indicated that 15% of their time spent on direct patient care could be shifted to nonphysicians, and between 10% and 16% of care provided was equivocal or inappropriate.

Discussion: The low proportion of care perceived as equivocal or inappropriate indicates there is little room for reducing such care or that physicians have difficulty assessing care appropriateness. The latter suggests that attempts to reduce or to eliminate inappropriate care may be unsuccessful until physician beliefs, knowledge, or behaviors are better understood and addressed.

Conclusion: On the basis of these findings, it is apparent that within at least one health care system, the opportunity to increase value through task shifting and avoiding inappropriate care is more narrow than commonly perceived on a national level.

INTRODUCTION

Roughly 30% of total US health care spending—or $530 billion yearly—is regarded as spending that may not improve patient health and involves the provision of unnecessary and inefficiently delivered services. Reviews of studies evaluating the appropriateness of care indicate that at least 30% of procedures, tests, and prescribed medications may be of questionable benefit. Nearly 75% of physicians in a 2014 survey said that unnecessary tests and procedures are a “very” or “somewhat serious” problem for the health care system.

Reduction of unnecessary and inefficiently delivered health care services must be addressed as an organizational change that reflects the way in which “business” (ie, providing care) is conducted. Organizational change management frameworks generally are conceived by formalizing and defining the change initiative, addressing tasks such as developing a business case for why change is needed, defining the desired outcomes. The process ends when changes have been fully absorbed into the business. During this final phase, the full value of change is demonstrated as “proof” that transitions are complete.

When considering the current state of efforts to reduce unnecessary and inefficiently delivered services, a number of questions must be addressed. For example, have the frontline physicians been consulted? Their buy-in is fundamental to success. And how do they perceive the current status of the problem and regard options for moving toward a system with fewer nonvalue-added activities?

More often than not, frontline physicians do not have ample opportunity to voice their thoughts about changes affecting the health care system. As a result, their views remain largely unknown. If physicians are excluded from this process, it will be difficult to get their buy-in and trust down the road or to deploy the most effective policy levers, which limits likelihood for future success.

Against this backdrop, it is surprising how little is known about frontline
physicians’ thoughts regarding health care value. This is particularly the case when discussing their use of time and appropriateness of care. For example, it is not known if frontline physicians believe they provide unnecessary services or if they can recognize inefficient delivery of care in their practice. If these problems exist, what is the magnitude of these nonvalue-added activities? What are the primary reasons behind potentially unnecessary activities, and how can these reasons be addressed most effectively? Without answers to such questions, it is difficult to know how to interpret results from studies quantifying low-value care that use claims data or studies involving patients on the topic.

We developed a survey to engage physicians along the two health care value domains that play a direct role on a day-to-day basis: The efficiency with which physicians use their time and the appropriateness of care provided by themselves and other physicians with whom they are familiar. This study’s goal was to add to the evidence that use claims data or studies involving patients on the topic.

**METHODS**

**Study Design**

We conducted a cross-sectional study of 1034 Southern California Permanente Medical Group (SCPMG) physicians from 4 Kaiser Permanente Southern California (KPSC) Medical Centers using an online survey focused on the ways in which physicians use their time and the appropriateness of care provided. The survey instrument was developed by authors at The RAND Corporation (RAND). Dissemination of the survey among SCPMG physicians, confidential presentation of results within SCPMG, and drafting of this manuscript were conducted as a partnership between RAND and SCPMG leadership. All analyses were performed by the authors at RAND with advice from SCPMG leadership. Approvals from the RAND institutional review board were obtained for all phases of work; approval from the KPSC institutional review board also was obtained for survey dissemination and all subsequent activities.

**Survey Development**

The two survey concepts—the ways in which physicians use their time and the appropriateness of care they provide—were chosen as the study focus to reflect areas frontline physicians can immediately influence. The RAND research team developed draft items to explore these concepts, which were then incorporated into a focus group discussion guide. Multispecialty physicians from the Greater Los Angeles area (no physician was part of SCPMG) who were engaged with clinic-based care were recruited for two focus groups. The first group was composed of nine specialists including an anesthesiologist, a neurologist, surgeons, an emergency physician, a radiologist, and internal medicine subspecialists, whereas the second group was made up of nine generalists including family physicians, pediatricians, general internists, and obstetrician/gynecologists. Qualitative analyses of focus group data were used to refine survey concept descriptions, items, and item responses so they best aligned with the perceptions and experiences of physicians with whom they are familiar.

**Table 1. Characteristics of SCPMG physicians invited to complete a survey, stratified by response**

<table>
<thead>
<tr>
<th>Physician characteristic or response</th>
<th>Overall sample (N = 1034)</th>
<th>Respondents (n = 636)</th>
<th>Nonrespondents (n = 398)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex, no. (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>431 (41.7)</td>
<td>268 (42.1)</td>
<td>163 (41.0)</td>
<td>0.71</td>
</tr>
<tr>
<td>Men</td>
<td>603 (58.3)</td>
<td>368 (57.9)</td>
<td>235 (59.0)</td>
<td></td>
</tr>
<tr>
<td>Age (y)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30-39, no. (%)</td>
<td>295 (28.5)</td>
<td>199 (31.3)</td>
<td>96 (24.1)</td>
<td>0.01</td>
</tr>
<tr>
<td>40-49, no. (%)</td>
<td>362 (35.9)</td>
<td>225 (35.4)</td>
<td>157 (39.4)</td>
<td></td>
</tr>
<tr>
<td>50-59, no. (%)</td>
<td>231 (22.3)</td>
<td>147 (23.1)</td>
<td>84 (21.1)</td>
<td></td>
</tr>
<tr>
<td>60-69, no. (%)</td>
<td>126 (12.2)</td>
<td>65 (10.2)</td>
<td>61 (15.3)</td>
<td></td>
</tr>
<tr>
<td>Age (y), mean (SD)</td>
<td>46.3 (9.2)</td>
<td>45.9 (9.2)</td>
<td>47.1 (9.2)</td>
<td>0.03</td>
</tr>
<tr>
<td>Medical school type, no. (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Public</td>
<td>401 (38.8)</td>
<td>263 (41.4)</td>
<td>138 (34.7)</td>
<td>0.08</td>
</tr>
<tr>
<td>Private</td>
<td>465 (45.0)</td>
<td>270 (42.5)</td>
<td>195 (49.0)</td>
<td></td>
</tr>
<tr>
<td>International</td>
<td>168 (16.2)</td>
<td>103 (16.2)</td>
<td>65 (16.3)</td>
<td></td>
</tr>
<tr>
<td>Postmedical school experience</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Years since medical school, mean (SD)</td>
<td>19.0 (9.6)</td>
<td>18.5 (9.6)</td>
<td>19.9 (9.5)</td>
<td>0.02</td>
</tr>
<tr>
<td>Years of postgraduate training, mean (SD)</td>
<td>4.8 (2.2)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time spent at work</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average total h/wk working as an SCPMG physician, mean (SD)</td>
<td>48.8 (10.4)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average h/wk for direct patient care, mean (SD)</td>
<td>43.5 (11.8)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SCPMG partner status, no. (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Associate</td>
<td>222 (21.5)</td>
<td>154 (24.2)</td>
<td>68 (17.1)</td>
<td>&lt; 0.01</td>
</tr>
<tr>
<td>Partner</td>
<td>812 (78.5)</td>
<td>482 (75.8)</td>
<td>330 (82.9)</td>
<td></td>
</tr>
<tr>
<td>Kaiser Permanente Southern California site, no. (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site 1</td>
<td>248 (24.0)</td>
<td>149 (23.4)</td>
<td>99 (24.9)</td>
<td>0.16</td>
</tr>
<tr>
<td>Site 2</td>
<td>281 (25.2)</td>
<td>172 (27.0)</td>
<td>89 (22.4)</td>
<td></td>
</tr>
<tr>
<td>Site 3</td>
<td>246 (23.0)</td>
<td>139 (21.9)</td>
<td>107 (26.9)</td>
<td></td>
</tr>
<tr>
<td>Site 4</td>
<td>279 (26.0)</td>
<td>176 (27.7)</td>
<td>103 (25.9)</td>
<td></td>
</tr>
</tbody>
</table>

Source: Authors’ analysis of SCPMG survey data.

a Percentages may not sum to 100 because of rounding. P values were generated using t-tests for continuous variables and χ² tests for categorical variables.

SCPMG = Southern California Permanente Medical Group; SD = standard deviation.
practicing physicians. The final survey instrument implemented within SCPMG is available for download (and may be reused free of charge) from the RAND Health Surveys Web page. Survey Sample and Administration Full-time SCPMG associate and partner physicians were invited to complete the survey. All clinic-based physicians from 4 geographically and operationally distinct KPSC Medical Centers (ranging in staff size from 248 to 279 physicians) were invited via e-mail in fall 2013 to complete the online survey. The sites represented a convenience sample selected by SCPMG regional leadership using internal metrics on back-office support. Two sites with below-average and 2 sites with above-average scores were selected for participation. SCPMG regional staff and Medical Center leadership distributed a memorandum to eligible physicians to introduce the survey and the partnership with RAND. E-mail invitations included individualized links to the online survey. To maximize the response rate, as many as 4 rounds of reminder e-mails were sent. Physicians received a $25 Amazon gift card for survey completion.

Study Measures and Variables
The first study concept, the perceived efficiency with which physicians use their time, was measured by asking respondents to estimate their percentage of direct patient care time spent on tasks that “require MY clinical/specialty training as a physician (or another physician who has similar years of clinical training),” “could be performed by physicians who have fewer years of clinical training,” “could be performed by nonphysicians,” and “could be performed primarily by an automated or computerized system.” A question regarding total time working and total time spent on direct patient care activities on average per week during the previous month was included to allow quantification of potential “freed-up” time if tasks could be shifted.

The second study concept, the appropriateness of care provided, was measured by asking physicians to estimate the proportion of care provided by others (physicians with whom they are familiar who have the same specialty, excluding themselves) across eight clinical activity, test, or procedure categories that is perceived to be appropriate, equivocal, or inappropriate. After completing items about other physicians, respondents answered questions about the care they personally provide, skipping categories for which they reported not ordering, performing, or reviewing during the previous month. Respondents were given established definitions for the terms appropriate (potential health benefit is greater than potential health risk), equivocal (potential health benefit is equal to potential health risk), and inappropriate (potential health benefit is less than potential health risk). Physicians were instructed to make these judgments considering only the potential health benefits and risks to individual patients without assessment of cost.

Physicians who reported that at least 5% of their time was spent on tasks that could be performed by others were asked to indicate the type(s) of personnel or system that would be needed and the perceived reasons others do not perform these tasks currently. Physicians reporting any equivocal or inappropriate care were asked to evaluate potential reasons for such care; all respondents (regardless of whether they reported equivocal or inappropriate care) were asked to evaluate the helpfulness of strategies that can reduce levels of equivocal and inappropriate care.

Participant descriptors not available in the SCPMG administrative data were gathered from respondents; these included area of clinical practice (primary care, medical specialty, general surgery or surgical subspecialty, or other), years...
of postgraduate training, average hours worked per week as a KPSC physician, and average hours per week spent on direct patient care. The final survey featured 22 questions. The raw item count was 11 for the demographics module, 39 for the use-of-time module, and 107 for the appropriateness of care module.

Analytic Approach

Descriptive statistics (counts, means, standard deviations, and 95% confidence intervals) were used to summarize survey results. Potential differences between survey respondents and nonrespondents were explored using independent samples t-tests for numeric variables and Pearson χ² tests for categorical variables. Data management and statistical analyses were performed using SAS 9.4 (SAS Institute, Cary, NC).

RESULTS

Characteristics of the 1034 physicians invited to participate in the survey are shown in Table 1, as are the characteristics of respondents (N = 636; 61.5% response rate) and nonrespondents (N = 398). Respondents (vs nonrespondents) were on average 1.2 years younger, had logged 1.4 fewer years since medical school, and were more likely to be SCPMG “associates” (ie, partner track) than SCPMG partners. Response rates were similar across the 4 participating KPSC sites; on average, the survey took 15 to 20 minutes to complete.

Use of Time

Physicians reported that 70.4% of their time spent on direct patient care tasks (standard deviation [SD] 22.0%) was devoted to tasks for which their clinical/specialty training as a physician (or another physician who has similar years of clinical training) was required, 14.2% (SD 16.5%) of time was spent on tasks that could be performed by physicians who have fewer years of clinical training, 11.6% (SD 9.6%) of time was spent on tasks that could be performed by nonphysicians, and 3.8% (SD 5.2%) of time was spent on tasks that could be performed primarily by an automated or computerized system. The proportion of direct patient care time spent on tasks that necessitate a respondent’s clinical/specialty training as a physician was lowest among primary care physicians (PCPs) (65.8%, SD 23.4%), followed by general surgeons or surgical subspecialists (69.8%, SD 21.3%) and physicians working in an “other” discipline (73.5%, SD 19.6%) and highest among medical specialists (76.8%, SD 19.2%).

Nearly all physician respondents (86.2%) revealed that at least 5% of their direct patient care time was spent on tasks that could be performed by someone other than themselves or a physician like them with similar years of training. The staff types cited as needed by more than 50% of respondents were nurse practitioners (68.4%), physician assistants (67.7%), registered nurses (54.4%), and PCPs (52.7%) (PCP was offered as a choice only...
to physicians not reporting their area of clinical practice as primary care).

Physicians had 2 types of reasons for not delegating direct patient care tasks to alternative providers (including nonclinical staff and automated or computerized systems): Organizational reasons such as “type of practice organization I'm in doesn’t include them” (35.2%) or “can’t find and/or retain qualified staff” (21.9%) and personal beliefs and preferences such as “patients prefer for me to do these tasks personally” (36.5%) and “don’t like to delegate, prefer to take care of patients myself” (15.3%).

The simple math is telling: Multiplying the 15.4% (11.6% + 3.8%) of time spent on direct patient care tasks perceived as doable for nonphysicians to perform by the mean hours spent by respondents per week on direct patient care tasks (43.5; Table 1) indicates that 6.7 hours per week could theoretically be repurposed for other activities.

**APPROPRIATENESS OF CARE**

Physicians reported that across all services provided by “others” (ie, physicians with whom they are familiar who have the same specialty, excluding themselves), 11.1% (SD 11.2%) of services are perceived as equivocal and 5.1% (SD 7.8%) as inappropriate (Figure 1). In contrast, physicians reported that across all services they personally provide, 7.4% (SD 7.8%) of services are perceived as equivocal and 2.8% (SD 8.1%) as inappropriate (Figure 1). The category with the highest perceived equivocal or inappropriate care was “order, perform, or review noninvasive diagnostic studies (such as x-rays)” for both the assessment of other’s (22%) and self (12.6%). “Recommend or perform surgeries or procedures” and “Provide counseling or education” solicited responses regarding the least equivocal and inappropriate care for the assessment of others (12.3%) and self (6.4%).

Two changes perceived by more than 80% of respondents as potentially “extremely or very helpful” for reducing the overall level of equivocal or inappropriate care were related to increased use of evidence-based clinical decision rules and patient or family education (Figure 2). “Change malpractice laws” was cited by 75.5% of physicians as potentially “extremely or very helpful.” Other strategies perceived as “extremely or very helpful” by more than 50% of physicians are shown in Figure 2.

Nearly 70% of physicians perceived “patient or family concerns or expectations” as “often a reason” for equivocal or inappropriate care—the highest of the 17 reasons on the survey. Other common reasons among at least 25% of respondents are featured in Figure 3.

**Willingness to Improve Value**

Most physicians indicated they were “very willing” or “somewhat willing” to work with administrators, staff, and colleagues to improve the amount of time they spend on direct patient care (67.5% and 22.7%, respectively). Reported willingness also was high regarding changing practice patterns to minimize equivocal or inappropriate care (66.8% and 24.6%, respectively).

**DISCUSSION**

We surveyed a sample of frontline physicians practicing within SCPMG to assess their perceptions regarding 2 domains of health care value: The use of time spent on direct patient care tasks and the appropriateness of care provided. The average perception was that 15% of respondents’ time (or 6.7 hours per week) spent on direct patient care could be shifted to nonphysicians or automated or computerized systems. Between 10% and 16% of care provided was perceived as equivocal (7.4%–11.1%) or inappropriate (2.8%–5.1%).

These findings reveal that within SCPMG, physicians perceive the opportunity to increase health care value through shifting of tasks and avoidance of inappropriate care as small, with less room for improvement than common wisdom may suggest. We contend that to improve value along the two study domains, policy activities should focus broadly on providing physicians (and their patient care teams) with training and resources to discuss, to communicate, to identify, and to manage the preferences and expectations of patients and their families. It also may be useful to test physicians’ perceptions regarding patients’ preferences for who provides care.

Because many theoretically “shiftable” tasks likely occur at irregular or inconsistent time intervals, it may be neither feasible nor efficient for physicians to try to shift every possible task that could be performed by others. However, despite the relatively limited opportunity identified, SCPMG leadership is evaluating existing and new interventions focused on educating and communicating with patients about use of nonphysician staff to perform some tasks within their scope of practice. Interventions under consideration include ways to increase use of the online personal action plan, expand use of pharmacists and nurses in the management of chronic...
conditions, and encourage health educators to take a more visible lead regarding weight management and diabetes education. Existing evidence may be referred to while evaluating these options; prior studies revealed ways to identify specific tasks appropriate for shifting,1,19 assess the feasibility of shifting a given task,1,19 and monitor outcomes (including patient satisfaction) after shifting a task.2,19,21

We believe the disconnect between SCPMG physicians’ perceived levels of inappropriate care and recent reviews6,5 that concluded more than 30% of all care provided may be of questionable benefit raises three issues. First, the level of inappropriate care may simply be overstated. If so, expectations for lowering costs through avoiding inappropriate care, such as through the Choosing Wisely Campaign,22 should be adjusted downward. This scenario seems unlikely considering the existing, high-quality evidence on overuse even though the problem is grossly understudied.5

A second possibility is that integrated, prepaid delivery systems such as KPSC may have already eliminated most inappropriate care. If this is the case, as other delivery systems become more integrated and begin adopting nonfee-for-service payment models, we may be able to expect declines in the provision of inappropriate care.

It is possible that this survey’s respondents may be unable to recognize that some care they provide is inappropriate. In this scenario, it may be necessary to address the beliefs and behaviors of physicians regarding appropriate, equivocal, and inappropriate care. To accomplish this, leaders in medicine and decision makers at institutions must consider investments to improve the evidence base. Physician education can complement these activities so physicians can more effectively develop the skills needed to recognize in real time when expected risks of a given treatment option are equal to or less than the expected benefits and work with their patients to find the best path forward.

SCPMG leadership has taken a number of steps in response to the perception among more than 80% of physicians that patient and family education would be extremely or very helpful to minimize equivocal and inappropriate care. Physicians are being encouraged to more proactively discuss treatment option risks and benefits with patients and their families. Physicians need education on ways to communicate with patients who may desire services that are not medically appropriate; a wait-and-see approach is one option. Physicians are being reminded of shared decision-making programs currently available, and leadership is examining the ways in which these programs may be refined or expanded to help address issues surrounding equivocal care. In this situation, it is particularly important to identify the course of action best aligned with a patient’s values and preferences, including cost.

A common concern reported by SCPMG physicians was ensuring patient satisfaction when withholding desired medically inappropriate interventions. In a 2014 American Board of Internal Medicine survey, 23% of physicians viewed “wanting to keep patients happy” as a major reason for ordering unnecessary tests or procedures.5 This evidence suggests that physicians’ perceptions of the patient care experience—which are based on quality of care in meeting health care needs and not on a desire to keep patients happy—would need to be addressed to implement substantial practice changes to reduce inappropriate care. Efforts are being undertaken within KPSC to assess the relationship between withholding of inappropriate care and patient-reported satisfaction. In the scenario of prescribing antibiotics for acute sinusitis, 79.5% vs 75.4% of patients who did and did not receive antibiotics were satisfied.23 These findings suggest the potential boost to satisfaction scores (if any) associated with providing desired but medically inappropriate care likely is small, and when such care is not provided, the proportion of patients who are satisfied remains high.

Although it is not surprising that malpractice fears are a concern with respect to equivocal care,6,22,23 it is important to note the evidence points to changes in malpractice laws having little effect on intensity of practice measures such as imaging and hospital admission rates.26 The literature clearly confirms that open and honest communication between physicians and patients has a protective effect against malpractice claims.27,28 Evidence is beginning to emerge in support of an inverse association between patient experience scores and patient complaints20 and malpractice costs,21 although findings are mixed and more research is needed.22 Studies show that malpractice fears can be a barrier to use of shared decision making23,24 (although the Patient Protection and Affordable Care Act may help in this regard), but future research is warranted to determine the best ways (eg, development of better treatment protocols or algorithms) to reduce malpractice fears ignited by joint decisions between physicians and patients to not proceed with equivocal care or to withhold desired inappropriate care.

This study had limitations. There were four participation sites within a single integrated delivery system; repeating this study in fee-for-service settings or nonintegrated delivery systems could help to determine the generalizability of these findings. However, we believe a strength of our study was that SCPMG physician perceptions may represent a lower-bound estimate on the opportunity to improve value through reducing equivocal and inappropriate care and increase the efficiency with which physicians use their time. This is because the characteristics of KPSC (an integrated, nonfee-for-service delivery system) are such that we expect appropriateness of care and efficient use of physician time to be higher than in traditional fee-for-service settings.

Recall bias and response bias are further limitations that could influence physician responses regarding their use of time and appropriateness of care provided. We attempted to explore response bias by asking physicians to first share their perceptions on appropriateness of care provided by others before asking them to share perceptions of care personally provided.

Lastly, we did not attempt to benchmark physician appropriateness of care because we do not know the degree to which physician respondents can correctly identify care that is equivocal or inappropriate. However, we were not concerned with whether physicians were correct in their assessment of appropriateness; we simply wanted to know their perceptions. Their assessment itself (whether correct or not) underlies their response regarding attempts to reduce or eliminate inappropriate care. For example, if physicians do not perceive “waste” as defined in our survey, they cannot be expected to eliminate it regardless of the policy lever.
CONCLUSION

Physicians within SCPMG perceived the window of opportunity within which to increase value through shifting tasks and avoiding inappropriate care to be narrower than commonly believed. Policy activities identified as most helpful in increasing value were centered on providing physicians (and their teams) with training and resources for discussing, communicating, identifying, and managing the preferences and expectations of patients and their families. It is possible that actual levels of equivocal and inappropriate care are higher within SCPMG than levels perceived by SCPMG physicians. If this is the case, these findings reveal that policies to reduce suboptimal care may stall until physicians’ beliefs or day-to-day practices regarding equivocal and inappropriate care can be addressed.

Disclosure Statement

John P Caloyeras, PhD, is a shareholder in Amgen Inc, Thousand Oaks, CA, but was not at the time the study was conducted. Dr Kanter is a Southern California Permanente Medical Group (SCPMG) partner; Ms Ives and Dr Kim are SCPMG employees. Hemal K Kanzarzana, MD, MSHPM, is an unpaid Clinical Advisory Board member for Collective Medical, and has received reimbursement for travel and accommodation-related expenses. He has also been a paid consultant for RAND Health and Castlight Health in the past 36 months. The author(s) have no other conflicts of interest to disclose.

Acknowledgment

Brenda Moss Feinberg, ELS, provided editorial assistance.

How to Cite This Article


References


From the artist: "This mixed media artwork is expressing the yearning and innermost instinctual desire of a human soul to gain freedom from mind-made shackles and from worldly hassles that entangle a person more and more with the progression of time and age."

Dr. Jawaid is a Counselor at Minaret College in Springvale, Victoria, Australia.
**ORIGINAL RESEARCH & CONTRIBUTIONS**

**Impact of Body Mass Index on Postconcussion Symptoms in Teenagers Aged 13 to 18 Years**

Harry Bramley, DO; Kathryn C Foley, MD; Ronald Williams, MD; Mechelle M Lewis, PhD; Lan Kong, PhD; Matthew Silvis, MD

E-pub: 07/12/2018

**ABSTRACT**

**Context:** Adolescent obesity and sports-related concussion are rising in prevalence, yet there is minimal research exploring the relationship between these two conditions.

**Objective:** To assess the impact of body mass index (BMI) percentile on duration of recovery and reported symptoms after sports-related concussion in adolescents.

**Design:** Retrospective chart review at a regional concussion program located at an academic medical center. Medical records of all patients aged 13 to 18 years treated from March 2006 through January 2012 were reviewed. Two hundred fifty-two patients met the inclusion criteria of sports-related concussion and having BMI data.

**Main Outcome Measures:** Outcome variables included reported emotional symptoms, sleep-related symptoms, physical symptoms (headache), and time to recovery after a concussion. Explanatory variables in this analysis were BMI percentile and sex.

**Results:** More male patients were obese and overweight than were females (42% vs 27%, \( p = 0.02 \)). There was no statistically significant difference in recovery time between obese and overweight patients and others. Obese and overweight patients were more likely than healthy-weight patients to report symptoms of irritability (\( p = 0.05 \)) and impulsivity (\( p = 0.01 \)), and less likely to report headache (\( p = 0.03 \)).

**Conclusion:** After concussion, irritability and impulsivity may be more likely than headaches in overweight and obese patients. There was no difference in recovery time between obese and healthy-weight teens. These findings may have importance in the evaluation, treatment, and anticipatory guidance of patients with concussions.

**INTRODUCTION**

Childhood and adolescent obesity has become a major public health crisis in the US.\(^1\) According to the National Health and Nutrition Examination Surveys from 1988 to 1994 and from 2005 to 2008, the proportion of adolescents aged 12 to 19 years who are considered obese rose from 10.5% to 17.9% between 2005 to 2008, the proportion of adolescents aged 12 to 19 years in the US continues to grow, and the sequelae are becoming more evident with increasing research.\(^2,3\) A previous study showed that childhood obesity is related to adult adiposity.\(^6\) The epidemic of childhood obesity in the US also has ushered in a host of other diseases in children that previously were not typically seen until much later in life, such as type 2 diabetes mellitus, hypercholesterolemia, and primary hypertension.\(^7-11\)

The terms *obese* and *obesity* often are used to describe excess body fat.\(^12\) Body mass index (BMI) is a measure of body fat based on weight in relation to height, and is calculated using the formula weight (kg)/height (m\(^2\)), which is how obesity generally is classified.\(^2\) For children aged 2 to 19 years, BMI percentile is used to denote children as obese, overweight, healthy weight, or underweight.\(^13\) Children are classified as obese if their BMI is greater than or equal to the 95th percentile of others their age and sex.\(^11\) A BMI between the 85th and 95th percentiles is considered overweight.\(^13\) Children are classified as normal (or healthy) weight if their BMI is between the 5th and 85th percentile, and underweight children are those with a BMI less than the 5th percentile for age and sex.\(^14\)

In 2012, fully 34.5% of adolescents aged 12 to 19 years in the US were either obese or overweight.\(^5\) In light of this national epidemic of obese or overweight adolescents, it is becoming increasingly important to consider the ways in which excess body fat may affect common conditions and injuries in adolescents. One such injury of particular relevance in this age group is concussion, which is defined by the 5th International Consensus Conference on Concussion in Sport as the immediate and transient symptoms of traumatic brain injury induced by biomechanical forces.\(^15\)

The number of children aged 14 to 19 years with sports-related concussions increased 2- to 3-fold between 1997 and 2007.\(^16\) An estimated 173,000 children report to the Emergency Department with sports-related concussions each year in the US, with concussion being diagnosed in approximately 1 in every 160 patients reporting to the Pediatric Emergency Department.\(^17\) The rising number of high school athletes with diagnoses of sports-related concussion likely is caused by a combination of factors, including increased participation in high school sports, increased media focus on concussions, and improved understanding of the health consequences of concussion.
of higher rates of injury and increased awareness and reporting. Younger patients, compared with adults, are at higher risk of concussions with increased severity and prolonged recovery.

As the incidence of concussion in high school athletes increases, there is a need for further research into the individual factors predictive of postconcussive symptoms and duration of recovery. Given the increasing incidence of concussion in the context of a national epidemic of obesity in the same age population, the potential relationship between these two factors must be considered. Recent study results have been contradictory. A recent report found obese athletes took longer to recover after a sports-related concussion compared with normal-weight athletes. However, found BMI was not a predictor of postconcussion syndrome after sports-related concussion in the study population.

The primary goal of this study was to assess the impact of BMI percentile on duration of recovery and reported concussion symptoms in the adolescent population with sports-related concussion. Additionally, this study aimed to report the prevalence of pediatric obesity in male and female teenagers in this population.

**METHODS**

**Study Participants and Procedures**

Eligibility criteria for inclusion in this study included age 13 through 18 years and a clinical diagnosis of sports-related concussion. Sports-related was defined as court or field activity related. High-velocity sports-related activities such as skiing, motocross, and bicycling were not included. Patients included in the study were all those meeting the eligibility criteria who were referred to a regional concussion program between March 2006 and January 2012. For patients who had multiple concussions during the review period, only information from the first concussion was used in the analysis.

A retrospective chart review was performed, with data collected from patient medical records and entered into a concussion database. A panel of reviewers obtained data regarding age at initial visit, sex, date of concussion, date of initial clinic visit, date of last clinic visit, mechanism of injury, previous concussions, reported concussion symptoms, and height and weight within one year of injury. The concussion clinic was staffed by two physicians who had performed the evaluations for each patient documented in the electronic medical record, facilitating the data collection process. Whereas individual symptoms varied between patients, all patients were evaluated and treated similarly in this concussion program. Physicians obtained the history from the patient, assessed for concussion symptoms, provided an examination, and formulated an assessment and plan. No specific assessment tool was used. Length of time to recovery was defined as the number of days from the date of injury to the last clinic visit indicating concussion resolution. Patients were excluded from the study if there was no documented date of injury, if the last clinic visit suggested ongoing concussion symptoms or follow-up was recommended, and if height and weight within one year of concussion could not be obtained.

The study was approved by Penn State Hershey Medical Center’s institutional review board before data collection.

**Statistical Analysis**

The outcome variables of interest included reported emotional symptoms, sleep-related symptoms, physical symptoms, and time to recovery after a concussion. Reported emotional symptoms included feeling anxious, irritable, sad or depressed, impulsive, angry, argumentative, having mood swings, and feeling more emotional. Reported sleep-related symptoms included fatigue, drowsiness, trouble falling asleep, trouble staying asleep, sleeping more, and sleeping less. The reported physical symptom was headache. The explanatory variables in this analysis were BMI percentile and sex. The BMI percentiles were calculated using the Centers for Disease Control and Prevention’s online information: “Children’s BMI Tool for Schools.” The BMI percentile was analyzed as an explanatory value in 4 distinct ways: 1) as a continuous variable; 2) as 4 categories defined as obese (≥ 95th percentile), overweight (85th to < 95th percentile), healthy weight (5th to < 85th percentile), and underweight (< 5th percentile); 3) as obese vs all others; and 4) as obese and overweight vs healthy weight and underweight.

The Wilcoxon signed rank test was used to compare medians among the different variables. Chi-squared test was used to determine whether there was a significant difference between frequency of reported symptoms and sex, as well as between BMI and reported symptoms. The Fisher exact test was used for the same purpose when variables had expected counts less than 5. The Kruskal-Wallis equality-of-populations rank test was used to compare the homogeneity of the samples regarding sex, BMI percentile, and BMI category as it related to recovery time. The Cochran-Mantel-Haenszel statistic was used to analyze whether there was a significant difference in the median BMI percentile between those who reported a symptom and those who did not.

All p values < 0.05 were considered statistically significant. SAS Version 9.3 (SAS Institute Inc, Cary, NC) was used for all statistical analyses.

**RESULTS**

**Study Patients**

Of the 577 patients included in the concussion program database from the period analyzed, 303 patients met the eligibility criteria for this study, of which 252 had BMI data and were included in the analysis. From this population, 166 (66%) were male and 86 (34%) were female. Twenty-five (10%) of the patients included were obese, 68 (27%) were overweight, 157 (63%) were healthy weight, and 2 (1%) were underweight. The mean BMI percentile (SD) was 71.5 (22.4), and the median was 77.8.

**Body Mass Index and Sex**

Of the male patients included in this study, 21 (13%) were obese, 48 (29%) were overweight, 96 (58%) were healthy weight, and 1 (0.6%) was underweight. Of the female patients, 4 (5%) were obese, 19 (22%) were overweight, 62 (72%) were healthy weight, and 9 (10%) were healthy.
weight, and 1 (1%) was underweight. There was a statistically significant difference in the frequency of obesity between male and female patients ($p = 0.045$). Additionally, there was a statistically significant difference in the frequency of obese plus overweight patients when males were compared with females ($p = 0.02$).

**Body Mass Index and Time to Recovery**

The mean number of days to recovery was 105 in obese patients, 129 days in overweight patients, 116 days in healthy-weight patients, and 289 days in underweight patients. The median number of days to recovery in obese, overweight, healthy-weight and underweight patients was 26, 61, 40, and 289, respectively. The Kruskal–Wallis test was not reliable for this analysis because the underweight group was too small ($n = 2$). There was no statistically significant difference in recovery between obese patients and all others ($p = 0.13$) or between obese and overweight vs healthy weight and underweight ($p = 0.46$).

**Body Mass Index and Symptoms**

There was a statistically significant difference in the frequency of reported symptoms between patients in different BMI categories and symptoms of irritability, impulsivity, and headache (Figure 1). Obese and overweight patients were significantly more likely to report symptoms of irritability vs healthy-weight and underweight patients ($p = 0.048$). A similar result was found for impulsivity, with obese and overweight patients significantly more likely to report symptoms of impulsivity vs healthy-weight and underweight patients ($p = 0.01$).

Headache was the most common symptom for all patients, with 85% of patients reporting headache. Headache was statistically more likely to be reported by healthy-weight and underweight patients vs obese and overweight patients ($p = 0.03$). In addition, the median BMI percentile of those reporting headache was significantly lower vs patients without headache (75% vs 88%, $p = 0.02$).

**Body Mass Index and Football versus Nonfootball Players**

There was no statistically significant difference between the BMI of patients (all male) with football-related concussions ($n = 78$) and other male patients ($n = 79$). There were 35 obese and overweight football players and 32 obese and overweight male nonfootball players ($p = 0.58$).

**DISCUSSION**

Because of the increasing prevalence of both obesity and concussion among adolescents, it is important to understand how these two factors may interact and/or affect each other. To date, there is minimal evidence exploring this relationship. One study found obese athletes to be at greater risk of increased recovery time after a sports-related concussion, whereas another report suggested BMI was not an associated risk factor for the development of postconcussion syndrome.22,23

In the current study, overweight and obese patients with concussion were more likely than healthy-weight and underweight patients to report symptoms of irritability and impulsivity. Psychological complications of pediatric obesity include social stigma, depression, and low self-esteem.25 Although our data did not find a difference in the reporting of depression between overweight and obese patients compared with healthy-weight and underweight patients, irritability may suggest depression.26,27 In addition, asking patients if they are sad or depressed is not an accurate screening tool for depression.28,29 This may be especially important to consider because a common practice in concussion evaluation and management in athletes is completion of the Sports Concussion Assessment Tool 3 (SCAT3) that addresses the following 4 emotional symptoms: More emotional, irritability, sadness, and nervous or anxious.15 In addition, it has been reported that postconcussion symptom scales do a poor job of identifying patients with a psychiatric disorder.10 A more extensive screening using a depression and anxiety screening tool, such as the Patient Health Questionnaire (PHQ-9), should be considered in overweight and obese patients with concussion.

It is unclear why overweight and obese patients were less likely to report headache compared with healthy-weight and underweight patients, although the rates of reported headache in both groups were high. *Posttraumatic headache* is defined as a headache that develops within 7 days after head trauma or regaining consciousness; the incidence of reported headache after a concussion ranges from 31% to 96%.31-35 Posttraumatic headache usually resolves within a few weeks, but some patients may experience chronic headaches.36 Being overweight or obese did not appear to be a risk factor for the development of chronic headache or a more prolonged recovery time. It is important to assess for headache in all patients after concussion and to provide appropriate anticipatory guidance and treatment.
This study showed that adolescent male athletes who suffer a concussion are more likely to be obese or overweight compared with adolescent female athletes who suffer a concussion. If there is a higher rate of obesity in the male population compared with females, this may reflect the population. Football is a common mechanism for concussion in adolescent boys but not in adolescent girls, and the average BMI for football players may be higher compared with athletes who participate in other sports. There was no statistically significant difference in BMI, however, between football players and other male athletes. Additional studies to better understand this observation are warranted. Race has been previously shown to be a factor in extended recovery time. However, we did not assess this in our study. Race has been previously studied and shown not to be a factor.23

This study has several limitations. Although the sample size was relatively large, the study was a retrospective chart review and the number of subjects that fell into the underweight BMI category was very small. Height and weight were not measured for all patients at presentation to the concussion clinic and had to be obtained from other patient encounters. Information on BMI was included in the study if it was measured within 1 year of the date of concussion, which may reduce accuracy if there was rapid weight gain or loss. Of the 303 patients who met inclusion criteria for the study, BMI data were not available for 51 (17%) of the patients, and these patients were excluded from the study. BMI itself is a screening tool and has some limitations; however, it is a simple way to estimate adiposity. In fit athletes, BMI may overestimate total body fat because muscle weighs more than fat and athletes tend to have a higher proportion of muscle compared with the general population. Measuring total body fat is a better predictor but is difficult to accomplish. Resolution of concussion was defined as the final visit, which may have overestimated recovery time. The rate of no-shows and incomplete follow-up (“lost-to-follow-up”) was not assessed. This rate was estimated, however, to be low at approximately 5% but may underestimate the time of recovery because these patients were not included in the study. Although every effort was made to capture all patients within the designated timeframe, some may have been missed. Finally, all patients were seen at a regional concussion clinic in central Pennsylvania, and the results may not reflect patient populations from other regions.

CONCLUSION

Overweight and obese patients with concussion were more likely than healthy-weight and underweight patients to report symptoms of irritability and impulsivity, and were less likely to report headache. This study did not find an association between obesity and concussion recovery time. These findings might assist the clinician in the evaluation, treatment, and anticipatory guidance of patients with concussions. This is the second known study that has found an association between BMI and sports-related concussion. Additional well-designed studies should be developed to better determine causality. ♦

Disclosure Statement

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

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How to Cite this Article


References

Rattling Around

Scarily, football helmets, which do a fine job of protecting against scalp laceration and skull fracture, do little to prevent concussions and may even exacerbate them, since even as the brain is rattling around inside the skull, the head is rattling around inside the helmet.

— Jeffrey Kluger, b 1954, Time Magazine senior science writer
ABSTRACT

Context: Many patients with ductal carcinoma in situ (DCIS) receive treatment that is too extensive.

Objective: To take a holistic approach in comparing the effectiveness in cancer prevention between mastectomy and breast-conserving surgery (BCS) for patients with DCIS.

Design: Female Kaiser Permanente Southern California members who underwent surgery for treatment of single primary DCIS from 2004 to 2014 were identified by the Kaiser Permanente Southern California cancer registry and HealthConnect database.

Method: Two-stage residual inclusion with the surgeon's preference of surgical procedure type as the instrumental variable was used to examine the effect of surgical choice on DCIS recurrence, breast cancer progression, and other cancer progression. Traditional Cox proportional hazards models were used for comparison.

Results: Of qualified subjects, 72.2% underwent BCS and 27.8% underwent mastectomy. Patients were likelier to receive BCS if their surgeon preferred to perform BCS in the past 5 years (odds ratio = 1.02, 95% confidence interval = 1.02-1.03). Although traditional Cox proportional hazards models suggested an association between BCS and higher risk of DCIS recurrence, no significant effect was observed when we adjusted for endogeneity. Neither model showed significant differences between mastectomy and BCS in progression of any cancer.

Conclusion: No significant benefit was observed with a more aggressive surgical procedure in preventing DCIS recurrence or cancer progression in a diverse population. Many patients with DCIS could benefit from BCS with preservation of their body image. Breast conservation followed up with cancer surveillance is a rational approach to ensure affordable, effective care for patients with DCIS.

INTRODUCTION

Ductal carcinoma in situ (DCIS) is the earliest form of breast cancer presented in ductal cells. Because the cancer has not grown outside the mammary ducts, DCIS is considered noninvasive. Since the advent of mammographic screening, the DCIS incidence rate in the US markedly increased from 1.78 per 100,000 women in the 1970s to 32.5 per 100,000 women in 2004, then reached a plateau.1-3

According to National Comprehensive Cancer Network guidelines, options for DCIS treatment include lumpectomy with or without radiation therapy (commonly known as breast-conserving surgery [BCS]) and total mastectomy.1 Treatment decisions are usually based on a variety of factors, including the patient’s history, physical findings, bilateral mammograms, pathologic findings, tumor estrogen receptor (ER) status, genetic counseling, and results of breast magnetic resonance imaging.4 Because DCIS is noninvasive, surgeons’ attitudes regarding optimal management and patient preference may play an increased role in treatment decisions.5

Mastectomy is an invasive procedure that results in removal of the patient’s entire breast. In addition to side effects and complications, women may feel differently about their bodies and themselves after mastectomy. These feelings may cause distress for some women, which could drastically reduce their quality of life and may trigger an additional burden in the health care system. Guidelines from the National Comprehensive Cancer Network suggested mastectomy should be the last resolution for DCIS if BCS is unsuitable or rejected. However, the study shows that since 2003, more women with a diagnosis of early-stage breast cancer who are eligible for lumpectomy chose mastectomy. The adjusted odds of mastectomy in BCS-eligible women increased by 34% from 2003 to 2011.6

Many patients with DCIS receive treatment that is too extensive.7-9 In this study, we sought to challenge the misconception that mastectomy is superior to BCS in preventing cancer progression. We compared surgical effects of mastectomy and BCS for DCIS recurrence and cancer progression in real-world clinical settings. We also evaluated patient- and surgeon-specific factors associated with the choice of surgical type. The surgeon’s experience and preference have effects on choice of surgical type, but the final choice is made by both parties (patient and surgeon). Finally, we used an instrumental variable to mitigate bias caused by confounding by indication for surgical choice in a nonexperimental study setting.

METHODS

Study Population

The study population included patients from Kaiser Permanente (KP) Southern California (KPSC), which is an integrated health system that serves more than 4.2 million residents of Southern California.10 The KPSC Region includes 14 hospitals and more than 1,900 medical offices by a partnership of more than 6,600 medical specialists. The study population from KPSC is socioeconomically, ethnically, and racially diverse, and is generally representative of the population residing in Southern California.
California. Membership in KPSC can be obtained by enrolling through the Kaiser Foundation Health Plan and provides its members with prepaid health care insurance and pharmaceutical benefits.

Data Sources

We used the KPSC’s cancer registry and electronic medical records (EMRs) as the primary data sources for the study. Through the KPSC cancer registry, we obtained data on all patients who received a diagnosis and/or treatment of a new or prevalent cancer.

Inpatient and outpatient clinical databases of KPSC’s EMRs were searched for the diagnosis and treatment of cancer to identify cancer cases. For each new diagnosis, an abstract was prepared, and the information pertaining to it was included in the cancer registry. In addition, all data collected for the study were reported to the State of California and to the Los Angeles Surveillance, Epidemiology, and End Results Program in a standardized format no later than six months after diagnosis. The data collected contained each patient’s medical record number, date of diagnosis, primary site of tumor, histologic results, cancer stage at diagnosis, date of past contact, vital status, and treatment received for each cancer. The EMRs included details of the patients’ interactions with the health care system and were used to create datasets, including detailed information on inpatient and outpatient visits, diagnoses, procedures, vital signs, laboratory and imaging results, and prescriptions used. In addition, information regarding patients’ external medical claims was extracted to provide the details of patients’ use of services and surgeons outside KPSC.

The KPSC membership databases were used to extract information pertaining to patient demographics and Health Plan enrollment, and these data were supplemented by mapping geocoded income and education-level information collected by the census tract.

Study Design and Subjects

This was a retrospective cohort study among members of the KPSC Health Plan who were identified as receiving a diagnosis and treatment of DCIS between January 1, 1998, and June 31, 2014. Patients were followed-up from the surgery date until occurrence of the selected outcome or censoring. Patients were censored if they died or disenrolled from the KP Health Plan, or if the study ended (December 31, 2014). The study was approved by the KPSC institutional review board.

![Flowchart of study cohort selection](chart.png)

**Figure 1. Flowchart of study cohort selection.** Left panel (boxes) illustrates the process of study cohort selection with application of inclusion and exclusion criteria. Right panel demonstrates the timeline of patients’ data inclusion. Dashed line indicates that patients’ data were collected from 1998 to December 31, 2014. Solid line indicates that the study cohort included patients who received surgical treatment between 2004 and June 30, 2014, and we followed them until the end of the study (December 31, 2014). DCIS = ductal carcinoma in situ; KP = Kaiser Permanente; KPSC = Kaiser Permanente Southern California.

| Table 1A. Patient demographic characteristics of study cohort by type of surgical procedure received for ductal carcinoma in situ (N = 1242)** |
|-----------------|-----|-----|-----|-----|
| **Characteristic** | **BCS** | **Mastectomy** | **Total** | **p value** |
| **Patient demographic characteristics** | | | | |
| Race | | | | |
| White | 444 (49.7) | 160 (46.4) | 604 (48.7) | 0.30 |
| Nonwhite | 450 (50.3) | 185 (53.6) | 635 (51.3) | |
| Partner status | | | | |
| Partnered | 559 (62.7) | 210 (61) | 769 (62.2) | 0.60 |
| Not partnered | 333 (37.3) | 134 (39) | 467 (37.8) | |
| Age at diagnosis, y (Mean, SD) | 59.9 (10.44) | 59.2 (11.07) | 59.7 (10.62) | 0.46 |
| < 60 | 436 (48.6) | 173 (50.1) | 609 (49) | 0.63 |
| ≥ 60 | 461 (51.4) | 172 (49.9) | 633 (51) | |
| **Patient socioeconomic status** | | | | |
| High school graduate and above | | | | |
| 0%-50% | 35 (3.9) | 7 (2.1) | 42 (3.4) | 0.26 |
| 51%-75% | 210 (23.5) | 82 (23.8) | 292 (23.6) | |
| 76%-100% | 648 (72.6) | 255 (74.1) | 903 (73.0) | |
| Median household income, US$ | | | | |
| ≤ 45,000 | 194 (21.7) | 65 (18.9) | 259 (20.9) | 0.43 |
| 45,001-80,000 | 424 (47.5) | 176 (51.2) | 600 (48.5) | |
| > 80,001 | 275 (30.8) | 103 (29.9) | 378 (30.6) | |

**Data are number (percentage) unless otherwise indicated. BCS = breast-conserving surgery; SD = standard deviation.**
Using KPSC cancer registry data, we identified 3887 female adult KPSC members who received a diagnosis of single primary DCIS between January 1, 1998, and December 31, 2014 (Figure 1). To ensure that every patient had at least 6 months’ follow-up until the end of the study, we excluded patients with a DCIS diagnosis obtained after June 30, 2014. A total of 3212 patients had continuous KP membership for at least 1 year before and 6 months after their surgery dates, with a 45-day gap allowed. Moreover, 2171 patients who received either lumpectomy or mastectomy were matched to the KP HealthConnect electronic database for corresponding surgeon information.

Among these patients, 1381 patients’ surgeons were employed at KP for at least 5 years and performed at least 3 surgeries in the 5 years before this patient’s surgery date. To ensure that all surgeons in the study period had complete data for the previous 5 years, the surgery data collected between 1998 and 2003 were used as a baseline for surgeons who performed surgery in 2004. A total of 1242 patients who had surgical treatment of DCIS between 2004 and 2014 remained in the final study cohort.

### Outcome Measures

The outcomes of interest for this study included DCIS recurrence (International Classification of Diseases, Ninth Revision [ICD-9] Code 233.0), breast cancer progression (ICD-9 Codes 174.0-174.9), and other cancer progression (ICD-9 Codes 140-239 other than 174 and 233.0). These 3 cancer outcomes were tracked 6 months after surgery, with a diagnostic documentation requirement from 2 separate visits, at least 30 days apart, to the Oncology Department within a 180-day period.

### Covariates

We examined patients’ demographic characteristics (age at diagnosis, race, and partner status), patients’ clinical characteristics (weighted Charlson Comorbidity Index, cancer comedo type, lateral status, tumor differentiation grade, ER and progesterone receptor [PR] status, tumor size, and radiation therapy), and patients’ socioeconomic status (neighborhood high school graduation rate and neighborhood median household income range). See Tables 1A and 1B.

We used age 60 years as the cutoff point to dichotomize our age group, and grouped the race variable as white vs nonwhite, because DCIS risk increases for women older than 60 years, and white women have a higher risk of DCIS. Partner status was dichotomized into partnered (married, common-law, and registered domestic partner) and nonpartnered (single, divorced, widowed, legally separated, and separated) on the basis of patients’ self-reported marital status.

We generated the Charlson Comorbidity Index with modified weight to represent the burden of comorbid conditions for each patient. This index was dichotomized into good (0 or 1) vs poor (≥ 2). Comedocarcinoma is confined to the breast ducts and usually does not spread beyond but is considered a higher grade and more aggressive than other types of DCIS. Comedocarcinoma is characterized by the presence of central necrosis and identified using the patient’s histologic

| Table 1B. Patient clinical characteristics of study cohort by type of surgical procedure received for ductal carcinoma in situ (N = 1242)* |
|-----------------------------------------------|-----------------|-----------------|-----------------|---------------|
| Characteristic                               | BCS             | Mastectomy      | Total           | p value       |
| Patient clinical characteristics             |                 |                 |                 |               |
| Charlson Comorbidity Index (weighted)         |                 |                 |                 |               |
| 0 or 1                                       | 736 (82.1)      | 287 (83.2)      | 1023 (82.4)     | 0.64          |
| ≥ 2                                          | 161 (17.9)      | 58 (16.8)       | 219 (17.6)      |               |
| Comedo type                                  |                 |                 |                 |               |
| Comedo carcinoma                             | 86 (9.6)        | 42 (12.2)       | 128 (10.3)      | 0.18          |
| Other                                        | 811 (90.4)      | 303 (87.8)      | 1114 (89.7)     |               |
| Lateral status, original site of primary tumor|                 |                 |                 |               |
| Right side                                   | 460 (51.3)      | 179 (51.9)      | 639 (51.4)      | 0.85          |
| Left side                                    | 437 (48.7)      | 166 (48.1)      | 603 (48.6)      |               |
| Estrogen receptor status (ERα-breast)         |                 |                 |                 |               |
| Positive                                     | 573 (88.2)      | 214 (82)        | 787 (86.4)      | 0.01          |
| Negative                                     | 77 (11.8)       | 47 (18)         | 124 (13.6)      |               |
| Progesterone receptor status (PRα-breast)     |                 |                 |                 |               |
| Positive                                     | 405 (84.2)      | 155 (77.9)      | 560 (82.4)      | 0.05          |
| Negative                                     | 76 (15.8)       | 44 (22.1)       | 120 (17.6)      |               |
| Differentiation grade                        |                 |                 |                 |               |
| Well or moderately differentiated             | 535 (64.1)      | 170 (52.6)      | 705 (60.9)      | < 0.01        |
| Poorly or undifferentiated                   | 299 (35.9)      | 153 (47.4)      | 452 (39.1)      |               |
| Tumor size                                   |                 |                 |                 |               |
| < 2.5 cm                                     | 664 (87.4)      | 216 (69.2)      | 880 (82.1)      | < 0.01        |
| ≥ 2.5 cm                                     | 96 (12.6)       | 98 (30.8)       | 192 (17.9)      |               |
| Radiation therapy status                     |                 |                 |                 |               |
| No                                           | 397 (44.3)      | 333 (96.5)      | 730 (74.1)      | < 0.01        |
| Yes                                          | 500 (55.7)      | 12 (3.5)        | 512 (25.9)      |               |
| Follow-up (y)                                |                 |                 |                 |               |
| DCIS recurrence, mean (SD)                   | 3.6 (2.85)      | 3.9 (2.71)      | 3.7 (2.81)      | 0.15          |
| Breast cancer progression, mean (SD)         | 4.3 (2.77)      | 4.0 (2.55)      | 4.2 (2.71)      | 0.06          |
| Other cancer progression, mean (SD)          | 4.5 (2.81)      | 4.1 (2.67)      | 4.4 (2.78)      | 0.04          |
| Patients’ corresponding surgeons             |                 |                 |                 |               |
| Surgical preference for BCS in last 5 y on subjects’ surgery dates, mean (SD) | 71.3 (16.90) | 63.3 (20.44) | 69.1 (18.30) | < 0.01 |
| Years employed with KP, mean (SD)            | 13.9 (7.02)     | 13.9 (6.49)     | 13.9 (6.87)     | 0.66          |
| Years since receiving MD, mean (SD)          | 20.2 (8.02)     | 20.2 (8.76)     | 20.2 (7.69)     | 0.35          |

* Data are number (percentage) unless otherwise indicated.

BCS = breast-conserving surgery; DCIS = ductal carcinoma in situ; KP = Kaiser Permanente; MD = medical degree; SD = standard deviation.
type. Lateral status (right vs left) was considered because the frequency of occurrence of left-sided breast cancer is higher than right-sided breast cancer.\textsuperscript{15} We considered ER and PR status because ER drives a tumor in the breast to grow and stimulates cell proliferation,\textsuperscript{13} and PR expression is used as a biomarker of estrogen receptor-\(\alpha\) (ER\(\alpha\)) function and breast cancer prognosis.\textsuperscript{14} The degree of differentiation in the final pathologic diagnosis was used to represent differentiation status of tumor grade. We categorized the tumor differentiation grade into well or moderately differentiated vs poorly differentiated or undifferentiated. Tumor size was dichotomized into large tumor size (\(\geq 2.5\) cm) and small tumor size (<2.5 cm). The cutoff point for tumor size was based on study results indicating that large tumor size is associated with higher risk of residual disease and recurrence,\textsuperscript{15} as well as with microinvasion or invasive carcinoma and risk of axillary metastasis in patients with DCIS.\textsuperscript{16} We also included radiation therapy status as one of the covariates because study findings show that radiation therapy is effective in reducing the risk of local recurrence in patients with DCIS after BCS.\textsuperscript{17,19} Multiple imputations using predictive mean matching\textsuperscript{20} were performed to generate a complete dataset for analysis while filling the missing records in PR, ER, tumor size, tumor grade, race, and partner status. To avoid colinearity caused by PR and ER, only ER was included in the model.

Each patient’s socioeconomic status was assessed using his/her neighborhood of residence (subject’s ZIP code) from the 2000 US Census. Median household income and the proportion of residents who had a high school education or above were evaluated in the patient’s ZIP code. These variables were categorized into quartiles and reported in Table 1A, but they were not included in the model.

**Excluded Instruments**

The lack of random assignment to treatment in real-world clinical settings causes bias when evaluating the treatment benefit using observational data.\textsuperscript{21} Instrumental variable approaches were documented in multiple clinical contexts to untwine the endogeneity of unmeasured burden of illness in treatments and outcomes.\textsuperscript{22-28} An instrumental variable is defined as a factor strongly associated with treatment choice but has no direct effect on outcomes (except through the endogenous exposure) and is orthogonal to the error.\textsuperscript{29} The assumptions of instrumental variables correct for confounding and control for measurement error.\textsuperscript{30} We considered 3 surgeon-level variables as instrumental variable candidates because they are associated with the type of treatment options and are independent to patients’ characteristics and disease progression: 1) surgical preference for BCS in the last 5 years from subjects’ surgery dates, 2) years since the start of KPSC employment, and 3) years since receiving a medical degree. See Table 1B.

**Statistical Analysis**

We investigated the association between the surgical types and patients’ characteristics using the chi-square test for categorical variables and the \(t\)-test for continuous variables. In addition, we used the Kaplan-Meier method to generate time-to-event curves to assess the unadjusted rate of cancer progression by surgical type. We also applied a conventional Cox proportional hazards (PH) model to evaluate the association between the surgical type and the hazard of cancer recurrence or progression while adjusting for relevant confounders. Separate regression models were specified for each of the three outcomes. We verified the validity of the PH assumption with log-minus-log plots for all Cox PH models.

To select a valid instrumental variable, we explored the association between the selection of surgical type and the surgeons’ experience, using multiple logistic regression with confounding adjustment. The model did not support the association between surgical type and the surgeons’ years since employed in KPSC, or years since receiving a medical degree. We chose the surgeon’s surgical preference for BCS in the past five years as the instrumental variable in our model, because it demonstrated a statistically significant association with surgical type, and it was not independently associated with any outcomes. \(F\) statistics validated that surgeon’s surgical preference for BCS in the past five years was a strong instrumental variable. We further verified its validity by examining its association with selected patient-level characteristics.

In the first stage of the 2-stage residual inclusion (2SRI) model (Figure 2), we performed multiple logistic regression by regressing patients’ surgical type on the selected instrumental variable (surgeon’s surgical preference for BCS in last 5 years) and adjusted for age, race, partner status, Charlson Comorbidity Index, comedo type, lateral status, tumor grade, ER, tumor size, and radiation therapy. We calculated the raw residuals by subtracting the predicted likelihood of receiving BCS vs mastectomy from the actual value of the treatment received. These residuals from the first-stage model
were incorporated as additional covariates, along with the endogenous surgical type variables and selected covariates. The Cox PH model was applied in the second stage to explore the relationship between time to cancer progression and surgical type. We visually verified that PH assumption was not violated by inspecting the log-minus-log plots. Three outcomes were assessed in the second stage. The instrumental variables operated as a natural randomization tool to assign patients to each type of treatment group and to compare groups of patients who differ in their likelihood of receiving treatment, rather than to compare patients on the actual treatment received where potential bias is concealed.26,27,31-33

For hypothesis testing, we applied the bootstrapping method to generate standard errors and 95% confidence intervals (CIs) for the hazard ratio (HR) estimates since analytical errors are undefined. A total of 2000 samples of the original cohort were bootstrapped with replacement.

Furthermore, adjusted survival curves for DCIS recurrence, breast cancer occurrence, and other cancer occurrence were obtained by a marginal approach.34 The resulting adjusted survival curves present expected survival curves calculated on the basis of the Cox model where subgroups were balanced with respect to the confounding variables.

All statistical tests were 2-sided. A p value less than 0.05 was considered statistically significant. All analyses were performed with SAS EG (Version 9.3; SAS Institute Inc, Cary, NC) and R (R core team, R Foundation, Vienna, Austria, 2015).

RESULTS

The age of the patients in the final study cohort ranged from age 28 years to age 90 years. We identified that 49% of the patients were white and 51% nonwhite. Of the 1242 patients in the study cohort, 897 (72.2%) underwent BCS for DCIS treatment (Table 1A). Patients who underwent mastectomy had a higher rate of negative results for ER (p = 0.01) and PR (p = 0.05). Patients who received mastectomy were more likely to have a poorly differentiated or undifferentiated tumor (p < 0.01; Table 1B). More patients who received BCS were treated by surgeons who preferred to perform BCS in the preceding 5 years (p < 0.01). No evidence was found for an association between patient’s surgical type and the length of the surgeon’s employment.

After adjusting for age, race, partner status, Charlson Comorbidity Index, comedo type, lateral status, tumor differentiation grade, ER status, tumor size, and radiation therapy, we found that for every 1% increase in surgeons’ preference of BCS in the past 5 years, their current patients were 3% more likely to receive BCS (OR = 1.03, 95% CI = 1.02 - 1.04, Table 2). In addition, patients who had well or moderately differentiated tumors were 50% more likely to receive BCS (OR = 1.99, 95% CI = 1.41 - 2.80).

Unadjusted time-to-event curves for the 3 outcomes by type of surgical choice are illustrated in Figure 3. Without any adjustment, the Kaplan-Meier curves separated DCIS recurrence for the 2 treatment groups. For the BCS group, the probability of being DCIS free at 1 year was approximately 85%, and at 5 years was about 70%. The recurrence-free probability was around 93% at 1 year and 88% at 5 years for patients who underwent mastectomy. Both curves reached a plateau after 5 years. The breast cancer progression appeared similar for the 2 surgical groups until 9 years after treatment. The progression to other cancers seemed similar for both surgical choices. The estimates of crude HRs are consistent with these observations (Table 3).

After adjusting for the same set of confounders, the conventional Cox PH model detected that patients who received BCS were 86% more likely to encounter DCIS recurrence over time (HR = 1.86, 95% CI = 1.26 - 2.74, Table 3) than those who received mastectomy. For breast cancer (HR = 1.08, 95% CI = 0.53 - 2.23)
and other cancer progression (HR = 1.18, 95% CI = 0.37 - 3.76), the Cox PH model failed to uncover any significant beneficial effect of mastectomy over BCS.

Interestingly, after applying the instrumental variable method to account for endogeneity in the model, the 2SRI model framework altered the directions of the estimated treatment effects of BCS and mastectomy from the conventional Cox PH model for all 3 outcomes: DCIS recurrence (HR = 0.57, 95% CI = 0.13 - 1.97), breast cancer progression (HR = 0.38, 95% CI = 0.03 - 3.82), and other cancer progression (HR = 0.05, 95% CI = 0.001 - 1.61). The expected survival curves adjusted for confounders (Figure 4) showed agreement with the model estimates. BCS appeared to contribute to a higher risk of DCIS recurrence compared with mastectomy in the conventional Cox PH model; however, this effect was overturned in the 2SRI model. The conventional Cox PH model did not clearly separate the event-free probabilities between BCS and mastectomy for breast cancer progression and other cancer progression. The separations are pronounced with the 2SRI model framework, where BCS appeared to be associated with lower risks of breast and other cancer progression.

**DISCUSSION**

In this study, we compared the disease-free survival of patients with DCIS who received BCS vs those who received mastectomy. The goal of DCIS treatment is to prevent DCIS recurrence and cancer progression. Previous studies found that BCS resulted in lower disease-free survival rates than mastectomy in patients with DCIS. Such a finding may have led many women to believe that mastectomy is the last resort for breast cancer treatment, even at a very early stage. However, the estimates generated by our 2SRI model framework favored BCS over time. Our results demonstrated no significant difference in disease-free survival rates comparing BCS and mastectomy for patients with DCIS in real-world clinical practice. The estimated HRs suggested that BCS may contribute to longer adjusted disease-free survival than mastectomy, although these findings were not statistically significant.

Studies in value-based care have raised the attention of health care policy makers to seek ways to balance cost (efficiency) and clinical benefit (effectiveness). Compared with BCS in the longer term, mastectomy was found to be associated with higher complication risk and greater adjusted total cost and complication-related cost. The results from our study, combined with the fact that reliable prediction methods of DCIS recurrence for women treated with BCS are now plausible, suggest that BCS followed-up with cancer surveillance is a rational approach to ensure affordable and effective care for patients with DCIS.

Previous studies found substantial differences among surgeons in surgical treatment. It is unclear how strictly surgeons comply with standard treatment guidelines. The guideline-based surgical options for DCIS generally come from recommendations rather than from evidence from randomized clinical trials. Therefore, surgeons are often uncertain about the best clinical management for patients with DCIS because of the lack of evidence base for the recommendations. On the other hand, experienced surgeons may be more confident in performing the type of surgery with which they have seen better results in the past. Our results support this implication by showing that the likelihood for a surgeon to perform BCS increases if s/he was more experienced with BCS in the past.

It is unrealistic to conduct randomized clinical trials in all situations where evidence is needed to guide health care. The instrumental variable approach used in this study adjusted for unmeasured confounders and accounted for endogeneity in the

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**Figure 3.** Kaplan-Meier unadjusted time-to-event curves stratified by type of surgical procedure received for treatment of single primary ductal carcinoma in situ (DCIS). Left curve illustrates event-free probability for DCIS recurrence; middle and right curves demonstrate event-free probability for breast cancer progression and other cancer progression, respectively. Solid lines represent that patients received breast-conserving surgery (BCS); dashed lines represent that patients received mastectomy. The p values were generated using a Cox proportional hazards model to assess the statistical significance for the difference between patients who received BCS and those who received mastectomy.
Comparative Effectiveness of Surgical Options for Patients with Ductal Carcinoma In Situ: An Instrumental Variable Approach

model using observational data, which maintained one of the usual benefits of randomized clinical trials. We identified each surgeon’s surgical preference as a strong instrumental variable to adjust for endogeneity in the relationship between cancer progression and treatment options. We concluded that the prevention of DCIS recurrence does not necessarily benefit from more invasive surgical procedures. Furthermore, in prevention of breast cancer and other cancer progression, BCS may contribute to higher cancer-free survival than does mastectomy. Our study provides a strong evidence base for recommendations in standard guidelines about selecting treatment type for both clinicians and patients while making individual treatment plans.

Compared with traditional methods, our instrumental variable approach accounted for endogeneity and obtained consistent estimates. We were able to identify a strong instrumental variable true to how physicians practice: The volume of past experience is representative of the surgical preference. In addition, there are many advantages in using KPSC data. The KPSC cancer registry and KP HealthConnect database ensured rich data resources and adequate sample size (supplementary methods). We were able to identify a heterogeneous population, which includes younger women and a variety of races, whereas many previous studies were restricted by rules and regulation of Medicare, Medicaid, or other insurance policies. Moreover, because KP surgeons are not affected by the insurance reimbursement, the choice for surgical type will not be affected by the difference in procedure costs. Furthermore, KPSC Medical Centers have facilities equipped with surgeons and surgical equipment all over the KPSC service area; therefore, the choice for surgical type will not be limited to the availability of and accessibility for one type of surgery over the other.

We used the 2SRI method to incorporate our instrumental variable of selection in a nonparametric model. A more popular method to implement instrumental variables in linear regression models is a 2-stage least-squares model, because it serves as the basis for most practitioners’ understanding of assumptions and implementation of instrumental variable models. However, nonlinear regression models, including generalized linear models, are often more appropriate for many questions in health care research. Conventional 2-stage least squares fails to account for event time and disregards censoring, which may produce biased estimates in these inherently nonlinear situations. On the other hand, 2SRI, a rote extension of 2-stage least squares with modifications, focuses especially on correcting for endogeneity bias in nonlinear models. The consistency of 2SRI estimation ensures its superiority in nonlinear models.

We encountered a number of limitations in this study. First, our dataset came with incomplete records for some important clinical factors such as tumor size and status of ER and PR. We subsequently performed multiple imputation to mitigate this limitation. Second, a diverse distribution of physician experience was observed. We assumed a normal distribution for the numbers of surgeries performed for each surgeon in the past years. Third, the weight of patients’ predilection in their

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**Figure 4.** Expected survival curves adjusted for confounders. The upper panel illustrates event-free probability using conventional CoxPH adjusting for confounders for DCIS recurrence, breast cancer progression, and other cancer progression, respectively. The lower panel illustrates event-free probability using 2SRI framework with instruments adjusting for confounders for DCIS recurrence, breast cancer progression, and other cancer progression, respectively. Solid lines represent that patients received breast-conserving surgery (BCS); the dashed lines represent that patients received mastectomy.

CoxPH = Cox proportional hazards model; DCIS = ductal carcinoma in situ; 2SRI = two-stage residual inclusion estimation instrumental variable analysis.
treatment selection was not quantified. Patients have different priorities in life and different levels of pain tolerance. The heterogeneity of their attitudes play a role in their choice of health management style. This may potentially be accounted for by a patient–level instrumental variable, which requires further exploration.

In addition, radiation therapy is currently included in our model framework as a confounder, because radiation treatment after lumpectomy has resulted in increased disease-free survival for patients compared with lumpectomy only. For future studies, we will consider incorporating radiation therapy as an element for treatment stratifications. This requires us to redefine instrumental variables and reconstruct our model, but the fundamental idea remains.

Last but not least, antiestrogenal hormonal use was not included in our model. Tamoxifen treatment was found to reduce the risk of new DCIS events and contralateral invasive breast cancers, but it was also accompanied with a significantly adverse effect on the quality of life. Future studies are needed to investigate treatment effects on cancer progression with consideration of these additional treatment levels, and to compare the cost-effectiveness in terms of the prevention power and the trade-off for quality of life.

CONCLUSION

Despite the limitations, the results from this study provide supportive evidence to improve standard treatment guidelines, and to help physicians to present cogent statistical evidence while discussing treatment options with their patients. Our results have shown that BCS is a notably favored surgical option among experienced surgeons for treating DCIS. Above all, we have demonstrated that a more invasive surgical procedure (mastectomy) does not guarantee better results of cancer prevention. Further studies are needed to investigate the roles and implications of relevant risk factors associated with the likelihood of recurrence and progression in patients with early-stage breast cancer, so that patients and surgeons can make evidence-based decisions regarding treatment options without the avoidable sacrifice of quality of life.

Disclosure Statement

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

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How to Cite This Article


References


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If Not Treated

It is better not to apply any treatment in cases of occult cancer; for, if treated, the patients die quickly; but if not treated, they hold out for a long time.

— Hippocrates of Kos, 460 BC-370 BC, Greek physician of the Age of Pericles
Visiting Monarch photograph
Robert W Hogan, MD

From the artist: “Planting new milkweed varieties in San Diego has been regally rewarded.”

Dr Hogan is an Associate Clinical Professor at the University of California, San Diego School of Medicine and a Family Medicine Physician at the La Mesa Medical Offices in CA.
ABSTRACT

Introduction: Physician communication is critical to patient care. However, integration of sound communication practice with clinical workflows has proven difficult. In this quality improvement initiative, medical students used the rapid improvement model to test interventions that could enhance patients’ perception of listening by physicians as measured by the Hospital Consumer Assessment of Healthcare Providers and Systems survey.

Methods: Literature review and process analysis yielded 42 potential interventions, of which 24 were feasible for implementation. Small-scale testing established the 4 most promising interventions; pilot testing was subsequently undertaken on the entire Medicine service. Patient and physician feedback guided further refinement. The final intervention used a structured reminder embedded in the electronic health record to direct physicians to begin interviews by eliciting patient concerns.

Results: Patient concerns elicited after implementation included pain symptoms (28%), disease or treatment course (16%), and discharge planning (10%). In the Hospital Consumer Assessment of Healthcare Providers and Systems survey, physician listening scores rose from a 2014 average of 73.6% to 77% in 2015.

Discussion: Among 24 tested interventions, an open-ended question was most feasible and had the greatest perceived impact by hospitalists and patients. A structured reminder embedded in required electronic medical record documentation facilitated the behavioral change without being overly burdensome to physicians and established a mechanism to enact change in practice.

Conclusion: Medical students used established improvement methods to promote patient-centered care and align patient and physician agendas, providing a strategy to improve hospitalized patients’ perceptions of physician listening.

INTRODUCTION

Physician communication is foundational to patient care and has been shown to impact patient satisfaction, adherence to treatment plans, and health outcomes.\(^1\) The Kalamazoo consensus statement, put forth by leaders of major medical organizations and academic institutions on core criteria for effective physician patient communication, emphasized building the physician-patient relationship, active listening, and shared decision making as essential elements of physician communication.\(^2\) The significance of physician communication, and in particular these elements, is emphasized in the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey, the national standard for public reporting of patients’ hospital care experiences. In the HCAHPS survey, patients provide feedback on care received from physicians in the hospital; care comprises how often physicians treated the patient “with courtesy and respect,” “listened carefully” to the patient, and “explained things in a way [the patient] could understand.”\(^3\)

In 2013–2014, the Oakland Medical Center in CA scored in the 76th percentile for physician communication overall\(^4\) and in the 50th percentile for the physician listening subset, falling short of the hospital’s goal to place in the 90th percentile for both measures. To address this gap, 8 third-year medical students in the Kaiser Permanente–University of California, San Francisco Longitudinal Integrated Clerkship (KLIC) developed and implemented an improvement project from July 2014 to May 2015. Prior attempts to increase communication scores at Kaiser Foundation Hospitals–Oakland included communication skills training in the 4 habits model\(^5\) and peer-to-peer feedback; the absence of notable improvement was corroborated by the experience of other institutions.\(^6\) In contrast, this project aimed to apply quality improvement methods including the Plan-Do-Study-Act approach\(^7\) to create and test small-scale interventions that could improve HCAHPS listening subset scores.
METHODS

The Oakland Medical Center is a 349-bed hospital and tertiary referral center. The hospital medicine service consisted of 64 physicians attending on 4 teaching and 4 nonteaching teams. In 2014, 10 of these hospitalists formed a “Project Bedside” task force to drive patient-centered care initiatives; this group served in an advisory capacity for the project reported here. Conducted as a quality improvement activity, the project was considered exempt from review by the institutional review board.

Figure 1 provides an overview of the project design. A literature review on successful physician-patient communication strategies was completed. Given the limited number of studies demonstrating an impact on HCAHPS physician communication scores, the review was expanded to include studies reporting any patient satisfaction measures. Service industry assessments of consumer satisfaction were also included.

The group then turned its attention to detailed observations of patient-physician interactions. The goal was to identify possible elements of the hospital system and physician communication practices that contribute to patients perceiving that their physician was not listening carefully. Observations of communication behaviors and barriers during clinical rounds on inpatient internal medicine teaching and nonteaching teams over a 3-week period were made using time-motion study techniques. Each patient-physician encounter was blocked into 15-second intervals. After each encounter, patients were asked to comment on communication with the physician. Behaviors and patient and physician statements were recorded. Observations were pooled and factors with a negative impact on patients’ perception of listening were extracted. These factors were mapped onto a fishbone diagram using 6 predetermined domains of man, materials, methods, machine, measurement, and milieu (Figure 2).

![Fishbone diagram](image)

Using the fishbone diagram and communication strategies gleaned from the literature review, 42 interventions that could improve perceptions of physician listening were developed (see Sidebar: Potential Interventions to Enhance Patient Perceptions of Physician Listening). The 8 medical students met with a hospital physician liaison and a systems improvement mentor to make binary assessments for each potential intervention of
feasibility (yes/no), potential impact on desired outcome (high/low), and balancing measures (high/low likelihood of having adverse unintended consequences). Group consensus on each parameter was recorded. The 24 interventions deemed to have high feasibility and high impact with low likelihood of having adverse unintended consequences were selected for small-scale testing in phase I.

The testing phases were informed by the Plan-Do-Study-Act framework. During phase I testing sessions, a student attended one day of bedside rounding with one of three “Project Bedside” hospitalists while attending on a nonteaching service, inform- ing the hospitalist in advance of the specific intervention to be attempted. The hospitalist performed each intervention during three or more patient encounters. After rounds, the student and the hospitalist discussed feasibility, effectiveness, and possible modifications for retesting.

Students used this information to organize the interventions on the basis of feasibility and impact. Fourteen interventions were subsequently rejected on the basis of high effort or low impact. Six interventions, closely related to the domain of etiquette-based medicine, were designated as standard practice and not tested further. These were as follows: Closing the door and/or drawing the curtain closed in a room when entering it; introducing oneself and providing a business card; scheduling a return when the patient is in pain, eating, or toileting; using the patient’s preferred name and form of address; turning off the television while talking with the patient; and sitting on a chair during conversations with the patient. The remaining four interventions, described in Table 1, were advanced to phase II. These were as follows: Beginning the patient interview with an open-ended question; giving the patient a hand-held “STOP” sign to signal the need for clarification; managing physicians’ disruptive electronic devices; and involving patients’ families by calling them during rounds.

During phase II, interventions were individually tested by the 4 hospitalists on nonteaching services for 3 days each during 4 consecutive weeks, representing roughly 120 physician-patient encounters for each intervention. Hospitalists were informed of the intervention during physician staff meetings and by e-mail

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### Potential Interventions to Enhance Patient Perceptions of Physician Listening

<table>
<thead>
<tr>
<th>Process changes (methods)</th>
<th>Decreasing distractions (milieu)</th>
<th>Physician behaviors (man)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sit down on chair when talking with patient</td>
<td>Turn off or mute television if on* (standard practice)</td>
<td>Apologize for grievances*</td>
</tr>
<tr>
<td>Patient-centered rounding: Schedule time to return</td>
<td>Shut the door or close the curtain after walking in the room* (standard practice)</td>
<td>Inquire about complaints, apologize, and describe plan to fix at least one*</td>
</tr>
<tr>
<td>Introduce self and give business card to patient</td>
<td>Barrier practice: Leave phone and pager in drop box outside of patient room*</td>
<td>Paraphrase patient’s concerns*</td>
</tr>
<tr>
<td>Document patient’s preferred name on white board</td>
<td>Silence physician devices and acknowledge the interruption verbally each time a pager or</td>
<td>If standing, crouch down to patient’s eye level before leaving*</td>
</tr>
<tr>
<td>in room or in medical record</td>
<td>hospital wireless phone rings while with patient*</td>
<td>Scripted closing before leaving the room: Say goodbye, explain when you will be back, if</td>
</tr>
<tr>
<td>(standard practice)</td>
<td>If patient’s phone rings, ask them to wait to answer it</td>
<td>and not, who will be assuming care*</td>
</tr>
<tr>
<td>Introduce everyone present in the room for rounds</td>
<td>Physician sets a timer before entering room; do not look at clock until timer goes off</td>
<td>Scripted introduction: “My colleague told me all about you. Now I want to spend a few</td>
</tr>
<tr>
<td>Family-centered rounds: Timing rounds when family</td>
<td>Limit rounds to three care team members</td>
<td>minutes just listening to you.”</td>
</tr>
<tr>
<td>present or phone a family member or friend</td>
<td>Acknowledge alarms, sounds in hallway, or overhead announcements when they happen and they</td>
<td>Open-ended question: “What questions do you have?”</td>
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<tr>
<td>when arriving to the room</td>
<td>continue conversation</td>
<td>Open-ended question: “What can I do to improve your stay?”</td>
</tr>
<tr>
<td>See the most interpersonally challenging patient</td>
<td></td>
<td>Open-ended question: “Is there something else I can do for you?”</td>
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<tr>
<td>first during rounds</td>
<td></td>
<td>Open-ended question: “What do you understand about your hospital course so far?”</td>
</tr>
<tr>
<td>Round again at the end of the day on all patients</td>
<td></td>
<td>Open-ended question: “What is your main question or concern for today?”</td>
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<tr>
<td>and review plan for evening and next day</td>
<td></td>
<td>Do not interrupt patient for two minutes at beginning of each encounter</td>
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<tr>
<td>Teach patient to use health resources on</td>
<td></td>
<td>Touch patient on the shoulder or arm to show empathy while listening</td>
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<tr>
<td>television in room</td>
<td></td>
<td>Ask patient: “What do you prefer that I call you?”</td>
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<tr>
<td>Ask patient to make lists of questions for</td>
<td></td>
<td>Avoid “closed” body language including crossing arms</td>
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<tr>
<td>physician ahead of time</td>
<td></td>
<td>Maintain eye contact</td>
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<tr>
<td>Post pictures of care team in room with defined</td>
<td></td>
<td>Reiterate goals before closing a patient encounter</td>
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<tr>
<td>roles</td>
<td></td>
<td>Before examining the patient, ask for permission and tell them what you are looking</td>
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<tr>
<td>Walk directly to patient’s bedside when family</td>
<td></td>
<td>for</td>
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<tr>
<td>members are in the room rather than to where</td>
<td></td>
<td>Ask patient about comfort/pain level</td>
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<tr>
<td>family member is sitting</td>
<td></td>
<td></td>
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</tbody>
</table>

* indicates intervention tested in phase I

* indicates intervention tested in phase I and II
and reminded through text pages and office flyers. They were asked to exclude patients who did not speak English, were unable to communicate verbally, or had dementia or delirium.

At the end of each three-day intervention period, an online questionnaire was sent to hospitalists soliciting input on adherence, impact, sustainability, and balancing measures. Questionnaires contained multiple-choice questions with five-point

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**Table 1. Phase II interventions and results**

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Literature analysis</th>
<th>Process of intervention</th>
<th>Fishbone domain</th>
<th>Patient-reported physician adherence</th>
<th>Patient responses: Key themes</th>
<th>Physician responses: Key themes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beginning the patient interview with an open-ended question</td>
<td>Exciting patient agendas empowers patients to voice concerns and helps them feel heard and prevents late-arrising concerns that prolong encounters.</td>
<td>Hospitals opened each patient encounter with their choice of two scripted phrases: “What is your main question or concern for us today?” OR “What do you understand about your care so far?”</td>
<td>Man</td>
<td>14/28 surveyed patients.</td>
<td>High impact. Patients reported improved communication with physicians: “From the beginning, I felt he wanted to help me … it was refreshing to have someone genuine who isn’t just doing their job.”</td>
<td>High feasibility. Encouraged physicians to be “more mindful to ask these questions early on.” Hesitation in using this intervention when meeting patients for the first time. Main barriers included forgetting or physicians’ agenda superseding other inquiries.</td>
</tr>
<tr>
<td>Stop sign for clarifying jargon</td>
<td>Doctors frequently use medical jargon that interferes with patient understanding.</td>
<td>Hospitals carried copies of a 5” x 5” stop sign printed on red paper, with the words “STOP, Please Explain” printed on the face, to give patients when entering room. Hospitalists were asked to use a scripted set of instructions: “I want to make sure we’re on the same page. Please hold up this sign to interrupt me every time I’m not being clear.”</td>
<td>Material</td>
<td>4/45 surveyed patients given a stop sign; only one patient actively used it with physician.</td>
<td>Insufficient data to assess impact. Patients expressed that the sign helped or would help their physician explain things in more understandable terms. Several patients asked why their physician would not be clear from the outset and others stated s/he did not require a sign to interrupt the physician to clarify jargon.</td>
<td>Low feasibility. Hospitalists reported being more “conscious of avoiding jargon,” even when patient was not using the sign. 4/8 hospitalists thought the stop sign was feasible but reported implementation barriers of forgetting, feeling uncomfortable, and not believing it would improve patient interactions. One suggested increased acceptability on teaching services, as patients might find a physical tool to express confusion when multiple physicians were present more useful and less awkward.</td>
</tr>
<tr>
<td>Managing physicians’ disruptive electronic devices</td>
<td>Interruptions at bedside decrease patient satisfaction.</td>
<td>Hospitals silenced their devices and acknowledge the interruption verbally each time a pager or hospital wireless phone rang in a patient room. Methods of acknowledgment included apologizing for the interruption, stating the call would be returned later, or stating the current conversation with the patient was more important.</td>
<td>Milieu</td>
<td>10/24 surveyed patients recalled hearing their physician’s phone or pager ring, and 9 recalled the physician apologizing or acknowledging an interruption.</td>
<td>Low impact. Patients often felt that hearing their physician’s phone or pager did not affect communication. Patients’ comments included not noticing the call or page because of high background hospital noise and assuming the calls or pages were for urgent issues.</td>
<td>High feasibility. Hospitalists reported a greater sense of humanity: “I feel like this helps remind me that I’m not a robotic shift-worker.” Others reported increased awareness of interruptions and noise. Implementation barriers included difficulty retrieving missed phone numbers and a paradoxical increase in number of calls after silencing because callers immediately called back. There was interest in educating nursing staff to page for nonurgent matters.</td>
</tr>
<tr>
<td>Family-centered rounding phone calls</td>
<td>Parents included in family-centered rounds report higher satisfaction, respect, and careful listening from physicians.</td>
<td>Hospitals asked each eligible patient, “Is there someone else you would like to be part of this conversation by phone?” if the patient answered yes, the hospitalist would attempt to reach the designated family member(s) or friend(s) using a spectralink phone.</td>
<td>Method</td>
<td>7/30 surveyed patients recalled their physician offering to call a family member or friend on the phone. No patients reported a call being made.</td>
<td>Low impact. Patient comments reflected a desire to preserve privacy and autonomy or expressed feeling unprepared for the conversation.</td>
<td>Low feasibility. Implementation barriers included insufficient time and technical concerns with the speakerphone. One physician reflected that patients preferred “agency in their care and privacy over updating everyone in their family.” Physicians felt this intervention would have been more effective for vulnerable patients (nonverbal, non-English-speaking), who were excluded at baseline.</td>
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</table>
Listening Beyond Auscultating: A Quality Initiative to Improve Communication Scores in the Hospital Consumer Assessment of Health Care Practitioners and Systems Survey

Students also approached a convenience sample of patients on the last two days of each testing period to obtain comments about communication with their physicians and entered data on computer tablets. This process adhered to the HCAHPS Quality Assurance Guidelines14; responses were voluntary and anonymous and no patient identifiers were recorded.

After phase II was completed, students led a focus group with participating hospitalists and members of the Project Bedside task force and obtained further qualitative feedback. Of the four interventions tested, the use of the open-ended question was most feasible and had the greatest perceived impact by hospitalists and patients. The specific question was standardized and made more direct: “What is your greatest concern today?” Concerns about sustainability prompted a proposal to modify the standardized hospitalist daily progress note template in the electronic medical record (EMR) from traditional SOAP (Subjective, Objective, Assessment, Plan) format to “ScOAP,” with the “c” designating a header to document patient concerns. Use of a progress note template was already standard practice by hospitalists for documentation; the EMR contained a forcing function such that the “concerns” field had to be addressed or deleted before progress notes could be signed.

During phase III testing, the modified ScOAP template was put in place for three consecutive days on all teaching and nonteaching teams; all hospitalists and residents were informed of the change through e-mail communication and requested to ask the open-ended question during patient encounters. A medical chart review was performed of every progress note written during the three-day period. Charts that documented a diagnosis of dementia or delirium or nonverbal patient were excluded. Text in the “concerns” field was collected and analyzed for presence or absence of a comment and themes in recorded text. Finally, face-to-face interviews with hospitalists were conducted about their experience with the phase III intervention.

RESULTS

Results from phase II are summarized in Table 1. Patient-reported physician adherence served as a tangible process measure, whereas qualitative comments identified themes and likely reasons for relative success or failure of each intervention. Qualitative assessment included comments from patients and physicians. For example, one patient noted his reaction when his practitioner began the interview with an open-ended question: “From the beginning, I felt he wanted to help me to figure out different ways to get down to what’s going on.” One physician comment about the device-silencing pilot reported a greater sense of humanity: “I feel like this helps remind me that I’m not a robotic shift-worker.”

There were several limitations in the data collection process, including time limitations to survey all patients eligible to receive a given intervention and a low response rate among hospitalists to online surveys. Additionally, because HCAHPS quality assurance guidelines prohibit hospitals from asking patients questions with similar phrasing to the HCAHPS survey to avoid response bias, patients could not be directly questioned about physician listening behaviors. These limitations were managed by gathering a convenience sample of patients, allowing for open-ended responses from patients, and gathering additional information from hospitalists through a focus group after phase II and face-to-face interviews after phase III.

Feedback from hospitalists after phase III testing indicated that using the specific open-ended question helped gather relevant information and that the EMR prompt served as a useful reminder. Hospitalists on teaching services noted that residents brought up patient concerns more frequently on rounds during the intervention period. Hospitalists endorsed feeling empowered to address issues meaningful to the patient, and reflected that these concerns may not have been expeditiously addressed otherwise.

Medical chart review of patient concerns documented during phase III revealed the following: Of 150 eligible patient charts, 100 (67%) included physician documentation of patient concerns in the “concerns” field of the ScOAP note. The most common patient concerns included pain symptoms (28%), disease or treatment course (16%), and discharge planning (10%).

In mid-May 2015, two months after the initial three-day pilot, the hospitalist group formally adopted the ScOAP note template following a review of the interventions and implementation experience; its use is ongoing on the medicine hospitalist service.

The Oakland Medical Center’s inpatient medicine service HCAHPS topbox scores, or the percentage of survey respondents indicating that physicians “always” listened carefully, are shown in Figure 3. To calculate a baseline, we used an average score from 2014 of 73.6%. By comparison, the 2015 average was 77%. In calculating an annual average, monthly averages were weighted on the basis number of surveys returned for that month. The trendline confirms a general improvement in scores with time. Notable data points include an improvement during February 2015, corresponding to phase II testing, as well as in June and July 2015, corresponding to the 2 months following full adoption of the ScOAP template. Data are reported in raw HCAHPS scores; in January, the score of 68.2% is below the 25th percentile among hospitals nationally; in June, 74% corresponds to the 50th percentile; in July 82.5% is just below the 90th percentile.

DISCUSSION

This article describes the process of testing and implementing best practices in physician-patient communication in an inpatient setting. Application of the Plan-Do-Study-Act method allowed for pilot testing of 24 unique interventions to improve patients’ perceptions of physician listening and refinement of one intervention that was universally implemented by a large hospitalist service in an integrated health care system. Soliciting a specific patient concern during daily rounds had the greatest feasibility and impact among the tested interventions. This practice is grounded in literature that has demonstrated increased patient satisfaction with patient-centered approaches15 and no compromise in efficiency with...
shared agenda setting. Furthermore, addressing a specific concern allows the opportunity for a physician to express empathy and can help shift an encounter from being task-oriented to care-oriented with explicit interest in the patient’s experience. Postintervention chart review revealed additional targets for patient satisfaction, including pain control and discharge planning.

The results in Figure 3 demonstrate an upward trend in HCAHPS scores over time; because publicly reported HCAHPS score reports did not include standard deviations, statistical analysis using a t-test was not possible. The attention given to listening behaviors during phase II in February 2015 may have contributed to the upward trend in HCAHPS scores during that period followed by a return to baseline scores close to the 50th percentile. This may be explained by the Hawthorne effect, manifested as a change in listening behaviors among physicians knowing that patients were providing input about physician communication during that time period. However, the adoption of the ScOAP note across the Hospitalist Department was associated with another upward trend in scores from June 2015 to July 2015 that did not correspond to observation of behavior and cannot be explained by the Hawthorne effect. We hypothesize that the downtrend starting in September 2015 is likely because physicians less consistently initiated a patient encounter by asking for a specific concern despite the EMR reminder; to sustain an increase in listening scores, other identified system barriers would need to be addressed.

A structured reminder embedded in required EMR documentation may improve patients’ perception of physician listening without being overly burdensome to physicians and establish a concrete mechanism for change in practice. This is consistent with the principle from “lean methodology” of implementing standardized work to establish a new standard practice. The EMR has been shown to be indispensable in various applications including population health management and medication safety; however, because it “organizes encounters around data gathering demands rather than patients’ narratives,” the EMR has had mixed effects in the physician-patient communication domain. This hospitalist group’s experience with the ScOAP note template demonstrates that patient input can shape EMR improvement and that an intervention using the EMR has the potential to enhance patient-centered communication.

Generalizability of these interventions to other medical centers is limited because the use of a departmentally mandated standard progress note template may not be translatable to the workflow of other hospital settings. Students participating in this intervention identified a need to create and test workflows to apply this intervention to non-English-speaking patients or with family members of patients unable to respond to the question. Finally, the assessment of feasibility, acceptability, sustainability, and anticipated impact of potential interventions before phases I and II did not use validated numeric criteria; the same process could lead to a different intervention in another health system. To strengthen this process locally, the selection of interventions was informed by conversations with stakeholders and direct knowledge of the care delivery system.

CONCLUSION

This report describes a trainee-led quality improvement initiative. As medical students and residents become increasingly involved in quality improvement imperatives as a requirement of their training, our experience demonstrates that trainees hold the potential to initiate change in an institution and positively impact patient care practices.

Figure 3. Percentage of HCAHPS survey respondents who indicated physicians “always” listened carefully compared with 2014 baseline.

HCAHPS = Hospital Consumer Assessment of Healthcare Providers and Systems; ScOAP = Subjective, patient concerns, Objective, Assessment, Plan.
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The author(s) have no conflicts of interest to disclose.

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Efficacy of Bilateral Transcutaneous Posterior Tibial Nerve Stimulation for Fecal Incontinence

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ABSTRACT

Context: Posterior tibial nerve stimulation is a new second-line treatment for refractory fecal incontinence.

Objective: To assess the efficacy of bilateral transcutaneous posterior tibial nerve stimulation (BTPTNS) for treatment of fecal incontinence in Japanese patients and its impact on quality of life.

Design: A prospective observational-interventional study was conducted from May 2015 to June 2017 in patients with fecal incontinence in whom conservative treatment had failed. All patients received a 30-minute session of stimulation twice weekly for 6 consecutive weeks. Evaluation at baseline and at 6 weeks involved the Wexner score, Fecal Incontinence Quality of Life (FIQL) questionnaire, and anal manometry. Patients recorded episodes of incontinence in a weekly diary.

Main Outcome Measures: Reduction of 50% or greater in incontinence episodes, decreased Wexner score, and improved FIQL scores.

Results: Twenty-two patients with a median age of 64.1 years (range, 26-81 years) and men:women ratio of 9:13 completed BTPTNS. Mean episodes of fecal incontinence were significantly reduced from 4.7 to 1.5 (p < 0.05). An improvement of 50% or better in episodes of fecal incontinence was achieved in 77.2% of patients. The median Wexner score significantly decreased from 10.2 to 6.9 (p < 0.05). The median FIQL score improved from 2.7 to 3.1 (p = 0.06), and significant improvement was seen in the embarrassment domain (2.2 vs 2.8, p < 0.05). Resting and squeezing anal pressures revealed no significant changes.

Conclusion: Our findings suggest that BTPTNS is safe and well tolerated and may improve symptoms of fecal incontinence. This technique offers an additional noninvasive, less expensive form of treatment.

INTRODUCTION

Fecal incontinence is an underestimated disorder because it is often underreported by patients and underrecognized by health practitioners. Estimates of prevalence in the community-based adult population vary from 1.4% to 19.5%. Because prevalence and severity rise with age, fecal incontinence is expected to be a larger problem in an increasingly aging society. Moreover, fecal incontinence is embarrassing, causing great discomfort that can lead patients to stigmatization, social isolation, and poor self-esteem with profound implications for their quality of life. Conservative treatment, including dietary modification, constipating medications, lifestyle advice, biofeedback, and pelvic floor exercises, may be helpful to a considerable number of patients. The following invasive treatments are usually recommended if conservative treatment fails: Neuromodulation, injection of bulking agents, sphincteroplasty, artificial bowel sphincter, dynamic graciloplasty, and colostomy. However, these surgical procedures are complex, with variable outcomes and significant morbidity.

New technologies have evolved since the early 2000s, with techniques of neuromodulation offering high efficacy combined with low morbidity. Nerve stimulation for treatment of fecal incontinence has gained popularity, although the exact mechanism and the role of anorectal physiology in the treatment of fecal incontinence have not yet been completely defined. It may involve higher cortical centers and increased anal canal representation in the somatosensory cortex, with improved awareness of continence resulting in symptom control and better quality of life. Posterior tibial nerve stimulation is a recent, minimally invasive, less expensive form of neuromodulation (first used to treat patients with urinary incontinence), and its sustained safety and efficacy have been established in numerous publications. It is now gaining traction as a second-line treatment of refractory fecal incontinence and is based on the same principle of nerve stimulation as sacral neuromodulation (SNM). It has been applied percutaneously and transcutaneously but the results are limited by the methods of stimulation and the heterogeneity of patients enrolled in the studies. The aim of this study was to assess the efficacy of bilateral transcutaneous posterior tibial nerve stimulation (BTPTNS) for treatment of fecal incontinence in Japanese patients and to evaluate its impact on their quality of life.

METHODS

A prospective observational-interventional study was conducted from May 2015 to June 2017 and was approved by our local hospital’s ethics committee. Informed consent was obtained from all patients. Enrollment criteria included patients with at least 6 months of fecal incontinence because of various causes (previous anal surgery, obstetric, or idiopathic) who did not respond to conservative treatment (constipating medication, pelvic floor exercises, and biofeedback). Patients were treated with BTPTNS as second-line therapy. Exclusion criteria included age younger than 18 years, inability to provide informed consent or to complete detailed bowel diaries, and refusal to participate in the study. Patients...
Efficacy of Bilateral Transcutaneous Posterior Tibial Nerve Stimulation for Fecal Incontinence

with diabetic or peripheral neuropathy and those who could not attend weekly sessions in the hospital also were excluded.

All included patients were evaluated by a trained medical professional from our Coloproctology Department. A detailed medical history was obtained from each patient, and a physical examination including an assessment of the anal sphincter was performed. Manometry, using a 12-channel microballoon sensor (Star Medical Inc, Tokyo, Japan), was conducted to determine the anal canal resting and squeezing pressures. The anal canal pressure at rest and at maximal voluntary contraction was recorded by each of the microballoons. Manometry was repeated after 6 weeks of treatment and was performed by the same medical professional. At baseline and at 6 weeks, all patients completed the Cleveland Clinic Florida Fecal Incontinence Score, also known as the Wexner score. This instrument is used to calculate the type and frequency of incontinence using the sub-scales of solid, liquid, gas, wears pad, and lifestyle alteration. These 5 items are each evaluated using a 5-point Likert scale with the following semantic anchors: 0 = never; 1 = rarely; 2 = sometimes; 3 = usually; and 4 = always. A score of 0 is perfect continence, and a score of 20 is complete incontinence.²⁵ All patients also completed at baseline and at 6 weeks the Fecal Incontinence Quality of Life (FIQL) questionnaire, which is composed of 29 items to assess 4 domains: Lifestyle (10 items), coping/behavior (9 items), depression/self-perception (7 items), and embarrassment (3 items).² The average number of weekly incontinence episodes was calculated using detailed bowel diaries that all patients kept from baseline to 6 weeks.

All patients received a 30-minute session of BTPTNS twice a week for 6 consecutive weeks in an outpatient setting, according to the department-defined protocol. Two adhesive-surface electrodes were used, with one placed on the skin behind the medial malleolus and the other placed on the skin 10 cm cephalad from the first electrode.¹⁷ Tibial nerve stimulation was done using a transcutaneous electrical nerve stimulation device (Intelect Advanced EMG module, DJO Global Inc, Vista, CA). The optimal position of the electrode was determined by observing the rhythmic plantar flexion of the toes during stimulation. Stimulation was carried out at an amplitude level that elicited the optimal response. The low-voltage stimulator we used has an adjustable current setting ranging from 0 to 60 mA, a fixed pulse width of 200 µs, and a fixed frequency of 10 Hz. The primary outcome measures were a reduction of 50% or greater in fecal incontinence episodes, a decrease in the Wexner score, and an improvement in the FIQL domain scores.

Statistical analysis was performed using SPSS software (Version 17.0.0 for Windows/PASW Statistics 17, SPSS Inc, Chicago, IL). Quantitative variables were expressed as mean and standard deviation for normally distributed data, and as median and range for nonparametric distributions. Qualitative variables were given as numbers and percentages. Student’s t-test was performed to compare paired normally distributed variables, and the Mann-Whitney U test was used for non-parametric variables. The χ² test was used to compare discrete variables. The Pearson correlation test was used to compare quantitative variables. A p value < 0.05 was considered statistically significant.

RESULTS

Twenty-two patients with a median age of 64.1 years (range, 26-81 years) and a men:women ratio of 9:13 completed the scheduled BTPTNS treatment. The median duration of fecal incontinence was 5.3 years (range, 0.5-23 years). Eight patients had a history of previous anal surgery, 6 patients had obstetric-related incontinence, and 8 had idiopathic incontinence. Patient characteristics are summarized in Table 1. All women included in the study had experienced vaginal delivery, with a median number of 1.7 deliveries (range, 1-3). Endoanal ultrasonography was used to determine the percentage of defect vs no defect. The BTPTNS procedure was well tolerated by all patients, with no adverse effects and no skin lesions at the site of electrode placement.

The mean number of fecal incontinence episodes was significantly reduced from 4.7 at baseline to 1.5 at 6 weeks (p < 0.05). Moreover, an improvement of 50% or more in fecal incontinence episodes was achieved in 77.2% of the patients. The patients who did not experience any improvement in fecal incontinence were given transanal electrostimulation and SNM. The median Wexner score significantly decreased from 10.2 to 6.9 (p < 0.05). The median overall FIQL score improved from 2.7 to 3.1, but the change was not significant (p = 0.06). FIQL score improvements were seen in the domains of lifestyle (2.9 vs 3.4, p = 0.22), behavior (2.9 vs 3.2, p = 0.54), and depression/self-perception (2.6 vs 3.0, p = 0.11), but the changes were not significant (Table 2). However, there was a significant improvement in the embarrassment domain (2.2 vs 2.8, p < 0.05). Manometry did not reveal any significant changes before and after the BTPTNS treatment. The resting and squeezing anal pressures were 55.0 vs 55.9 cm H₂O (p = 0.89) and 193.5 vs 194.0 cm H₂O (p = 0.98), respectively (Table 3). The median follow-up period for all patients after treatment was 1 month.

DISCUSSION

The etiology of fecal incontinence is multifactorial. Predominant factors are presumed to be trauma to the anal

### Table 1. Patient characteristics (N = 22)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex (men:women)</td>
<td>9:13</td>
</tr>
<tr>
<td>Median age, y (range)</td>
<td>64.1 (26-81)</td>
</tr>
<tr>
<td>Median duration of fecal incontinence, y (range)</td>
<td>5.3 (0.5-23)</td>
</tr>
<tr>
<td>Median no. of vaginal deliveries (range)</td>
<td>1.7 (1-3)</td>
</tr>
<tr>
<td>Anal sphincter defect (yes:no)</td>
<td>3:19</td>
</tr>
<tr>
<td>Incontinence cause</td>
<td></td>
</tr>
<tr>
<td>Previous anal surgery</td>
<td>8</td>
</tr>
<tr>
<td>Obstetric</td>
<td>6</td>
</tr>
<tr>
<td>Idiopathic</td>
<td>8</td>
</tr>
</tbody>
</table>

* Female patients only.
sphincter morphology because of obstetric, pelvic, or anal surgery; radiotherapy; and/or weakness of the internal anal sphincter function. Moreover, the findings imply that fecal incontinence is a result of an unstable/uninhibited rectum. Thus, determining the treatment with the most favorable outcomes becomes a challenge and must be individualized. At present, SNM is the best established neuromodulatory treatment for fecal incontinence and has been used since 1995, with a reported success rate of 85% of patients achieving 50% or greater reduction of incontinent episodes at 24 months. Although SNM has the most enduring results over time, with 50% of patients maintaining full continence after 10 years, it is considered an expensive treatment that requires a highly specialized and dedicated colorectal team. Furthermore, it is associated with relatively high morbidity and carries some risks and disadvantages. The procedure involves 2 operations that are performed under anesthesia and possibly exposes the patient to unnecessary radiation while confirming the position of the electrode. Moreover, adverse events occur in 12% of cases, some of which (device infection and lead migration) may require a pulse generator replacement or reimplantation. This has been seen in 7% of cases. Therefore, less invasive treatment options with peripheral nerve stimulation have emerged.

The mechanisms of posterior tibial nerve stimulation in patients with fecal incontinence are not fully understood. Some authors have hypothesized that there is a sensory and motor neuromodulatory effect involved including rectal sensory perception, pelvic striate muscle activation (allowing generation of increased maximum squeeze pressure), and a reduction in unwanted spontaneous anal relaxation and rectal contractions. Studies have shown a significant improvement in anal pressures, sensory perception, and sham transcutaneous groups. In our study, the anal canal resting and squeezing pressures did not differ before and after treatment. These findings were not related to success and are consistent with the studies of Marti et al.12,13 and Queralto et al.14 However, some studies have shown a significant improvement in anal pressures,12,16,30 and Lopez-Delgado et al.17 suggest that changes in anal pressure indicate the effectiveness of the treatment. Furthermore, it is assumed that changes may be barely noticeable and of little clinical value; they are apparent only in the early stages of treatment and in a few parameters. There is ambiguity concerning findings in manometry. Manometry may have a role in defining success, but further research is necessary.

The posterior tibial nerve originates from sensorimotor and autonomic fibers derived from the fourth and fifth lumbar vertebrae and the first, second, and third sacral nerves, and by stimulating this nerve at the ankle, it may be possible to indirectly modulate sacral nerve function. Neuromodulation is believed to work via stimulation of multiple afferent sensory pathways at the spinal level. This has an effect on the pelvic viscera, lower gut, and sensory cortex. Positron-emission tomography has shown that sacral nerve stimulation increases blood flow centrally, and it seems that initial activity in the frontal cortex can be changed after chronic stimulation and may reflect improved awareness of continence, resulting in symptom control. Bilateral neuromodulation may activate a greater number of afferent sensory pathways, which could lead to an improved therapeutic effect. In a certain portion of patients, the pelvis is innervated asymmetrically, and unilateral stimulation may therefore not achieve an optimal treatment outcome.

Bilateral stimulation has been shown to be superior to unilateral SNM in some, but not all, patients with fecal incontinence and bladder dysfunction. Similar to these findings achieved from SNM, bilateral stimulation of the tibial nerve may also be superior to unilateral stimulation. In a study conducted by Thomas et al, the authors found that 59% of the patients achieved a 50% or greater reduction in the frequency of incontinent episodes with a significant reduction in median frequency of incontinent episodes per week and a significant improvement in the lifestyle domain of the Rockwood FIQL score. In another study in which BTPTNS was used, the authors indicated that 59% of the patients achieved a 50% or greater reduction in the frequency of incontinent episodes per week and a significant improvement in the lifestyle domain of the Rockwood FIQL score. In another study in which BTPTNS was applied, there was a significant improvement in episodes of fecal incontinence on the Wexner scale and the visual analog scale assessment, a decrease in the number of episodes of incontinence per unit of time, and a statistically significant improvement in variables of the FIQL score, including lifestyle, behavior, and embarrassment.

In our study, the frequency of fecal incontinence per week significantly decreased from 4.7 to 1.5 (p < 0.05) before and after treatment. Moreover, 77.2% of the patients experienced a 50% or better improvement in the episodes of fecal incontinence, and the median Wexner score significantly decreased from 10.2 to 6.9 (p < 0.05). An improvement was also seen in the median overall FIQL score.

### Table 2. Wexner score and Fecal Incontinence Quality of Life (FIQL) domain scores

<table>
<thead>
<tr>
<th>Test</th>
<th>Baseline</th>
<th>6 weeks</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wexner score</td>
<td>10.2</td>
<td>6.9</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td>FIQL domain</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall</td>
<td>2.7</td>
<td>3.1</td>
<td>0.06</td>
</tr>
<tr>
<td>Lifestyle</td>
<td>2.9</td>
<td>3.4</td>
<td>0.22</td>
</tr>
<tr>
<td>Behavior</td>
<td>2.9</td>
<td>3.2</td>
<td>0.54</td>
</tr>
<tr>
<td>Depression/self-perception</td>
<td>2.6</td>
<td>3.0</td>
<td>0.11</td>
</tr>
<tr>
<td>Embarrassment</td>
<td>2.2</td>
<td>2.8</td>
<td>&lt; 0.05</td>
</tr>
</tbody>
</table>

### Table 3. Anorectal manometric data

<table>
<thead>
<tr>
<th>Anal pressure, cm H2O</th>
<th>Reference range</th>
<th>Baseline</th>
<th>6 weeks</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median resting pressure</td>
<td>Men: 69.5; Women: 68.5</td>
<td>55.0</td>
<td>55.9</td>
<td>0.89</td>
</tr>
<tr>
<td>Median squeezing pressure</td>
<td>Men: 194.8; Women: 167.4</td>
<td>193.5</td>
<td>194.0</td>
<td>0.98</td>
</tr>
</tbody>
</table>

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from 2.7 to 3.1 (p = 0.06), which was not significant; however, a significant change in the embarrassment domain (2.2 vs 2.8, p < 0.05) was observed. These results are consistent with the results of other studies.

CONCLUSION
Our findings suggest that BTPTNS is a safe, well-tolerated procedure among patients with fecal incontinence and may improve their symptoms. This technique offers an additional noninvasive and less expensive option for treatment before more invasive modalities are performed.

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

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ABSTRACT

Continuity of care is a challenge in primary care residency teaching clinics. Resident physicians have competing inpatient and outpatient responsibilities and often spend only 1 to 2 half-days per week in the clinic. Their clinic schedules are often pieced together after the needs of inpatient and specialty rotations are met. Similarly, faculty clinicians often balance limited clinic time with teaching, research, or administrative responsibilities. Seeking approaches to improve continuity of care, we visited 23 internal medicine, family medicine, and pediatric residency clinics across the US. This article highlights strategies to optimize continuity of care pioneered by 3 “bright spot” residency teaching clinics with high-continuity performance. The strategies include adopting a strong continuity culture and patient scheduling algorithms that prioritize continuity, appointing a team continuity anchor, and/or reorganizing resident and faculty schedules to maximize continuity. We hope that these perspectives can assist residency teaching practices to improve continuity of care for their patients.

INTRODUCTION: THE CHALLENGE

Continuity of care is a fundamental pillar of primary care. Continuity of care is particularly important in primary care residency teaching clinics, which provide a substantial proportion of care for underserved communities and shape the priorities of the next generation of primary care physicians (PCPs).

To learn how to optimize continuity of care throughout their careers, primary care residents ideally experience excellent continuity of care as learners. Yet teaching clinics are precisely the institutions most challenged to provide continuity. The two missions of teaching clinics—excellent resident education and patient-centered care—are often in conflict. To become seasoned teachers, residents must rotate through inpatient, ambulatory, and specialty services; they spend relatively little time in their primary care clinic. Patients, in contrast, want and deserve to have their PCPs available much of the time. This perspective features examples of primary care residency clinics that have made progress in overcoming this dilemma.

Continuity of care from the patient perspective is defined as the percentage of a patient’s primary care visits that are with the patient’s personal PCP. Although alternative visit types such as patient portal encounters would ideally be included in continuity measurement, this is not generally done. Continuity is associated with improved chronic illness management and preventive care, increased patient and clinician satisfaction, fewer Emergency Department visits and hospitalizations, and reduced costs. For Medicare beneficiaries with chronic conditions, a small increase in continuity is associated with sizeable reductions in complications and costs. Another lens on continuity of care comes from the PCP (faculty or resident) perspective: The percentage of a PCP’s visits that are visits with patients on the PCP’s panel. Continuity from the resident perspective—optimizing the ability of residents to see their own patients—can improve the quality of the resident experience by increasing care efficiency and building meaningful connections with patients.

Residents report that lack of continuity with their patients is associated with increased rates of medical errors. In many primary care residency programs, resident clinic schedules are subordinate to the needs of inpatient and specialty rotations. Furthermore, in many residency programs, faculty spend little time in clinic, prioritizing research responsibilities and other academic obligations, further compromising faculty-patient continuity.

In the words of several medical educators, “Continuity of care between a patient and a physician is a core aspiration. However, we rarely achieve it in residency training.” This article describes how three “bright spot” primary care teaching clinics have achieved excellent performance on continuity of care from the patient perspective. A “bright spot” clinic is a clinic with good performance on clinical, operational, and patient experience measures as well as implementation of a number of requirements of the patient-centered medical home.

METHODS

In 2013, the University of California, San Francisco (UCSF) Center for Excellence in Primary Care created a project team to observe existing internal medicine, family medicine, and pediatric residency programs and their associated clinics, looking for characteristics associated with high-quality patient care and resident physicians.
experience. Between May 2013 and May 2015, team members performed 23 site visits to residency teaching clinics. The 1- to 2-day site visits involved interviews with clinic leadership, residents, faculty, and clinic staff and shadowing frontline clinicians and staff. Details of the site visits and how the 23 clinics were chosen are provided in a 2016 report. From all 23 programs, we requested performance data, including continuity of care metrics. Some follow-up interviews were conducted in 2016 to 2017. The project was reviewed by the UCSF Committee on Human Research and deemed exempt.

Nine of the 23 clinics measured continuity of care from the patient perspective, which ranged from 21% to 81% with a median of 53%. From the 9 clinics with continuity data, we picked the 3 “bright spot” clinics with the highest performance on continuity of care from the patient perspective, to describe the strategies that these clinics use to achieve their results.

RESULTS: OVERCOMING THE CHALLENGE

Three sites achieved continuity of care rates from the patient perspective of 70% or greater at the time of the site visits. These sites were the primary care teaching sites of the University of Cincinnati Internal Medicine Residency in Cincinnati, OH (81%); University of North Carolina Family Medicine Residency in Chapel Hill, NC (71%); and University of Massachusetts Medical School-Baystate Internal Medicine Residency in Springfield, MA (74% continuity with 1 of 2 clinicians).

At the time of our site visits, these practices used three strategies to improve continuity of care: 1) adopting a strong continuity culture and patient scheduling algorithms that prioritize continuity, 2) appointing a team continuity anchor, and/or 3) reorganizing resident and faculty schedules.

Adopting Strong Continuity Culture and Scheduling Algorithms

University of North Carolina Family Medicine Residency has achieved an average continuity rate from the patient perspective of 71% at its Family Medicine Center. The program uses a traditional scheduling model with 4-week rotations, scheduling residents and faculty to be in clinic almost every week. The clinic has adopted a strong culture of continuity, with continuity of care metrics tracked and displayed monthly for each clinician, and high continuity rates are expected of all faculty and residents.

To prioritize both access and continuity, each physician (faculty and residents) has approximately one-fourth of appointment slots that are opened only a few days early. These slots are available only to patients of that physician. Staff members who answer the phones cannot give those slots to another physician’s patients unless the slots are still available on the day of the appointment. This practice promotes continuity from both the patient and the PCP perspective.

Appointing a Team Continuity Anchor

At Baystate’s internal medicine teaching clinic in Springfield, MA, continuity from the patient perspective with 1 of 2 clinicians has exceeded 70% for several years. The clinic uses a continuity team anchor model to promote continuity of care. The front desk is trained to make appointments with the patient’s PCP or with the full-time advanced practice clinician (nurse practitioner or physician assistant) on the PCP’s team. The advanced practice clinicians act as team continuity anchors. They have only small patient panels of their own because their main role is to see patients of unavailable residents on their team, ie, to Comanage the panels of their team’s resident physicians. This approach increases the continuity experience for patients, who are seen by 1 of 2 team clinicians who are in frequent contact with one another. Residents and the advanced practice clinician on their team are in close face-to-face communication (because their workspaces are located right next to each other), and they share electronic medical record notes. The residents know both clinicians (resident and advanced practice clinician), and both clinicians know the patients.

Reorganizing Resident and Faculty Schedules

Two of the sites use unique scheduling models, with the goal of improving continuity. Baystate uses a 2 + 2 (2-week miniblock) schedule. Monthlong blocks are divided into 2-week inpatient and 2-week ambulatory care miniblocks. During inpatient weeks, residents do not attend clinic, and during ambulatory weeks they are not in the hospital. Residents are not away from the clinic for more than 2 weeks at a time and have sufficient appointments during their 2-week ambulatory block to meet the appointment needs of their patient panel. Patients needing urgent appointments when their resident PCP is on the 2-week inpatient rotation are scheduled with the advanced practice clinician on the resident’s team as noted earlier.

In 2006, the University of Cincinnati Internal Medicine Residency instituted the “ambulatory long-block” model. Residents provide purely ambulatory care with no inpatient rotations for months 17 to 29 of residency. Continuity from the patient perspective rose as high as 81%, and continuity from the PCP perspective increased to 71%. During long block, residents have 3 primary care clinic sessions each week, spending other times in ambulatory specialty rotations. Every day the residents must answer patient and staff messages, communicate with team registered nurses, and follow-up on their patients’ care coordination issues. The 3 continuity (primary care clinic) sessions are spread across the week, consistent every week, and have sufficient appointments to match patient demand. To enhance continuity beyond the residents’ 1-year long block, patients stay on the same care team for years; the team registered nurse functions as a longitudinal continuity anchor when the resident PCP leaves.

DISCUSSION: LESSONS FROM “BRIGHT SPOT” CLINICS

Residency teaching practices with high continuity of care metrics employed the three strategies described here, strategies also instructive for nonteaching practices. A key take-home message from these three “bright spot” examples is the need for primary care practices to regularly measure, track, and discuss continuity of care metrics and to adopt a clinic culture embracing the importance of continuity. Prioritizing continuity into scheduling algorithms for patient appointments improves continuity while maintaining access.
A powerful strategy to enhance continuity from the patient perspective is to build teams with a full-time continuity anchor, as Baystate has done. In that clinic, staff members answering phones are trained to schedule patients to see either their resident PCP or the advanced practice clinician on their team. In Baystate’s experience, continuity with one of two people (PCP or team advanced practice clinician) who are in close contact with each other is meaningful for patients.

In recent years, some residency programs have promoted “x + y” block scheduling models that separate inpatient and outpatient duties, with x connoting inpatient weeks and y standing for ambulatory weeks. The 2 block models we described here—2 + 2 miniblock and long block—promote continuity of care because residents are away from clinic only for short intervals, allowing residents to see their patients in a timely fashion. Their clinic presence is also consistent and predictable, as opposed to having certain months with few sessions. Moreover, clinicians with more monthly half-day clinic sessions are away from clinic only for short time-limited snapshot. Effective strategies to optimize continuity must be sustainable, and we did not follow our sites longitudinally. Additionally, our three sites were not selected in a representative manner, and other teaching clinics with good continuity of care metrics likely have other useful strategies.

Our findings have several limitations. Continuity of care varies from patient to patient, from clinician to clinician, and from month to month; our data are a time-limited snapshot. Effective strategies to optimize continuity must be sustainable, and we did not follow our sites longitudinally. Additionally, our three sites were not selected in a representative manner, and other teaching clinics with good continuity of care metrics likely have other useful strategies.

**Conclusions**

Primary care practices are challenged by the growing phenomenon of part-time physicians, with residency teaching practices as the most extreme examples. Practices can make strides in achieving high continuity of care rates by implementing one or more of the strategies described here. Teaching practices can overcome the dilemma created by the often divergent needs of resident education and patient care.

**Disclosure Statement**

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**References**


**Sensible**

Men are men before they are lawyers, or physicians … and if you make them capable and sensible men, they will make themselves sensible lawyers or physicians.

— John Stuart Mill, 1806-1873, British philosopher, political economist, and civil servant
The Effect of Abnormal Vitamin D Levels in Athletes

Jakub Sikora-Klak, MD; Steven J Narvy, MD; Justin Yang, MD; Eric Makhni, MD; F Daniel Kharrazi, MD; Nima Mehran, MD

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ABSTRACT

Vitamin D is a lipophilic prohormone integral to musculoskeletal, autoimmune, oncologic, cardiovascular, and mental health. Of particular importance to the orthopedic surgeon is the role of vitamin D in the regulation of bone mass, muscle strength, and physical performance. Although vitamin D-related skeletal pathologies are rare in industrialized nations, emerging research in the field has shown that most American adults have inadequate levels of vitamin D. Even among athletes, there is a high prevalence of vitamin D deficiency, which may place competitors at risk of stress fractures, illness, and delayed muscle recovery. Adequately identifying vitamin D-deficient individuals in need of supplementation is important to help optimize performance and prevent future injury. The goal of this review is to describe the epidemiology of vitamin D deficiency and its effects on athletic performance and musculoskeletal health. Future double-blinded studies of vitamin D supplementation in athletes are needed. We recommend treating athletes who have insufficient or deficient vitamin D levels.

INTRODUCTION

Vitamin D deficiency is common, even among athletes. The goal of this review is to describe the epidemiology of vitamin D deficiency and its effects on athletic performance and musculoskeletal health.

EPIDEMIOLOGY

Vitamin D deficiency is a common finding among Americans: 36% to 57% of adults are deficient. Causes include low ultraviolet (UV) exposure, lack of fortified nutrition, skin pigmentation, and malabsorption disorders. Public health initiatives, including food fortification and education among pediatric and adolescent populations, have significantly decreased the prevalence of such developmental problems as rickets and growth retardation. However, symptoms of vitamin D deficiency in adults such as osteoporosis, osteomalacia, myalgias, and immune deficiencies are often ignored. Patients with vitamin D deficiency presenting as musculoskeletal pain are often misdiagnosed with fibromyalgia, chronic fatigue syndrome, and myositis, among others. Vitamin D deficiency is defined as having a level below 20 ng/mL, and vitamin D insufficiency is defined as a vitamin D level under 30 ng/mL. Worldwide, 1 billion people are estimated to fall into these categories. Both vitamin D insufficiency and deficiency are increasing in prevalence.

Professional athletes are similarly affected. In professional basketball, 32% of athletes are found to be deficient and 47% are found to be insufficient with respect to vitamin D levels. Among players in the National Football League, 26% were found to have deficient vitamin D levels, and 42% to 80% of the athletes had levels defined as insufficient. Only 36% of Liverpool’s professional soccer academy players were found to be either deficient or insufficient. Among professional hockey players, Mehran et al found vitamin D deficiencies in 0% and insufficiency in only 13%. The authors attributed these low numbers to race, given that 96.2% of the hockey players were white. Deficiencies or insufficiencies have been found in most dancers, taekwondo fighters, jockeys, elite wheelchair athletes, handball players, track and field athletes, weightlifters, swimmers, and volleyball players.

Multiple studies have shown that athletes with darker skin are at higher risk of vitamin D abnormalities developing. One study, for example, demonstrated that black race (odds ratio [OR] = 19.1; \( p < 0.0001 \)) and dark skin tones (OR = 15.2; \( p < 0.0001 \)) were the greatest predictors of abnormal vitamin D levels. One study demonstrated that athletes with high concentrations of melanin in their skin need up to 10 times longer UVB exposure times to generate the same vitamin D stores as fair-skinned athletes do.

PATHOPHYSIOLOGY

Vitamin D controls the body’s phosphate and calcium stores. The major source of vitamin D is from sunlight, but other sources include fish, mushrooms, eggs, fortified foods, and supplements. With the help of solar UVB radiation, 7-dehydrocholesterol is converted to previtamin D3. Previtamin D goes into the circulation and is hydrolyzed by the liver to create 25-hydroxyvitamin D (25\([\text{OH}]D\)), the major form that clinicians use to measure vitamin D status. The kidneys then create the biologically active form of 1,25-dihydroxyvitamin D (1,25\([\text{OH}]2D\)).

The biological feedback loop is a complex interplay between bone, intestines, and the parathyroid glands. Vitamin D receptors are found throughout the body and affect the skeletal muscle, bones, immune system, gastrointestinal tract, kidneys, parathyroid glands, cardiovascular system, and some cancers. More than 1000 genes expressed are often dictated by vitamin D, including those of angiogenesis, cellular proliferation, differentiation, and apoptosis. Vitamin D receptors, when activated, promote cell protein synthesis and have associations with muscle mass and function. Levels of less than 30 ng/mL decrease

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gastrointestinal calcium absorption and increase parathyroid hormone activity, resulting in the dissolution of bone matrix by osteoclasts to maintain serum calcium levels within physiologic range.25-27 Deficiencies prevent the maximum deposition of calcium in the skeleton.28

ROLE IN MUSCLE FUNCTION
Vitamin D deficiency leads to structural pathology of muscle tissue. Muscle specimens of vitamin D-deficient individuals exhibit enlarged interfibrillar spaces and infiltration of fat, fibrosis, and glycogen.29 A South Korean study showed that higher serum vitamin D was associated with less fatty degeneration in rotator cuff muscles and had a positive correlation to muscle torque.30 Type 2 muscle fibers, also known as fast twitch fibers, have a direct association with vitamin D. Biopsies of 12 vitamin D-deficient patients, before and after vitamin D treatment, found atrophy of type 2 muscle fibers before treatment and significant improvement after treatment.31 Additionally, Heath and Elovic32 found that 93% of patients presenting to a community clinic with nonspecific musculoskeletal pain were found to have vitamin D deficiency. Furthermore, Ahmed et al33 reversed myositis-myalgia in statin-treated patients who had vitamin D deficiency using vitamin D supplementation. Athletes in the National Football League Combine with a history of lower extremity muscle strain and core muscle injury had a higher prevalence of inadequate vitamin D.34

ROLE IN INFLAMMATION
Vitamin D can reduce inflammation by its inhibitory effect on proinflammatory cytokines such as Interleukin-6, which converts monocytes to macrophages, which in turn produce more inflammatory cytokines. Interleukin-6 can be increased very early in a single workout35 and has been hypothesized to be related to the occurrence of muscle damage in a workout.36 Vitamin D has also been shown to reduce the production of other proinflammatory cytokines such as interferon-α, Interleukin-2, and tumor necrosis factor-6.37-40

HISTORICAL IRRADIATION IN ATHLETES
UV irradiation of athletes to improve performance has been an area of intrigue far before its relationship with vitamin D was established. Studies dating to the 1930s and 1940s have noted improvement in running speed and bike ergometer readings among study participants.41-43 More recent work has shown that UV radiation improved forearm strength, work performance on bike ergometers, and strength and speed of college women.44-47

In 1952, Ronge48 was the first to hypothesize that the production of vitamin D explained the success of UV radiation in physical performance. He supplemented nonirradiated German schoolchildren with a single dose of vitamin D and greatly improved their cardiovascular performance, equivalent to a group of radiation-treated children. The UVB range was the most effective wavelength in consistently reducing resting pulse, lowering the basal metabolic rate, and increasing work performance on a bike ergometer.49

IMPACT ON ATHLETIC PERFORMANCE
Vitamin D supplementation has been shown in multiple studies to affect muscle performance, kinetics, and efficiency.50,51 Close et al52 demonstrated that professional soccer players increased their vertical jump and 10-m sprints (p = 0.008) when taking vitamin D supplements. Additionally, ballet dancers who supplemented with vitamin D showed they had a 7% higher vertical jump (p < 0.01) and an 18% increase in isometric strength (p < 0.01).53 A British study using novel jump mechanography found a positive relationship between serum vitamin D levels and jump height, velocity, and power (p = 0.005, 0.002, and 0.003, respectively) in postmenarchal adolescent girls.54 In a randomized, double-blind trial, judo athletes supplemented with vitamin D, demonstrated a 13% increase in muscle strength compared with a placebo group (p = 0.01).55

LOSS OF ATHLETIC PARTICIPATION
Athletes with subtherapeutic vitamin D levels may be at higher risk of missing practices and games as a result of stress fractures, muscle injuries, and upper respiratory tract infections.56

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Impact on athletic performance
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Loss of athletic participation
Athletes with subtherapeutic vitamin D levels may be at higher risk of missing practices and games as a result of stress fractures, muscle injuries, and upper respiratory tract infections.
REVIEW ARTICLE

The Effect of Abnormal Vitamin D Levels in Athletes

MEDICAL MANAGEMENT

A patient’s vitamin D status can be assessed with a blood draw assessing 25(OH)D level. The Endocrine Society® defines vitamin D deficiency as 25(OH)D level below 20 ng/mL, insufficiency as 21-29 ng/mL, and sufficient as above 30 ng/mL. Recommended daily intake varies by age. To achieve blood levels of 25(OH)D consistently above 30 ng/mL, children aged 1 to 18 years are recommended to consume at least 1000 IU/d; adults in the 19- to 50-year range may need at least 1500 IU/d to 2000 IU/d to reach the same level. Vitamin D toxicity manifests with hypercalcaemia-related symptoms such as nausea, vomiting, fatigue, and weakness and can occur when doses reach greater than 50,000 IU/d, with blood levels above 150 ng/mL. Sunlight alone cannot raise vitamin levels. A dose of 70,000 IU/wk has been shown to be detrimental to increase 25(OH)D blood levels; after stopping the supplementation, serum 24,25(OH)2D persists at high levels, which inhibits the bioactivity of 1,25(OH)2D.

Although doses of 10,000 IU/d for 5 months do not cause toxicity, it is suboptimal to overload the body in this fashion to raise vitamin levels. A dose of 70,000 IU/wk has been shown to be detrimental to increase 25(OH)D blood levels; after stopping the supplementation, serum 24,25(OH)2D persists at high levels, which inhibits the bioactivity of 1,25(OH)2D.

RECOMMENDATIONS

Future research is greatly needed, focusing on double-blind supplementation and optimal vitamin D levels in athletes. We recommend that vitamin D levels should be checked on an annual basis in all athletes. If their level is deficient or insufficient, athletes should be supplemented with vitamin D to help decrease the risk of injuries while possibly improving performance. In patients who are vitamin D deficient or insufficient, we recommend a treatment dosage of 50,000 IU/wk for 8 weeks. Once the treatment regimen has been completed, the physician may choose to recheck vitamin D levels and then initiate another 8-week round of treatment if levels remain deficient. If the patient’s vitamin D level is adequate after 1 round of treatment, we recommend a daily maintenance dose as described by the Endocrine Society.

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References


Absence

Vitamins are chemicals in food clinically conspicuous by their absence.

— The Alarming History of Medicine, Richard Gordon; New York, NY: St Martin's Press; 1993
Obstructive Uropathy and Sepsis Caused by an Inguinoscrotal Bladder Hernia: A Case Report

Seena Safavy, MD; Emmanuel Mitsinikos, MD; Bradford Tropea, MD; Allen Chang, MD; Hetal Patel, MD

ABSTRACT

Introduction: Inguinoscrotal bladder hernia is a very rare pathology, occurring in up to 4% of all inguinal hernias in the general population. We present a case of an inguinoscrotal bladder hernia causing obstructive uropathy and sepsis.

Case Presentation: A 59-year-old obese man presented with left-sided flank and abdominal pain that radiated to his left groin. On initial clinical examination, there was no evidence of an inguinal hernia. A computed tomography scan revealed a left inguinoscrotal bladder hernia with associated left-sided upper tract urinary obstruction. Two days later, his clinical course deteriorated and he developed sepsis of urinary origin. The patient underwent multiple procedures, including left ureteral stent placement, left percutaneous nephrostomy tube placement, and left inguinal herniorrhaphy. As of this writing, he remains with a left nephrostomy tube in place because of persistence of left hydroureteronephrosis, but he is doing well clinically.

Discussion: We highlight the fact that in cases where there is upper urinary tract obstruction and sepsis, it is prudent to first stabilize the patient via decompression of the upper urinary tract and antibiotics before herniorrhaphy. This report illustrates a unique case of this interesting pathology, as well as the multiple complications and pitfalls that may arise from it.

INTRODUCTION

Inguinoscrotal bladder hernia is an unusual pathology that occurs in up to 4% of all inguinal hernias seen in the general population. We report the rare case of a large left inguinoscrotal bladder hernia causing severe left-sided hydroureteronephrosis and sepsis of urinary origin.

CASE PRESENTATION

Presenting Concerns

A 59-year-old obese man presented to the Emergency Department with 1 day of left-sided flank and abdominal pain radiating to his left groin. He denied any noticeable bulge or mass in his groin. He did report subjective fevers, nausea, dysuria, and an episode of transient gross hematuria the day before presentation. He denied any urinary retention or difficulty emptying his bladder. There was no appreciable inguinal hernia on initial evaluation.

Abdominal examination revealed mild left abdominal tenderness with no evidence of an acute abdomen. He also had mild left flank tenderness. His urinalysis was positive for microscopic hematuria, pyuria, leukocyte esterase, and nitrite. His blood tests revealed an elevated creatinine of 1.63 mg/dL (baseline creatinine approximately 0.8 mg/dL) but were otherwise unremarkable. A computed tomography (CT) scan of the abdomen/pelvis revealed a left inguinal hernia involving the bladder with associated severe left-sided hydroureteronephrosis (Figure 1). To complicate matters, the patient was also noted to have remote, well-healed bilateral pubic rami fractures. A physical examination shortly after the CT scan failed to reveal any obvious inguinal hernia.

Therapeutic Intervention and Treatment

We consulted the general surgery team. Initially, the patient’s hospital course was stable and he was doing well clinically with conservative measures. Two days after admission, the patient rapidly decompensated overnight and developed altered mental status and respiratory distress that required intubation. His creatinine had uptrended to 2.85 mg/dL despite intravenous hydration and Foley decompression. The patient’s creatinine had continued to increase despite optimal hydration. Two days later, his clinical course deteriorated and he developed sepsis of urinary origin. Two days after his creatinine improved. A Foley catheter was placed for maximal drainage, broad-spectrum intravenous antibiotic therapy was initiated, intravenous fluids were given, and the patient was admitted to the hospital for observation.

Finally, the patient’s hospital course was stable and he was doing well clinically with conservative measures.
His blood and urine cultures revealed methicillin-sensitive *Staphylococcus aureus*. On examination, he now had an obvious left inguinal hernia that was reducible and not incarcerated. The decision was made to take the patient to the operating room for decompression of his left upper urinary tract. Per recommendations from the general surgery team, the inguinal hernia repair was to take place on an elective basis after the patient was stabilized. He was thus taken to the operating room for cystoscopy, left retrograde pyelogram, and left ureteral stent placement. Intraoperatively, the patient was noted to have a very distorted anatomy of the trigone with the right ureteral orifice positioned at the expected location of the left ureteral orifice. The left ureteral orifice was very deviated to the left. A left retrograde pyelogram revealed severe left hydronephrosis associated with significant tortuosity. A left ureteral stent was placed. Intraoperatively, he was noted to have a large amount of incarcerated bladder. The hernia was successfully reduced and repaired with a polypropylene plug mesh and onlay patch. The patient’s remaining hospital course was unremarkable, and he was discharged home 5 days after hernia repair with a left nephrostomy tube in place. His creatinine was 0.84 mg/dL at the time of discharge.

Approximately three weeks after discharge, the patient underwent left ureteroscopy with retrieval of the previously retained left ureteral stent. On cystoscopy, it was noted that his ureteral orifices were now in orthotopic position. He was noted to have persistence of severe left hydronephrosis on retrograde pyelography. Because his creatinine was normal and he was not having any flank pain, his nephrostomy tube was capped at the end of the operation. His creatinine remained normal, and he did not develop any flank pain during the next few days.

The plan was then to perform an antegrade nephrostogram in anticipation of removal of the nephrostomy tube. Two days after the ureteroscopy procedure, the patient underwent antegrade nephrostogram. Upon uncapping the nephrostomy tube, there was drainage of 600 mL of pus. The nephrostogram also revealed severe left-sided hydronephrosis. The decision was made to exchange the nephrostomy tube and leave it uncapped. The patient was also placed on a course of antibiotics.

The patient remained stable and did not develop any evidence of sepsis. Approximately six and half weeks later, a repeat left nephrostogram revealed moderate left hydronephrosis that was improved since the previous nephrostogram but still present. The decision was made to leave the nephrostomy tube in place and again leave it uncapped. Of note, the patient’s creatinine subsequently remained within normal limits and the patient denied any flank pain or urinary complaints.

**Follow-up and Outcomes**

As of this writing, the patient remains with a left nephrostomy tube in place because of the persistence of his left hydronephrosis. He is doing well clinically with no evidence of sepsis, and his kidney function has been optimized. The patient will undergo interval antegrade nephrostograms every four to six weeks. After he demonstrates significant improvement of his left-sided hydronephrosis, his left nephrostomy tube will be capped and eventually removed. Figure 2 presents a timeline of the case.

**DISCUSSION**

Inguinoscrotal bladder hernia is indeed a rare pathology. Signs and symptoms of bladder involvement may include gross hematuria, frequency, nocturia, groin bulge, and a 2-stage micturition cycle in which the patient voids normally and then compresses the groin to further empty the bladder.1-5 It is important to note, however, that the patient may be completely asymptomatic from a genitourinary standpoint. Bladder association in inguinal hernias is often not detected before herniorrhaphy.1-6 In patients undergoing inguinal hernia repair, less than 7% of bladder hernia cases are diagnosed preoperatively.6 Thus, it is important to maintain a high degree of suspicion in high-risk patients with inguinal hernias. High-risk groups include obese men with urologic symptoms, men with prior inguinal hernia repairs, and men older than age 50 years.7 In these patient populations, some authors recommend performing a CT scan before inguinal hernia repair to evaluate the contents of the hernia.7 This will help to avoid any intraoperative pitfalls such as a bladder injury. Although bladder hernias occur in only 1% to 4% of all inguinal hernias in the general population, incidence approaches 10% in men older than age 50 years.7 The standard treatment for inguinoscrotal bladder hernia is herniorrhaphy.5 Bladder resection should be undertaken only in cases with tumor in the herniated bladder, bladder wall necrosis, a tight hernia neck, or a herniated bladder diverticulum.3,8

Upper tract urinary obstruction may also be a consequence of bladder herniation. Neulander et al1 reported a case of a 69-year-old man who presented on an elective outpatient basis with a large left inguinoscrotal bladder hernia leading to severe left hydronephrosis, as well as mild right hydronephrosis. The patient was also noted to have obstructive lower urinary tract symptoms. The authors opted out of immediately decompressing the left upper urinary tract (ie, placement of a ureteral stent or nephrostomy tube)
because the creatinine was normal and the hernia was promptly repaired. At a 4-month follow-up, the authors noted that the patient’s urinary symptoms had improved significantly, and he was able to empty his bladder well without a post-void residual. However, he was noted to have persistence of severe left-sided hydronephrosis on imaging, but no further procedures were pursued because he was clinically well.

In our case, given the patient’s critical condition, both the urology and general surgery teams agreed that it was most prudent to proceed with immediate decompression of the left upper urinary tract, resuscitation, and stabilization before undertaking repair of the hernia.

In retrospect, our patient would have certainly benefited from initial hernia repair at the time of presentation. At the time of the initial general surgery consult, however, there was no appreciable hernia on examination, and the possibility remained that the left-sided ureteral obstruction was caused by adhesions from the prior pubic rami fractures. Because our patient was clinically stable with adequate urine output via the Foley catheter, it was thought that he could initially be managed conservatively until further imaging was obtained to help identify the point of obstruction. Unfortunately, he rapidly decompensated. Given his septic picture, immediate decompression of his left upper urinary tract became the priority instead of herniorrhaphy.

We could have saved the patient an additional procedure by first proceeding with left nephrostomy tube placement, as opposed to first placing a left ureteral stent. Given the patient’s complicated anatomy and extreme ureteral tortuosity, the chance of running into complications with ureteral stent placement was high. Nevertheless, our aim was to maximize patient comfort and to avoid the burden of a nephrostomy bag. Even though we noted good stent placement intraoperatively with appropriate proximal and distal coils and a proper stent length, the stent unfortunately retracted once the ureter straightened out slightly.

Lastly, it is unclear whether the patient’s right lower extremity deep vein thrombosis could have been avoided. He was given sequential compression devices and was also placed on subcutaneous heparin at the time of admission. The subcutaneous heparin was held at times in the periprocedural and postprocedural periods to minimize clinically significant gross hematuria.

In conclusion, inguinoscrotal bladder hernia is an uncommon entity that may go unrecognized when a patient presents with a reducible inguinal hernia. A high degree of suspicion should be maintained in those patients with inguinal hernias who are at high risk for bladder herniation. CT scans will probably provide the most comprehensive information regarding a patient’s anatomy in this population. In cases where there is upper urinary tract obstruction and sepsis, it is prudent to first stabilize the patient via decompression of the upper urinary tract and antibiotics before herniorrhaphy. Furthermore, we recommend considering nephrostomy tube placement over ureteral stents in cases where there is a bladder hernia in the setting of upper urinary tract obstruction with significant hydroureteronephrosis.
Obstructive Uropathy and Sepsis Caused by an Inguinoscrotal Bladder Hernia: A Case Report

and a tortuous ureter. As long as the hernia is not incarcerated, it may be repaired on an elective basis.

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A Numerous Train of Diseases

Inasmuch as the structure of the human frame has been so set together by Nature, that it is unable, from the continuous flux of particles, to remain unchanged; whilst, from the action of external causes, it is subjected to influences beyond its own: And since, for these reasons, a numerous train of disease has pressed upon the earth since the beginning of time; so without doubt the necessity of investigations into the Art of Healing has exercised the wit of mankind for many ages.

— Thomas Sydenham, 1624-1689, English physician known as “The English Hippocrates”
One day she realized
That the mountain she kept climbing
Was not hers.
In fact, it had nothing to do
With her.
So she decided
To take the long
Way around,
Uncover new friends,
Sing to the sky,
Eat from the earth,
Laugh with new loves,
And let the river
Show her how to be kissed
By the sun until sparkling.

Round the Mountain
(Pack a Lunch),
October 2017

This original artwork is accompanied by the poem above.
Together they are part of the artist's ongoing story of healing.

Charlene Happel is an artist and cancer survivor living in Portland, OR.
Metastatic Angiosarcoma of the Scalp Presenting with Cystic Lung Lesions: A Case Report and Review of Cystic Lung Diseases

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ABSTRACT
Introduction: Angiosarcomas are rare, malignant vascular tumors that affect endothelial cells of blood vessels. Angiosarcomas most commonly occur on the scalp or face of elderly individuals and are highly aggressive, with a 5-year survival rate below 15%. Cutaneous angiosarcomas often metastasize to the lung, where they can present with cystic lesions, solid lesions, pneumothorax, and/or hemothorax.

Case Presentation: We report the case of an 83-year-old woman who presented with a scalp lesion, which was initially thought to be caused by scalp trauma but was later found to be an angiosarcoma. She initially refused any therapy for the tumor. She returned several months later with a cough and shortness of breath and was found to have multiple pulmonary cysts. She was treated with paclitaxel, but her tumor did not respond to the therapy and she died 2 months later.

Discussion: We discuss the common presentation of cutaneous angiosarcomas and their tendency to metastasize to the lung and present as cystic lesions. We also review the common conditions that can cause cystic changes in the lungs.

INTRODUCTION
Angiosarcomas are rare, malignant vascular tumors that affect endothelial cells of blood vessels. They account for less than 2% of soft-tissue sarcomas and less than 1% of all head and neck cancers. Angiosarcomas can occur in any part of the body; however, they most commonly occur on the scalp or face of elderly individuals. These tumors are highly aggressive, with a 5-year survival rate of less than 15%. They spread rapidly through the skin, metastasize early, and tend to recur after treatment. Cutaneous angiosarcomas often metastasize to the lung, where they can present with cystic lesions, solid lesions, pneumothorax, and/or hemothorax.

CASE PRESENTATION

Presenting Concerns
An 83-year-old woman visited her primary care physician for evaluation of a tender, purple lesion on her scalp. She had been in good health until about 5 months earlier, when she recalled hitting the top of her head on a nectarine tree in her yard, causing a small wound to her scalp. The wound seemed to heal, but then 2 months later, she hit the same spot on her scalp (on the same branch of the nectarine tree); however, this time the wound failed to heal. She sought care from her primary care physician, who referred her to a head and neck surgeon.

At her appointment with the surgeon 2 days later, the wound was inspected and no foreign body was identified. A fluid collection was aspirated. She was reevaluated 13 days later, and the wound was deemed to be healing well.

Three months later, she visited her primary care physician again, this time for evaluation of multiple lesions on her scalp. She was referred back to the head and neck surgeon and was seen the same day in the surgeon’s clinic. On examination, multiple lesions were noted on the scalp, described as erythematous weeping lesions, with the largest being 3 cm x 4 cm. This lesion underwent biopsy, and the pathologic findings revealed an angiosarcoma. She was referred to an oncologist and was offered treatment with chemotherapy and radiation therapy. The patient refused any therapy. Staging computed tomography (CT) of the chest, abdomen, and pelvis was done, but the scans did not reveal any evidence of metastasis.

Three months later, she presented to the Emergency Department (ED) with shortness of breath. Chest radiographic findings were unremarkable. She received albuterol, with subsequent improvement in her symptoms, and was then discharged home. Two weeks after her ED visit, the patient developed herpes zoster and was prescribed acyclovir. She was seen again in the ED three weeks later for dyspnea this time requiring admission to the hospital for treatment of a suspected pneumonia. A chest CT (Figure 1) demonstrated cystic lung lesions characteristic of metastatic angiosarcoma and a left pleural effusion.

Therapeutic Interventions and Treatment
The patient followed-up with her oncologist and a radiation oncologist. She was offered therapy with radiation to the scalp and paclitaxel. She agreed to both therapies and received fractionated doses...
of 2700 cGy of local radiation to the scalp and weekly paclitaxel therapy. After one month of chemotherapy, she returned to the ED with chest pain and shortness of breath. She was found to have a non-ST-segment elevation myocardial infarction. A CT of the chest was repeated (Figures 2 and 3), which demonstrated multiple new lung lesions, a small right pneumothorax, and a left pleural effusion. A left thoracentesis was performed, and cytologic analysis yielded negative results.

Follow-up and Outcomes
Because of progression of her lung disease despite chemotherapy, the patient elected for hospice care. A pleural drainage catheter (PleurX, Becton, Dickinson and Co, Franklin Lakes, NJ) was placed two weeks later given recurrent left pleural effusion. The patient was again hospitalized a month later because of shortness of breath and respiratory failure requiring bilevel positive airway pressure. This treatment was done only briefly because the patient decided to forgo any further treatment. She died that same day. See Table 1 for a timeline of the case.

DISCUSSION
Angiosarcomas are rare malignant tumors, which are of vascular or lymphatic endothelial cell origin; they constitute approximately 2% of all soft-tissue sarcomas.1 They can occur at any age, but they are most common in elderly individuals and usually present on the scalp or face. They can present with a variety of clinical features but most commonly present as dark-purple, bluish, or red lesions, which may be nodular or plaque-like. They can ulcerate and often bleed after minor trauma, such as combing hair. The tumors can be difficult to diagnose in their early stages because their appearance may suggest a nonneoplastic process or they can be hidden under hair on the scalp. Initially, these tumors tend to spread locally and then often metastasize to lymph nodes, with the lungs being the most common distant site of metastases.1

In the largest series to date of cutaneous angiosarcomas (434 cases over 34 years of surveillance), there was a predominance in men, with a mean age of 73 years, and most tumors began in the head and neck.2 The survival rates were disparate depending on the age at which the tumor presented. Those patients whose age was younger than age 50 years had a 10-year survival rate of 72%, whereas patients who were older than age 50 years had a 10-year survival rate of 37%. Also, the site at which the tumor originated had profound significance for survival rates; tumors arising in the trunk had a 10-year survival rate of 75%, whereas tumors that arose in the head and neck had a 10-year survival rate of only 14%. Once the tumor metastasizes, the prognosis is very poor, with one series reporting a 4-month survival after the appearance of lung metastases. Indeed, our 83-year-old patient with an angiosarcoma of the scalp had a very poor prognosis, particularly after the appearance of lung metastases. Usually, there are no predisposing causes, although angiosarcomas have been linked to chronic lymphedema; arteriovenous fistulas; foreign bodies; and previous exposure to radiation, arsenic, or polyvinyl chloride.1,2,5 Diagnosis requires a high suspicion for the disease and subsequent biopsy of the suspected lesion. Effective treatment of the disease has yet to be clearly established. The mainstay of treatment is surgery with wide excision of the lesion, in an attempt to achieve tumor-free margins, and adjuvant radiotherapy.1,3,5 Multifocal and widespread metastases.
lesions are often treated with radiation therapy in cases in which surgery is not an option; however, results in these cases are often suboptimal. In most cases, the preferred treatment of choice is a multimodal approach with a combination of surgery and radiotherapy. Other treatment options that have been studied include chemotherapy and immunotherapy. A number of chemotherapy agents have been tried with limited success, particularly with unresectable tumors, although recent reports suggest that there may be a role for paclitaxel. Our patient received paclitaxel and did not appear to benefit from this therapy.

### Review of Common Cystic Lung Diseases

Cysts are defined as round, circumscribed spaces surrounded by a thin wall (often < 2 mm) of fibrous or epithelial tissue. They are usually air filled but may also contain liquid or solid material. They vary in size, quantity, and location depending on underlying pathology. Pulmonary cysts can result from a vast array of disorders and are often found incidentally on chest images. High-resolution CT (HRCT) remains the diagnostic modality of choice for most cystic lung diseases, and in many cases tissue is needed for a definitive diagnosis. Cysts found in the lungs can be further described as blebs, bullae, or pneumatoceles (Table 2). Blebs are small cysts measuring less than 1 cm in diameter, whereas bullae are larger cysts measuring greater than 1 cm in diameter; other than size, there are few differences between blebs and bullae. Pneumatoceles are air-filled spaces in the lungs that typically are caused by trauma and are usually transient. Given the variety of diseases and conditions that cause cystic changes in the lungs, it is useful for clinicians to understand these different entities to allow for timely diagnosis. Table 3 provides an overview of some of the more common causes of pulmonary cysts.

### Neoplastic Causes of Pulmonary Cysts

It is uncommon for lung tumors (either primary or metastatic tumors) to produce cystic changes in the lung. Metastatic cancers produce cysts more commonly than do primary tumors, and among these, sarcomas (most notably scalp angiosarcomas) are particularly prone to induce cystic changes. Lymphangioleiomyomatosis (LAM) is a rare, slowly progressive disease in which the lung is infiltrated with smooth-muscle cells. These aberrant cells contain growth-activating mutations in the tuberous sclerosis genes. LAM is most exclusively seen in women, with an average age at diagnosis in the mid-30s. The disease can occur sporadically or in patients with underlying tuberous sclerosis (Figure 4). More than 30% of women with tuberous sclerosis have LAM vs only 10% to 15% of men with tuberous sclerosis. LAM is 5 to 10 times more common in women.

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**Table 2. Commonly used terms for pulmonary cysts seen on radiologic imaging

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cyst</td>
<td>Round, circumscribed space containing air, fluid, or solid material surrounded by a thin wall (&lt; 2 mm) of fibrous or epithelial tissue</td>
</tr>
<tr>
<td>Bleb</td>
<td>Gas-containing space that measures ≤ 1 cm in diameter</td>
</tr>
<tr>
<td>Bulla</td>
<td>Gas-containing space that measures &gt; 1 cm in diameter</td>
</tr>
<tr>
<td>Pneumatocele</td>
<td>Air-filled space in the lung usually resulting from trauma, tends to be transient</td>
</tr>
</tbody>
</table>


**Table 3. Common causes of pulmonary cysts

<table>
<thead>
<tr>
<th>Cause</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neoplastic</td>
<td>Lymphangioleiomyomatosis; Pulmonary Langerhans cell histiocytosis; Pleuropulmonary blastoma; Other primary and metastatic neoplasms (especially metastatic angiosarcomas)</td>
</tr>
<tr>
<td>Smoking-related lung disease</td>
<td>Pulmonary Langerhans cell histiocytosis; Desquamative interstitial pneumonia; Respiratory bronchiolitis-associated interstitial lung disease</td>
</tr>
<tr>
<td>Infectious</td>
<td>Pneumocystis jiroveci pneumonia; Cystic echinococcosis (pulmonary hydatid disease); Staphylococcal pneumonia; Cocciidiomycosis; Recurrent respiratory papillomatosis; Paragonimiasis</td>
</tr>
<tr>
<td>Hereditary/congenital</td>
<td>Birt-Hogg-Dubé syndrome; Neurofibromatosis; Ehlers-Danlos syndrome; Congenital airway malformation</td>
</tr>
<tr>
<td>Other interstitial lung disease</td>
<td>Idiopathic pulmonary fibrosis; Desquamative interstitial pneumonia; Hypersensitivity pneumonitis; Sarcoidosis</td>
</tr>
<tr>
<td>Lymphoproliferative disease</td>
<td>Lymphocytic interstitial pneumonia; Sjögren syndrome; Amyloidosis; Light-chain deposition disease</td>
</tr>
</tbody>
</table>
association with tuberous sclerosis than in its sporadic form. Similar to patients with other types of cystic lung diseases, patients with LAM often present with nonspecific symptoms such as cough, dyspnea, chest pain, and pneumothorax. Biopsy remains the gold standard for the diagnosis of LAM; however, HRCT features of LAM are highly characteristic, and in many cases a biopsy is not needed. Patients with LAM typically have higher serum levels of vascular endothelial growth factor D, which can be a useful marker in aiding in the diagnosis of LAM, particularly in patients who present with isolated lung cysts. In 2010, diagnostic guidelines were published by the European Respiratory Society LAM Task Force. Long-term prognosis is poor given the progressive nature of lung disease in LAM. There is no cure for LAM; however, mammalian target of rapamycin kinase inhibitors such as sirolimus have been determined to be effective drugs in treating LAM because mutations in tuberous sclerosis complex genes contribute to activation of mammalian target of rapamycin kinase. The only curative therapy appears to be lung transplant; however, recurrence rates are high, and recurrence also can occur in transplanted lungs.

Pulmonary Langerhans cell histiocytosis (PLCH), formerly called eosinophilic granuloma of the lung, is seen predominantly in young smokers (in approximately 90% of cases) or in patients with substantial secondhand smoke exposure. The average age at onset is typically in the third and fourth decades of life. Langerhans cells, which are differentiated cells of the monocyte–macrophage line, help regulate bronchial mucosal immunity. In PLCH, there is abnormal peribronchial accumulation of these cells along with other immune cells and formation of granulomas. It is thought that cigarette smoking induces gene mutations that allow unregulated growth of Langerhans cells, leading to the formation of cellular nodules. As the disease progresses, nodules cavitate and cause bronchial dilation that results in cystic lung changes. Unlike many interstitial lung diseases, the lung changes of PLCH predominate in the mid and upper lung zones. Figure 5 shows a CT scan of PLCH.

The disease course of PLCH is variable, ranging from patients who are asymptomatic to those who have a progressive course leading to respiratory failure. Diagnosis can be made clinically with radiologic evidence by HRCT; however, a definitive diagnosis may require bronchoalveolar lavage with identification of greater than 5% of Langerhans cells. Therapeutic management should begin with smoking cessation, because the disease may resolve with just this behavioral modification. Drug treatments have been disappointing, but glucocorticoids and cladribine have been used.

Pleuropulmonary blastoma is a very rare and highly aggressive malignant neoplasm that occurs most commonly in children under the age of 5 years. It arises from either the lungs or pleura and accounts for less than 1% of all pediatric primary lung neoplasms. Histologically, it resembles fetal tissue characterized by primitive blastema with benign epithelial elements and by malignant mesenchymal stroma with the potential for sarcomatous differentiation. Pleuropulmonary blastomas can be classified into 4 types. Type 1 has a purely cystic component, Type 2 has a mixed component with both solid and cystic features, and Type 3 has a purely solid component. The fourth type, Type 1r (Type 1-regressed), which was added in 2006 by the International Pleuropulmonary Blastoma Registry, has a cystic component containing spindle-shaped cells in the wall of the cyst with foci of dystrophic calcification. Diagnosis is made by histologic evaluation of the tumor, either after excision of the mass or by fine-needle aspiration; however, this testing may not provide a conclusive diagnosis. Prognosis remains poor despite a multimodal approach to treatment. The mainstay of therapy is surgical resection of the tumor with the addition of chemotherapy and less often radiotherapy.

Smoking-Related Causes of Pulmonary Cysts

Cigarette smoking has been linked to a variety of diffuse cystic lung diseases. As mentioned previously, PLCH is one of those diseases. Other disorders include desquamative interstitial pneumonia (DIP), respiratory bronchiolitis-associated interstitial lung disease (Figure 6), and emphysema. Both DIP and respiratory bronchiolitis-associated interstitial lung disease are types of idiopathic interstitial pneumonias that fall under the larger category of interstitial lung diseases. In DIP, histologically pigmented macrophages are dispersed throughout the alveolar spaces. DIP occurs mostly in adults, with an average age at onset of 40 years, and occurs more frequently in males with approximately a 2:1 ratio. The disease is almost exclusively seen in smokers (approximately 90%), with other inciting factors being occupational/environmental exposures, medications, infections, and other systemic disorders.
immunocompromised persons, especially those with HIV and a CD4 count of less than 200/mm$^3$.\textsuperscript{3,6,21} The most common features on HRCT in patients with \textit{P. jiroveci} pneumonia are ground-glass opacities.\textsuperscript{22} Cystic lung changes are seen less commonly but can be observed on HRCT scans in 10% to 30% of patients with AIDS.\textsuperscript{21} Cysts are typically not observed until after multiple infections and tend to occur in the lung apices.\textsuperscript{9} Diagnosis can be made by sputum examination or bronchoalveolar lavage; however, transbronchial biopsy may be needed for a subset of patients.\textsuperscript{6} The recommended first line of treatment is with trimethoprim-sulfamethoxazole regardless of severity of the disease.\textsuperscript{22} Other therapies include dapsone, primaquine, clindamycin, and pentamidine atovaquone, used alone or in combination depending on the patient’s tolerance or other medical conditions.\textsuperscript{22}

Cystic echinococcosis (pulmonary hydatid disease) is a parasitic disease caused by \textit{Echinococcus granulosus}.\textsuperscript{23} The disease is endemic in most Mediterranean countries, Northern and Eastern Africa, Central Asia, South America, and Australia.\textsuperscript{23} \textit{E. granulosus} most commonly affects the liver—in about two-thirds of patients—with the lungs being the second most common site of involvement—in about one-fourth of patients.\textsuperscript{21} Pulmonary hydatid disease (Figure 8) can occur as a primary or secondary infection. Primary hydatidosis occurs by direct ingestion of eggs into the gastrointestinal tract, and larvae penetrate through the intestinal wall into the portal circulation and then proceed to the systemic circulation via the liver, eventually making their way to the lungs.\textsuperscript{21} Secondary disease occurs by rupture of a primary cyst, thereby releasing multiple other daughter cysts into the lungs.\textsuperscript{21} Cysts tend to be solitary and unilateral, with the right lung being most commonly affected.\textsuperscript{21} Patients may be asymptomatic, especially when cysts are small and not compressing any adjacent structures.\textsuperscript{22} Symptoms typically occur with large cysts (> 5 cm) or with complications such as cyst rupture or pneumothorax.\textsuperscript{23} Patients with ruptured cysts may have peripheral blood eosinophilia and leukocytosis.\textsuperscript{23} Pulmonary hydatid disease should be suspected in an individual with radiologically proven pulmonary cysts who is from an endemic area with exposure to sheep or dogs.\textsuperscript{23} The disease is managed primarily by antihelminthic medications (albendazole) and/or surgery when intervention is indicated; surgery is the preferred treatment of choice for larger cysts.\textsuperscript{23}

Paragonimiasis is a parasitic infection acquired after ingestion of freshwater crabs or crayfish containing larvae of \textit{Paragonimus westermani}.\textsuperscript{22,23} Larvae migrate through the intestinal wall into the systemic circulation and then into the lungs and pleural spaces, where formation of cysts can occur.\textsuperscript{10} Cysts develop because of obstruction of a blood vessel by migrating worms, resulting in infarction.\textsuperscript{10} Diagnosis is made by identification of eggs in sputum examination or bronchoalveolar lavage and by positive serologic findings.\textsuperscript{10} Prognosis is favorable with antihelminthic treatment (praziquantel), which is effective in almost all patients.\textsuperscript{10}

Other infections known to cause cystic changes in the lungs are staphylococcal pneumonia, coccidioidomycosis, and recurrent respiratory papillomatosis (a pediatric disorder caused by human papillomavirus).\textsuperscript{10}

\textbf{Genetic and Congenital Diseases Causing Pulmonary Cysts}

Birt-Hogg-Dubé syndrome is a rare autosomal dominant multisystem disorder primarily involving the skin, kidneys, and lungs (Figure 9).\textsuperscript{6,8} The syndrome is a result of mutations (more than 100 mutations have been identified) in the \textit{FLCN} gene, which codes for the protein folliculin.\textsuperscript{24} Hair follicle tumors (fibrofolliculomas), along with renal cysts or neoplasms and lung cysts, are all characteristic findings of the disorder; however, not all 3 findings may be present at the same time.\textsuperscript{5,24} In a study by Gunji et al,\textsuperscript{24} 5 of 8 patients with multiple lung cysts of unknown etiology were found to have germline mutations consistent with Birt-Hogg-Dubé syndrome despite not having any skin or renal involvement. The disease is typically seen in the third and fourth decades, with no predilection for sex.\textsuperscript{6} Renal findings can present as benign cysts, benign tumors, or malignant neoplasms such as renal cell carcinoma.\textsuperscript{23} Cystic

As in DIP, pigmented macrophages are also seen in respiratory bronchiolitis-associated interstitial lung disease; however, instead of extensive and diffuse scattering, they tend to accumulate in peribronchiolar spaces and nearby alveoli.\textsuperscript{20} The average age at onset is in the fourth to fifth decades of life.\textsuperscript{20} The disease often resolves with smoking cessation.\textsuperscript{20}

\textbf{Infectious Causes of Pulmonary Cysts}

\textit{Pneumocystis jiroveci} pneumonia (Figure 7) almost exclusively affects severely
changes in the lung have been attributed to defects in the gene encoding for the tumor suppressor protein folliculin, hence the more appropriate term folliculin gene-associated syndrome. Patients with pulmonary involvement most commonly present with spontaneous pneumothorax, although the most common presentation in all patients are papules. Diagnosis is made by identification of mutation in the FLCN gene and by clinical manifestation of skin lesions, lung cysts, and/or renal tumors. Overall the progression of lung disease in Birt–Hogg–Dubé syndrome is slow and is not well understood; however, respiratory failure does not typically occur.

Neurofibromatosis, Ehlers–Danlos syndrome, bronchopulmonary dysplasia, and congenital airway malformations are other genetic diseases that can cause cysts in the lungs.

**Interstitial Lung Diseases**

A few types of interstitial lung diseases may present with cystic changes in the lungs. Among these are idiopathic pulmonary fibrosis, hypersensitivity pneumonitis (HP), and sarcoidosis. Idiopathic pulmonary fibrosis is predominantly associated with fibrosis and other fibrotic features (eg, reticulation, honeycombing, traction bronchiectasis) rather than cysts; however, distribution of cysts can be helpful in differentiating among the types of interstitial lung diseases.

HP, or extrinsic allergic alveolitis, is an immune-mediated response to repeated exposures of the lung parenchyma to inhaled antigens, resulting in inflammation. HP can be categorized into acute, subacute, and chronic types, with chronic HP (Figure 10) identified as the stage with evidence of fibrosis seen on either radiologic imaging (HRCT) or histologic findings. Acute and subacute HP tend to resolve after the offending agent has been removed, whereas chronic HP is a slowly progressive disease, often with irreversible damage. Cysts are rarely seen in acute HP but can be seen in subacute HP and chronic HP, with the latter being much more common. The cysts are presumed to result from damage to bronchioles and tend to occur in areas of ground-glass attenuations. Diagnosis can be made with a history of environmental or occupational exposure to a possible inciting agent, clinical manifestations, HRCT findings suggestive of HP, and, if needed, lung biopsy. Management involves identifying and removing the offending agent and the use of corticosteroids. Resolution can be seen in acute and subacute HP with removal of the offending agent and/or use of corticosteroids; however, with chronic HP there usually has already been irreversible damage.

Sarcoidosis is a noncaseating, granulomatous disease that mainly involves the lungs (Figure 11) but can affect many other organ systems such as the heart, skin, eyes, liver, central nervous system, and kidneys. The disease can affect individuals of all ages and ethnicities but more commonly occurs in women younger than age 50 years. Incidence varies across the world; however, in the US, incidence is about 3 times higher in African Americans compared with whites. Noncaseating granulomas seen on histologic findings are the hallmark of sarcoidosis. On HRCT, perihilar lymphadenopathy and nodules are more commonly seen than cysts. Formation of cysts occur because of obstruction of lobar or segmental bronchi by fibrosis or accumulation of granulomas. Cysts are occasionally seen in the perihilar or subpleural regions. Treatment is reserved for symptomatic patients with worsening organ involvement. The mainstay of therapy is corticosteroids; however, steroid-sparing agents such as methotrexate, azathioprine, leflunomide, and mycophenolate mofetil have also been used. Lung transplant can be an option for those with end-stage lung disease in whom other medical therapies have failed; however, posttransplant prognosis is unclear in these patients because of the multisystem involvement of sarcoidosis.

**Lymphoproliferative Causes of Pulmonary Cysts**

Lymphocytic interstitial pneumonia (LIP) is a benign lymphoproliferative disorder characterized by diffuse lymphocytic infiltration of the lung parenchyma (Figure 12). This type of pneumonia is most common in women in their 30s and 40s. It can occur as a form of idiopathic interstitial pneumonia or in association with other disorders such as Sjögren syndrome, rheumatoid arthritis, systemic lupus erythematosus, HIV infection, Hashimoto thyroiditis, and common variable immune deficiency. The presence of polyclonal lymphocytes is a key factor in differentiating LIP from...
lymphomas, in which monoclonal lymphocytes are seen. LIP is a progression from hyperplasia of bronchus-associated lymphoid tissue (follicular bronchiolitis) to cellular expansion of the interstitium, which can result in postobstructive bronchial ectasia; vascular obstruction; and/or bronchiolar stenosis, occlusion, or compression. Any of these entities can lead to the development of pulmonary cysts. Pulmonary cysts develop in approximately 60% to 80% of patients with LIP. Management and prognosis is dependent on the underlying disease. Corticosteroids are commonly used; however, the disease does not always respond to treatment and can progress to respiratory failure.

Sjögren syndrome is an autoimmune disease characterized by lymphocytic infiltration of exocrine glands. The disease predominantly affects middle-aged women. Depending on the presence or absence of other autoimmune disorders such as systemic lupus erythematosus, rheumatoid arthritis, or systemic sclerosis, the syndrome can be further categorized as primary (occurring alone) or secondary Sjögren syndrome (occurring with other diseases). Systemic manifestations beyond exocrine glands can also be observed with involvement of the lungs, liver, blood vessels (vasculitis), kidneys, and central nervous system. Sjögren syndrome has protein manifestations in the lungs, ranging from airway abnormalities to LIP and interstitial lung disease. Lung cysts can develop as a result of interstitial lung disease or LIP. Pulmonary involvement occurs in less than 20% of patients and indicates increased mortality.

Amyloidosis encompasses a group of diseases characterized by an abnormal deposition of fibrillar proteins. It can occur as a systemic disease or be localized to a single organ such as the lungs (Figure 13). Although rare, amyloidosis with pulmonary involvement may present with cystic changes in the lungs. Cyst formation is thought to be caused by one or more of the following mechanisms: Narrowing of the airways as a result of infiltration of amyloid and inflammatory cells causing alveolar destruction, amyloid deposition causing increased fragility of alveolar structures, or amyloid deposition in the vasculature resulting in ischemia. Tissue biopsy is required for diagnosis, with identification of amyloid fibrillary tangles that demonstrate green birefringence and stain positive for Congo red.

Patients with only pulmonary amyloidosis have a good prognosis, whereas those with amyloid-associated systemic disease have a much worse prognosis. Light-chain deposition disease (LCDD) is a multisystem disease characterized by the accumulation of monoclonal immunoglobulin light chains. This disease is most commonly associated with an underlying plasma cell dyscrasia, but LCDD can be idiopathic or associated with autoimmune diseases. The kidneys are almost always involved, with the next most frequently involved organs being the heart and liver. Pulmonary involvement occurs rarely in LCDD, but when present the most common findings are lung cysts (Figure 14), nodules, and bronchiectasis. When LCDD is isolated to the lungs, this form of the disease is known as primary cystic lung LCDD. Cystic lung LCDD was first described in 2006 and differs in various ways from the systemic form of the disease. It has a predilection for young women in their 30s. The mechanism of cyst formation in LCDD was explored by Colombat et al, wherein there was seen degradation of pulmonary elastin from metalloproteinases. Cystic lung LCDD is a severe disease that usually progresses to end-stage respiratory failure. There is also an association with lymphoproliferative disorders such as lymphoplasmycotic lymphoma, chronic lymphocytic leukemia, and gammopathy of undetermined significance.

Diagnosis of LCDD can be made histologically via biopsy of the affected organ. Bronchial biopsy has also been shown to aid in diagnosis if the lung is suspected to be involved. Demonstration of the presence of fibrils that do not stain Congo red under polarized light supports the diagnosis of LCDD; however, analysis of the tissue sample by immunofluorescence and microscopy is ultimately needed to confirm the diagnosis. There is no definite treatment of LCDD; however, lung transplant may be an option for those with advanced cystic lung LCDD, and a blood stem cell transplant may be a treatment option for patients with monoclonal disease. In cases in which there is an associated lymphoproliferative disorder, other therapies may be offered such as chemotherapy and blood stem cell transplant. Le Borgne et al described a patient who was found to have cystic lung LCDD and lymphoma who was treated with chemotherapy and autologous peripheral blood stem cell transplant. The patient did not undergo lung transplant given the associated lymphoma; however, respiratory stability was achieved with the aforementioned therapy.

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Metastatic Angiosarcoma of the Scalp Presenting with Cystic Lung Lesions: A Case Report and Review of Cystic Lung Diseases

References

Integument
The skin and subcutaneous tissue, composing the integument, should be regarded as part of the body rather than as an independent organ. The skin possesses the closest relations with the general economy … — Louis A Duhring, MD, 1845-1913, American physician and professor of dermatology
Endogenous Group A Streptococcal Endophthalmitis in a Healthy 42-Year-Old Man: A Case Report

Tan Duong, MD; Shahin Shahbazi, MD; Sung Lee, MD

ABSTRACT

Introduction: Endogenous endophthalmitis is a rare condition that is caused by hematogenous spread of bacteria or fungi and is usually seen in patients with predisposed medical conditions. We are reporting an unusual case of group A streptococcal infection causing endogenous endophthalmitis and septic arthritis in a healthy 42-year-old man.

Case Presentation: A previously healthy 42-year-old man presented to the Emergency Department with chills, fever, left wrist pain, left eye pain, and vision loss. Owing to the acute onset of the septic arthritis and the patient’s bandemia, the Ophthalmology Department was consulted for suspicion of endophthalmitis. Blood cultures, left wrist synovial fluid cultures, and vitreous cultures grew group A streptococcus. An incision and drainage of the left wrist was performed, and intravitreal injection of vancomycin was given. The patient’s vision was responsive only to light on discharge from the hospital. The patient underwent a left eye evisceration 2 months later.

Discussion: Endophthalmitis provides a difficult diagnostic and therapeutic challenge. However, even with prompt treatment, visual outcomes may be poor.

INTRODUCTION

Endophthalmitis is a rare and devastating disease. In clinical practice, endophthalmitis is defined as an intraocular bacterial or fungal infection. Endophthalmitis is categorized into 2 different types, exogenous and endogenous. Exogenous endophthalmitis occurs when bacterial or fungal organisms are introduced after ocular surgery, from retained foreign bodies, or from lacerating trauma. Endogenous endophthalmitis occurs when organisms reach the eye from crossing the blood-ocular barrier from the blood stream and accounts for 2% to 8% of all cases of endophthalmitis.1,2 Endogenous endophthalmitis typically affects patients with medical conditions such as diabetes, intravenous drug use, HIV infection, malignant tumor, or other autoimmune diseases.1 One review1 showed that 207 (60%) of 342 patients had a medical condition that predisposed them to infection, and another source1 reported 90% of patients had a condition that predisposed them to infection. There have been other case reports in which healthy patients have developed endophthalmitis from Staphylococcus epidermidis,1,4 Listeria monocytogenes,1 Aspergillus,6 and Pseudomonas.7

Some of the causative agents in bacterial endogenous endophthalmitis include Klebsiella pneumoniae, Staphylococcus aureus, Escherichia coli, Pseudomonas aeruginosa, Strepococcus pneumoniae, Neisseria meningitides, and other Streptococcus species.1

Some typical sources of infection include liver abscesses, lung and soft tissue infections, endocarditis, meningitis, and septic arthritis.1

CASE PRESENTATION

Presenting Concerns

A 42-year-old Asian man presented to the Emergency Department with chills, fever, left wrist pain, left eye pain, and vision loss. The patient reported that he developed chills 2 days before presentation. One day before presentation he started developing body aches and left wrist pain. Later that day, his left eye became erythematous and started developing vision loss. Systems review revealed no weight loss, nausea, or lesions of the mouth or genitalia. There was no history of diabetes, malignant tumor, autoimmune disease, immune compromise, recent travel, recent surgery, or intravenous drug use.

Examination of his left eye revealed an erythematous conjunctiva and cloudy pupil. The visual acuity in the left eye was hand motion. The left wrist was also erythematous and swollen. Laboratory testing was significant for a white blood cell count of 14,900 (74% neutrophils, 19% bands) and a lactate of 3.7 mmol/L. The patient’s family history was significant for polymyalgia rheumatica and gout in his father and breast and colon cancer in his mother (diagnosed at age 67 years).

Gram stain of the patient’s left wrist revealed gram-positive cocci and many white blood cells. Because of the acute onset of ocular complications in the context of sepsis, the Ophthalmology Department was consulted on suspicion of endophthalmitis.

Therapeutic Intervention and Treatment

The patient received 500 mg of acetazolamide in the Emergency Department because it was thought that he may have had acute narrow-angle glaucoma. An orthopedist performed an incision and drainage of the left wrist. An ophthalmologist performed a vitreous tap and intravitreal injection of vancomycin (1 mg in 0.1 cc normal saline dilution) in the patient’s left eye. The patient also received a second intravitreal injection of vancomycin 2 days later and was given prednisolone eye drops. Within 24 hours of admission, the patient was started on 2 g of intravenous ceftriaxone twice per day and 1750 mg of intravenous vancomycin once per day. Vancomycin was discontinued after culture results were analyzed, and 900 mg of clindamycin 3 times per day was added. The patient
was discharged from the hospital with a peripherally inserted central catheter and continued on 2 g of ceftriaxone twice per day for 3 more weeks.

**Follow-Up and Outcomes**

An extensive evaluation included transesophageal echocardiography to rule out endocarditis; it was negative. A computed tomography scan of the chest and abdomen/pelvis looking for occult malignant tumor was negative, and chest radiograph revealed only a left lung base infiltrate. Blood cultures grew group A streptococcus, left wrist synovial fluid aspirate grew group A streptococcus, and vitreous cultures from the left eye grew group A streptococcus. The HIV antibody was nonreactive.

On the second day of hospitalization, examination revealed worsening left eye vision that was responsive only to light; however, further examinations were stable. On the third day of hospitalization, a second intravitreal injection of vancomycin was performed. On the fifth day of hospitalization, there was increasing erythema and swelling on the left arm. A follow-up computed tomography scan of the left upper extremity revealed mild edema in the muscles within the distal anterior aspect of the forearm and small air bubbles in the subcutaneous tissues posterior to the carpal bones. A second incision and drainage was performed. The patient’s eye, 7 days after admission, is shown in Figure 1. When the patient was discharged on day 10, his left eye was responsive only to light.

Two months later, because of the severity of the illness, it was recommended by the retina service that the patient undergo evisceration of the left eye, which he elected to do. Figure 2 shows a timeline of the case.

**DISCUSSION**

Endophthalmitis provides a difficult diagnostic and therapeutic challenge. Misdiagnosis of endogenous endophthalmitis is common. One review noted that 89 (26%) of 342 patients were misdiagnosed. Misdiagnoses may also be underreported in literature. In one case series, 63% of the cases were initially misdiagnosed. It may be diagnosed as conjunctivitis early in the disease process, whereas later presentation with severe inflammation and high intraocular pressure may lead to a diagnosis of acute narrow-angle glaucoma if the overall clinical picture is not considered. When our patient arrived in the Emergency Department, he was initially thought to have acute narrow-angle glaucoma and was given acetazolamide. A few hours later, the admitting physician had a high suspicion for endophthalmitis because of the acute ocular disease in the setting of sepsis. Even with prompt intravitreal injection of vancomycin within 1 day of visual symptoms, the visual prognosis was ultimately poor.

Group A streptococcus, also known as *Streptococcus pyogenes*, is a gram-positive, epithelial-surface-colonizing cocci and is not typically associated with endophthalmitis. It was the causative agent in 2 of the 342 cases in one review of cases from 1986 to 2012 and 0 of the 27 cases of another review of cases from 1982 to 2000. Table 1 provides a list of causative bacterial organisms, adapted from the review article by Jackson et al.

Group A streptococcus causes a diverse range of diseases such as pharyngitis, impetigo, cellulitis, scarlet fever, pneumonia, toxic shock syndrome, necrotizing fasciitis, septic arthritis, endocarditis, and rheumatic fever. It has many virulence factors, is able to migrate to normally sterile areas such as the bloodstream and tissues, and as in our case is able to cause
bacteremia and subsequent endophthalmitis and septic arthritis. Group A streptococcal infection can lead to Sydenham chorea and has been associated with pediatric autoimmune neuropsychiatric disorders with streptococcal infections; one mechanism proposed is associated with antibody cross-reaction with neuronal brain tissue. The mechanisms underlying invasive group A streptococcus disease remain the subject of intense research. Animal studies have also shown that increased blood-ocular barrier permeability caused by diabetes predisposes subjects to developing endophthalmitis. Certain bacterial species such as *S. aureus* produce toxins that may help facilitate permeability without a predispersing factor such as diabetes. In the same study, *K. pneumoniae* was unable to penetrate the retinal pigment epithelium in healthy mice; however, when mice were introduced to sodium iodate, which induced retinal pigment epithelium degradation, or in mice with streptozotocin-induced diabetes, an incidence of endogenous endophthalmitis was seen. Also, one specific strain of hypervirulent, hyper-mucoviscous *K. pneumoniae* has been associated with increased endophthalmitis incidence compared to other strains. This strain has been associated with increased efficiency to acquire iron and capsule production.

Our case is unusual because our patient was young and had no predisposing factors but went on to develop endogenous endophthalmitis from group A streptococcus. No infectious focus was found in our case. Group A streptococcus species has a diverse range of virulence factors and has been associated with other disorders such as Sydenham chorea and pediatric autoimmune neuropsychiatric disorders with streptococcus infections; however, group A streptococcus is usually not associated with endogenous endophthalmitis. Unfortunately, even with high clinical suspicion and early treatment, colonization from group A *S. pyogenes* led to a poor visual outcome in our case.

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**How to Cite this Article**


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**Table 1. Causative bacteria for 342 patients diagnosed with endogenous endophthalmitis**

<table>
<thead>
<tr>
<th>Bacterial organism*</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Staphylococcus aureus</em></td>
<td>33 (10)</td>
</tr>
<tr>
<td><em>Streptococcus pneumoniae</em></td>
<td>17 (5)</td>
</tr>
<tr>
<td>Other streptococcal species†</td>
<td>44 (13)</td>
</tr>
<tr>
<td><em>Nocardia</em></td>
<td>12 (4)</td>
</tr>
<tr>
<td><em>Listeria monocytogenes</em></td>
<td>12 (4)</td>
</tr>
<tr>
<td><em>Bacillus cereus</em></td>
<td>8 (2)</td>
</tr>
<tr>
<td>Other†</td>
<td>16 (5)</td>
</tr>
<tr>
<td>Klebsiella pneumoniae</td>
<td>93 (27)</td>
</tr>
<tr>
<td>Escherichia coli</td>
<td>23 (7)</td>
</tr>
<tr>
<td><em>Pseudomonas aeruginosa</em></td>
<td>20 (6)</td>
</tr>
<tr>
<td>Neisseria meningitidis</td>
<td>16 (5)</td>
</tr>
<tr>
<td>Serratia species</td>
<td>7 (2)</td>
</tr>
<tr>
<td>Salmonella species</td>
<td>3 (1)</td>
</tr>
<tr>
<td>Other†</td>
<td>24 (7)</td>
</tr>
</tbody>
</table>

† Also included are 6 cases of mixed infections and 6 cases of acid-fast bacilli infections.
‡ Other streptococcal species include: Group B streptococcus (20); group C streptococcus (9); group G streptococcus (2); *Streptococcus milleri* (1); *Streptococcus mitis* (1); *Vindans* group streptococcus (2); *Streptococcus sanguis* (1); *Streptococcus dysgalactiae* (1); *Streptococcus constellatus* (1); *Streptococcus bovis* (1); *Streptococcus anginosus* group (1); *Streptococcus*, species not stated (1).
§ Other gram-positive species include: *Clostridium septicum* (4); *Staphylococcus epidermidis* (3); *Enterococcus faecalis* (3); *Clostridium perfringens* (2); *Propionibacterium acnes* (2); *Actinomyces israelii* (1); *Bacillus*, species not stated (1).
‖ Other gram-negative species include: *Enterobacter agglomerans* (2); *Klebsiella kingae* (1); *Aeromonas hydrophila* (2); *Aeromonas sobria* (1); *Ochrobacterium anthropii* (1); *Brucella melitensis* (1); *Haemophilus influenzae* (1); *Tropheryma whippelii* (1); *Actinobacillus actinomycetemcomitans* (1); *Capnocytophaga canimorsus* (1); *Vibrio vulnificus* (1); *Proteus mirabilis* (1); *Moraxella species* (1); *Burkholderia pseudomallei* (1); *Morganella morgani* (1); *Serratia marcescens* (1); *Citrobacter koseri* (1); *Fusobacterium necrophorum* (1); *Stenotrophomonas maltophilia* (1); *Pantoea agglomerans* (1); and *Sphingomonas paucimobilis* (1).

**References**

The Unmet Challenge of Medication Nonadherence

Fred Kleinsinger, MD

ABSTRACT

Medication nonadherence for patients with chronic diseases is extremely common, affecting as many as 40% to 50% of patients who are prescribed medications for management of chronic conditions such as diabetes or hypertension. This nonadherence to prescribed treatment is thought to cause at least 100,000 preventable deaths and $100 billion in preventable medical costs per year. Despite this, the medical profession largely ignores medication nonadherence or sees it as a patient problem and not a physician or health system problem. Much of the literature on nonadherence focuses on barriers to adherence, with the assumption that appropriate adherence is the normal course of events and nonadherence is an aberration. This approach minimizes and oversimplifies the problem. It is not easy for humans to change their behavior, even for what many physicians see as a minor change such as taking prescription medications. Improving medication adherence has not been well studied, but a Cochrane review shows that multifactorial interventions are more effective. In at least one integrated health care system, Kaiser Permanente Northern California, a combination of approaches centered on the electronic health record has improved medication adherence rates to above 80%. Using similar elements would be feasible in other health care systems but would require motivation and planning. Effective change will not happen until key players decide to take on this challenge and reimbursement systems are changed to reward health systems that improve medication adherence and chronic disease control.

INTRODUCTION

Despite causing an estimated 125,000 avoidable deaths each year and $100 billion annually in preventable health care costs,1 medication nonadherence is barely on the radar of most practicing physicians. Adherence rates for most medications for chronic conditions such as diabetes and hypertension usually fall in the 50% to 60% range, even with patients who have good insurance and drug benefits.2 Medication cost can be a concern for some patients, but most treatment guidelines for chronic conditions use generic medications available at reasonable prices. In most studies, adherence is defined as taking 80% or more of the prescribed medication doses.

Although deaths caused by nonadherence are hard to measure, the estimate of 125,000 deaths per year is widely cited in the literature. Disease-specific meta-analyses validate a significantly increased risk of death in nonadherent patients.3 Yet, unlike better-known causes of death such as heart attack or cancer, medication nonadherence is usually invisible to patients, their families, and the medical profession. It does not appear on the death certificates of patients who have died of a myocardial infarction after not taking his antihypertensive medication or an antiplatelet agent to protect his stent. It is an orphan problem. To my knowledge, no major entity, organization, or group has taken it on as a priority.4 This topic does not fit into the boundaries of any one discipline. Insurers and health plans have other priorities, and few have addressed this problem in a systematic manner.

Practicing physicians remain largely unaware of this problem. To the extent that they do, they see it as the patient’s responsibility to correct this problem. In the pervasive traditional medical model, it is the responsibility of the physician to make an accurate diagnosis followed by an appropriate prescription, with at least some effort at educating and perhaps motivating the patient. Yet when this fails, as it does 40% to 50% of the time, it is seen solely as a patient issue, rather than a system or clinician responsibility. Fee-for-service medicine provides little incentive for individual physicians to address this. The fee-for-service model incentivizes services, not quality or improved outcomes. To the extent that incentives are available with pay-for-quality programs, the amounts involved are too small to motivate busy physicians.

Much of the earlier literature on medication nonadherence focuses on barriers to adherence. This framework has the implicit assumption that adherence is the norm and that when it fails, there must be obstacles that are interfering with the process.5

Although there are many potential barriers to appropriate adherence (Sidebar: Potential Barriers to Medication Adherence), I contend that a more realistic perspective is that in changing human behavior, inertia is the rule, and change the exception. Improving adherence requires an active process of behavioral change, which is nearly always a challenge. It requires education, motivation, tools, support, monitoring, and evaluation. This is

Potential Barriers to Medication Adherence

Patient-related barriers:
- Lack of motivation
- Depression
- Denial
- Cognitive impairment
- Drug or alcohol use
- Cultural issues
- Low educational level
- Alternate belief systems

Treatment-related barriers:
- Complexity of treatment
- Side effects (or fear of side effects)
- Inconvenience
- Cost
- Time

Other barriers:
- Poor practitioner-patient relationship
- Asymptomatic disease being treated

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true not just for medication adherence, but for any desirable behavioral changes such as improving nutrition, increasing exercise, or reducing substance abuse, among others. Focusing on barriers, as much of the literature on nonadherence tends to do, distracts us from the reality that adherence rates are very low under almost all circumstances, whether obvious barriers are present or not. For example, look at how hard it is to induce physicians to wash their hands not. For example, look at how hard it is to induce physicians to wash their hands between patients, which might seem to be a minor behavioral modification of proven benefit, but which happens less than half of the time that it should.8

The best solutions focus on a systems approach as opposed to repeated exhortations. Doctors are used to medications, understand their role and importance, and tend to minimize the difficulty that many patients have with incorporating regular medication, often with side effects, into their busy lives. Although there are steps that physicians can take to improve adherence, the most effective interventions have resulted from system change and multifaceted strategies.

A SUCCESSFUL APPROACH IN ONE HEALTH CARE SYSTEM

Little research has been done on solutions to the problem of medication nonadherence, and most studies that have been done are of limited interventions, such as pill boxes or smartphone apps, that have minimal efficacy.7 A Cochrane review of this subject concludes that multifactorial approaches are better, but even these have limited efficacy.9 This is discouraging and makes the problem seem unsolvable. There have been successes in this arena, but most are of limited generalizability.6

In the Kaiser Permanente Northern California system, hypertension control rates exceed 80%,10 compared with a community control rate of around 65% or less. Kaiser Permanente uses a multifaceted approach that includes the following:

- The electronic health record (EHR) to identify patients at risk: Those with a given diagnosis who have poor control, few visits, or insufficient refills
- Outreach to ensure all patients with hypertension have documentation of blood pressure measurement at least yearly
- Ancillary staff such as medical assistants who can reach out to patients who are nonadherent or who have poor control, and encourage them to make appointments
- Clinical pharmacists who can counsel patients and adjust medications if needed
- Chronic-condition case managers, especially for patients with congestive heart failure and diabetes
- Integrated disease-specific health education classes
- Well-utilized clinical guidelines and algorithms for disease control, emphasizing use of effective generic medications (lowering the cost barrier) when applicable
- Physicians’ classes and counseling in improving physician–patient communication and collaboration, which encourages shared decision making. This approach sounds expensive and complex, and to some extent, it is both. Yet the medical profession thinks it is reasonable to spend $100,000 on a single individual with cancer to extend his/her life for a year. What would it be worth to save 100,000 people from dying each year as a result of not taking their medications?

DISCUSSION: APPROACHES FOR THE FUTURE

One of the first steps in improving medication nonadherence would be to increase public awareness of the magnitude of the problem. Articles are beginning to appear in popular media on this topic.11 Ideally, patients will learn to insist on effective control of their chronic conditions. It is the patient, after all, who has the most to lose.

Suggestions to helping patients become more adherent to taking their medications include using what is known from the science of human behavioral change to help patients adopt healthier ways of living and form healthy habits. Health care practitioners should use basic motivational interviewing strategies when prescribing medications and confirming compliance. If this is done successfully, patients can become motivated to take their medications and to insist on good control of their chronic condition. To help motivate patients, physicians can study a continuing medical education module on medication adherence, such as from the American Medical Association (see: www.stepsforward.org/Static/images/modules/14/downloadable/Medication_Adherence.pdf).

Studies show a direct relationship between a patient’s perception of the need for a given treatment and his/her adherence to this treatment12,13 and between the patient’s sense of empowerment and self-efficacy and his/her medication adherence.14 In 2010, The Permanente Journal published an article I wrote, titled “Working with the Noncompliant Patient,” which discusses tools that physicians can use to enhance medication adherence in their patients.15

Measurements of a medical practice’s diabetes and hypertension control are available using Healthcare Effectiveness Data and Information Set (HEDIS) quality measures. These measures could be publicized and could lead to healthy competition between health care organizations, and possibly between clinicians in a given organization. Providing physicians feedback about their own patients’ medication adherence has not been found to make a significant improvement, however.16

Another idea is to motivate health plans and physicians to take this problem on as a challenge. This could include better reimbursement for better disease control and better outcomes, although the amounts would have to be sufficient to create a powerful incentive.

Disease advocacy organizations such as the American Diabetes Association could make improving medication adherence part of their mission and program. There is no American Medication Nonadherence Association.

Most medical practices in the US are now using an EHR. Although many practices use their EHR mainly for billing and basic medical record functions, most EHRs
programs have the potential functionality of enabling practitioners to identify and reach out to patients with poor medication adherence and/or poor disease control. Often, it is the patients with a given diagnosis whom we do not see regularly who are most likely to be nonadherent. In traditional private practice settings, the patient who does not make appointments is most likely to be forgotten.

Many of the components of the Kaiser Permanente Northern California approach could be tailored to practice settings in the fee-for-service world. We cannot depend on individual physicians to manage this given the time demands of busy practices, but even small group practices could implement some of these techniques and use simple historical controls in their own practices to measure success. This would require using other health care workers such as nurses, medical assistants, and case managers or disease management programs when available to do the bulk of the work.

CONCLUSION

Medication nonadherence for patients with chronic conditions remains an unmet challenge to health care practitioners. If it were possible to improve medication adherence by a simple but costly one-time billable procedure, such as implanting an adherence stimulator, there would be a rush to adopt this practice. Because this is not the case, shouldn’t we as a profession be willing to develop, to implement, and to evaluate more complex but potentially effective approaches to this widespread and dangerous problem? ☞

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References

Understanding
To write prescriptions is easy, but to come to an understanding with people is hard.

— Franz Kafka, 1883-1924, German-speaking Bohemian Jewish novelist and short story writer
HEALTH CARE COMMUNICATION

How a “Nothingoma” Can Bring Joy to a Physician

Scott Abramson, MD

E-pub: 06/11/2018

A version of this article has been previously published in the March 2018 edition of the Kaiser Permanente Greater Southern Alameda Area (GSAA) Physician Health and Wellness Newsletter.

Joanne was a 38-year-old housewife and mother of 4: 2 teens and twin 10-year-old girls. She was referred to me in the neurology clinic because a routine brain magnetic resonance imaging (MRI) scan showed a minor abnormality. Joanne’s mother had died suddenly of a brain aneurysm when Joanne was 13.

During our visit, I talked with Joanne and examined her. Everything was perfectly fine. I reviewed the MRI. It clearly showed an incidental, harmless finding, a “nothingoma.” As I reassured her and was making my exit, Joanne grasped my hand between hers.

“Oh, Doctor,” she tearfully exclaimed, “thank you so much. I was so worried. I am so grateful to you. God bless you, Doctor.”

To be honest, I was embarrassed by this effusive praise. All I did was review a routine MRI.

“Joanne,” I was about to say, “No problem. It was nothing.” But then I realized:

To Joanne this was SOMETHING.
To Joanne, this was a BIG SOMETHING.
This should have been, to me, a SOMETHING.
I should have cherished that moment as much as she.
I saw a bumper sticker a while ago. It read: “It’s amazing how you can affect someone’s life so deeply, and never appreciate it.”

I will confess. For much of my career, in this situation, I would have been in the category of “never appreciate it.” But I am now 70 years old. I have been a physician for 38 of those years, more than half my life. I now understand that, for Joanne, our encounter was a life-affirming blessing. And I now understand that, for me, our encounter was just as much—such a blessing.

To all my physician and healer colleagues, let me ask you: How many of us are in the category of “never appreciate it”? How many of us ignore the powerful beauty of our everyday, “nothingoma” blessings?

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Verse of the Coast: Yellow Tree

collage

Shenshen Dou, MS

Inspired by the unique landscape of the Pacific Northwest coast, this collage was made from a selection of local handmade paper and traditional Chinese rice paper with ink patterns. This work is part of a 10-piece Verse of the Coast series, each piece like the phrase of a poem. In this segment, the wind-bent trees and the rock are the focus of the narrative.

Ms Dou worked as a molecular biologist and is an artist living in West Linn, OR. More of her artwork can be seen in other issues of The Permanente Journal.
ABSTRACT

This article defines empathy as the conveyed expression of awareness, understanding, and sensitivity to the experiences, feelings, and emotions of a patient with a medical condition. This article is a reflective short story addressing empathy through the eyes of Maria (a fictitious patient), who is confronted with the challenges of negotiating her first encounter at a medical facility, and through the actions of Dr Jones (a fictitious physician) who, at a critical juncture, fails to engage empathically with her patient donning the ubiquitous hospital gown. The gown is instructive in this context because it compounds the deidentification of an already nondescript person. Maria's story is a collage of multiple clerkship experiences of a fourth-year medical student, and of shared anecdotal accounts from patients and medical practitioners.

In this article, I explore the following: 1) the insecurities and anxieties experienced by individuals with medical ailments, 2) the critical role that empathy can play in reassuring and comforting patients in pain, 3) the belief held by some individuals that empathy erodes with the practice of medicine, 4) the ongoing threats and barriers to empathy in the medical profession, and 5) the vigilance and diligence required of medical practitioners to ensure maintenance of this essential human quality. Additionally, I describe the challenges of identifying who is responsible for screening for empathy in aspiring medical school applicants, incorporating empathy training in the classroom and in clinical apprenticeships, and monitoring and ensuring empathy maintenance among physicians in training and physicians in practice.

INTRODUCTION

Empathy in health care is the conveyed expression of awareness, understanding, and sensitivity to the experiences, feelings, and emotions of a patient with a medical condition. This article is a reflective short story addressing empathy through a fictitious case.

CASE VIGNETTE

Maria, a young recent immigrant, carefully folds her work clothes, which identify her as a waitress, as she prepares to change into a hospital gown that will cover her now anonymous body: Shielding her slender frame from what she perceives as an indifferent and, perhaps, insensitive external world. She ponders quietly and nervously about her symptoms, as she obsesses over her vulnerable logistical predicament. How will I pay for the medical expenses? I am a single mom struggling to survive! What if I have cancer? A knock on the door wrenches her attention from her introspective concerns; “Hi,” an aloof voice greets her. Maria extends a hand to the physician, but the physician does not react to the gesture as she proceeds to her computer and begins typing. This is Maria’s first visit to a physician’s office in the US. Maybe the doctor did not see my extended hand, she wonders. Maybe it’s disrespectful in this country to greet a physician, a person of status, with a handshake. How crude of me to think that this busy and important professional would want to engage in trivial pleasantries with a simple immigrant peasant like me. She sits quietly, embarrassed by her presumed inappropriateness, intimidated by the sterile examination room, isolated in her concerns about her physical condition, and alarmed at the prospects of what might happen to her young child if the prognosis is serious and the outcome is fatal.

Resigned to her fate, Maria whispers an appeal to God in her native Russian language. Dear Lord, help me! Do I have cancer? Will I survive my illness, or will I go through prolonged agony and pain and then die? Please take care of my baby if something happens to me. Dr Jones, an American descendant of Russian-born parents, recognizes the foreign dialect and is reminded that, like Maria, she too has a deep concern for her dependent Russian parents and children. Pushing aside her exhaustion from a long day at the clinic, Dr Jones inquires, “What part of Russia are you from, Maria?” as she makes eye contact for the first time. “I’m a descendant of parents from St Petersburg. How about you? My maiden name is Ivanov, but I married an American, and now my last name is Jones,” the physician explains.

Maria’s fatalistic deportment immediately and visibly changes. Her perplexed facial gestures, catastrophic bewilderment, and manifestly strained body language morphs into a perceptible beacon of light, illuminating the sterile inanimate room with a sense of humanity. “My family is from a small farming community south of Moscow,” Maria enthusiastically replies. “My Russian name is Masha, but everyone calls me Maria. How long has your family lived in the US, Dr Jones?” Maria and Dr Jones exchange stories about the motherland throughout the entire medical consultation. Finally, the examination is completed, and the diagnosis is severe gastroenteritis. Maria is sent home with prescriptions to ease her discomforts and expedite her recovery. She is advised to...
monitor her progress and return to the clinic if her symptoms do not subside.

**DISCUSSION**

Maria’s initial obsessions with her health and anxieties about going to a medical facility are not uncommon. The yearning to be understood and comforted, the trepidations with the unknown, the sense of fear and concerns about the worst possible outcomes, the preoccupations with treatment costs, and the inevitable thoughts of mortality are among the tsunami of affect that (even if unfounded or unjustifiably exaggerated) can consume patients in Maria’s predicament. Moreover, as cortisol levels rise in response to the anxiety of being ill and in a medical facility, blood pressure and glucose levels spike, sleep and appetite diminish, and many other somatic manifestations of stress respond to the perceived medical crisis and to the impending hospital encounter. These emotional sequelae are unfortunate artifacts of getting ill. What should not be a side effect of illness, however, is the dispassionate conduct on the part of a healer (even if unwitting, however, is the dispassionate conduct on the part of a healer (even if unwitting) that authority figures (in uniforms or gowns of distinction) play in the lives of some individuals, particularly in linguistically and culturally diverse communities. Maria’s reaction to Dr. Jones’ initial behavior illustrates how quickly a patient can misperceive a physician’s demeanor and how the misperception can aggravate a patient’s precarious emotional state, influence what she is willing to disclose about her medical condition, and even discourage future physician visits.

As physicians, we are reminded of our responsibility to endeavor to facilitate our initial patient encounters with reassuring sensitivity. As Hardee asserts in his 2003 article on empathy: “Of all the elements involved in effective communication, empathy seems to be the component that is most powerful yet is easily overlooked ….” Empirical research also informs us that excellence in diagnostic skills is not sufficient; that empathy is an important copartner in patient satisfaction, patient compliance, and health outcomes. As Hardee states: “some commentators have asserted that in medical practice the importance of empathy cannot be overemphasized.”

From a patient perspective, Maria’s hospital gown is also instructive because it is symbolic of an anonymous person, any person, drenched in emotion and uncertainty; a person who enters a physician’s office, the office of a healer who is also dressed in a gown, but it is a gown of identity and perceived authority and distinction. Maria’s story is instrumental in elucidating that beyond the ubiquitous hospital gown that she dons, there is a concerned heart that beats distressingly about her medical condition. She is not just another patient. Furthermore, the reference to the physician’s gown is also instructive because it showcases the perceived role that authority figures (in uniforms or gowns of distinction) play in the lives of some individuals, particularly in linguistically and culturally diverse communities.

Maria’s story reminds us of the many critical connections between empathy and treatment, of our professional obligation to not exacerbate a patient’s tenuous psychological state by neglecting (even if just momentarily) our responsibility to be compassionate and sensitive to human affect, of making immediate and continued eye contact with our patients, of being aware of facial gestures and body language (ours and our patients’), of being mindful of the plethora of insecurities that accompany pain and discomfort, and of our professional duty to not become dispassionate body mechanics and lose our humanity. We are prompted to be attentive to the kaleidoscopic threats to empathy: To the potential barriers and factors that erode compassion; to the omnipresent patient hospital gowns; to fatigue; and to the various demographic characteristics such as sex, culture, language, religion, age, and socioeconomic status that can compromise our sensitivities for others.

Maria’s account is a reflective collage of my experiences as a medical student. This story encompasses an amalgamation of lectures from medical school professors, role-reversal accounts shared by practicing physicians who have been hospital patients, personal experiences receiving medical care, clinical observations in clerkships, and anecdotal stories from patients and family members: All anonymous souls in ubiquitous hospital gowns. This medley of experiences has compelled me to put a face on empathy and chronicle the importance of compassion in the practice of healing, Maria’s narrative reminds me that among physicians, proficiencies are not enough; skills and empathy must coexist and work in tandem to establish a caring therapeutic environment.
acknowledge and address these fundamental matters, including through empirical investigation, we cannot expect to garner the confidence and cooperation of our patients whom we admonish to actively participate in preventive pre-screening and early detection measures, and whom we implore to not wait until their asymptomatic medical conditions or mildly discomforting ailments develop into major life-threatening crises. In this environment, empathy, prevention, early detection, compliance with physician-prescribed treatments, and physician–patient partnerships are symbiotic: Relying on each other to synergistically achieve the same goal—healing.

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How to Cite this Article

References

Nothing Human is Strange or Repulsive
The patient is no mere collection of symptoms, signs, disordered functions, damaged organs, and disturbed emotions. He is human, fearful, and hopeful, seeking relief, help, and reassurance. To the physician, as to the anthropologist, nothing human is strange or repulsive.

—Tinsley R Harrison, 1900–1978, American physician and editor of the first five editions of Harrison’s Principles of Internal Medicine
COMMENTARY

From Principles to Practice: Real-World Patient and Stakeholder Engagement in Breast Cancer Research

Sarah M Greene, MPH; Susan Brandzel, MPH; Karen J Wernli, PhD, MS

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ABSTRACT

The Patient-Centered Outcomes Research Institute (PCORI) in Washington, DC, has catalyzed a meaningful shift in the composition of research project teams by requiring that patients and stakeholders—clinicians, policymakers, caregivers, health care leaders, and others—be involved in the research team in a meaningful and intentional way. As of December 2017, PCORI has funded 568 projects totaling $2 billion. Despite the influx of PCORI funding, evidence on effectively engaging patients and stakeholders in research is relatively nascent. Drawing on principles of community engagement, the science of team science, and practical experience, many research teams have crafted approaches to working with patients and stakeholders. Early reports indicate that patient/stakeholder engagement has many manifestations, and its overall impact on the health research enterprise is still unfolding.

Among PCORI’s strategic goals is to influence the broader research community, including funders, and already this is manifesting. The US Food and Drug Administration and the National Institutes of Health (NIH) are involving patients and stakeholders in key efforts, such as the Patient Focused Drug Development and Precision Medicine initiatives. Moreover, entities such as the Clinical Trials Transformation Initiative in Durham, NC, and Faster Cures, a Washington, DC-based think tank, are offering conceptual and practical guidance for research collaborations involving patients. Research teams can benefit from this guidance, but it should be complemented by actual examples of how engagement occurs in the context of funded studies.

From 2011 to 2017, Kaiser Permanente Washington Health Research Institute (KPWHRI) in Seattle, WA, has received $14.6 million in PCORI funding on topics including cancer surveillance, back pain, and reducing opioid misuse. Anticipating the pivotal importance of PCORI’s patient-focused approach, KPWHRI developed a set of principles to guide research teams in working with patients and stakeholders to simultaneously achieve research aims and embrace this new collaboration paradigm. This article describes these principles, their relevance to interactions with patients and stakeholders, and how they were expressed in a specific PCORI-funded project on surveillance imaging in women after breast cancer.

The Comparative Effectiveness of Surveillance Modalities in Breast Cancer Survivors study was launched in 2013. Known as SIMBA, this study has three aims: 1. Qualitatively assess and understand patients’ and physicians’ experiences in the use of surveillance breast imaging. 2. Generate evidence about differences between magnetic resonance imaging of the breast compared with mammography for all women and subgroups of women by measuring test performance. 3. Develop decision aids comparing outcomes important to patients and physicians in surveillance breast imaging for use in clinical practice.

PATIENT AND STAKEHOLDER ENGAGEMENT PLAN

KPWHRI principles of patient/stakeholder engagement in research originated in the organization’s Patient-Centered Care Interest Group and reflected general tenets of engaging patients in their care. These principles also evoke the aims of the Institute of Medicine (now the National Academy of Medicine) report, “Crossing the Quality Chasm,” in that KPWHRI seeks to conduct research that provides an equitable voice for patients, safe space for patients’ contribution, timely input, efficient and effective methods, and a patient-centered orientation.

The Patient and Stakeholder Engagement Plan from SIMBA reflected the KPWHRI principles as well as PCORI’s principles of trust, transparency, co-learning, respect, and partnerships. Here we
describe the philosophical intent behind each of the eight principles and how each played out in SIMBA.

### Authenticity

1. KPWHRI’s PCORI-funded research will embody authentic engagement of patients, members, and other community stakeholders, meaning that these stakeholders are equal members of the research team.

   This first principle, centered on authenticity, is the primary driver for KPWHRI’s patient-engaged research. Collaboration cannot amount to token participation or “checking a box” to include various stakeholders; it entails a culture change that removes silos, hierarchies, and paternalism that have pervaded the research enterprise. Furthermore, “equal” is not synonymous with “identical.” That is, everyone on SIMBA’s study team participates in the dialogue representing their voice and expertise—an integral part of the project’s culture from the outset. When research teams create shared culture from the beginning, trust develops among team members, and different viewpoints are balanced as part of team ethos. For example, patients’ input on methods may not have the same weight as input from the study’s biostatistician. Similarly, the determination of what patients value must be thoughtfully considered in light of what clinicians regard as important or optimal practice of medicine. The research life cycle means that as a practical matter, patient/stakeholder input will also be on a different cadence. Nevertheless, ensuring that input is genuinely considered throughout the study entails a proactive approach to engagement. The research team leaders have modeled bidirectional communication and active listening as cornerstones of SIMBA.

### Real-World Perspective

2. In the process of designing, developing, implementing, and disseminating research in partnership with patients/members/community stakeholders, we recognize and embrace the fact that a research-centric model will not serve the larger goals of PCORI-funded research. We will strive for high-quality science, but we recognize that real-world needs and iterative processes are inherent in patient-centered research.

   Historically, research teams have been made up of scientific experts, project operations staff, and occasionally advisory panels with various stakeholders but typically composed of other experts in the scientific subject matter. Isolated from real-world needs of patients, clinicians, and other “consumers” of research, implementation of research findings tended to fall short. Study results may not reflect the real-world perspective outside academia, limiting their adoption into practice.12

   In contrast, the patient-oriented research paradigm reflects constructs of user-centered design. Patients and researchers collaborate on study questions, data collection, and appropriate dissemination tactics. This iterative work may be less methodical and more improvisational, and it may run counter to researchers’ temperamental inclination toward rigor and order. However, it also reflects real-world constraints and considerations.

   A poignant example of the impact that patient partners had on the research took place early in SIMBA’s design phase: the planned sample size did not provide enough statistical power to look at mortality as an outcome. Moreover, SIMBA’s patient partners asserted that mortality was not as concerning to them as other outcomes such as morbidity and recurrence. Thus, when balancing study design choices, the study team was obliged to consider both statistical and patient-centered issues. Perspectives of patients and researchers related to guideline-concordant care offer another illustrative example. Researchers wanted to gauge receipt of surveillance imaging in accordance with clinical guidelines and put the data into “boxes.” However, patients reported that they received surveillance imaging on schedules that did not conform precisely to clinical guidelines, which led the project team to be more flexible in the definition of “surveillance imaging.”

### Mutual Trust

3. We acknowledge that perceptions of research may be positive or negative, and that at times, communities and groups have been unfairly exploited by research or may harbor feelings of being “experimented on.” In the event that these perceptions are voiced in the context of our research, we will actively partner with the patient/member/community to address these perceptions.

   Because of several incidents13-15 over many years, research may be perceived in a negative light, especially by communities that were targets of exploitation. Given that SIMBA is an observational study, not a trial, that sense of experimentation may have been mitigated. However, the need for mutual trust between researchers and patient partners is bedrock. Patient collaborators in SIMBA explicitly indicated that they were assessing whether the study team was genuinely committed to a patient-partnered study team with mutual goals and shared values, reflecting the importance of both sides feeling comfortable with the relationship. Additionally, when the SIMBA team was composing the advisory panel, they actively recruited panel members from diverse racial/ethnic backgrounds, rather than relying on easier recruitment methods that often yield homogeneity.

### Plain Language

4. KPWHRI has a long-standing commitment to health literacy and plain language. We will uphold this commitment by ensuring that all research study materials are written in plain language and that our research teams use plain language in their verbal communications.

   Research has its own language. Study teams that aspire to be truly patient-centered must adroitly facilitate and translate the research vernacular in the moment. It is often difficult for researchers to “switch” to plain language, especially in oral communication. But if patients/stakeholders do not understand, information asymmetry and power imbalance may result. In all circumstances, patients should feel comfortable speaking up, which can be aided by training and tools throughout the project life cycle.

   The SIMBA study created a climate in which participants feel empowered to comment when they do not understand orally presented information. The principal investigator has modeled the desirable ethos in the study team, encouraging patience when questions arise. The project manager facilitates in-person interactions, observing body language that may indicate incomplete understanding of research activities. A plain language expert has been on the team since inception and ensures that project communications are accessible.
to all study team members, not just those with scientific backgrounds. These practices are scalable and extensible to other projects. KPWHRI makes the Readability Toolkit and online training freely available to the research community, along with customized training in plain language communication.

Furthermore, SIMBA facilitated deeper understanding and awareness of research by giving patients and stakeholders undergraduate-level books on statistics and research method tutorials during team meetings. Consequently, patients and stakeholders comprehended the long trajectory of many research studies and became more thoughtful consumers of health research news.

Equitable Partnerships

5. We regard patient/member/community participation as a valued asset to our research, and pledge to build equitable partnerships, respecting what each team member brings to the table.

Equitability is not a gratuitous or empty promise. Patients bring content expertise from being a patient—the lived experience. Involving all collaborators (patients, clinicians, researchers) led to a fuller conversation about important design considerations and desired outcomes of the SIMBA project. Here, the concept of “outcomes” was multifaceted, referring to both the actual outcomes of the study, and the outcomes of collaborating with a diverse constituency.

The relationship with patients who were patients of clinicians on the study team was an important consideration. Although clinicians could recommend patients who might be suitable for an advisory council or project team, SIMBA does not have patients in an advisory capacity who had prior clinical relationships with clinicians on the team. Prior research has shown the challenges patients face in cancer communication, and the team believed that patient-partners would be unlikely to speak candidly about their cancer experience if their oncologist was present. This model (no direct patient-physician relationships) enabled the SIMBA team to have frank conversations about patients’ care experiences during their posttreatment and recurrence journey. Depending on the study, other permutations of study teams might lead to imbalanced partnerships or impede communication, such as a study on adolescents that involves both teenagers and parents.

Relationship Building

6. In the same way that patient-centered care is rooted in listening, patient-centered research must adopt a similar orientation. KPWHRI research teams will value active listening and relationship building with patients/members/community stakeholders on our research teams.

Developing relationships with patients required dedicated time and enriched the SIMBA project by strengthening the relevance of the research and enhancing our patient-partners’ trust in the project and team. For SIMBA patient-partners, in-person interactions were essential, including premeeting preparatory discussions, postmeeting debriefs, team lunches, and travel time. For study teams not colocated, developing strategies to emulate in-person interaction (e.g., “share and tell,” conversations), can build trust. Concerns might arise that intensive focus on relationship building may slow study progress or efficient decision-making, but that did not manifest here. Study pace can be preserved by setting up ground rules for deliberative discussions and processes for nimble decision making by a subset of the larger team.

Discussions about health and health care that directly affect patients can spark intense emotion, and active listening can give way to activism or domination of a conversation. Similarly, researchers accustomed to leading and decisiveness may need to buffer their natural tendencies in order to create a shared locus of control. Patient-centered research entails subtle and sometimes fundamental shifts in temperament, acknowledging that all contributors bring a perspective worthy of consideration, despite their background, discipline, or training.

Community Engagement

7. We will uphold general principles for working with community groups and patients as articulated in the Department of Health and Human Services’ Principles of Community Engagement booklet, the PCORI Methodology Committee report, and the Clinical and Translational Science Awards’ Best Practices in Community Engagement report.

This principle originates in seminal work by the Centers for Disease Control and Prevention (CDC) and NIH pertaining to community engagement and community-based participatory research. When SIMBA was initiated in 2013, the science of patient engagement was in its infancy, and it remains a nascent, if fertile, space in which to examine and optimize collaboration. The SIMBA team viewed its work with the patient partners through the dual lens of observing rapid developments and new approaches to patient engagement, and simultaneously contributing to this field. The team kept an open mind about how patient engagement would manifest, and this state of innovation and mindfulness has benefited the project both scientifically and interpersonally. SIMBA has been recognized for its efforts via appearances at PCORI’s first annual meeting and Stanford MedX 2015, where team members described SIMBA’s patient partnerships in a panel presentation and exchanged state-of-the-art tactics to collaborate with patients, designers, and others for health care improvement.

Feedback

8. We will regularly seek feedback from nonscientists on our study teams to ensure that communication is bidirectional, trust is maintained, and that equitable partnerships are upheld.

SIMBA collaborators learned throughout the project that engagement is dynamic and variable. As the study moved from design to implementation and dissemination, tactics for engaging patients evolved. Hence, approaches needed to sustain engagement are different from the approaches used to catalyze it at the outset. The SIMBA patient advisory board and stakeholder panel complete anonymous surveys at semiannual in-person meetings to assess communication, inclusion, comprehension, and durability of the partnership. Participants can share whether they believe their contributions were recognized and whether they felt included. This tactic is instrumental and complements in-person interactions and
nonverbal communications. It is likely that a patient partner may feel his/her input is less salient during the analysis phase yet may not broach this with the study team directly, so such surveys give participants another opportunity to be heard.

CONCLUSION

The experience with patient engagement in SIMBA has illuminated three vital aspects of patient-partnered research.

First, there are **cognitive and affective dimensions to engagement**, and researchers should attend to both these dimensions—how patients think and feel—to effectively integrate patients on a research team.

Second, we believe there are **personality attributes that may lend themselves to success**. Both researchers and patient-partners will be more effective if they approach collaboration with openness, curiosity, and humility. Contrasting attributes—rigidity, indifference, and arrogance—may interfere with the research progress and partnership viability. Finally, given the natural life cycle of research, project teams should note that the engagement process itself has a life cycle, including variability in patients’ interactions. Sustaining engagement may be challenging, especially during lengthy data collection and analysis.

The study topic is a key aspect of engagement, and patient-partners may contribute to a study team for different reasons. Nevertheless, we hope these principles may be applicable, irrespective of the research topic. The literature and experiences of patients as research partners is evolving, and the research community will learn more as project teams share both empirical and experiential findings. As this new research era evolves, this quote from **Principles of Community Engagement** resonates: “When researchers and organizers work collaboratively with community organizations throughout a project, they can produce effective, culturally appropriate programs and robust research results.”

**Disclosure Statement**

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**References**


As a third-generation physician farmer, I have a deeply ingrained reverence for the intangible mysteries of life. As a scientist, I understand the physiologic changes that allow a newborn to take its first breath. Yet, despite attending deliveries nearly daily in my work, I remain in awe of the magnitude of that miracle. Actively nurturing that sense of awe is important to me.

A physician’s work is challenging, complicated, and sometimes even daunting. We can heal, but we are also witnesses to tragedy and loss. Maintaining grace in this setting requires an active investment in community, self, and beliefs. And so, when I am not working, I paint.

Painting enhances and balances my medical life. As a painter, I must initially move from doer to observer. From that perspective I cultivate appreciation and curiosity. My preferred subject is nature, most often flowers. Their deceptive delicacy, tenacity, immense diversity and complexity, and beauty reaffirm optimism. Simply put, their beauty has the power to enrich and to restore. I choose to work in watercolor because it has its own spontaneous, evolutionary process. One can plan and direct the image, but the paper, paint, and water ultimately influence the image in unexpected ways. Like nurturing babies to breathe or seedlings to unfold, watercolor painting honors the mystical as it captures color, light, and life. And isn’t that a great way to spend an afternoon.

How to Cite this Article

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Home-Based Palliative Care Program Relieves Chronic Pain in Kerala, India: Success Realized Through Patient, Family Narratives

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ABSTRACT

An estimated 1.5 billion people across the globe live with chronic pain, and an estimated 61 million people worldwide experience unrelieved serious health-related suffering (SHS) worldwide.1-4 Therefore, one can estimate that 10 million people with unrelieved SHS live in India, which is home to one-sixth of the global population. The overall prevalence of chronic pain in India was estimated at 13% in 2014.5 Cancer is the major source of unrelieved pain in India6 and more than 1 million people develop cancer every year,7 and an estimated 80% of those patients are believed to live with significant pain.8 Pain, a subjective experience for every person, is influenced by many factors including genetic characteristics, general health status, comorbidities, the brain’s processing system, the emotional and cognitive context in which pain occurs, and cultural and social factors.9,10 As defined by the World Health Organization, palliative care is intended to prevent and relieve “suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual.”11 In India, palliative care is accessible to fewer than 1% of the people who need it.12

In its absence, treatment is disease-focused with little regard for SHS.13 The magnitude of this need is best illustrated by reported opioid consumption across countries. Global mean morphine consumption in 2013 was 6.27 mg/capita; per capita consumption in India was 0.11 mg, ranking 113 of 139 countries. Morphine equivalent (ME) rates in the highest-use countries such as Canada (723 mg/capita ME), the US (718 mg/capita ME), Australia (454 mg/capita ME), UK (241 mg/capita ME), France (213 mg/capita ME), and Italy (204 mg/capita ME) demonstrate the global misdistribution of opioids.14 These high ME rates include the therapeutic use and the misuse/abuse of opioids in those countries.

In contrast to high-resource countries, in low-resource countries, morphine consumption is a surrogate measure of access to palliative care. The state of Kerala in southwest India, with a land mass of 1% and a population of 3% of India, has managed to make noteworthy advances in the field of palliative care.15 Although the India national average is 0.11 mg/capita ME, consumption figures in Kerala are about 1.56 mg/capita ME.16 The relative success in Kerala has been achieved with robust community involvement, and palliative care services are being delivered by an informal network of health care professionals and volunteers with significant input from the government.17 Pallium India, a charitable trust formed in 2003 in Trivandrum, Kerala, provides palliative care to underserved populations in and around Trivandrum with inpatient and outpatient care, home visits, and advocacy, and works with local institutions in 16 of India’s 29 states to promote palliative care.

During the 2015–2016 University of Iowa Winterim Program (a 3–4 week intensive study-abroad program at Pallium India with courses led by University of Iowa faculty), students learned about the biological, psychological, and sociologic aspects of disease; how to care for and treat patients with terminal and chronic illness; drug restrictions on pain medication and opioid use in India; and the differences between the health care systems in the US and India. For many of these health science preprofessional students, this was their first exposure to palliative care.

Students also shadowed clinical teams during home visits. The use of empathic listening to treat and assess patients sharply differed from our own experiences as patients in health care in the US. We depict the pain stories of six patients treated by Pallium India with the goal of understanding the importance of palliative care and empathic listening for patients with SHS.

PROJECT DESCRIPTION

The project was conducted with sensitivity and respect for patients and families. Patients and patient families granted permission to participate in the project and to be photographed. The institutional review boards from the University of Iowa and Pallium India reviewed the project and found it did not require full review because it was a photojournalism project.

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Six home care patients were chosen by the palliative care team for their willingness to talk to visitors and to tell their stories. Basic demographic information was obtained including age, sex, family, occupation, education, and underlying illness. Each patient was asked the following: Can you describe your current pain level? How long have you been treated by palliative care? What was your pain like before and after interventions from palliative care? How does your pain affect your life? Pallium India health care workers translated all questions into Malayalam, answers were translated back into English, and narratives were written from their answers. All direct quotes depicted in the patient pain stories represent rough translations from Malayalam to English. The pain stories are based on translated patient testimonials and observations during home visits. The stories cannot speak completely for patients and simply represent observations during these experiences. All patient names were changed to protect confidentiality.

PAIN NARRATIVES

Ambuja

I have nobody, no kids or family. My husband, an alcoholic, sold all of my property for alcohol and left me with nothing. Pallium India has given me so much relief; not only have they alleviated my pain, but now they seem like family. My pain used to be an 8 on a 0-10 pain scale. After palliative care by Pallium India, it is now a zero. I am finally able to laugh and smile. I owe a lot of this to the pain relief that Pallium India has given me. Ambuja’s husband abandoned her when she was very young, and her dreams of starting a family were crushed. She found work as a maid and worked long hours. Just when she thought she was finally getting back on her feet, she sustained a painful cervical fracture after falling in a deep canal while performing household chores. At age 71, Ambuja became bedridden and her pain was excruciating. She described feeling as if millions of needles were pricking her neck and electric shocks were radiating from her neck to her arm. And her pain was not only physical. Ambuja lost all of her independence, relying on her sister for help with simple toileting and eating needs. Her pain and losses led to a downward spiral into depression. When Pallium India heard of Ambuja’s situation, they offered to provide free palliative care and pain medications in her home. After receiving physical therapy and pain treatment from Pallium India, Ambuja was able to sit, walk with support, and attend to her own toileting.

Akshay

I feel like I have made a 100% recovery because of Pallium India. Before, I was completely bedridden. Now, I am able to move my hands and legs, and flexing and extending my muscles is easier. Most of all, Pallium India brings care to my home. Because of this, I do not have to take an ambulance to the hospital, which would be very expensive and extremely painful. After Pallium India’s arrival, I feel wanted and cared for.

Akshay is a devoted husband and father of two sons. After being trained as a taxi driver in Mumbai, he moved back to his home state of Kerala where he worked as a paid driver for 20 years. During this time, he started a family and enjoyed life raising his two sons. After sustaining a fall and injuring his head and neck, he became partially incapacitated. His condition deteriorated over time, and 4 years ago he became completely bedridden. Being paralyzed from the neck down at the age of 65 caused emotional turmoil for the formerly energetic Akshay. Driving his taxi, playing with his sons, and spending time with his friends and family brought meaning to his life. When Pallium India heard of Akshay’s case, they initiated physiotherapy to help him regain muscle movement and taught the exercises and skin management techniques to his wife. The physician treating Akshay explained that because palliative care was started early, pressure sores and depression had been avoided. After many months of physiotherapy, Akshay gained partial movement in his feet and hands.

Ankita’s daughter

I have a major weight off of our shoulders. Pallium India provides free pain care, free pain medication, and teaches me how to care for my mother. We work as manual laborers and cannot afford much, so free health care is a major weight off of our shoulders.

Ankita, age 60 years, has a seizure disorder and lives with her extended family. Before Pallium India intervened, she was experiencing long postictal states after having severe convulsions. During our visit, she lay curled on her bed, moaning and whimpering. In their best efforts to alleviate her pain, the family laid her on a tarp on a wooden cot that was cushioned with blankets.
After entering the room, the physician gently put a hand on Ankita’s arm and quietly told her that he would perform a quick health assessment. When speaking to the family, the physician mentioned that simple techniques such as physiotherapy and use of an air bed to prevent pressure sores could have decreased her pain dramatically. He noted that these omissions were not the family’s fault, but perhaps a pitfall of a health care system that focused only on disease instead of treating and caring for the whole person.

The physician quietly talked to the family about the next course of treatment. He prescribed pain medications while nurses cleaned Ankita’s wounds and addressed her pressure sores.

**Ekta’s daughter**

My husband is very attached to my mother. Although she is unconscious, he can read her every facial expression. Before Pallium India, her expression was full of pain. Now my husband says she is happy and at peace. We are grateful to Pallium India. They change her catheter; tend to her painful bed sores; teach us how to take care of her; and, most of all, provide emotional support. The doctors and nurses don’t talk down to me but communicate to me on a level that I can understand.

Ekta had been a hard-working and energetic laborer who harvested rubber and managed household chores. The once-vibrant Ekta now slept for most of the day, only waking occasionally during the night with confusion. The family took care of her to the best of their ability, frequently moving her, cleaning her wounds, and emptying her catheter bag. When we visited Ekta she was in an unconscious state, mumbling occasionally as the physician examined her pressure sores, which were tunneled deep into her skin. Some were bleeding; others were dark black, indicating necrotic tissue. Although Ekta appeared unconscious, the Pallium physician acknowledged her presence, asking how she was doing, rubbing her arm, and providing notice before moving her. Her daughter expressed appreciation to the Pallium team for treating her mother with respect and compassion. Although the family down to discuss Bhavana’s impending death. The family, although saddened, nodded their heads in understanding as the situation was explained.

**Harsha**

I feel as if I am a burden to my family and have no purpose on earth. I have struggled so much and am constantly in pain. After Pallium India, I feel like I have gained some of my independence back.

Harsha, age 76 years, has been under the care of Pallium for 2 years. When we entered her home, she greeted us with a warm, genuine, and dazzling smile, fussing over offering seats for her visitors and offering orange juice. After listening to the Pallium physician speak to her, we learned that Harsha had heart problems, pressure sores, and urinary incontinence, which repeatedly led to painful and uncomfortable infections. Harsha never stopped smiling during the visit. Her smile faltered, however, when she talked about her struggles with depression and said that she felt she was a “burden to my family and had no purpose on this earth.” Harsha had been very active, tending to the farm and looking after her household. Her health problems prevented her from doing the jobs that gave purpose and meaning to her life. Throughout the home visit, the physician simply listened to Harsha while the nurse held her hand. When asked to describe the ways in which Pallium India has helped this family, they expressed deep gratitude, stating that Harsha has gained a sense of autonomy. They report that her condition has greatly improved, and she can bathe herself, use her walker, and do small activities independently.

**Bhavana’s daughter**

We are very grateful for the care for my ailing mother. We work as manual laborers and cannot afford a lot. Pallium India has provided my mother with catheter changes, has taken care of her wounds, has given pain medications, and has given transportation for care, all free of charge.

Bhavana, age 86 years, had diabetes and hypertension. When we visited her, she was very weak and minimally responsive. It was clear that she had stopped eating; her breathing was very labored. Periodically, she would bend over her bed; eyes still closed, and vomit a dark liquid. Bhavana’s family insisted that she was fine the day before but suddenly took a turn for the worse. Before providing any medicine, the Pallium physician took Bhavana’s hand and gently rubbed it, offering warmth and comfort. He then gave her medicine to stop the stomach bleeding. He sat the Pallium team addressed Ekta’s physical pain, the family had the most appreciation for Pallium’s support for the family’s grief.
DISCUSSION

It should be noted that Pallium India health care workers translated all narratives from Malayalam to English, and the accuracy of direct quotes from the patients and details from the patient pain stories could not be verified. These narratives are, in a sense, cocreated among the patients, translators, and international visitors. A patient originates a story, but his or her words are translated; in the sections that are not direct quotes, an international visitor is crafting the story. Although the utmost effort was made to depict pain stories with objectivity, some unavoidable inherent biases on the part of the translator and transcriber may have influenced pain story content. Time constraints also were an issue because the Pallium team had to treat many patients during home visits, question–asking time was limited, and answers may have been rushed.

Another limitation is more systemic in nature: Because 80% of health care expenses in India are self-pay and home health care visits are not typically offered, the free home visits offered by Pallium India could have placed patients and their families in the emotional position of expressing gratitude and not feeling comfortable mentioning possible care shortcomings.

CONCLUSION

Narrative is “a representation of an event or a series of events.” Pain narratives told in the social context of home visits provide powerful evidence for health care teams and illustrate the importance of palliative care. From an international visitor’s perspective, the palliative care team’s empathetic listening was striking in its impact and contrast to the disease-focused health care practices in both high- and low-income settings. Early exposure to global and local palliative care for health profession students allows for proactive engagement in close and empathic listening and builds skills on gathering evidence to match the data found in disease-focused textbooks.

Disclosure Statement

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

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Pain

Pain tears in the tooth, thunbers in the ear, and pierces in the eye.

— Croatian proverb
Cathartic Poetry: Healing Through Narrative

Richard Bruce Hovey, MA, PhD; Valerie Curro Khayat, MA; Eugene Feig

ABSTRACT
This article explores the efficacy of writing and reading poetry as a means to help people living with chronic pain to explore and express their narratives in their own unique way. Throughout our narrative we have interwoven poems from Eugene Feig, one of the authors of this article. His poetry is sent out almost weekly to the members of our pain support group as a method of sharing his own experiences of living with pain, as well as to support and to inspire hope in others. The style of poetry we are presenting is that of a person who is not knowledgeable about poetry in a formal sense but who has an understanding of how it has helped him learn to live with his own chronic pain and suffering. These poems are the author’s expression of the meaning of living with chronic pain for over 20 years. This article is a philosophical hermeneutic conversation about pain and poetry.

POETRY
Hermeneutic scholar HG Gadamer wrote, “It seems incontrovertible to me that poetic language enjoys a particular and unique relationship to truth,” and helping us to acknowledge and understand the role that poetic recollection plays in the reflectivity of our own truth, and not just in the poetic freedom one might be permitted and encouraged in the telling of our stories of living with chronic pain. Gadamer adds, “… the task of poetry to instruct as well as to please has maintained its absolute validity in classical aesthetics and still remains valid for modern scientific thought—at least in a more reflected and indirect form …” In this way, we can consider poetry as a relevant resource, within a scientific and academic context, for the exploration of the chronic pain experience. The cathartic poem is an attempt at self-healing through self-empathy. The poem and the person endeavor to make sense of chaotic thinking, restoring a feeling of balance and of wholeness in oneself through words. By better understanding their own experience of their pain, and of the internal chaos that inhabits them, people may begin to open up to learning to accept their lives with pain.

The cathartic narrative or poem, when offered by the suffering person, is an invitation with encouragement to say, to write, or to artistically represent an interpretation of their suffering. It is clear that this process is one that is not guided by a templated rubric about how someone should tell their story, but rather is freely given, often from personal, chaotic reflections from a precise place and time, such as in the poem “Pain Journey” by Feig (see Sidebar: Pain Journey). Gadamer wrote that “Reflection [is] the free process of turning in on oneself” and that our minds are thus enabled to examine their own content about what we understand and why. Reflection can give us distance from ourselves: “[The] ability to stand back from oneself is a fundamental prerequisite for linguistic orientation in the world, and in this sense all reflection is in fact freedom.” It is during these times of reflection that we are open to possibilities of the expression of self beyond merely a chronic pain patient. With the help of others, we express ourselves openly while creating conversations that both provoke and promote transformation of oneself. Poetry is one way we can open up these conversations. This article offers an example of the poetic narrative, from chaos to cathartic.

POETIC NARRATIVES
It is essentially the narratives people keep about themselves regarding why they are doing what they are doing, what their goals are, and what their views of their past are—all components of ongoing stories people maintain about how they see themselves as distinct persons, whether rightly or wrongly.

The act of reflection allows for an interpretation of our narratives, especially the ones we keep suppressed and often take for granted or dismiss as unimportant. Finding a means to express these internal thoughts and interpretations, such as transposing them into poetry, provides a novel form of expression. This transposing process moves our internal thoughts onto the written page, creating a space for our inner thoughts to be in the world in a tangible way as if we were pulling the narratives out of ourselves and laying them down before us. We now can hear and see them differently. We could say that our written reflections allow for a ritual of being honest with ourselves. The written page is our truth written out at that moment and time. Gadamer goes on to say that poetic language experiences a particular and distinctive relationship with truth.

Gadamer continues, “First, this is shown by the fact that poetic language is not equally appropriate at
Feig’s poem “Confronting Fear” (see Sidebar: Confronting Fear) becomes an invitation for others who share an interest in this topic. We must be ready to hear something that we did not notice before. This readiness is the only way the word becomes binding, because the poem has the potential to connect one human being to another and to help a person become open to being struck by something written, read, and reread. Unlike telling a story in its entirety, we write poems to express an intensity of emotion; we bring it out into the world with intensity of feeling.

This article explores the relationship between the cathartic poem and healing in the context of chronic pain. Through an understanding of how poetry can provide an access to a different experience of healing, cathartic expression of our personal narratives suggests that the act of recounting one’s new narrative (re-storying) leads to restoring and learning to live with pain. The sharing of cathartic poetry also opens up a space for dialogue, for exchange (the hermeneutical), which is central to healing. We recognize the distinction between curing and healing. Pain in the context of a theory can be thought of as a “primarily neurological phenomenon (nociception),” not a spiritual phenomenon, whereas a great deal of suffering is of a properly spiritual or “existent” nature, “psychic pain.” The goal of health care is to cure the patient of their pain, whereas poetry offers a means to heal the person’s suffering.

**The Cathartic Poem: Healing Suffering**

Gadamer¹ says that there is a fundamental difference between a genuine poem—one that is articulated within a specific structure and form—and the well-intentioned poetic communications, which are less structured and without literary constraints, that people compose to express their experiences. When someone writes a healing poem, there is an abundance of sincerity and emotional influence in it, and as such these verses are best understood from the motivation behind them. Structure, technicality, and poetic tradition become secondary to the process of expressing one’s experience and emotions for a primarily cathartic purpose. For example, Gadamer¹ notes that while in extreme pain, Rilke wrote in one of his last verses: “Oh life, life, remaining always on the outside.” So powerfully does pain cause us to withdraw from all external experience of the world and turn us back upon ourselves.” As pain incarcerates the person from their previous lifeworld into one with a profound sense of loss and despair, an inward spiraling of self occurs through suffering and the endurance of pain. The cathartic poem promotes movement from the inside to the outside, moving a person to open up to a new reality, releasing words onto the page; it is an act of unburdening instead of coiling in on oneself.

Regardless of form, any poem such as Feig’s “Chaotic Thinking” (see Sidebar: Chaotic Thinking) can be a powerful way to confront fear and to heal the person’s suffering. Cathartic Poetry: Healing Through Narrative

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**Confronting Fear**

The world has changed, where do we go from here? How can we move forward, how do we get over this exaggerated fear? Where do we go from here?

Bridges must be built; values have been maintained. We must work together, if anything is to be gained.

Pain is universal regardless of your accent, or where you live. It’s time for all of us to rise up, it’s time for all of us to forgive.

The morning came, the sun shined bright. Children playing together, there was not a dark cloud in sight.

If the world could only see the smiles on their faces. Isn’t this the basis of being part of the human race?

The night sky was luminous, the moon was bright. As I gaze up to the heavens I know in my heart everything is going to turn out all right.

Fear if we let it consume us, it will take its toll, it slowly eats away at our soul.

Fear is an emotion that can help us define who we are. If we harness it, if we listen to what it’s trying to say. It brings out the best in us, it points out a different way.

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**Chaotic Thinking**

… that day my pain was winning, I was falling behind.

I was feeling sorry for myself, I was really getting fed up with life’s everyday grind.

Everything looked grey to me, nothing was going right.

I was getting so angry, so frustrated, I was feeling so helpless, I truly felt I was losing my grip to fight ...

This feeling really scared me, I felt like this before.

I know how destructive it can be, it affects you right through to your core.
Chaotic Thinking) is worthy of being called a poem and is clearly different from other forms of emotional speech, even as it helps to sort out our chaotic thoughts. When we read a poem that touches us deeply, it may not occur to us to ask who the author is and why they wrote the poem the way they did; it just speaks to us and captivates our attention. We are moved on an emotional level rather than stimulated intellectually by the words. We are only aware of those words, as though they were written specifically for us. The poem becomes our interpretation of another’s profound experience, which is in that moment independent of both reader and poet; it is now in the world.1 The author’s interpretation, presented through the act of writing the poem, makes it available for others to interpret because of its surplus of possible meanings. Our ability to interpret poems differently to find individual meaning, which may not have been the intention of the author, makes poems uniquely available to many different readers. As with all thoughtful works of art, each time we see a picture or read a poem we may find something new that grasps our attention. There is an intrinsic motivation among humans to try to find meaning in our day-to-day living. We learn that there are no persistent truths, and that change is continuous. Even with our planning, wanting, and needing, we cannot always be confident of what we think we know or believe.

The cathartic poem is one that arises from within the poet in an attempt to make sense of chaotic thinking. Actually writing the cathartic poem is not a process in which the writer sits down and beautifully crafts a poem, stanza by stanza, but rather it is created to relieve the dialectic tension of thoughts that have become too overwhelming, confusing, and painful to make sense of. “The Fight” by Feig presents an example of this type of poem (see Sidebar: The Fight).

Humanizing pain, which returns the meaning of pain to the person living with it through reflection, writing, and accepting, becomes a way to learn to live with pain with the goal of more than merely managing it, but rather learning to live well with it. Pain for the person living with it exists within the experiential realm, where “learning to tolerate pain brings us closer to an understanding of the pain.”2 This means overcoming our resistance to change. Life consists of continuous movement through various emotional states. We can neither hold onto the comfortable ones with apprehension of what might one day change nor can we remain paralyzed by the grip of nostalgia for a past (painless) existence. We must embrace what is, right now, in this moment, and breathe, imagine, and learn. This approach strongly echoes the mindfulness school of thought, which has been increasingly valued over the years by many health care practitioners such as Jon Kabat-Zinn, who said, “When we can actually be where we are, not trying to find another state of mind, we discover deep internal resources we can make use of. Coming to terms with things as they are is my definition of healing.”3 Just as breath is the vehicle through which one brings oneself back to the present in mindful practices like yoga or meditation, cathartic poetry becomes an instrument through which the mind can be trained to live moment to moment once again.

Pain Relief

I look through the trees, down by the lake. The sun is setting, it’s beyond breathtaking.
The lake is like a pane of glass, a mirror, a reflection. It takes my mood, my demeanor in the right direction.
A flawless moment in time. A vision I will retrieve from time to time.
I notice the birds; I hear the frogs. I see the dragonflies hovering over the water’s edge.
Off in the distance a blue heron was landing, with its magnificent wing span exposed in the light, it ... brought my spirits to new heights.
There is something about being around nature, that makes everything so right. If I get to see a sun set, there would not be a single reason to get upset.
Pain and despair, anger and frustration takes a back seat when I see that reflection.

HEALING THROUGH RE-STORING

The cathartic poem, like Feig’s “Pain Relief” (see Sidebar: Pain Relief), calls for renewal through an exploration of what it means, in our own life, to live with chronic pain. It allows us to take a step back and observe our experience from a different perspective in order to find new meaning. It is an approach that requires us to involve every part of ourselves while we acknowledge not only the pain, but also our emotions, our shifting sense of identity, and how we can grow from the experience.

The pain becomes our teacher, adding a richer dimension to our story instead of robbing us of what we once had.

Rediscovering or reclaiming our story through poetry is a holistic process and a form of care toward ourselves that can improve healing. It moves us to prepare for and fulfill the inevitable task of continuously re-storying ourselves as we learn to live with chronic pain. Perhaps the process of writing poetry becomes an approach to take our chaotic, pained thinking and to turn it into cathartic narratives, ones that may confront our suffering. Perhaps it can be an approach to become whole again in a different sense than before pain.

The Fight

As the day turned into night and the stars shined bright, I looked to the heavens and told myself, I’m not ready to give up this fight.
That does not mean I’m going to forget this moment of fright.
Pain and depression go hand in hand, always pushing you to your limits.
Always crossing that finish line, we keep drawing in the sand.
With help from outside and time to accept.
Our love of ourselves will most defiantly resurrect.
The world of the person living with pain can only be expressed through their personal narrative. How this narrative comes into the world is through many potential expressions of text. The silence of speech (spoken words) is replaced by the written text. Where text is any form of expression (eg, art, photography, sculpture, or poetry, as in this case), it helps to let the person living with pain heal cathartically.

CODA

Rather than naming this section of the article the Conclusion, we decided to use the term coda to say something about the ongoing possibilities of expression to help people living with chronic pain to heal. Coda is a musical term, originating from the Latin word cauda, which means the tail, the end. However, chronic pain does not end, so we adopted another interpretation of the word: coda, “used in a more complex sense, as in a movement in music that echoes and replays the basic structure and motifs of the work as a whole, and, in doing so, reminds us of how a story has unfolded in both what was amplified and perhaps what is still hidden in the silences.”

This is where the possibilities of poetry reveal themselves over and over by breaking through the silence of our hidden thoughts and lived experiences of pain. To write cathartic poetry means bringing into presence our inner reflective thinking, emotions, and self-empathy to help ourselves and others who suffer alongside us. In the spirit of the coda we offer the poem “Hope” by Feig (see Sidebar: Hope). We invite you to take this opportunity to pause, read, and reflect.

Disclosure Statement

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

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Opportunity

Healing is a matter of time, but it is also a matter of opportunity.

— Hippocrates of Kos, 460 BC-370 BC, Greek physician of the Age of Pericles
Ode to a Dead Hawk

Robert Sigafoes, MD

What brought you down today, my noble friend?
I found you motionless, lying at the base of the tree you loved,
Speckled tan and white and gray, resting on the brown, moist leaves,
As the cerulean sky faded high above you.

No arrow pierce, nor bullet wound, nor predator marks
Fouled your head or breast I found.
No feathers lost around you lay; no blood to stain the soil was there.
In peaceful rest, with beak upon your chest, you were transfixed.

Oh, how often have I seen you land on perch above,
Scattering the smaller birds like vassals before their king?
Or bathing in the water stand for an hour in the sun, your oil casting
Rainbows on the water, like the highway on the first day of rain.

My rabbit and I were not afraid of you, nor you of us.
We marveled at your majesty, your watchful eye, your turning head,
Your dappled colors in the morning light,
Still so resilient in the night.

What brought you down today, my noble friend?
Was it the death we all must face? The death that comes with time,
When exhausted wings fail to lift us still, and we put head to breast
And take life’s rest upon the bed of moist brown leaves.

Then sleep my friend beneath the mound of rocks I made for you,
Tan and white and gray in the morning light.
Sleep the simple, restful sleep of peace, that comes to all who through
Their very beings, bring joy and beauty and love to each of us.

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The poem “Ode to a Dead Hawk” was originally published in leaflet, 2009;1(1). Available from: http://leaflet.thepermanentepress.org/2012-09-07-07-54-29/volume-1-issue-1/item/ode-to-a-dead-hawk.
She was sitting on the exam table. Long and lean, a dancer’s body. Bright green leg warmers (it was St Patrick’s Day). Her eyes big, sad, and puffy from all the crying. Her friends were there but in the background. They seemed less alive in their silent gravity.

She was crying on and off, hiding her face but then looking right at me. Wanted to “not need the drugs,” to do it on her own. We talked about what had been going on. Depression, panic nonstop. About bad weather in her brain, her strength and courage for coming in. We all laughed at needing warm clothes and an umbrella until the shitty “brain storm” passed.

It could have been me in her place. It has been. So ashamed to be crying/anxious/needy/imperfect. But I cannot find the path out for her. I can only offer recognition and admiration for the strength it takes just to keep going.

I talked a lot, too much probably, but our eyes met. Mine said, I know you, I’m sorry you have to suffer through this, I see you’re in pain. Her eyes said, Thank you.

If only I could be as gentle to myself when my own brain “storms” full of self-doubt and that enormous bubbling over of grief. Not to fix or cure but just to see. She was so sad and yet she looked so alive with her big red eyes and her bright green leg warmers.

How to Cite this Article


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Tracks

Wynne Morrison, MD, MBE

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He is a slave to the yearning
that has become his life.
Hard cords wind up his arm,
toxic tributaries running
to the river through his heart.
The arm is bruised
and scarred by overuse,
a strip-mined landscape
on a mountainside.

Bits of his life erode
and fall apart until the end.
Lying on a bathroom floor,
syringe still clutched
in a blue hand,
long sleeves of the
turtleneck rolled up,
revealing the stigmata
of the sacrificial lamb.

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Accompanying artwork:
Tracks by Ty Ennis

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Ty Ennis lives and works in Portland, OR. He graduated from Pacific Northwest College of Art in 2003 with a BFA in Printmaking. Ennis is represented by Nationale in Portland, OR.
ABSTRACT
A neurology fellow describes an emotionally draining workday beginning with a long commute delayed by a scene of accidental death. During patient rounds, the day continued with misery as this physician watched and declared brain death in two patients. Opioids took away the life of a young, loving father from his growing family. Opioids robbed an unborn child from seeing her mother. Opioids made this physician feel helpless and caused him to think, Why is this happening? How to stop it? And when does it end? This narrative essay illustrates, with words and art, the need to stamp out the opioid epidemic.

INTRODUCTION: PERSONAL REFLECTIONS
As I entered the room, a balloon exclaimed: “Come home soon.” Several other colorful balloons decorated the room and surrounded the young man in the intensive care unit bed. A heart-shaped, red balloon expressed endless love. A wrinkled blue balloon begged him to come back home. A small stuffed elephant carried a pink balloon gesturing, “Be well.” In the corner, a furrowed-flesh golden balloon glowed with remnants of the phrase “Recover soon.”

The harsh sound of the ventilator and the loud beeping of the monitors took me back in time to earlier that morning. I sat for hours behind the steering wheel on my way to work. Stop-and-go traffic was the theme. It was dark, cold, and wet. The lights of emergency vehicles filled the horizon. Erratic lightning dominated the sky. Sirens intermixed with thunder. A murder (flock) of crows overflowed the shivering trees of Ohio’s winter while paramedics tried to resuscitate a man found unresponsive in his vehicle. I made it through the traffic jam but arrived late to work. I was emotionally exhausted. The morning scene stuck in my mind. I rushed to the physician lounge, took off my coat, ignored my wrinkled suit, forgot my coffee, and proceeded to patient rounds.

As I walked my way through the balloons and prevailed over my distraction, I greeted the patient’s wife, who clutched her husband’s pale left hand. I introduced myself as the neurologist and asked for permission to start my neurologic assessment. A blue teddy bear in the corner looked at me while I tried to call our patient’s name. That same teddy bear held a colorful drawing of a happy family, signed by a young boy, who happened to be our patient’s 6-year-old son. Despite several attempts to call our patient’s name, I received no answer. While trying to call his name again, I noticed a small piece of paper next to the electroencephalogram decorated and warmly colored by the man’s 4-year-old daughter. As my soul continued its distraction, my mind attempted to draw my attention to the neurologic examination. I tried to elicit a pupillary response. However, the man’s eyes did not avoid the intense beam of light I shined at them. I took out a syringe filled with sterile saline from the cabinet next to his bed. His eyes did not blink to drain the falling drops of salty water away from his drying cornea. He could not cough or gag while I suctioned his copious secretions. He did not move an arm or a leg no matter how strongly I stimulated a hidden part of his sweaty back. Despite a beating heart, his body was cold, swollen, and limp. The mechanical ventilator drove air in and out of his 30-year-old lungs.

The sound of the ventilator accompanied me to the next room. There I could see a young woman lying in the hospital bed; next to her sat the patient’s mother, a gray-haired woman who was grasping her daughter’s pale left hand. After greeting them and introducing myself, I asked for permission to perform my neurologic assessment. Then I noticed the colorful “Get well soon” balloons all around the room. While I stared, my mind experienced déjà vu. Could it be another brain-death examination? I noticed that the patient was pregnant. I called the patient’s name but received no response. I then yelled her name. However, I noted that her mother was not as surprised by the lack of response as I was.
as I was, so I took a deep breath and continued with the examination. I could feel the moving fetus deep inside the patient’s abdomen. Sadly, the patient herself was motionless, and she showed only limited signs of life. I overcame my distraction and continued my neurologic assessment. I elicited no pupillary response. I could not get her to blink when I tested the corneal reflexes. I failed to elicit any meaningful movement from her limbs. The only movements, other than those of her energetic fetus, were the brisk spinal reflexes. The baby girl was due in a few weeks, and her grandmother asked me to predict if the little one would ever meet her mom. My blank stare and a glistened tear on my face were apparent to her as I answered.

Neurologic diseases deprive us of the many things we take for granted; they hinder our natural capacity to move, walk, and talk. They rob our memories, hamper our thinking, and attenuate our abilities to see, hear, smell, taste, and touch. Sometimes brain death happens and takes us away from our loved ones. Opioid overdose puts the human body into a hypoxic state of cessation. Neurons are particularly susceptible, and brain damage or death may follow. Sometimes, lives are taken away in a matter of a few hours or days.

Earlier that day, paramedics failed to resuscitate the man who had reportedly overdosed in his car. Both my patients, according to their family members, had just relapsed after years of sobriety. The father of the young family had started a new job and a new chapter of a healthy, productive life. However, it was not long until he relapsed. He used a similar amount of heroin as he had before sobriety. Because he lost his opioid tolerance, the amount was too much and resulted in an accidental overdose. The young woman was living a sober life. She started a family and had a toddler boy at home waiting anxiously to meet his little sister. Unfortunately, the mother relapsed and accidentally overdosed. She sustained a massive anoxic brain injury, which ultimately led to her death only a few weeks after I met her. Luckily, she delivered safely, and the grandmother decided to raise the boy and his newborn sister.

**DISCUSSION: THE EPIDEMIC**

Ninety-one Americans die every day of opioid overdose, the Centers for Disease Control and Prevention report. The incidence is outrageous and continues to increase despite the availability of naloxone. Although deaths associated with prescription opioids steadily rose over the past 2 decades, heroin and fentanyl-related deaths have recently risen out of proportion. In 2016, fatalities attributed to fentanyl increased 540% compared with 2013. Public health experts suggest that prescription opioid misusers later make a transition to cheaper and more potent alternatives such as heroin. Sales of prescribed opioids have increased by 300% during the past 2 decades. Specialists suggest a combination of intertwined factors behind the current opioid crisis. Such risk factors include race (white), younger age, male sex, poverty, lower education, psychiatric comorbidities, and prior use of prescription opioids.

In addition to proper regulations and altering the practice of prescribing opioids, a comprehensive plan is necessary to combat the opioid abuse epidemic. Community efforts and targeted education can play an integral role together with legislation in fighting this epidemic. Teaching about the dreadful consequences of substance abuse should be discussed as early as possible in school curricula, at community gatherings, and in homes. Improved efforts such as raising awareness about the harmful effects of substance abuse, identifying individuals at risk and those in need of treatment, and promoting alternative methods of managing and coping with chronic pain are desperately needed. A dedicated team of teachers, community leaders, physicians, nurses, paramedics, police officers, parents, and caregivers should work together to plant balloons of hope in the community, alongside the path to recovery from the current opioid crisis.

**CONCLUSION**

The balloons in the hospital rooms were of false hope—balloons of despair—signaling love, health, and joy but masking suffering and death. The furrowed balloons narrated lengthy tales of intensive care unit stays owing to accidental opioid overdoses. One day, I hope, balloons will mark the end of the opioid epidemic.

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

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**How to Cite this Article**

**References**
Turbo Metabolism: 8 Weeks to a New You
by Pankaj Vij, MD, FACP, and Joel Fuhrman, MD

Review by Charles R Elder, MD, MPH, FACP

The market is already saturated with self-help books promoting various dietary and lifestyle regimens for combating obesity and diabetes. Nevertheless, Pankaj Vij, MD, has bravely attempted entry into this highly competitive sector. His new book turns out to be a fine addition, providing both enjoyable reading and useful clinical insights.

Turbo Metabolism lays out an overview of Dr. Vij’s multimodality program for reversing obesity, diabetes, and metabolic syndrome. The author opens with an excellent review of the etiology and physiology of metabolic syndrome. Here, as in other sections of the book, Dr. Vij does an admirable job of explaining the material in a way that is not only scientifically accurate but also both readable and comprehensible for the general public. He next examines various holistic paradigms for understanding how to approach the reversal of obesity and diabetes in a systematic yet natural way. He directs special attention to reviewing basic concepts of ayurveda, which is the traditional health care system of India, and likely the oldest system of natural health care in the world that has been in continuous practice along with traditional Chinese medicine. By couching his approach to weight management within ayurveda, Dr. Vij effectively emphasizes the importance of deploying a deeper, whole-person strategy for managing weight, encompassing mind, body, and spirit.

The author next turns to the practical steps necessary for losing weight and improving health. After detailing various tests needed for monitoring, he describes a “trash list” of foods that must not be eaten, and then he provides a shopping list of the various types of foods that should be eaten. These include whole grains, legumes, fruits, and vegetables. Subsequent chapters detail classic dietary and behavioral strategies that can form the basis of successful weight management. The importance of drinking plenty of fluids, the critical role of physical exercise, the necessity of controlling stress, and the central role of proper sleep hygiene are all laid out in a clear, accurate, and straightforward way. Dr. Vij provides additional material about avoiding environmental toxins while favoring organic foods, as well as discussing the role of probiotics, prebiotics, and spices. The book also includes a substantial number of recipes, plus insights into strategies for adopting and maintaining behavior changes.

Although I like the book overall, I found myself rolling my eyes over inconsistencies. The author plainly understands, and effectively communicates, that weight loss and maintenance require lifestyle change over the long term, yet in some measure undercuts this premise from the very start. The subtitle, “8 Weeks To A New You” may catch people’s attention and help sell books; however, the promise of instant gratification detracts from the message of reversing obesity and metabolic syndrome is a long-term journey, and this book provides a decent compass.

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

How to Cite this Article

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Dear Editor,

We enjoyed greatly the article “Lifestyle Medicine: A Brief Review of Its Dramatic Impact on Health and Survival” written by Bodai et al.1 The article encourages and inspires us.

Following World War II, Japan experienced an economic, nutritional, and epidemiologic transition. Stroke (apoplexy) replaced tuberculosis as the leading cause of death in 1951. Three diseases (cancer, coronary heart diseases, and stroke) became the main causes of death, accounting for about two-thirds of all deaths. Japan’s Ministry of Welfare designated these diseases “adult diseases” in 1956 in an attempt to diagnose and treat the diseases early in persons in their prime. Forty years later, in 1996, the term “adult diseases” was replaced with “lifestyle-related diseases,” considering the importance of lifestyle starting at childhood for prevention of chronic diseases. At that time, diabetes mellitus and hypertension were added to the three diseases above to form the five major lifestyle-related diseases. Consequently, “lifestyle disease” is a familiar term to the Japanese people. 2 It is obvious that the majority of diseases we face are chronic diseases (lifestyle diseases) caused by an unhealthy lifestyle.3,4 Therefore, incorporation of a healthy lifestyle in medicine, namely lifestyle medicine, is fundamental for prevention and treatment of chronic diseases.3,4 Bodai et al described the effect of lifestyle medicine in obesity, diabetes, cardiovascular disease, and cancer.1 We want to comment on our experience of lifestyle medicine in inflammatory bowel disease (IBD): Crohn disease (CD) and ulcerative colitis (UC).

We regard IBD as a lifestyle disease mainly mediated by westernized diets, which tend to cause reduced gut microbial diversity.4,5 We have provided a primarily plant-based diet (PBD) (lacto-ovo-vegetarian diet) for all IBD inpatients since 2003.4 Meat and fish are served once every 2 weeks and once a week, respectively. Sweets are not served. Fruits, vegetables, legumes, potatoes, and yogurt are served daily. We also provide information on healthy lifestyle habits: No smoking, regular physical activity, moderate or no use of alcohol, regularity of meals, and not eating between meals.6 We give each patient a dietary and lifestyle recommendation on discharge. We recommend a PBD for meals, active exercise, and maintenance of healthy lifestyle. We have 15 years of experience of such lifestyle medicine involving more than 159 patients with UC and 70 patients with CD.7 In CD, infliximab combined with PBD induced remission in 44 consecutive cases without fail.8 This remission rate is excellent considering that around 30% of sufferers are primary nonresponders to infliximab. PBD is effective in the maintenance of remission in CD: 100% and 90% at 1- and 2-year follow-up, respectively.9 This remission rate is achieved without scheduled maintenance therapy with infliximab. We recommend a short period of educational hospitalization for patients with mild UC to replace their omnivorous diet with a PBD. The cumulative relapse rates after educational hospitalization at 1 and 5 years of follow-up were 2% and 19%, respectively.9 Although our patients were mild cases, these relapse rates are far better than those reported in the literature (28% to 50% at 1 year and 57% to 78% at 5 years). PBD score,7 which evaluates adherence to the PBD, was significantly better relative to baseline both at short-term (14 months) and long-term (47 months) follow-up.9 We now treat mild cases of UC with PBD first, not medication.9,10 PBD without medication can induce remission in a subset of patients with mild UC.9,10 Our success with lifestyle medicine in IBD was greater than we expected and as dramatic as that described by Bodai et al1 in representative chronic diseases. It is regrettable that the PBD menu and dietary guidance for PBD by a registered nutritionist are not currently covered by health insurance. ♦

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References
To the editors:

On behalf of the authors, I wish to thank the Drs Chiba, Nakane, and Komatsu for taking the time to review our article regarding Lifestyle Medicine and for preparing their insightful response. It is apparent that they have done extensive work in the area of the serious and often debilitating disease: Inflammatory bowel disease (IBD), and how it can be affected by lifestyle changes. Their work further demonstrates that yet another chronic illness, in addition to those described in our article, can be substantially affected by altering the lifestyle that contributes to such chronic conditions.

Our article places strong emphasis on inflammation as a common denominator in the majority of chronic conditions that are responsible for a significant portion of our health care expenditure. Additionally, the article specifically mentions the strong association of inflammation and the development of colorectal malignancies, the incidence of which is much higher in patients with IBD, who have been shown to have a substantially increased risk of developing other malignancies such as breast cancer.

Our current understanding of disease is in its infancy. Dr Chiba et al reinforce the urgent need to move forward in exploring alternative treatment options in the management of chronic diseases, using lifestyle alterations as opposed to the prescribing of medications that treat only symptoms and fail to address the root causes of these conditions.

Many equate screening for disease with prevention. Modern screening technologies may find malignancies, but in no way are they preventive. Medicine must evolve into being truly preventive, not reactive. Dr Chiba et al have made a major contribution to moving health care forward with their extensive work in the field of IBD. We are totally in concurrence with their conclusion that dietary guidelines, focusing on a whole food, plant-based diet as treatment for chronic diseases is not only needed, but must be implemented.

We appreciate Dr Chiba et al’s call for further support for the much-needed paradigm shift in the future of medicine.

Balasz I Bodai, MD
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Response to Drs Chiba, Nakane, and Komatsu

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Our article places strong emphasis on inflammation as a common denominator in the majority of chronic conditions that are responsible for a significant portion of our health care expenditure. Additionally, the article specifically mentions the strong association of inflammation and the development of colorectal malignancies, the incidence of which is much higher in patients with IBD, who have been shown to have a substantially increased risk of developing other malignancies such as breast cancer.

Our current understanding of disease is in its infancy. Dr Chiba et al reinforce the urgent need to move forward in exploring alternative treatment options in the management of chronic diseases, using lifestyle alterations as opposed to the prescribing of medications that treat only symptoms and fail to address the root causes of these conditions.

Many equate screening for disease with prevention. Modern screening technologies may find malignancies, but in no way are they preventive. Medicine must evolve into being truly preventive, not reactive. Dr Chiba et al have made a major contribution to moving health care forward with their extensive work in the field of IBD. We are totally in concurrence with their conclusion that dietary guidelines, focusing on a whole food, plant-based diet as treatment for chronic diseases is not only needed, but must be implemented.

We appreciate Dr Chiba et al’s call for further support for the much-needed paradigm shift in the future of medicine.

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**Section A.**

**Article 1.** (page 4) Relapse Prevention in Ulcerative Colitis by Plant-Based Diet Through Educational Hospitalization: A Single-Group Trial

Which of the following statements is correct?
- a. a low-residue diet is adequate for inflammatory bowel disease
- b. high consumption of meat is a risk factor for inflammatory bowel disease
- c. lifestyle change cannot regress coronary atherosclerosis
- d. evening tea with a scone is one of the recommended healthy habits
- e. the amount of carbohydrate consumption during dietary westernization is appropriate

Which of the following statements is correct?
- a. oral steroid hormone is the first choice of treatment for mild ulcerative colitis
- b. genetic factors are more important than environmental factors in the onset of inflammatory bowel disease
- c. diet can modify gut microbiota
- d. onset of inflammatory bowel disease is decreasing in Asia
- e. people who have omnivorous diets exhibit longer life than those who have plant-based diets

**Article 2.** (page 19) Potentially Preventable Hospital and Emergency Department Events: Lessons from a Large Innovation Project

Which of the following factors are helpful in identifying patients at greater risk for potentially preventable events?
- a. patient age
- b. poor control of diabetes
- c. Hispanic ethnicity
- d. presence of an ambulatory care-sensitive condition
- e. lack of a family member to help them manage their health

In this study, were patients with more than five Emergency Department visits or hospitalizations in the past year more likely to have a particular event be potentially preventable?
- a. yes
- b. no
- c. this question wasn’t evaluated by the study

**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?

**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: ____________________
Title: ____________________
E-mail: ____________________
Address: ____________________
Signature: ____________________
Date: ____________________
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ORIGINAL RESEARCH & CONTRIBUTIONS

14 Repeal Prevention in Ulcerative Colitis by Plant-Based Diet Through Educational Hospitalization: A Single-Group Trial. Mitsuko Chida, MD, PhD; Hiroshi Nakaaki, MD, PhD; Toshiko Tjiai, MD; PhD; Sabino Suada, MD, Kyoko Ishii, MD, PhD; Hiroshi Ohno, MD; Kazuma Watanabe, MD; Masaru Kanmatsuse, MD; Koki Yamaida, MD; Takeji Sugawara, MD. No known published study has focused on a plant-based diet in the treatment of ulcerative colitis (UC). In a prospective study of 60 patients with mild UC or UC in remission who did not need immediate treatment (23 initial episodes and 31 relapse episodes), the cumulative relapse rates at 1, 2, 3, and 4 years of follow-up were 2%, 4%, 7%, 19%, and 19%, respectively. Relapse rates after educational hospitalization providing a plant-based diet were far lower than those reported with medical therapy. Educational hospitalization is effective at inducing quiescent disease changes.

15 Marjorie’s Influence on Pain Palliation, Initial Weight Loss, and Other Bariatric Surgical Outcomes. Frank T. Dauer, MD; William M. DiPietro, MD; Harris H. Faddis, MD; Adam O. Taa, MD; Brian J. Potott, MD; Jason M. Johnson, DO; Loren L. Silverman, PhD; Farhid A. Hamaan, MD. Pain management can be challenging following bariatric surgery, and obese patients tend to increase opioid use after undergoing surgery. Data were collected for 434 consecutive patients undergoing weight reduction surgeries (5/2014-7/2015) among whom 34 (7.8%) reported marijuana (MJ) use. Perioperative opioid requirements were significantly higher in the MJ-user group despite lower subjective pain scores (3.0 vs 4.24). The differences in opioid requirements suggests an interaction between MJ use and opioid tolerance or pain threshold. The percentage of total body weight loss, improvement in medical comorbidity, and incidence of postoperative complications at 60-day follow-up were not affected by MJ use in this cohort analysis.

16 Potentially Preventable Hospital and Emergency Department Events: Lessons from a Large Innovation Project. Lali S. Gobind, MD; Kira A. Onel, RN; MPH; Emily D. Parker, PhD; MPH; Robert Ferguson; Sauna Magrany; MD; PhD; Robin R. Whelan; PhD; Claire Neely; Emily Brandonfels, MD; MS; Mark O. Williams; MD; Mark Ohmsen, MD; Todd Hemenkamp, RN; Jeanette Y. Ziegler, PhD. There are few proven strategies to reduce the frequency of potentially preventable hospitalizations and Emergency Department visits. Of the studied events, zero were consumed to be potentially preventable (30% of Emergency Department visits and 44% of hospitalizations) and 4% of patients had 40% of events. Only type of insurance coverage; patient lack of resources, onus to recognize and allow access to care; and inability to access clinic care were more frequent in those with preventable events. Neither disease control nor ambulatory care-sensitive conditions were associated with potentially preventable events.

22 Understanding Waste in Health Care: Perspectives of Forensic Physicians Regarding Time Use and Appropriateness of Care Time and Others Provide. John P. Cagayan, PhD; Michael H. Kantor, MD; Nicole R. Hendershot, MPH; Chong J. Yie, PhD; Hern An Kanzara, MD; MHPM; Sandra H. Bay, MA; Robert H. Block, MD, BS. In a cross-sectional online survey of all Southern California Permanente Medical Group physicians primarily providing clinic-based care (1054), 61% of respondents indicated that 15% of their time spent on direct patient care could be shifted to nonphysician, and between 10% and 16% of care provided was equivalent or inappropriate. It appears that at least one quarter of health care system, the opportunity to increase value through task shifting and avoiding inappropriate care is more narrow than perceived on a rational basis.

24 Impact of Body Mass Index on Postconcussion Symptoms in Teenagers Aged 13 to 18 Years. Barry Stanley, CO; Kathryn O. Foley, MD; Ronald Williams, MD; Michelle M. Lewis, MD; Karen L. King, PhD; Matthew Silvis, MD. In a retrospective chart review at a rural children’s hospital, during the years 2006 to 2012, 195 patients with traumatic brain injury were reviewed with postconcussion symptoms in the follow-up visits. Of these, 166 were eligible for analysis. The average age of patients was 15.8 years and the average weight was 93.5 kg. In the group of normal weight patients, the average BMI was 18.5 kg/m² and in the overweight group the average BMI was 22.8 kg/m². The proportion of patients with postconcussion syndrome was 69.7% in the normal weight group and 75.7% in the overweight group. The difference was not statistically significant. Overweight patients tend to have lower BMI but higher rates of postconcussion symptoms. The findings are further supported by the significant correlation between BMI and postconcussion symptoms and the fact that BMI is a reliable and easily accessible measure for assessing weight status.

29 Current Trends in the Treatment of Inflammatory Bowel Disease: Ulcerative Colitis. Farah A. Husain, MD; Jason M. Johnson, DO; Lori J. Silveira, PhD; Kimberly D. Smith; Ronald Williams, MD; Todd Hemenkamp, RN; Jeanette Y. Ziegler, PhD. Ulcerative colitis (UC) is a chronic inflammatory disease of the large intestine and rectum that affects up to 700,000 Americans. The disease can cause severe inflammation, abdominal pain, and bleeding. The most common complications of UC are colorectal cancer and perforation. Anti-TNF-α agents have revolutionized the treatment of UC, but there are still some patients who do not respond to these medications. The most common factors associated with poor response to anti-TNF-α agents are concomitant use of nonsteroidal anti-inflammatory drugs (NSAIDs) and smoking. The use of mesalazine in addition to anti-TNF-α agents is associated with improved remission rates and lower rates of relapse. However, the use of mesalazine is limited by side effects, such as diarrhea and nausea. The aim of this study was to evaluate the effectiveness of mesalazine in patients with UC who do not respond to anti-TNF-α agents. A total of 24 patients with UC who had been treated with anti-TNF-α agents and were intolerant to them were included in the study. Patients were started on mesalazine at a dose of 2 g/day and titrated to 4 g/day. The response was evaluated based on the change in the clinical activity index (CAI) and the endoscopic activity index (EAI). The results showed that mesalazine significantly improved the CAI and EAI in the majority of patients. The use of mesalazine in combination with anti-TNF-α agents is a promising strategy for improving outcomes in patients with UC who do not respond to anti-TNF-α agents.
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