BackSlit Aspens
Near Monitor Pass,
California 2012
by Stuart Hahn, MD
This photograph of a beautiful aspen grove in autumn was taken in the Sierra Nevada Mountains near the border of California and Nevada.

Dr Hahn retired from The Permanente Medical Group in 2010. He has been seriously exploring photography since 2000 and his artwork is focused on landscape photography. For further information about his artwork, Dr Hahn can be contacted at: hahnsrk@globalnet.co.uk.

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40  A Pilot Study Comparing Anatomic Failure after Sacrocolpopexy with Absorbable or Permanent Sutures for Vaginal Mesh Attachment. Jasmine Tan-Kim, MD, MAS; Shawn A Menenee, MD; Quinn Lippmann, MD, MPH; Emily S Lukacz, MD, MAS; Karl M Lubhr, MD; Charles W Nager, MD. The authors reviewed the medical records of 193 women who underwent sacrocolpopexy with 2 different types of sutures attaching polypropylene mesh to the vagina: delayed absorbable sutures (median follow-up, 43 weeks) and permanent sutures (median follow-up, 106 weeks). Failure rates for the 45 subjects in the delayed absorbable group and 148 subjects in the permanent suture group were similar and not statistically different in any compartment: apical, anterior, or posterior. Delayed absorbable monofilament suture appears to be a reasonable alternative to permanent suture for mesh attachment to the vagina during sacrocolpopexy.

45 Differences in Perceived Difficulty in Print and Online Patient Education Materials. Michael Farnsworth, MA. Patients are often intimidated by the task of reading patient education materials, perceiving the materials’ difficulty levels as prohibitive, even when they do not exceed the patients’ reading abilities. Some first-year college students perceived online patient education materials to be more difficult to read than print-based ones—even when the reading level of the patient education materials was similar. Patients’ perceptions of the difficulty of patient education materials influenced their ability to effectively learn from those materials.

52 Behavior Medicine Specialist. Phillip Tusso, MD, FACP, FASN. A behavioral medicine specialist is a psychologist who works in the medical home with the primary care physician. The key to achieving Total Health will be to transform the current health care system from a focus on treating disease to a focus on preventing disease. This transformation will require complex behavior change interventions and services not usually provided in the medical home. The behavioral medicine specialist will bring the knowledge and experience used to treat mental illness into the medical home to help the primary care physician improve the care of all patients in the medical home.

Special Report

58 Mindful Mood Balance: A Case Report of Web-Based Treatment of Residual Depressive Symptoms. Jennifer Felder, MD, MA; Sona Dimidjian, PhD; Arne Beck, PhD; Jennifer M Boggs, MSW; Zindel Segal, PhD. Residual depressive symptoms are associated with increased risk for relapse and impaired functioning. Although there is no definitive treatment, Mindfulness-Based Cognitive Therapy (MBCT) has been shown to be effective, but access is limited. Mindful Mood Balance (MMB), a Web-based adaptation of MBCT, was designed to address this care gap. The authors describe a composite case that is representative of the course of intervention with MMB and its implementation in a large integrated delivery system. MMB may be a cost-effective and scalable option in primary care for increasing access to treatments for patients with residual depressive symptoms.

Special Report

64 Thinking about Thinking and Emotion: The Metacognitive Approach to the Medical Humanities that Integrates the Humanities with the Basic and Clinical Sciences. Quentin G Eichbaum, MD, PhD, MPh, MFA, MFAHC, FCAP. The explosion in medical knowledge has exceeded the capacity of the individual human brain to absorb the entirety of this knowledge. This suggests we no longer expect medical students to continue simply memorizing facts. Instead, we must develop in students a competency as flexible thinkers and agile learners so they can adeptly deal with new knowledge, complexity, and uncertainty in a rapidly changing world. Such a competency would entail not only cognitive but also emotional skills essential for the holistic development of their professional identity. This article will argue that meta-cognition—“thinking about thinking (and emotion)”—offers the most viable path toward developing this competency.

58 Mindful Mood Balance: A Case Report of Web-Based Treatment of Residual Depressive Symptoms. Jennifer Felder, MD, MA; Sona Dimidjian, PhD; Arne Beck, PhD; Jennifer M Boggs, MSW; Zindel Segal, PhD. Residual depressive symptoms are associated with increased risk for relapse and impaired functioning. Although there is no definitive treatment, Mindfulness-Based Cognitive Therapy (MBCT) has been shown to be effective, but access is limited. Mindful Mood Balance (MMB), a Web-based adaptation of MBCT, was designed to address this care gap. The authors describe a composite case that is representative of the course of intervention with MMB and its implementation in a large integrated delivery system. MMB may be a cost-effective and scalable option in primary care for increasing access to treatments for patients with residual depressive symptoms.

Special Report

85 Vasal Injury During Inguinal Herniorrhaphy: A Case Report and Review of the Literature. Lawrence Flechner, MD, PhD; James Smith, MD, MS; Patrick Treseler, MD, PhD; John Maa, MD. An injury to the vas deferens during inguinal herniorrhaphy from possible tethering of the vas has not, to our knowledge, previously been described in the surgical literature. We report a case of iatrogenic injury of the vas deferens that occurred during elective hernia repair in a 28-year-old man who had previously sustained blunt trauma to the abdomen and pelvis.

CASE STUDIES

65 Mindful Mood Balance: A Case Report of Web-Based Treatment of Residual Depressive Symptoms. Jennifer Felder, MD, MA; Sona Dimidjian, PhD; Arne Beck, PhD; Jennifer M Boggs, MSW; Zindel Segal, PhD. Residual depressive symptoms are associated with increased risk for relapse and impaired functioning. Although there is no definitive treatment, Mindfulness-Based Cognitive Therapy (MBCT) has been shown to be effective, but access is limited. Mindful Mood Balance (MMB), a Web-based adaptation of MBCT, was designed to address this care gap. The authors describe a composite case that is representative of the course of intervention with MMB and its implementation in a large integrated delivery system. MMB may be a cost-effective and scalable option in primary care for increasing access to treatments for patients with residual depressive symptoms.

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LETTERS TO THE EDITOR

93 Narratives In Medical Education: The Next Steps. Brad Christian McDowell, MD. The core principle of implementing healthy behavior change is making the healthy choice the easy choice. Putting this motto into practice requires removal of barriers to live a healthy lifestyle. It is important to look at the bigger picture when helping patients reach optimal health, looking closely at exercise levels and home life. Environmental factors cause strain and present challenges also. The Care Management Institute and Kaiser Permanente are changing default behaviors so optimal lifestyles become the norm, rather than the exception.

REVIEWS

76 A Business Case for Tele-Intensive Care Units. Alberto Coustasse, DrPh, MD, MBA, MPH; Stacie Deslisch, MA, MS; Deanna Bailey, MS; Alecia Hairston, MS; David Paul, DDS, PhD. A tele-intensive care unit (tele-ICU) uses telemedicine, in an intensive care unit (ICU) setting, to care for critically ill patients by off-site clinical resources. This literature review examined a large number of studies of implementation in hospitals. The evidence supporting cost savings was mixed. Implementation of a tele-ICU system was associated with cost savings, shorter lengths of stay, and decreased mortality. However, two studies suggested increased hospital cost after implementation. Intensivists working these systems are able to more effectively treat ICU patients, providing better clinical outcomes for patients at lower costs compared with hospitals without a tele-ICU.
CASE STUDIES
Reverse Pseudohyperkalemia in a Patient with Chronic Lymphocytic Leukemia.
Taurino Avelar, MD

A man, age 78 years, with a history of chronic lymphocytic leukemia presented to clinic for evaluation of a cough. This case report highlights the importance of distinguishing cases of true hyperkalemia from pseudohyperkalemia and reverse pseudohyperkalemia.

An Incidental Discovery of Low-Grade Appendiceal Mucinous Neoplasm.
Aaysha Kapila, MD; Jennifer Pemister, MD; Pranav Patel, MD;
Chakradhar M Reddy, MD; Ravindra Murthy, MD; Mark F Young, MD

A 65-year-old man with a history of hyperplastic polyps underwent a surveillance colonoscopy, which revealed a large, smooth cystic bulge at the appendicular orifice. Subsequently, a computed tomography of the abdomen with contrast revealed an appendiceal mucocoele measuring 13.3 x 4.5 cm.

Latrodectus Envenomation in Greece.
Garyfallia Nikolaos Antoniou, MSc; Dimitrios Iliopoulos, PhD; Rania Kalkouni, MD; Sofia Iliopoulos, MSc; Giorgos Rigakos, MD; Agonitsa Baka, MD

During the summer period 2011-2012, seven widow spider bites in Greece were reported to the Hellenic Center for Disease Control and Prevention. Widow spiders (in the genus Latrodectus) are found all over the world. Antivenin was administered to four patients upon the request of their physicians. The most important goal for all of these patients is early pain relief.

ORIGINAL RESEARCH & CONTRIBUTIONS
Financial Implications of the Continuity of Primary Care.
Marcus J Hollander, MA, MSc, PhD; Helena Kadlec, MA, PhD

Passive Cigarette Smoke Exposure and Other Risk Factors for Invasive Pneumococcal Disease in Children: A Case-Control Study.
Colleen S Chun, MD; Sheila Weinmann, MPH, PhD; Karen Riedlinger, MT, MPH; John P Multilooy, PhD

Plant-Based Diet, Atherogenesis, and Coronary Artery Disease Prevention.
Phillip Tuso, MD, FACP, FASN; Scott R Stoll, MD; William W Li, MD

ANNOUNCEMENT:
CME Credits Now Available for Reviewers
See inside back cover for details.
ORIGINAL RESEARCH & CONTRIBUTIONS

Mindfulness-Based Stress Reduction in an Integrated Care Delivery System: One-Year Impacts on Patient-Centered Outcomes and Health Care Utilization

Tracy McCubbin, MD; Sona Dimidjian, PhD; Karin Kempe, MD, MPH; Melissa S Glassey; Colleen Ross, MS; Arne Beck, PhD

Editor’s note: Please see related article on page 58.

Abstract
Background: Mindfulness-based stress reduction (MBSR) programs have demonstrated clinical effectiveness for both mental and physical health conditions. Less research exists on health services utilization, self-efficacy, or work productivity outcomes.

Objective: To assess one-year outcomes of MBSR in patients with chronic pain, chronic illness, or stress-related problems, measuring functional status, pain, self-efficacy, depression, anxiety, somatization, psychological distress, work productivity, and changes in health services utilization.

Methods: A prospective single cohort design evaluated an eight-week MBSR program for Kaiser Permanente Colorado members. Patient-reported measures were collected at baseline, eight weeks, and one year following MBSR. Differences in health services utilization were compared from six months before MBSR to six months following the one-year anniversary of MBSR.

Results: Most of the 38 participants were white (28; 74%), female (30; 79%), employed part-time (35; 92%), and average age 52.6 years, with multiple comorbidities (averaging 16.4 unique diagnoses), the most common being joint or back pain (28; 74%) and psychological disorder (20; 53%). Repeated measures analyses at 8 weeks (n = 26) and at 1 year (n = 24) showed significant improvements in self-reported mental and physical function, pain, psychological symptoms, and self-efficacy, but not work productivity. Significant decreases at 1 year were observed for visits in primary care (-50%, p < 0.0001), specialty care (-38%, p = 0.0004), and the Emergency Department (-50%, p = 0.04), and for hospital admissions (-80%, p = 0.02).

Conclusion: The MBSR program was associated with improvements in several patient-centered outcomes over 1 year and reductions in health services utilization up to 18 months.

Introduction
Chronic diseases are the leading causes of death and disability in the US. It is estimated that one of two adults in the US experiences at least one chronic illness and seven of ten deaths are attributable to chronic disease. As many as one in three individuals report chronic pain; nearly half of them experience poor control over their symptoms, highlighting the limitations of drug therapy as well as the complexity of the psychosocial and physical aspects of chronic pain.

Mindfulness-based therapies, which include mindfulness-based cognitive therapy and mindfulness-based stress reduction (MBSR), have emerged as effective treatments for a variety of conditions, including chronic pain, anxiety, depression, and psychological distress. Such treatments aim to help patients develop an understanding of their vulnerabilities to illness and to build resilience through shifting cognitive, affective, and behavioral responses to both internal distress and external stressors. Through the practice of mindfulness, which has been described as paying attention, on purpose and without judgment in the present moment, patients are taught to increase awareness and acceptance and to develop more skillful ways of responding to mental and physical experiences.

MBSR is typically delivered as a group intervention in eight class sessions with a separate six-hour retreat. In addition, one recent study has looked at the feasibility of an online mindfulness program for stress management. Patients who benefit from this type of therapy include those experiencing stress-related illness such as irritable bowel syndrome, muscle tension, fibromyalgia, and chronic migraine, as well as patients who have chronic diseases or chronic pain and are not coping well because of anxiety, depression, stress, or lack of family support.

Since the publication of Kabat-Zinn’s original study on mindfulness training in the medical setting, a burgeoning literature has described the effectiveness of MBSR and similar mindfulness-based therapies on a variety of outcomes, including pain, function, quality of life, and psychological symptoms. However, few have examined the effect of MBSR on health care utilization—a question of interest to health care systems that might support an MBSR program if it demonstrated reductions in the unnecessary use of health care services. In addition, patient-centered outcomes such as self-efficacy and work productivity have not been studied extensively. If MBSR improves function, pain, and psychological symptoms, then it might also...
be expected to increase participants' self-efficacy—that is, their confidence in being able to manage their chronic pain and/or illness. Similarly, improvements in general function and symptoms might also lead to improvements in work function, including less absence from work and increased productivity while at work. Such findings would be of considerable interest to employers when evaluating the benefit of MBSR for their workforce members. Moreover, most outcomes of MBSR are measured immediately following the eight-week class and at six months, though some studies have examined longer-term outcomes for selected patient populations. Additional research on the persistence of the aforementioned outcomes would be of value.

We report here the results of an MBSR program provided through group classes in a large integrated care delivery system, beginning in 2005. The aims of this study were to assess the impact of MBSR on a broad range of patient-centered outcomes, including health and functional status, pain, work productivity impairment, self-efficacy, symptoms of depression, anxiety, somatization, and overall psychological distress, and to assess changes in health care utilization.

We hypothesized that MBSR would
1. increase participants' mental and physical functional status, work productivity, and self-efficacy
2. reduce symptoms of depression, anxiety, somatization, and psychological distress
3. decrease primary care, specialty care, mental health, Emergency Department visits, and hospital admissions.

**Methods**

**Design and Procedures**

This study was a prospective, single cohort design with patient-centered outcomes assessed at the beginning and end of the eight-week MBSR program and at one year after the baseline assessment. Changes in health care utilization were compared for the six-month period before the first MBSR class and the six-month period after the one-year anniversary of completion of the last class. The study protocol was approved by the Kaiser Permanente Colorado (KPCO) institutional review board on August 25, 2005.

**Study Participants**

Participants were all members of KPCO, a large, not-for-profit, integrated health care system that provides comprehensive, prepaid medical coverage to over 600,000 members in Colorado’s Denver, Boulder, and Colorado Springs metropolitan areas. Data for the present study were obtained from 38 participants for whom 18 months of health services data were available. These participants were enrolled in 7 separate MBSR class cycles conducted from September 2005 through June 2009.

Study participants initially were referred by primary care physicians from two of KPCO’s outpatient clinics following an informational meeting to describe the program and distribute program flyers. Flyers for patients describing the study were also posted in outpatient clinics where KPCO offered other complementary and alternative medicine services (eg, massage therapy, acupuncture, chiropractic therapy) to encourage self-referral.

Participation in the MBSR program was open to Health Plan members who were aged 18 years or older, with chronic pain, a chronic illness, or a stress-related problem. Individuals were excluded from participation if they had a poorly controlled psychiatric illness, severe antisocial behavior, or dementia; lacked English language skills; or were participating in a concurrent study. Additional inclusion criteria were applied during a 30-minute intake interview in which a clinical psychologist, who served as one of the MBSR instructors, took a brief medical and psychiatric history, determined final eligibility for participation, and obtained informed consent from participants. The additional inclusion criteria assessed at the intake interview were the following: has appropriate goals and expectations for the MBSR class, including understanding the difference between attempts to alleviate pain and attempts to alleviate suffering; agrees to participate fully in the program and make a commitment to the home practice of meditation and movement/exercise; understands his or her diagnosis and believes s/he has received appropriate medical evaluation and treatment and/or mental health services for medical conditions or psychiatric diagnoses; and understands MBSR as a complement to medical care.

After the intake interview, participants completed baseline questionnaires on health and functional status, psychological symptoms, self-efficacy, and work productivity.

**Intervention**

The eight-week MBSR program was offered through KPCO’s Center for Complementary Medicine, which provided complementary medicine services at three outpatient clinics in the Denver and Boulder metropolitan areas. Classes were led by one of two instructors (a clinical psychologist and a family physician) trained to provide the Kabat-Zinn program of MBSR.

Mindfulness-based stress reduction is an 8-week group intervention combining meditation techniques with psycho-education to improve an individual’s capacity to manage stress, reduce the impact of physical and psychological symptoms, and maximize the ability to thrive through all of life’s circumstances. The intervention consisted of eight 2- to 2.5-hour classes conducted once a week and a 6-hour guided retreat held before the last class. Participants were also asked to complete 30 to 45 minutes of home practice and awareness exercises each day. Core practices include a guided body scan, mindfulness movement (yoga), and sitting and walking meditation. The core skills taught included:

- understanding of attitudes, perceptions, and unskilful thought patterns
- understanding and modulating one’s reaction to stressors
- recognizing pleasant and unpleasant emotions, thoughts, and sensations
- using mindfulness in daily activities including interpersonal communication
- focusing attention on internal states and sensations (such as awareness of the breath) and maintaining an open, nonjudgmental, self-monitoring attitude.

**Outcome Measures**

Participants completed questionnaires on health and functional status, psychological symptoms, self-efficacy, and work productivity at baseline before the MBSR class, at the final session
Mindfulness-Based Stress Reduction in an Integrated Care Delivery System: One-Year Impacts on Patient-Centered Outcomes and Health Care Utilization

Analyses using SAS Proc Mixed, allowing for differing numbers of measurements and times of measurements, were employed to examine change over time in self-reported patient outcomes from baseline through eight weeks and one year following the MBSR program.

Results

Initially, 45 participants were eligible for and attended the first MBSR class. However, 7 individuals ended their KPCO Health Plan membership before the 1-year follow-up period and thus were ineligible for study participation. Results are reported for the remaining 38 participants for whom 1-year health services utilization and self-report data were available. Table 1 provides descriptive statistics of these study participants.

Follow-up questionnaire data were obtained from 26 (68%) participants at 8 weeks and 24 (65%) at 1 year. To determine whether participants who did not complete follow-up questionnaires differed from those who did complete them, we analyzed differences between these 2 groups in demographic characteristics, baseline questionnaire scores, and health services utilization. No significant differences for any of these variables were found.

Repeated measures analyses of scores from the Medical Outcomes Study Short-Form 36 Health Survey, BSI-18, and Self-Efficacy measures (Table 2) showed significant changes from baseline to 8 weeks and 1 year. Improvements in mean MCS and bodily pain scores were seen at 8 weeks, averaging 7.5 (p < 0.01) and 4.5 (p < 0.05), respectively, and the magnitude of improvement was greater at 1 year, averaging 11.8 and 5.7, respectively (p < 0.01 for both scores). The PCS and general health scores also increased at 8 weeks by an average of 3.1 and 4.4, respectively (p < 0.05 for both), but remained unchanged from 8 weeks to 1 year.

The BSI-18 scores for anxiety, depression, and somatization and the global severity index all declined significantly from baseline to 8 weeks, with reductions ranging from 42% to 54% (p < 0.01 for all scores). These scores continued to decline at 1 year, with reductions from baseline ranging from 54% to 65%, with the exception of the MBSR class, and one year after the last MBSR session, when they were contacted by phone to complete the questionnaires.

Data on visits to primary care, specialty care (eg, orthopedics, neurology, cardiology), the Emergency Department, and hospital admissions were collected from KPCO’s electronic administrative and claims data for the period of six months before the class (baseline) and six months following the one-year anniversary of the last MBSR class (follow-up).

Patient self-report measures included the following:

- Medical Outcomes Study Short-Form 36 Health Survey. Developed by Ware and colleagues, the Medical Outcomes Study Short-Form 36 Health Survey is a validated self-report instrument that measures overall health (“How would you rate your health?” with responses on a Likert-type scale ranging from “poor” to “excellent”) and 8 specific domains of function. The 8 scales can be combined into 2 summary scales, which measure physical function (physical component summary [PCS]) and mental function (mental component summary [MCS]). We report here on results for the rating of overall health, PCS, MCS, and the pain subscale. A higher score on all of these measures indicates better health and function.

- Health and Work Performance Questionnaire. The Health and Work Performance Questionnaire, validated by Kessler and colleagues, provides a global assessment of work absence and productivity impairment caused by health conditions. It is used to calculate, over the previous 2 weeks, the percentage of hours worked (number of hours one actually worked divided by the number of hours one was expected to work), as well as a rating of one’s usual job performance on a 10-point scale, with higher values representing higher levels of productivity.

- Brief symptom inventory (BSI-18). The BSI-18 assesses self-reported symptoms of depression, anxiety, and somatization and provides a global severity index of overall psychological distress. Lower scores on the BSI-18 indicate lower symptoms.

- Self-efficacy. Self-efficacy questions have been developed and widely used by Lorig and Holman and others for assessing patients’ confidence in managing a variety of health conditions, including arthritis and other chronic diseases. Self-efficacy questions were used to assess MBSR participants’ ratings of their confidence (0 = “not at all confident,” 10 = “extremely confident”) in undertaking several activities:

  - “Do all the things necessary to manage conditions on a regular basis”
  - “Do things other than just take medication to reduce how much your illness affects your everyday life”
  - “Control any other symptoms or health problems you have so that they don’t interfere with the things you want to do.”

Data Analyses

All analyses were conducted using SAS, version 9.1.3 (SAS Institute, Cary, NC). Analyses comparing one-year questionnaire completers with noncompleters were performed using Wilcoxon and χ² tests for continuous and categorical variables, respectively. The signed-rank test was used to assess change in utilization of health care services (ambulatory, primary, and specialty care visits, Emergency Department visits, and hospital admissions) from baseline to follow-up. Repeated measures
of somatization, which remained unchanged from 8 weeks to 1 year (p < 0.01 for all scores at 1 year compared with baseline). The 3 self-efficacy items showed increases in average scores from baseline to 8 weeks ranging from 0.5 to 1.4. Two of the 3 increases were significant: “confidence in managing conditions” (p < 0.05) and in “controlling symptoms so they don’t interfere with activities” (p < 0.01). However, all 3 self-efficacy scores decreased between 0.4 and 1.8 points from baseline to 1 year, and these decreases were significant for 2 items: “confidence in managing conditions” and in “doing things other than taking medication to reduce effects of illness in everyday life” (p < 0.05 for both items).

Although the Health and Work Performance Questionnaire variables of percentage of expected hours worked and productivity ratings increased from the baseline to 8 weeks by 9% and 6%, respectively, these increases were not significant. At 1 year, the percentage of expected hours worked decreased slightly but remained above baseline by 4%, whereas productivity ratings decreased by 6% from baseline. Neither result was significant.

Health services utilization (Table 3) decreased significantly from baseline to follow-up in visits to primary care (p < 0.0001), specialty care (p = 0.0004), and in hospital admissions (p = 0.02).

Discussion

Completion of the MBSR program at KPCO was associated with statistically significant and clinically meaningful improvements at eight weeks in health and functional status, pain, symptoms of depression, anxiety, somatization, and overall psychological distress. These results are consistent with other studies reporting improvements in both psychological and physical outcomes following MBSR.5,7

Moreover, at the one-year follow-up, ratings for MCS and symptoms of anxiety and depression continued to improve, whereas the eight-week reductions in ratings for PCS, general health, pain, and somatization were sustained, suggesting that the magnitude of longer-term benefits of MBSR are greater for mental symptoms compared with physical symptoms and function. Other research on longer-term outcomes of MBSR also has shown positive results.32

Our findings regarding self-efficacy were more equivocal. Although significant increases were seen at eight weeks for two of the three items (“confidence in managing conditions” and in “controlling symptoms so they don’t interfere with activities”), there also were decreases in all three items at one year compared with baseline, two of which were significant (“confidence in managing conditions” and in “doing things other than taking medication to reduce effects of illness in everyday life”). Although these findings suggest that increases in self-efficacy resulting from MBSR may be more short-lived than other outcomes, this result may also reflect the small sample size. Still, they suggest that MBSR participants could benefit from additional interventions after eight weeks that support their ongoing confidence in their ability to manage their conditions more effectively.

The percentage of expected work hours completed and self-ratings of usual job performance showed small, nonsignificant increases following the MBSR classes, although these measures decreased at one year. Neither of the changes at one year was significant.

| Table 2. Descriptive statistics and univariate tests of patient questionnaire scores at baseline, eight weeks, and one year |
|-----------------------------------|----------------|-------------------|-----------------|----------------|-----------------|
| Outcome measured                  | Baseline, mean (SD) (n = 38) | 8 weeks, mean (SD) (n = 26) | p value | 1 year, mean (SD) (n = 24) | p value |
| SF-36 Health Survey               |                             |                               |        |                             |        |
| Mental composite score            | 41.9 (12.7)                 | 49.4 (9.0)                   | 0.0003 | 53.7 (5.0)                   | < 0.0001 |
| Physical composite score          | 46.9 (9.8)                  | 50.0 (7.5)                   | 0.0503 | 49.4 (8.6)                   | 0.1461  |
| Bodily pain                       | 45.1 (10.3)                 | 49.5 (9.2)                   | 0.0363 | 50.7 (8.3)                   | 0.0036  |
| General health                    | 46.9 (10.2)                 | 51.3 (6.1)                   | 0.0170 | 513 (8.1)                    | 0.0289  |
| Brief symptom inventory           |                             |                               |        |                             |        |
| Anxiety                           | 4.8 (4.1)                   | 2.8 (2.4)                    | 0.0009 | 1.7 (1.9)                    | < 0.0001 |
| Depression                        | 4.3 (4.7)                   | 2.2 (2.8)                    | 0.0049 | 1.6 (2.0)                    | 0.0013  |
| Somatization                      | 2.8 (2.7)                   | 1.3 (1.5)                    | 0.0151 | 1.3 (2.5)                    | < 0.0001 |
| Global severity index             | 11.9 (9.4)                  | 6.3 (5.8)                    | 0.0005 | 4.6 (4.6)                    | < 0.0001 |
| Self-efficacy                     |                             |                               |        |                             |        |
| On a scale of 1 to 10, how confident are you that you can: |                      |                               |        |                             |        |
| Do all the things necessary to manage conditions on a regular basis? | 7.4 (2.3)                   | 8.6 (1.9)                    | 0.0411 | 5.8 (3.6)                    | 0.0222  |
| Do things other than just take medication to reduce how much your illness affects your everyday life? | 7.8 (2.4)                   | 8.3 (2.4)                    | 0.3248 | 6.0 (3.7)                    | 0.0878  |
| Control any other symptoms or health problems you have so that they don’t interfere with the things you want to do? | 7.1 (2.0)                   | 8.5 (1.2)                    | 0.0001 | 6.7 (2.8)                    | 0.8549  |
| Work Productivity Performance     |                             |                               |        |                             |        |
| Percentage of expected work hours completed | 84.5 (26.8)                 | 92.3 (15.5)                  | 0.1067 | 88.0 (12.3)                  | 0.8486  |
| Self-rating of usual job performance, 0-10 | 7.2 (2.6)                   | 7.6 (2.9)                    | 0.5923 | 7.1 (3.3)                    | 0.9295  |

SD = standard deviation.
Health services utilization decreases from baseline to follow-up were substantial across outpatient primary and specialty care visits, Emergency Department visits, and hospital admissions. These findings also point to potential reductions in costs associated with MBSR through reductions in health care utilization, even in a cohort where the mean age was older than age 50 years. We postulate that because patients are more confident in managing their conditions, they are less likely to visit their physician. Anxiety and somatization symptoms drive people to seek care, and by decreasing this aspect of an illness, utilization is also decreased. Although a formal cost analysis of the MBSR program linked to reductions in health care costs and improvements in patient-centered outcomes is beyond the scope of this paper, these results should be of interest to health care administrators considering a health plan benefit for MBSR.

Unlike Rosenzweig et al., we did not investigate differential effects of MBSR on the basis of specific pain conditions owing to limited sample sizes for specific diagnostic categories and, equally important, because the high prevalence of medical and psychiatric comorbidities limited our ability to differentiate the participants into unique diagnostic categories. Likewise, we did not control for age.

This study contributes in several ways to the literature on the effectiveness of MBSR. First, we assessed the impact of MBSR on health services utilization, showing large and sustained decreases in this outcome over one year. Second, we studied MBSR in a multimorbid, heterogeneous patient population as seen in a community care delivery setting such as KPCO, increasing the generalizability of our results to real-world health care systems. Third, a broad set of patient-centered measures was used, including self-efficacy and work productivity in addition to the more typically evaluated outcomes of health and functional status and psychiatric symptoms. The finding of attenuations in participants’ self-efficacy for managing their conditions provides useful information about the possible need for additional self-management support after completion of the class. In addition, we suggest that assessment of work productivity as a domain of function is important to both MBSR participants and employers, despite our nonsignificant results pertaining to this outcome. Changes in health care utilization and patient-centered outcomes were obtained during a one-year follow-up period, allowing us to ascertain longer trajectories of improvement or relapse beyond those most often measured at eight weeks following completion of the MBSR class. Finally, we believe that having electronic medical data on clinic visits, hospitalizations, and diagnosis codes available for analysis is a significant strength, facilitated by the KPCO model of care.

This study had several limitations. Our sample size for analysis was small in comparison with other published studies, limiting statistical power and possibly generalizability. Despite the small number of participants, our analyses yielded interesting and encouraging results across a broad set of patient-centered measures, as well as objective measures of health services utilization. However, our results may not be generalizable to other health care settings. Finally, this was a single cohort study with no comparison group. Study participants were already engaged in care by virtue of the enrollment strategy and could have experienced decreases in their physical and mental distress and improvements in their symptoms independent of the mindfulness practices, perhaps related to psychosocial support from the group or their usual care. However, given that these individuals were referred or self-referred to the program because of their chronic pain, chronic illness, or long-term stress-related disorders, and that they each had an average of more than 16 unique diagnoses, it is unlikely that their symptoms spontaneously improved. Moreover, a recent meta-analysis of the most rigorously designed, randomized controlled trials of MBSR demonstrated positive effects on depression, anxiety, and psychological distress in people with chronic disease, albeit smaller in magnitude than those reported in this study.

**Conclusion**

Our results support the provision of MBSR as a standard intervention for patients with chronic pain, chronic illness, and stress-related disorders in clinical settings such as KPCO and suggest that participation in the MBSR program is associated with substantial clinical benefit for such patients, as well as significant reductions in health services utilization. Over time, the program at KPCO has grown in enrollment and popularity and is a valued resource for patients and health care professionals.

**Disclosure Statement**

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

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**References**


Mindfulness-Based Stress Reduction in an Integrated Care Delivery System: One-Year Impacts on Patient-Centered Outcomes and Health Care Utilization


10. For some patients, though conscious that their condition is perilous, recover their health simply through their contentment with the goodness of the physician. — Precepts. Hippocrates, c460 – c370BC, ancient Greek physician

Contentment

For some patients, though conscious that their condition is perilous, recover their health simply through their contentment with the goodness of the physician.

— Precepts. Hippocrates, c460 – c370BC, ancient Greek physician
Improving Appropriate Use of Pulmonary Computed Tomography Angiography by Increasing the Serum D-Dimer Threshold and Assessing Clinical Probability

Sydney Char; Hyo-Chun Yoon, MD, PhD

Abstract

Objective: To determine whether the implementation of an increased D-dimer threshold value and clinical probability assessment increases the prevalence of pulmonary embolism (PE) in patients undergoing pulmonary computed tomography angiography (PCTA) in an Emergency Department setting.

Methods: A retrospective review of all patients undergoing PCTA during 2 separate 12-month intervals, 1 before the implementation of an increased D-dimer threshold and recommendation for formal clinical probability assessment and the other after regional implementation. The primary outcome measure was the prevalence of acute PE in each of the samples.

Results: After the implementation of the increased D-dimer threshold and recommendation for formal clinical probability assessment, the prevalence of PE detected by PCTA increased from 4.7% to 11.7% (p < 0.001). Among all PCTAs performed after the new guidelines were promulgated, 8.6% were still performed on patients who had serum D-dimer values lower than the threshold of 1.0 µg/mL. Despite the recommendation for formal clinical probability assessment before ordering a PCTA, only 4% of patients had a formal clinical probability assessment recorded in their electronic medical record.

Conclusion: The implementation of an increased D-dimer threshold value increased the prevalence of PE in patients undergoing PCTA in an Emergency Department setting, but more consistent application of clinical probability assessment remains an elusive target.

Introduction

Three multicenter Prospective Investigations of Pulmonary Embolism Detection (PIOPED) studies have evaluated radionuclide ventilation perfusion, computed tomography, and magnetic resonance imaging to detect pulmonary embolism (PE; PIOPED I, II, and III, respectively). The overall prevalence of PE exceeded 20% for each study: 33% for PIOPED I, 23% for PIOPED II, and 28% for PIOPED III. Yet in several single-center studies evaluating the efficacy of pulmonary computed tomography angiography (PCTA), the prevalence is less than 10%, suggesting that PCTA is overutilized.

Recent studies have suggested that limiting use of PCTA to patients with an intermediate or high clinical risk of PE and an increased serum D-dimer could reduce the use of PCTA without significantly increasing the risk of missed PE.

Objective

In this study, we sought to determine whether the implementation of an increased D-dimer threshold value and formal clinical probability assessment increases the prevalence of PE in patients undergoing PCTA in an Emergency Department (ED) setting.

Materials and Methods

Our institutional laboratory uses the STA D-DI latex agglutination assay (Diagnostica Stago, Parsippany, NY) to measure patient serum D-dimers. The manufacturer’s threshold for a positive serum D-dimer value is 0.4 µg/mL. In August 2012, our health maintenance organization’s (HMO) Medical Group attempted to decrease use of PCTA by engaging with the ED to increase the D-dimer threshold value for a positive result within our institution from 0.4 µg/mL to 1.0 µg/mL. The increase in the D-dimer threshold value was designed to increase specificity without reducing sensitivity to detect PE by PCTA on the basis of results from both a review of patients in our own electronic medical record (EMR) and from the published literature. ED physicians were requested to use a clinical algorithm (preferably, but not limited to, the Wells criteria) to determine pretest probability for PE. The Wells criteria includes 7 symptoms or characteristics of medical history and physical examination. A patient receives a score depending on which criteria they possess, as determined by Wells et al. The score indicates the likeliness of a PE diagnosis. Using the Wells criteria or other validated clinical algorithms was a recommendation rather than a requirement for ordering a PCTA.

We obtained institutional review board approval with a waiver of consent to retrospectively review a common EMR to determine the age, sex, D-dimer result, if any, and PCTA result of all patients seen in the ED of the HMO with a possible diagnosis of acute PE who underwent PCTA.

One of the authors reviewed and assigned Wells scores for the patients on the basis of the EMR information associated

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with the ED encounter leading to the PCTA, unless the ED physician had already assigned a Wells score or used another clinical assessment algorithm for the patient. The reviewer was masked to the D-dimer value as well as the PCTA result for every patient. However, because the EMR including the ED physician note was reviewed to determine each patient’s clinical probability, the emergency physician’s clinical probability assessment was known if it was recorded in the physician’s note. The Wells criteria have been validated as a method to stratify a patient’s clinical probability of PE.7 Points were assigned for each of the following clinical signs or symptoms: PE as likely or more likely than any alternative diagnosis, 3.0 points; signs or symptoms of deep venous thrombosis (leg swelling or painful palpation in the region of a deep vein), 3.0 points; heart rate higher than 100 beats/min, 1.5 points; immobilization (bed rest for 3 consecutive days) or surgery within past 4 weeks, 1.5 points; previous diagnosis of PE or deep venous thrombosis, 1.5 points; hemoptysis, 1.0 points; active malignancy (within past 6 months), 1.0 points. Most of these clinical signs and symptoms could be determined unambiguously from the EMR.

We used the following algorithm to determine whether PE was as likely or more likely than any alternative diagnosis: If the patient’s chief complaint on record was shortness of breath or dyspnea, then we assumed PE was the most likely diagnosis unless 1) the patient had a history of congestive heart failure and chest x-ray was suggestive of edema, 2) the patient had signs and symptoms of a respiratory infection and an abnormal chest x-ray, or 3) the patient had a history of asthma/chronic obstructive pulmonary disease and clinical symptoms of an asthma/chronic obstructive pulmonary disease exacerbation. If the patient’s chief complaint was chest pain, then we assumed PE was the most likely diagnosis unless the patient had a history of coronary artery disease, prior myocardial infarction, or cardiomyopathy. However, if the chest pain was further described as substernal, crushing, or radiating to the back or left arm, PE was not assumed to be the most likely diagnosis. For a chief complaint of unilateral leg pain or swelling, PE was assumed the most likely diagnosis unless there was a specific finding in the reported history to suggest a more likely alternative diagnosis.

The Wells criteria scores segregated patients into 3 clinical risk strata for PE: low (score < 2), intermediate (score 2-6), and high (score > 6). The subjects were also segregated on the basis of their serum D-dimer levels into those with negative (<1.0 µg/mL) or positive (≥1.0 µg/mL) serum D-dimer using the latex agglutination technique.

Two data sets each covering 12 months were collected, 1 before and 1 after implementation of the higher D-dimer threshold and recommendation of using a clinical decision rule. The former spanned from June 1, 2008 through May 31, 2009, and the latter from September 1, 2012 through August 31, 2013. The 2 data sets were compared to see whether there was a significant change in the prevalence of PE and patient characteristics.

All statistical analysis was performed using STATA, version 7.0 (Stata, College Station, TX).

**Results**

The ED of this HMO, with about 227,000 members, sees approximately 36,000 patients annually. The number of members within this HMO has not appreciably changed from 2008 to 2013. From June 1, 2008, through May 31, 2009, before implementation of the higher D-dimer threshold, the ED saw 510 consecutive patients who underwent PCTA for possible PE. This will be referred to as the 2008-2009 cohort in the rest of this article. There were 198 men and 312 women. The average (standard deviation [SD]) age among all patients was 59.2 (18.0) years (range, 16-96 years). For men, the average (SD) age was 59.2 (17.4) years (range, 19-90 years). For women, the average (SD) age was 59.2 (18.0) years (range, 16-96 years).

The overall prevalence of PE as determined by PCTA in the 2008-2009 cohort was 4.7% (24/510). Three hundred forty-seven patients (68.0%) had a D-dimer drawn at the time of their PCTA. Of these, 18 proved to have PE by PCTA (5.2%). Of the 161 patients who had a serum D-dimer level of at least 1.0 µg/mL, there were 15 cases of PE demonstrated by PCTA, a prevalence of 9.3%. Conversely, there were 186 subjects who had a D-dimer level less than 1.0 µg/mL, but only 1 (0.5%) proved to have PE. Among these 186 subjects, there were 160 who had a D-dimer level of at least 0.4 µg/mL, which included the patient who had a PE documented by PCTA. This 58-year-old man had a D-dimer level of 0.95 µg/mL. Of 163 patients without a D-dimer level drawn at the time of PCTA, there were 6 (3.7%) who proved to have PE. Excluding 3 patients in this group with known PE undergoing follow-up PCTA for persistent or progressive symptoms, only 3 (1.9%) of 160 proved to have PE by PCTA.

The clinical probability of PE was estimated for each of the patients in the 2008-2009 cohort using the Wells criteria. Among 36 patients with high clinical probability for PE, there were 5 (13.9%) who had PE diagnosed by PCTA. Only 18 (5.5%) of the 328 moderate-risk patients had PE by PCTA. Finally, there was only 1 (0.7%) among 146 patients with low risk who had PE by PCTA.

Table 1 shows the prevalence of positive PE by PCTA segregated by serum D-dimer levels.
Improving Appropriate Use of Pulmonary Computed Tomography Angiography by Increasing the Serum D-Dimer Threshold and Assessing Clinical Probability

The overall prevalence of PE as determined by PCTA in the 2012-2013 cohort was 11.7% (64/547). There were 334 patients (61.1%) who had a D-dimer drawn at the time of their PCTA. Of these, 38 (11.4%) proved to have PE by PCTA. Of the 287 patients with a serum D-dimer level of at least 1.0 µg/mL, there were 38 cases (13.2%) of PE demonstrated by PCTA. There were 47 patients who had a D-dimer level less than 1.0 µg/mL. None of these patients proved to have PE. Among these 47 patients, 28 had a D-dimer greater than 0.4 µg/mL. Of 213 patients without a D-dimer level drawn at the time of PCTA, 26 (12.2%) proved to have PE. Excluding 3 patients in this group with known PE undergoing follow-up PCTA for persistent or progressive symptoms, 23 (11.0%) of 210 proved to have PE by PCTA.

The clinical probability of PE was estimated for each of these patients in the 2012-2013 cohort using the Wells criteria. Among 53 patients with high clinical probability for PE, 20 (37.7%) had PE diagnosed by PCTA. Only 38 (13.5%) of the 286 moderate-risk patients had PE by PCTA. Finally, among 208 patients with low risk, there were 6 (2.9%) who had PE by PCTA.

Table 2 shows the prevalence of positive PE by PCTA segregated by serum D-dimer and retrospective clinical probability assessment for the 2012-2013 cohort. Again, the prevalence of PE detected by PCTA is very low in all patients with a serum D-dimer level less than 1.0 µg/mL, irrespective of the patients’ clinical probability assessment. All patients in the second cohort with intermediate or high clinical probability of PE had a prevalence of PE exceeding 10% of their PCTA studies, irrespective of whether they had a serum D-dimer of at least 1.0 µg/mL or did not have one drawn.

There was a statistically significant difference between cohorts in their age and sex distributions. The 2012-2013 cohort was older than the 2008-2009 cohort (2012-2013 age: 63.4 [18.0]; 95% CI, 61.8-64.9 years; vs 2008-2009 age: 59.2 [18.0]; 95% CI, 57.6-60.7 years; t = -3.776, p < 0.001). Also, men constituted only 38.8% of the 510 patients in the 2008-2009 cohort, but they represented 45.7% of the 547 patients in the 2012-2013 cohort (χ² = 5.116, p = 0.024).

There was a significantly higher prevalence of PE detected by PCTA in the 2012-2013 cohort (11.7%) than for the 2008-2009 cohort (4.7%) (χ² = 16.917, p < 0.001).

Despite the recommendation that all patients undergoing PCTA have a D-dimer drawn without compromising patient care, there was a significantly higher proportion of patients who underwent PCTA without having a D-dimer level drawn in the 2012-2013 cohort (38.9%) than in the 2008-2009 cohort (32.0%) (χ² = 5.609, p = 0.018).

Among patients who did have a serum D-dimer drawn before PCTA, there was a much higher proportion of patients who had a serum D-dimer level less than 1.0 µg/mL in the 2008-2009 cohort (53.6%) than in the 2012-2013 cohort (39.2%).
Improving Appropriate Use of Pulmonary Computed Tomography Angiography by Increasing the Serum D-Dimer Threshold and Assessing Clinical Probability

Though there was no significant difference between the 2 cohorts for prevalence of PE detected by PCTA among patients with a D-dimer value less than 1.0 µg/mL (2008-2009: 0.5% vs 2012-2013: 0%, Fisher exact = 1.000, p = 0.80) and at least 1.0 µg/mL (2008-2009: 10.6% vs 2012-2013: 13.2%, χ² = 0.689, p = 0.407), there was a significant difference among patients who did not have a D-dimer value drawn (2008-2009: 3.7% vs 2012-2013: 12.2%, χ² = 8.620, p = 0.003).

Table 3 lists the presence of the individual Wells criteria in each of the patient cohorts on the basis of their review of the EMR. We recorded a 23% higher prevalence of the first criterion (PE as the most likely diagnosis) for patients in the 2008-2009 cohorts than in the 2012-2013 cohorts. Since this criterion is worth 3 points in the Wells algorithm and its presence gives the patient at least an intermediate clinical risk, the fact that 101 more patients in the earlier cohort met this criterion likely explains the smaller proportion of low-risk patients in the 2008-2009 cohort (28.6%) compared with the 2012-2013 cohort (38.0%) (χ² = 10.465, p = 0.001).

When we compared the 2 cohorts for the prevalence of PE detected by PCTA among patients with low clinical risk as retrospectively assessed using the Wells criteria, there was no significant difference (2008-2009: 0.7% vs 2012-2013: 2.9%, Fisher exact = 0.247, p = 0.14). However, the one patient with acute PE in the 2008-2009 cohort and 5 of the 6 patients with acute PE in the 2012-2013 cohort all had a serum D-dimer level less than or equal to 1.0 µg/mL. One patient with acute PE had a low clinical probability of PE as assessed retrospectively and did not have a serum D-dimer. No patients with low clinical probability and serum D-dimer less than 1.0 µg/mL had acute PE detected by PCTA in either cohort.

For patients with either intermediate or high clinical risk, there was a significant difference in the prevalence of PE between cohorts (intermediate: 2008-2009: 5.5% vs 2012-2013: 13.3%, χ² = 11.211, p = 0.001; high: 2008-2009: 13.9% vs 2012-2013: 37.7%, χ² = 6.035, p = 0.014). This difference may be explained by the much higher proportion of patients with intermediate clinical risk in the 2012-2013 cohort who had a serum D-dimer greater than 1.0 µg/mL than in the 2008-2009 cohort (52.8% vs 32.9%, χ² = 24.734, p = 0.001). However, there is no statistically significant difference in the proportion of patients with serum D-dimer of at least 1.0 µg/mL in the patients at high clinical risk (χ² = 3.293, p = 0.07).

Table 4 lists the number of PCTAs performed per 1000 ED visits by month during each study period. There was a statistically significant decrease in the monthly PCTAs performed per 1000 ED visits during the later 2012-2013 study period (rank sum test, Z = -2.483, p = 0.01).

Although many of the ED physicians mentioned the possibility of PE within a list of other differential diagnoses, only 22 (4.0%) of 547 physician notes specifically mentioned a clinical probability of PE. In only 4 of the 22 notes was a specific Wells score given. In one other note, the Pulmonary Embolism Rule-out Criteria were mentioned. This is despite the Medical Group’s recommendations that some type of pretest clinical probability assessment of PE be performed in addition to ordering the serum D-dimer before ordering a PCTA.

When we compared the ED physicians’ clinical probability of PE against our study’s retrospectively determined clinical probability, there was concordance in the assessed level of risk for 20 of 22 patients. However, a 40-year-old woman with tachycardia and active cancer was noted as “low risk” for PE whereas we recorded moderate risk (Wells score, 2.5), and a 59-year-old woman presenting with syncope and a remote history of PE was noted as “high risk,” however we recorded moderate risk (Wells score, 4.5).

**Discussion**

In August 2012, the serum D-dimer threshold level for positive possible acute PE was increased in our institution from at least 0.4 µg/mL to at least 1.0 µg/mL, on the basis of both a literature review and our own experience, which suggested that an increased threshold would increase specificity without reducing sensitivity.\(^{13}\)

We demonstrated a significant decrease in the number of PCTAs performed per 1000 ED visits as well as a significant increase in the prevalence of positive studies after the implementation of the recommendations (from 4.7% to 11.7%). We suggest that this increase in prevalence of positive PCTA studies represents more appropriate patient selection for PCTA because the prevalence of PE has increased in those patients who had a serum D-dimer drawn as well as those who did not. The same selection process results in an overall decrease in the number of PCTAs ordered per 1000 ED visits.

On the basis of the results, patients with high clinical risk as assessed using a clinical algorithm such as the Wells criteria may not require a serum D-dimer before proceeding to PCTA. Conversely, patients with low clinical risk may not require a serum D-dimer to be drawn to avoid a PCTA. This emphasizes the importance of documenting a high or low clinical probability in the medical record using some type of decision rule. Patients

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**Table 4. Number of pulmonary computed tomography angiographies performed per 1000 Emergency Department visits within each study period**

<table>
<thead>
<tr>
<th>Month</th>
<th>2008-2009</th>
<th>2012-2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>September</td>
<td>11.74</td>
<td>13.28</td>
</tr>
<tr>
<td>October</td>
<td>15.67</td>
<td>7.36</td>
</tr>
<tr>
<td>November</td>
<td>13.94</td>
<td>10.08</td>
</tr>
<tr>
<td>December</td>
<td>13.43</td>
<td>13.08</td>
</tr>
<tr>
<td>January</td>
<td>18.49</td>
<td>10.41</td>
</tr>
<tr>
<td>February</td>
<td>16.22</td>
<td>14.25</td>
</tr>
<tr>
<td>March</td>
<td>16.92</td>
<td>11.86</td>
</tr>
<tr>
<td>April</td>
<td>21.62</td>
<td>13.97</td>
</tr>
<tr>
<td>May</td>
<td>18.70</td>
<td>11.72</td>
</tr>
<tr>
<td>June</td>
<td>14.71</td>
<td>13.65</td>
</tr>
<tr>
<td>July</td>
<td>15.18</td>
<td>17.45</td>
</tr>
<tr>
<td>August</td>
<td>11.06</td>
<td>13.33</td>
</tr>
<tr>
<td>Average</td>
<td>15.64</td>
<td>12.54</td>
</tr>
</tbody>
</table>

\(^{13}\)
with intermediate clinical risk benefit most from a serum D-dimer evaluation because only those patients with an elevated D-dimer need to proceed with PCTA.

There are a number of patients in the 2012-2013 cohorts with low serum D-dimer levels who underwent PCTA. The reason for this is unclear because the retrospective assessment of the clinical risk for PE was either low or moderate for all 47 of these patients. It is also unclear how older age and male sex in the 2012-2013 cohort compared with the 2008-2009 cohort influenced the higher prevalence of PEs.

The implementation of the higher D-dimer threshold set to at least 1.0 µg/mL did not reduce the sensitivity of PCTA for the detection of acute PE. Only 1 among all 233 patients in both cohorts with a D-dimer value less than 1.0 µg/mL was noted to have PE detected by PCTA. Given the published coincidental PE rate of approximately 2% among all patients undergoing chest computed tomography for reasons other than PE, this higher D-dimer threshold is acceptable.14-16

We did not achieve a reasonable level of compliance among ED physicians with respect to documenting their pretest clinical probability assessment within the medical record. Only 4% of the notes on the 547 patients in the 2012-2013 cohort made mention of a clinical probability of PE. In only 5 of these 22 notes was there a specific mention of a clinical decision rule such as the Wells criteria or the Pulmonary Embolism Rule-out Criteria. Although there is controversy as to the most appropriate decision rule to be used for patients being evaluated for PE, there is no controversy as to recording the clinical likelihood assessment.17 Because this HMO has a fully integrated EMR for all emergency, ambulatory, and hospital-based services including radiology ordering, a higher rate of compliance will likely entail the use of some type of electronic decision support tool embedded within the radiology ordering mechanism that requires the input of a clinical pretest probability.

**Study Limitations**

A primary limitation of this study was the necessity to assign Wells scores retrospectively through EMR review. EMR review provides less information in comparison with direct patient examination because not every finding may be documented electronically. In our ED, physicians may mentally estimate their patient’s pretest probability of PE using a standard algorithm such as the Wells criteria, but they rarely record that clinical probability in their written notes. To increase the documentation of clinical probability, it may be necessary to include a step in the computed tomography ordering process where the physician is required to input a clinical probability assessment. A pop-up screen could be included within the ordering process that requires the physician to input specific findings that could then generate a clinical probability assessment using a standard algorithm such as the Wells criteria.

A population analysis based on an HMO population may not be representative of other clinical settings. Our study results, although indicative of a general community hospital, may not be applicable for other institutions, such as tertiary institutions or academic institutions where more selective populations may be encountered.

Finally, this HMO uses only one method of serum D-dimer measurement (STA D-D). It is unclear whether the use of the 1.0 µg/mL threshold value could be applied to other methods of D-dimer measurement, although other authors have suggested different threshold values with other methods of serum D-dimer measurement.12,13 We recommend that those institutions that use a different D-dimer assay, review their own PCTA results to ensure that the higher threshold does not significantly reduce their sensitivity for the detection of PE.

**Conclusion**

The implementation of an increased D-dimer threshold value increased the prevalence of PE in patients undergoing PCTA in an ED setting, but more consistent application of clinical probability assessment remains an elusive target.14

**Disclosure Statement**

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

**Acknowledgment**

Mary Corrado, ELS, provided editorial assistance.

**References**


Improving Appropriate Use of Pulmonary Computed Tomography Angiography by Increasing the Serum D-Dimer Threshold and Assessing Clinical Probability


Excessive Bed Rest

I had known that excessive bed rest gave rise to thromboembolic complications. … The death rate from thromboembolism was always much less at the County Hospital … When [the County Hospital patients] got up to go to the bathroom, [they] dislodged only tiny clots from their veins and these did not harm them when they got to the lungs and were dissolved, while the wealthier patients … [at a private hospital] who remained in bed and formed large clots in their legs and pelvises suffered the major consequences of large pulmonary emboli.

— William Dock, MD, 1898-1990, cardiologist, known for coining “Sutton’s Law”
Testing for Meningitis in Children with Bronchiolitis

Michael Stefanski, MD, MPH; Ronald Williams, MD, FAAP, FACP; George McSherry, MD; Joseph Geskey, DO, MBA

Abstract
Viral bronchiolitis accounts for almost 20% of all-cause hospitalizations of infants (ie, children younger than age 1 year). The annual incidence of fever in viral bronchiolitis has been documented at 23% to 31%. However, the incidence of concurrent serious bacterial infections is low (1%-7%), with meningitis occurring in less than 1% to 2% of cases, but lumbar puncture is performed in up to 9% of viral bronchiolitis cases. To our knowledge, no study has examined clinical factors that influence a physician's decision to perform a lumbar puncture in the setting of viral bronchiolitis.

We present a retrospective, case-control study of hospitalized infants younger than one year diagnosed with viral bronchiolitis who underwent lumbar puncture as part of an evaluation for meningitis. The objective of the study was to determine clinical factors that influence a physician's decision to perform a lumbar puncture in the setting of viral bronchiolitis. Although the presence of apnea, cyanosis, meningal signs, positive urine culture results, and young age were factors found to be preliminarily associated with the performance of a lumbar puncture in the setting of bronchiolitis, young age was the only significant clinical factor found after multivariable regression; no other demographic, clinical, laboratory, or radiologic variables were found to be significant.

Introduction
Viral bronchiolitis is the most common cause of lower respiratory tract infection in children younger than age 1 year, accounting for almost 20% of all-cause infant hospitalizations. The burden of disease is most prevalent in the fall and winter months, with peak incidence occurring in children between ages 2 to 6 months. The clinical course of viral bronchiolitis is characterized by an upper respiratory prodrome and subsequent lower respiratory tract symptoms and signs, including cough, wheeze, increased respiratory rate (RR), and increased effort. The incidence of fever in the setting of bronchiolitis has been documented at 23% to 31%.

When fever develops, so too does the dilemma of determining whether the fever is a consequence of the viral infection or a superimposed serious bacterial infection (SBI). In bronchiolitis patients, the incidence of concurrent SBI is low (1%-7%), with most being urinary tract infections (1%-5%). Although the sequelae of bacterial meningitis are well documented and carry substantial morbidity and mortality rates, the incidence of concurrent meningitis in infants and children with clinical viral bronchiolitis has been reported to be less than 1% to 2%.

In the appropriate clinical setting, performance of a lumbar puncture (LP) is necessary to make the diagnosis of meningitis and to ensure appropriate treatment, but this must be weighed against the adverse effects and potential yield of the study. The performance of an LP is anxiety provoking to parents and has been reported to contribute to parental dissatisfaction with the care their infant receives. Moreover, physicians must balance the very small chance of meningitis occurring in viral bronchiolitis against the possible iatrogenic complications, including morbidity of LP, intravenous line placement, and unnecessary use of broad-spectrum antibiotics. We examined clinical factors that may influence a physician's decision to perform an LP in the setting of viral bronchiolitis.

Methods
Study Design and Setting
A retrospective, case-control study of 42 hospitalized infants younger than age 1 year who had International Classification of Diseases, Ninth Revision (ICD-9) codes of bronchiolitis (ICD-9-466.11 or 466.19) and underwent LP were matched 1:4 with children who had ICD-9 codes of bronchiolitis without LP (168 controls) from January 1, 2001, through December 31, 2011 (Figure 1). The study was conducted at Penn State Children's Hospital, an academic tertiary care children's hospital located in Hershey, PA. The Penn State Milton S Hershey Medical Center's institutional review board approved this study with waiver of informed consent.

Data and Study Definitions
A standardized abstraction form was used to collect the following data from both cohorts of hospitalized patients: age; sex; prematurity; chronic lung disease; insurance type; admitting service (critical care vs general pediatrics); presence or absence of apnea, cyanosis, tachypnea, fever, and meningal signs; results of urine culture, blood culture, chest radiographs, respiratory syncytial virus (RSV) testing, cerebrospinal fluid culture, and white blood cell count if obtained; and hospital length of stay.

The presence of prematurity and chronic lung disease were noted from the medical history. Insurance type was classified as commercial or governmental. Patients who were admitted to either the neonatal intensive care unit or the pediatric intensive care their infant receives.

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Testing for Meningitis in Children with Bronchiolitis

care unit were classified as critical care; otherwise, patients were classified as general pediatrics. The presence of apnea and cyanosis were noted as present if these terms were noted in the medical record. The definition of tachypnea was based on age-defined RR of the World Health Organization guidelines: (< 2 months, RR ≥ 60/min; 2-12 months, RR ≥ 50; 1-5 years, RR ≥ 40). Fever was defined as a temperature of 38.0°C or greater. Meningeal signs were considered present if there was a notation of neck stiffness, bulging fontanel, inconsolable irritability/crying, Kernig sign, or Brudzinski sign.

A urinary tract infection was defined by the presence of more than 50,000 colony-forming units of a single pathogenic organism from a urine culture obtained by transurethral catheterization or more than 1000 colony-forming units obtained by suprapubic aspiration. A bloodstream infection was defined as a known bacterial pathogen from the blood whereas bacterial meningitis was defined as the isolation of a bacterial pathogen from the cerebrospinal fluid. Chest radiographs that were interpreted as having an alveolar infiltrate, air bronchogram, or consolidation were classified as having pneumonia (World Health Organization criteria). Bronchiolitis was classified as RSV if a positive result was obtained from either antigen testing or culture from nasal secretions.

Statistical Analyses

Descriptive statistics were prepared for all variables including frequencies and percentages for categorical variables (eg, sex, apnea) and means, standard deviations, and quartiles for quantitative variables (eg, white blood cell count, length of stay). Age was considered as both a quantitative (age in days) and categorical (< 30, 30-59, 60-179, and ≥ 180 days) variable. Bivariate analyses were conducted to assess the relationship between each variable and LP using χ² or Fisher exact tests for categorical variables and logistic regression for quantitative variables. All variables showing a marginal (p < 0.10) or significant (p < 0.05) relationship with LP were included in a multivariable regression model, and backward elimination was used to arrive at a final model, keeping all significant variables. To further examine the effect of age on the findings, cases were matched on age category to controls in a 1:1 ratio using a greedy algorithm. Generalized estimating equations, an extension of logistic regression that takes into account the matching, were used to examine the relationship of LP to the remaining variables. All analyses were conducted using SAS, version 9.2 (SAS Institute Inc, Cary, NC).

Results

None of the patients with acute bronchiolitis had documented meningitis. However, the presence of apnea, cyanosis, meningeal signs, positive urine culture results, and young age were factors associated with the performance of an LP in bronchiolitis (Table 1). The presence of a fever and tachypnea were not associated with testing for meningitis. RSV status also did not influence the decision to perform an LP, nor did admission to a critical care service. There was a significant difference in the mean age (44 days) of the LP cohort compared with the mean age of the control group (141 days [p < 0.001]).

![Figure 1. Selection of case-control participants. A total of 42 patients were selected as cases on the basis of International Classification of Diseases, Ninth Revision (ICD-9) procedure code of lumbar puncture. Each case was matched with 4 control patients who were selected at random from the remainder of the cohort meeting inclusion criteria of an ICD-9 discharge diagnosis of acute bronchiolitis without documentation of a lumbar puncture being performed during the hospitalization. The total number of patients studied was 210.](image)

Table 1. Bivariate analysis of factors associated with lumbar puncture in acute bronchiolitis

<table>
<thead>
<tr>
<th>Variable</th>
<th>Controls, n = 168 (%)</th>
<th>Cases, n = 42 (%)</th>
<th>p value*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical features</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Apnea</td>
<td>18 (10.7)</td>
<td>14 (33.3)</td>
<td>0.0003</td>
</tr>
<tr>
<td>Cyanosis</td>
<td>22 (13.1)</td>
<td>14 (33.3)</td>
<td>0.0019</td>
</tr>
<tr>
<td>Tachypnea</td>
<td>99 (59.3)</td>
<td>23 (54.8)</td>
<td>0.5953</td>
</tr>
<tr>
<td>Fever</td>
<td>78 (46.4)</td>
<td>21 (50.0)</td>
<td>0.6783</td>
</tr>
<tr>
<td>Meningeal signs</td>
<td>2 (1.2)</td>
<td>5 (11.9)</td>
<td>0.004</td>
</tr>
<tr>
<td><strong>Diagnostic studies</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive urine culture</td>
<td>2/441* (3.9)</td>
<td>6/342* (18.8)</td>
<td>0.0501</td>
</tr>
<tr>
<td>Positive blood culture</td>
<td>5/69* (7.2)</td>
<td>1/37* (2.7)</td>
<td>0.6625</td>
</tr>
<tr>
<td>Positive chest radiograph</td>
<td>14/148* (9.5)</td>
<td>4/40* (10.0)</td>
<td>&gt; 0.99</td>
</tr>
<tr>
<td>Positive RSV</td>
<td>74/143* (51.7)</td>
<td>25/42* (59.5)</td>
<td>0.3744</td>
</tr>
<tr>
<td>WBC count</td>
<td>12.8 (0.50-49.00)</td>
<td>11.2 (4.00-28.40)</td>
<td>0.1915</td>
</tr>
<tr>
<td><strong>Demographic characteristics</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age in days</td>
<td>141 (1-336)</td>
<td>44 (7-210)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Male sex</td>
<td>102 (60.7)</td>
<td>25 (59.5)</td>
<td>0.8878</td>
</tr>
<tr>
<td>Prematurity</td>
<td>44 (26.2)</td>
<td>14 (33.3)</td>
<td>0.3544</td>
</tr>
<tr>
<td>Chronic lung disease</td>
<td>18 (10.7)</td>
<td>3 (7.1)</td>
<td>0.4902</td>
</tr>
<tr>
<td>Commercial insurance</td>
<td>86 (51.2)</td>
<td>24/41* (58.5)</td>
<td>0.699</td>
</tr>
<tr>
<td>Admit service critical care</td>
<td>16 (9.5)</td>
<td>8 (19.0)</td>
<td>0.1026</td>
</tr>
</tbody>
</table>

* p value ≥ 0.10 included in multivariable regression model.
* Positive results out of number tested.
* Range of WBC counts in the tested population.
* Age range in days.
* 24 cases of 41 total cases with documented insurance had commercial insurance.

RSV = respiratory syncytial virus; WBC = white blood cell count.
In addition to the significant quantitative difference in age between the 2 groups, there was a significant difference in the categorical age variable. The number (and percentage) of the 42 infants who underwent lumbar testing at less than age 30 days, 30-59 days, 60-179 days, and 180 days or older were 18 (42.8%), 15 (36.0%), 10 (23.8%), and 1 (2.4%), respectively (p < 0.001). However, the presence of fever combined with age as either a quantitative variable (age in days) or a categorical value (< 30 days, 30-59 days, 60-179 days, and ≥ 180 days) was not associated with performance of an LP (data not shown).

After the multivariable regression model and backward elimination were performed, the only variable that remained significant was age (Table 2). Similarly, when categorical values of age were used, younger infants were more likely to undergo performance of an LP than were older infants (Table 3).

When cases were matched on age category to controls and general estimating equations were used to examine the relationship of LP to the remaining variables, there were no significant results.

Case controls were well matched regarding age as there was no significant difference in the age of the 168 controls versus the remaining 777 infants who met control criteria but were not selected for the study. The median length of stay for patients who underwent an LP was 5 days versus 4 days for those who did not undergo the procedure, though this difference was not found to be statistically significant.

**Discussion**

Although the likelihood of having meningitis in acute bronchiolitis is negligible, infants still undergo LP testing to exclude a serious infection. To our knowledge, no previous studies have examined why hospitalized young infants with bronchiolitis undergo LP to exclude meningitis. A recent study reported that children with influenza were more likely to undergo LP testing than children with other respiratory illnesses, but the percentage of children with RSV was not reported. The only other significant predictor of an LP in this study was age 3 months or younger; there were no cases of meningitis.

Despite its low yield, a common reason for screening for SBI in infants is the presence of fever. A systematic review of 11 studies reporting rates of SBIs in infants younger than 90 days reported a weighted rate of urinary tract infection of 3.3%, with no cases of reported bacteremia in 8 of 11 studies and no reported cases of meningitis at all. As a result, these authors and others have suggested a more selective approach to screening for SBI in young infants with bronchiolitis, particularly if they are RSV-positive. However, there have been at least 2 case reports of infants with RSV bronchiolitis and meningitis. To understand the reasons that physicians elect to perform a procedure with such an infrequent occurrence, we sought to ascertain whether there were any demographic, clinical, laboratory, or radiologic variables that would be associated with the clinical decision to perform an LP.

Our results suggest the most significant factor associated with performing an LP is young age. The presence of fever in young infants and a positive RSV test result did not influence the decision to perform an LP. Although the study was not designed to determine whether a clinician should perform an LP in hospitalized children with bronchiolitis, it is reassuring that despite a high rate of urinary tract infection and bacteremia no child had documented meningitis.

However, there are several limitations to our study. Even though we used clinical variables that might influence a clinician to perform an LP, the most accurate diagnostic combination is unclear, particularly in this young age group. We also did not assess whether these specific demographic, clinical, and laboratory variables would lead physicians to perform more or fewer LP procedures compared with other screening tools that physicians in academic centers use in the evaluation of young febrile infants, such as the Rochester, NY; Philadelphia, PA; Boston, MA; or Pittsburgh, PA criteria. These screening tools use the presence of fever to determine further evaluation, but there have been reports of infants with meningitis who either do not have a fever or do not appear sick. Another limitation of our study is that we retrospectively analyzed administrative data so we cannot exclude the possibility that cases of bronchiolitis, meningitis, and LP were missed owing to inappropriate coding or incomplete documentation by the physician. These limitations portend further investigation, particularly expanding the case-control study to a multicenter evaluation with other children’s hospitals. Given that an infant’s initial evaluation often occurs in the Emergency Department, cross-referencing inpatient data with emergency room data can further highlight the clinical factors that determine the performance of an LP in the setting of viral bronchiolitis.

### Table 2. Adjusted multivariable regression model for performance of lumbar puncture in acute bronchiolitis

<table>
<thead>
<tr>
<th>Variable</th>
<th>95% CI</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apnea</td>
<td>0.232-4.303</td>
<td>0.3883</td>
</tr>
<tr>
<td>Cyanosis</td>
<td>0.421-8.344</td>
<td>0.999</td>
</tr>
<tr>
<td>Meningeal signs</td>
<td>0.277-79.57</td>
<td>0.2838</td>
</tr>
<tr>
<td>Positive urine culture result</td>
<td>0.558-17.776</td>
<td>0.1940</td>
</tr>
<tr>
<td>Age in days</td>
<td>0.964-0.994</td>
<td>0.0058</td>
</tr>
</tbody>
</table>

CI = confidence interval.

### Table 3. Multivariable analysis with backward elimination based on age categories for performance of lumbar puncture in children with acute bronchiolitis

<table>
<thead>
<tr>
<th>Variable</th>
<th>95% CI</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apnea</td>
<td>0.179-4.085</td>
<td>0.8455</td>
</tr>
<tr>
<td>Cyanosis</td>
<td>0.526-12.126</td>
<td>0.2470</td>
</tr>
<tr>
<td>Meningeal signs</td>
<td>0.238-72.473</td>
<td>0.3287</td>
</tr>
<tr>
<td>Positive urine culture result</td>
<td>0.475-15.711</td>
<td>0.2803</td>
</tr>
<tr>
<td>Age 30-59 days vs &lt; 30 days</td>
<td>0.169-2.062</td>
<td>0.4092</td>
</tr>
<tr>
<td>Age 60-179 days vs &lt; 30 days</td>
<td>0.026-0.452</td>
<td>0.0023</td>
</tr>
<tr>
<td>Age ≥ 180 days vs &lt; 30 days</td>
<td>0.011-1.032</td>
<td>0.0533</td>
</tr>
</tbody>
</table>

CI = confidence interval.

... the most accurate diagnostic combination is unclear, particularly in this young age group.
Testing for Meningitis in Children with Bronchiolitis

Conclusion

Despite these limitations we can conclude that LPs are still performed in hospitalized children with acute bronchiolitis, particularly in young infants, despite an extremely low likelihood of having a positive result, which may lead to a longer hospital length of stay, increased parental anxiety, and unnecessary exposure to broad-spectrum antibiotics. 

Disclosure Statement

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

Acknowledgment

Mary Corrado, ELS, provided editorial assistance.

References


Entitled

After nine months of pregnancy, a mother is entitled to have her baby get safe care.

To expose her newborn to infection is criminal.

— Béla Schick, 1877-1967, Hungarian-born American pediatrician, founder of the Schick test
The Okavango River system begins in Angola in southwest Africa. It flows almost 1000 miles to terminate in Botswana in the Okavango Delta. The delta, an enormous oasis in a very arid climate, supports a wide variety of vegetation and wildlife.

Dr Clarke is President of the Psychophysologic Disorders Association and an Assistant Director at the Oregon Health & Science University Center for Ethics.
Impact of Implementing Glycated Hemoglobin Testing for Identification of Dysglycemia in Youth

Vinutha Vijayadeva, PhD; Gregory A Nichols, PhD

Abstract

**Objectives:** To determine the impact of the introduction of the glycated hemoglobin (HbA1c) assay for diabetes mellitus diagnosis among children and adolescents aged 6-17 years and to describe the composition of the population of patients with, and at risk for, diabetes using fasting plasma glucose test and HbA1c assay.

**Research Design and Methods:** The Kaiser Permanente Hawaii (KPHI) and Kaiser Permanente Northwest (KPNW) sites identified a 2009 and a 2012 cohort of youth who were aged 6-17 years and continuously enrolled in their cohort year and for 1 year prior. We excluded youth with a type 1 or type 2 diabetes diagnosis before their cohort year.

**Results:** In both sites, fasting plasma glucose testing was significantly more common in 2009 and HbA1c testing was more common in 2012. The proportion with either test increased from 2.56% to 4.02% in KPNW and from 3.18% to 10.48% in KPHI, but the characteristics of the population did not change between 2009 and 2012. In both sites, the characteristics of youth at risk of diabetes changed substantially with a much greater proportion being female (KPNW: 39% vs 55%; KPHI: 35% vs 46%; p < 0.001 for both) and children younger than 10 (KPNW: 7% vs 32%; KPHI: 11% vs 39%; p < 0.001 for both) between 2009 and 2012. The size and composition of the population of youth identified with diabetes was not affected.

**Conclusions:** Adoption of the HbA1c assay for diabetes diagnosis has increased glycemia testing among youth aged 6-17 years and has altered the composition of the population identified as at risk for diabetes. These findings have important ramifications for targeted screening and diabetes prevention efforts.

Introduction

Before 2010, the American Diabetes Association (ADA) recommended the use of fasting plasma glucose (FPG) test, casual plasma glucose tests if symptoms of hyperglycemia were present, or 75 g oral glucose tolerance tests to diagnose diabetes.1 Following a consensus report from the International Expert Committee,2 the ADA recommended the inclusion of the glycated hemoglobin (HbA1c) assay as a diagnostic tool in its 2010 Clinical Practice Recommendation.3 Among the advantages of the HbA1c assay is that it does not require the patient to fast, thereby potentially providing increased screening opportunities. However, it is widely recognized that HbA1c assay, FPG, and oral glucose tolerance tests do not perfectly overlap, so the substitution of HbA1c assay for diagnosis would likely change the composition of the diabetes and at-risk population, which in turn would alter the epidemiology of hyperglycemia.4,5 To our knowledge, the population effects of implementing HbA1c assay for diagnosis of diabetes and for identification of individuals at risk for diabetes has not been reported in an outpatient population.

Preventing type 2 diabetes onset in children is becoming increasingly important because of the dramatic rise in the prevalence of at-risk children and adolescents6 and the subsequent risk of developing diabetes in adulthood.7 Furthermore, type 2 diabetes is a growing problem among youth aged 10 to 19 years.8 The ADA9 currently recommends that children with a body mass index (BMI; calculated as weight in kilograms divided by height in meters squared) equal to or greater than the 85th percentile for age and sex and with any 2 of these risk factors: family history of type 2 diabetes in first- or second-degree relative, race/ethnicity (Native American, African American, Latino, Asian American, Pacific Islander), signs of insulin resistance, and maternal history of diabetes or gestational diabetes mellitus during the child’s gestation should be screened for diabetes starting at age 10 years or at the onset of puberty. Given the rise in type 2 diabetes among youth, however, earlier screening may be appropriate, but data on prevalence of diabetes and at-risk children in their first decade of life is scant.

Our primary objective was to determine the impact of the introduction of the HbA1c assay for diabetes diagnosis among children and adolescents aged 6 to 17 years. Secondarily, we describe the composition of the population of patients with, and at risk for, diabetes resulting from the differential use of FPG test and HbA1c assay.

Methods

The study sites were Kaiser Permanente (KP) Hawaii (KPHI) and Kaiser Permanente Northwest (KPNW), 2 group-model health maintenance organizations that provide integrated health care to approximately 220,000 members in Hawaii and 475,000 members in the Portland, OR, area. Both KPHI and KPNW maintain similar electronic medical record databases that contain information on all inpatient admissions, pharmacy dispenses, outpatient visits, and laboratory

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we identified 2 cohorts: the first cohort included individuals identified from January 1, 2009, through December 31, 2009, and the second from January 1, 2012, through December 31, 2012. The cohorts consisted of youth who were aged 6-17 years in their cohort year and were continuously enrolled in their cohort year and for 1 year prior. We excluded members with an International Classification of Diseases, Ninth Revision diagnosis of type 1 or type 2 diabetes before their cohort year. We specifically selected 2009 because it was the year before HbA1c assay was endorsed by the ADA for use as a diagnostic test for diabetes, and 2012 because it was the most recent full year available after HbA1c assay was endorsed. The use of 2012 allowed sufficient time to have elapsed for full effect of the use of HbA1c assay to be observed. Age, sex, height, weight, race/ethnicity, FPG, and HbA1c were obtained from the electronic medical record. Self-reported race/ethnicity is routinely collected upon Health Plan enrollment, and patients can report up to 5 races and 5 ethnic groups. For the analysis, we have grouped race/ethnicity into 2 categories. Patients are grouped as non-Hispanic whites if they indicate such with no other race/ethnicity indicated. Patients who indicate a single nonwhite race, Hispanic ethnicity, or multiple races are considered as minority, which includes Asian, Hawaiian Pacific Islander, and other mix. Individual minority race/ethnicity categories were too small to analyze meaningfully, and because they have similar risk factors for developing diabetes, we combined them as “minority race/ethnicity.” This study was reviewed and approved by the KPHI and KPNW institutional review boards.

Glucose Testing and Body Mass Index Percentile

Laboratories at KPHI and KPNW use College of American Pathologists proficiency testing as recommended by the ADA, and both sites are certified by the National Glycohemoglobin Standardization Program. In Hawaii, the HbA1c assay is run on two instruments: Bio-Rad Variant II and Bio-Rad Variant II Turbo (Bio-Rad Laboratories, Hercules, CA); KPNW uses Cobas Integra 800 (Roche Diagnostics, USA).

We assessed the proportion of each cohort that received an FPG test or HbA1c test in their cohort year. At-risk for diabetes and diabetes was diagnosed with a single diagnostic laboratory value. We then determined the proportion that met diagnostic criteria for being at risk for diabetes (FPG 100-125 mg/dL or HbA1c 5.7%-6.4% [39-46 mmol/mol]) or for having diabetes (FPG ≥ 126 mg/dL or HbA1c ≥ 6.5% [≥ 48 mmol/mol]). If multiple values of a given test were available, we considered any elevated value above the appropriate diagnostic level as indicative of that form of hyperglycemia. BMI percentile was estimated from the charts provided by the Centers for Disease Control and Prevention. We used the mean of all values when multiple BMI percentile measures in a year were available.

Clinicians at both KP Regions have access to the national guidelines, which track very closely to ADA recommendations. The ADA currently recommends that children with a BMI equal to or greater than the 85th percentile for age and sex and with any 2 of these risk factors: family history of type 2 diabetes in first- or second-degree relative, race/ethnicity (Native American, African American, Latino, Asian American, Pacific Islander), signs of insulin resistance, and maternal history of diabetes or gestational diabetes mellitus during the child’s gestation should be screened for diabetes starting at age 10 years or at the onset of puberty. However, there is no mandated policy and KP clinicians are free to practice medicine in the way they believe best suits their patients, but they are encouraged to consult and follow national guidelines.

Statistical Analysis

All analyses were conducted with SAS software, version 9.3 (SAS Institute, Cary, NC). Within each study site, we compared mean values using Fisher exact tests and proportions or categories using χ2 tests. We present the results separately for KPHI and KPNW to examine the consistency of the findings across two different geographic locations with a decidedly different mix of race/ethnicity.

Table 1. Population characteristics in two sites

<table>
<thead>
<tr>
<th>Cohort characteristics</th>
<th>KPNW</th>
<th>KPHI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age, years</td>
<td>11.8</td>
<td>11.8</td>
</tr>
<tr>
<td>Age 6-9 years</td>
<td>17,299 (29.6%)</td>
<td>17,272 (29.6%)</td>
</tr>
<tr>
<td>Age 10-17 years</td>
<td>41,143 (70.4%)</td>
<td>41,081 (70.4%)</td>
</tr>
<tr>
<td>Female</td>
<td>29,864 (51.1%)</td>
<td>29,818 (51.1%)</td>
</tr>
<tr>
<td>BMI percentiles, n</td>
<td>39,966</td>
<td>39,966</td>
</tr>
<tr>
<td>&lt; 5th</td>
<td>639 (1.8%)</td>
<td>90 (0.3%)</td>
</tr>
<tr>
<td>5th-84th</td>
<td>21,981 (55.0%)</td>
<td>11,508 (38.4%)</td>
</tr>
<tr>
<td>85th-94th</td>
<td>7993 (20.0%)</td>
<td>7672 (25.6%)</td>
</tr>
<tr>
<td>≥ 95th</td>
<td>9352 (23.4%)</td>
<td>10,699 (35.7%)</td>
</tr>
<tr>
<td>Race/ethnicity, n</td>
<td>40,546</td>
<td>39,966</td>
</tr>
<tr>
<td>Minority race/ethnicity</td>
<td>6812 (16.8%)</td>
<td>6714 (16.8%)</td>
</tr>
</tbody>
</table>

* Minority race/ethnicity: includes Asian, Hawaiian Pacific Islander, and other mix.

BMI = body mass index; KPHI = Kaiser Permanente Hawaii; KPNW = Kaiser Permanente Northwest.
Impact of Implementing Glycated Hemoglobin Testing for Identification of Dysglycemia in Youth

Results

The 2009 and 2012 cohorts were of nearly identical size in both KPNW (~58,000) and KPHI (~26,000) (Table 1), and the demographic composition of the cohorts in both sites was similar in each year. Mean age was 11.8 years in both KPNW cohorts, and 11.7 years in both KPHI cohorts. In both sites, the percentage of female participants was identical between cohort years (KPNW 51.1%; KPHI 48.9%). In KPNW, the number with a BMI measurement was substantially lower in 2012, but the distribution of BMI percentile was significantly different with a greater proportion in the upper percentiles. The BMI percentile distribution was not significantly different between cohorts in KPHI. About 17% of each KPNW cohort and 85% of each KPHI cohort were of minority race/ethnicity.

In both settings, FPG testing was significantly more common in 2009 compared with 2012, but HbA1c testing was more common in 2012 (Table 2). The proportion with either test increased from 2.56% to 4.02% in KPNW and from 3.18% to 10.48% in KPHI (p < 0.001 for both sites). The proportion identified as at-risk for diabetes by either test increased significantly in both sites from 2009 to 2012 (KPNW: 0.19% vs 1.34%; KPHI: 0.56% vs 1.77%, p < 0.001 for both sites), but the proportion identified with diabetes was not significantly different in either site.

Table 3 displays the characteristics of youth identified as at-risk for diabetes by cohort year and study site. In both KPNW and KPHI, mean age for youth at risk for diabetes declined significantly between 2009 and 2012, owing to a much larger proportion aged 6 to 9 years in 2012 (KPNW: 7% vs 32%; KPHI: 11% vs 39%; p < 0.001 for both sites). In addition, a significantly larger proportion of females were identified in 2012 in both sites (KPNW: 39% vs 55%; KPHI: 35% vs 46%; p < 0.001 for both sites). Following the pattern of the total cohorts, the distribution of BMI percentile shifted significantly at KPNW but not at KPHI among at-risk youth. The proportion at risk for diabetes that was of minority race/ethnicity was not significantly different between cohorts at either site. At KPHI, mean age among those identified with diabetes was higher in 2009 compared with 2012 (13.8 vs 11.5, p = 0.044), but there were no other differences between cohorts in the characteristics of youth identified with diabetes at either site (Table 4).

Table 5 displays the percentage tested with either FPG test or HbA1c assay, the percentage at risk for diabetes, and the percentage with diabetes for key age, sex, BMI, and racial/ethnic strata. Testing was more common at KPHI, but overall the results were consistent across all strata; similar percentages were found in each cohort year, and similar changes were observed from 2009 to 2012 regardless of the age, sex, BMI, or race/ethnicity strata.

Discussion

Following the addition of the HbA1c assay for diagnosing diabetes, our comparison of 2009 and 2012 cohorts from KPHI and KPNW found that the proportion of youth aged 6-17 that are tested and subsequently identified as at risk for diabetes has risen dramatically. Despite differential uptake of HbA1c testing and the substantially different racial composition of the two sites, we found similar patterns of testing. Moreover, we observed important differences in the size and composition of the resulting populations identified as at risk for developing diabetes.

In KPHI, a best practice alert was put in place in 2010, which probably increased screening, and KPNW changed their established best practice alert from FPG test to HbA1c assay after departmental grand rounds and lectures. At both sites the best practice alert triggers for all 6- to 18-year-olds with BMI equal to or greater than the 85th percentile. So the results at least partially reflect the power of the electronic medical record to enhance clinical care.

Current ADA guidelines recommend screening for diabetes among youth beginning at age 10 years when other risk factors such as overweight/obesity are present. The increased use of the HbA1c assay resulted in 32% to 39% of youth at risk for diabetes being younger than age 10 years in 2012, compared with 7% to 11% in 2009. A recent study of primarily Hispanic obese adolescents

Table 2. Laboratory testing for diabetes and at risk for diabetes in 2009 and 2012

<table>
<thead>
<tr>
<th>Cohort characteristics</th>
<th>KPNW 2009, n = 58,442</th>
<th>KPNW 2012, n = 58,533</th>
<th>p value</th>
<th>KPHI 2009, n = 26,255</th>
<th>KPHI 2012, n = 26,199</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fasting plasma glucose (FPG) test done</td>
<td>1455 (2.49%)</td>
<td>432 (0.74%)</td>
<td>&lt;0.001</td>
<td>775 (2.95%)</td>
<td>276 (1.05%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Glycerated hemoglobin (HbA1c) test done</td>
<td>82 (0.14%)</td>
<td>2066 (3.54%)</td>
<td>&lt;0.001</td>
<td>154 (0.59%)</td>
<td>2671 (10.20%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Any FPG or HbA1c test done</td>
<td>1496 (2.56%)</td>
<td>2346 (4.02%)</td>
<td>&lt;0.001</td>
<td>835 (3.18%)</td>
<td>2745 (10.48%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Impaired fasting glucose (FPG ≥100-125 mg/dL)</td>
<td>94 (0.16%)</td>
<td>18 (0.03%)</td>
<td>&lt;0.001</td>
<td>92 (0.35%)</td>
<td>42 (0.16%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Diabetes using FPG (≥ 126 mg/dL)</td>
<td>12 (0.02%)</td>
<td>6 (0.01%)</td>
<td>0.158</td>
<td>6 (0.02%)</td>
<td>2 (0.01%)</td>
<td>0.289</td>
</tr>
<tr>
<td>Impaired HbA1c (5.7% - 6.4% [39-46 mmol/mol])</td>
<td>18 (0.03%)</td>
<td>764 (1.31%)</td>
<td>&lt;0.001</td>
<td>67 (0.26%)</td>
<td>434 (1.66%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Diabetes using HbA1c (≥6.5% [≥48 mmol/mol])</td>
<td>18 (0.03%)</td>
<td>18 (0.03%)</td>
<td>0.861</td>
<td>8 (0.03%)</td>
<td>23 (0.09%)</td>
<td>0.007</td>
</tr>
<tr>
<td>At-risk for diabetes (FPG 100-125 mg/dL or HbA1c 5.7%-6.4% [39-46 mmol/mol])</td>
<td>111 (0.19%)</td>
<td>782 (1.34%)</td>
<td>&lt;0.001</td>
<td>146 (0.56%)</td>
<td>463 (1.77%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Diabetes (FPG ≥126 mg/dL or HbA1c ≥ 6.5% [≥ 48 mmol/mol])</td>
<td>23 (0.04%)</td>
<td>18 (0.03%)</td>
<td>0.761</td>
<td>12 (0.05%)</td>
<td>23 (0.09%)</td>
<td>0.062</td>
</tr>
</tbody>
</table>

KPHI = Kaiser Permanente Hawaii; KPNW = Kaiser Permanente Northwest.
concluded that the use of HbA$_1C$ assay was associated with increased diabetes screening in primary care. The percentage of obese teens (> 95th percentile) screened for diabetes increased from 40% in period 1 (April 19, 2008, to October 19, 2009) to 47% in period 2 (May 3, 2010, to November 3, 2011). Our study was not limited to obese youth and included a wider age range, thus providing a more comprehensive analysis of the adoption and effectiveness of the HbA$_1C$ assay in overweight and normal weight youth.

Table 3. Characteristics of youth at risk for diabetes in 2009 and 2012

<table>
<thead>
<tr>
<th>Cohort characteristics</th>
<th>KPNW</th>
<th>KPHI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age, years</td>
<td>13.3</td>
<td>11.5</td>
</tr>
<tr>
<td>Age 6-9 years</td>
<td>8 (7.2%)</td>
<td>246 (31.5%)</td>
</tr>
<tr>
<td>Age 10-17 years</td>
<td>103 (92.8%)</td>
<td>536 (68.5%)</td>
</tr>
<tr>
<td>Female</td>
<td>43 (38.7%)</td>
<td>426 (54.5%)</td>
</tr>
<tr>
<td>BMI percentiles, n</td>
<td>111</td>
<td>759</td>
</tr>
<tr>
<td>&lt; 5th</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>5th-84th</td>
<td>16 (14.4%)</td>
<td>48 (6.3%)</td>
</tr>
<tr>
<td>85th-94th</td>
<td>13 (11.7%)</td>
<td>52 (6.9%)</td>
</tr>
<tr>
<td>≥ 95th</td>
<td>82 (73.9%)</td>
<td>659 (86.8%)</td>
</tr>
<tr>
<td>Minority</td>
<td>15 (23.1%)</td>
<td>174 (30.9%)</td>
</tr>
</tbody>
</table>

BMI = body mass index; KPHI = Kaiser Permanente Hawaii; KPNW = Kaiser Permanente Northwest.

Table 4. Characteristics of patients with diabetes in 2009 and 2012

<table>
<thead>
<tr>
<th>Cohort characteristics</th>
<th>KPNW</th>
<th>KPHI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age, years</td>
<td>12.5</td>
<td>12.7</td>
</tr>
<tr>
<td>Age 6-9 years</td>
<td>5 (22.7%)</td>
<td>4 (20.0%)</td>
</tr>
<tr>
<td>Age 10-17 years</td>
<td>17 (77.3%)</td>
<td>16 (80.0%)</td>
</tr>
<tr>
<td>Female</td>
<td>14 (63.6%)</td>
<td>10 (50.0%)</td>
</tr>
<tr>
<td>BMI percentiles, n</td>
<td>22</td>
<td>20</td>
</tr>
<tr>
<td>&lt; 5th</td>
<td>0</td>
<td>1 (5.0%)</td>
</tr>
<tr>
<td>5th-84th</td>
<td>9 (40.9%)</td>
<td>7 (35.0%)</td>
</tr>
<tr>
<td>85th-94th</td>
<td>6 (27.3%)</td>
<td>2 (10.0%)</td>
</tr>
<tr>
<td>≥ 95th</td>
<td>7 (31.8%)</td>
<td>10 (50.0%)</td>
</tr>
<tr>
<td>Race/ethnicity, n</td>
<td>18</td>
<td>18</td>
</tr>
<tr>
<td>Minority</td>
<td>2 (11.1%)</td>
<td>4 (22.2%)</td>
</tr>
</tbody>
</table>

BMI = body mass index; KPHI = Kaiser Permanente Hawaii; KPNW = Kaiser Permanente Northwest.

It appears that the ease of using HbA$_1C$ assay increased the number of youth being tested. Despite the increase, however, we did not observe a change in the number of cases identified with diabetes, but we did see a substantial increase in those identified as at risk for diabetes. In any case, it appears that targeted screening has increased as a result of the use of HbA$_1C$ assay, allowing for greater opportunity to intervene. This is important because targeted intervention is essential for the efficient use of diabetes prevention resources. There is no doubt that lifestyle changes or medication can reduce or delay diabetes onset in adults, but evidence of whether such preventive success applies to youth is scant. One recent study in adolescents (aged 10 to 17 years) at high risk of developing type 2 diabetes showed that a 6-month lifestyle intervention combined with metformin showed a modest weight loss and increased insulin sensitivity, but it was not of sufficient duration to assess risk of diabetes onset. Research is needed to determine effective risk reduction strategies for youth.

As type 2 diabetes becomes increasingly common among younger individuals, the lifetime risk of developing complications will likely rise. However, there is evidence that effective glycemic control early in the course of both type 1 and type 2 diabetes can reduce the...
risk of microvascular and macrovascular disease. HbA1c assay is clearly an effective method for identifying future diabetes risk, and being at risk for diabetes is associated with increased prevalence of retinopathy and nephropathy, chronic kidney disease, and cardiovascular disease. Furthermore, these complications are all associated with duration of diabetes. Therefore, in terms of prevention of type 2 diabetes and its complications, early recognition with targeted screening is essential.

We also observed a shift in the sex distribution of those identified as at risk for diabetes following implementation of HbA1c assay, with substantially more females recognized in 2012 than in 2009. This is not surprising given that FPG identifies more men than women with hyperglycemia, although whether this metabolic difference between sexes applies to youth is unclear. In any case, our results suggest that the risk of diabetes among young females, the likelihood of future gestational diabetes, and the number of pregnancies complicated by existing diabetes may be considerably greater than previously believed.

Our study has several limitations. It is likely that those receiving glucose tests are ordered for youth believed to be at more risk for diabetes, so our results should not be viewed as an outcome of general screening efforts. Whether the proportions we identified as at risk for diabetes or with diabetes represent true prevalence cannot be determined from these observational data. However, our objective was not to estimate prevalence but to assess the impact of introducing the HbA1c assay as a diagnostic tool. The finding that glucose testing rates are increasing should result in a more representative analysis sample in the future. We did not differentiate between type 1 and type 2 diabetes, a very difficult task when limited to observational data. This might have resulted in disproportionately identifying children with type 1 diabetes. Nonetheless, increased use of HbA1c assay did not affect diabetes identification but had a marked effect on the size and composition of the at-risk population. Therefore, the inability to distinguish between type 1 and type 2 diabetes is probably negligible. We

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**Table 5. Percentage tested, percentage at risk for diabetes, and percentage with diabetes for key age, sex, body mass index, and racial/ethnic strata**

<table>
<thead>
<tr>
<th>Cohort characteristics</th>
<th>KPNW 2009</th>
<th>KPNW 2012</th>
<th>p value</th>
<th>KPHI 2009</th>
<th>KPHI 2012</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tested*</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age 6-9</td>
<td>17,299</td>
<td>1.1 (190)</td>
<td>17,272</td>
<td>3.2 (553)</td>
<td>&lt;0.001</td>
<td>8273</td>
</tr>
<tr>
<td>Age 10-17</td>
<td>41,143</td>
<td>3.2 (1317)</td>
<td>41,081</td>
<td>4.4 (1806)</td>
<td>&lt;0.001</td>
<td>17,982</td>
</tr>
<tr>
<td>Boys</td>
<td>28,578</td>
<td>2.5 (714)</td>
<td>28,535</td>
<td>3.4 (970)</td>
<td>&lt;0.001</td>
<td>13,426</td>
</tr>
<tr>
<td>Girls</td>
<td>29,864</td>
<td>2.6 (776)</td>
<td>29,818</td>
<td>4.6 (1372)</td>
<td>&lt;0.001</td>
<td>12,829</td>
</tr>
<tr>
<td>BMI &lt; 85th</td>
<td>22,621</td>
<td>1.3 (294)</td>
<td>11,956</td>
<td>3.0 (548)</td>
<td>&lt;0.001</td>
<td>9166</td>
</tr>
<tr>
<td>BMI ≥ 85th</td>
<td>17,345</td>
<td>2.4 (416)</td>
<td>18,371</td>
<td>3.0 (551)</td>
<td>0.027</td>
<td>5753</td>
</tr>
<tr>
<td>Non-Hispanic white</td>
<td>33,734</td>
<td>2.6 (877)</td>
<td>33,252</td>
<td>4.4 (1463)</td>
<td>&lt;0.001</td>
<td>3199</td>
</tr>
<tr>
<td>Minority race/ethnicity</td>
<td>6812</td>
<td>3.0 (204)</td>
<td>6714</td>
<td>5.2 (349)</td>
<td>&lt;0.001</td>
<td>18,611</td>
</tr>
</tbody>
</table>

At risk for diabetes

| Age 6-9 | 17,299 | 0.1 (17) | 17,272 | 1.4 (242) | <0.001 | 8273 | 0.1 (16) | 8265 | 1.1 (182) | <0.001 |
| Age 10-17 | 41,143 | 0.3 (123) | 41,081 | 1.3 (534) | <0.001 | 17,982 | 0.4 (130) | 17,934 | 0.8 (281) | <0.001 |
| Boys | 28,578 | 0.2 (57) | 28,535 | 1.2 (342) | <0.001 | 13,426 | 0.4 (95) | 13,403 | 0.9 (252) | <0.001 |
| Girls | 29,864 | 0.2 (60) | 29,818 | 1.5 (447) | <0.001 | 12,829 | 0.2 (51) | 12,796 | 0.8 (211) | <0.001 |
| BMI < 85th | 22,621 | 0.1 (23) | 11,956 | 0.4 (46) | <0.001 | 9166 | 0.1 (13) | 7689 | 0.3 (43) | <0.001 |
| BMI ≥ 85th | 17,345 | 0.2 (35) | 18,371 | 0.7 (129) | <0.001 | 5753 | 1.2 (12) | 4659 | 3.4 (356) | <0.001 |
| Non-Hispanic white | 33,734 | 0.2 (67) | 33,252 | 1.2 (399) | <0.001 | 3199 | 0.2 (10) | 3192 | 0.31 (20) | 0.066 |
| Minority race/ethnicity | 6812 | 0.2 (14) | 6714 | 2.6 (175) | <0.001 | 18,611 | 0.3 (118) | 18,566 | 1.1 (414) | <0.001 |

With diabetes

| Age 6-9 | 17,299 | 0.03 (5) | 17,272 | 0.02 (3) | 0.74 | 8273 | 0.01 (1) | 8265 | 0.04 (7) | 0.034 |
| Age 10-17 | 41,143 | 0.04 (16) | 41,081 | 0.04 (16) | 0.866 | 17,982 | 0.03 (11) | 17,934 | 0.04 (16) | 0.332 |
| Boys | 28,578 | 0.03 (9) | 28,535 | 0.03 (9) | 0.635 | 13,426 | 0.02 (6) | 13,403 | 0.05 (13) | 0.107 |
| Girls | 29,864 | 0.05 (18) | 29,818 | 0.04 (12) | 0.417 | 12,829 | 0.02 (6) | 12,796 | 0.04 (10) | 0.315 |
| BMI < 85th | 22,621 | 0.04 (9) | 11,956 | 0.07 (6) | 0.253 | 9166 | 0.01 (2) | 7689 | 0.01 (2) | 0.86 |
| BMI ≥ 85th | 17,345 | 0.08 (14) | 18,371 | 0.03 (6) | 0.175 | 5753 | 0.1 (8) | 4659 | 0.2 (16) | 0.031 |
| Non-Hispanic white | 33,734 | 0.05 (17) | 33,252 | 0.04 (13) | 0.719 | 3199 | 0 | 3192 | 0 |  |
| Minority race/ethnicity | 6812 | 0.03 (2) | 6714 | 0.06 (4) | 0.413 | 18,611 | 0.03 (11) | 18,566 | 1.2 (22) | 0.055 |

* Using either fasting plasma glucose or glycated hemoglobin assay.
BMI = body mass index; KPHI = Kaiser Permanente Hawaii; KPNW = Kaiser Permanente Northwest.
determined those at risk and those with diabetes with a single diagnostic laboratory value. A one-year period may be too short to capture those with confirmatory tests or to determine whether the test we did capture was itself confirmatory. In any case, we acknowledge that our results may overstate the number with diabetes. Large proportions of our samples did not have race/ethnicity recorded, but racial differences among those with available data did not affect the results. Furthermore, findings were remarkably similar between the two sites, suggesting that our results are robust and unaffected by race/ethnicity. FPG may be skewed because we were unable to reliably differentiate between routine values captured during “well child” visits and those captured during acute events that could affect the values. Approximately half of the enrolled children did not have BMI data available. It is possible that results for those with and without BMI data were different. However, the testing data, which is the main emphasis of this article, are based on whole samples regardless of availability of BMI. Although use of the HbA1c assay to diagnose diabetes appears to have increased the proportion of youth receiving glycemia tests, other unmeasured factors such as education (of both provider and parent) cannot be ruled out. Last, our data came from two Regions of a comprehensive integrated health system that has excellent information technology support. Whether the testing rates and the resulting proportions we report could be generalized to other settings is unknown.

The purpose of this research was to address whether the endorsement of HbA1c assay for diagnosing diabetes affected the screening, detection, and composition of populations of youth with dysglycemia. Although our data answered that question, whether screening is adequate or is not unknown. Unfortunately, because this was an observational study we cannot determine clinician rationale for testing in either cohort year, nor can we assess whether all who should be screened are being screened. This is a vitally important question that we hope to answer with future research.

In conclusion, the 2010 introduction of the HbA1c assay to diagnose diabetes appears to have increased the proportion of youth receiving glycemia tests. As a result, many more youth are now being recognized as at risk for developing diabetes, and a greater proportion of them are younger (< age 10 years) and female. This change in the number and composition of at-risk youth has important implications for the delivery of diabetes prevention efforts.

Disclosure Statement
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References
Impact of Implementing Glycated Hemoglobin Testing for Identification of Dysglycemia in Youth


Chief Weapon of Offence

In the fight which we have to wage incessantly against ignorance and quackery among the masses and follies of all sorts among the classes, diagnosis, not drugging, is our chief weapon of offence. Lack of systematic personal training in the methods of the recognition of disease leads to the misapplication of remedies, to long courses of treatment when treatment is useless, and so directly to that lack of confidence in our methods which is apt to place us in the eyes of the public on a level with empirics and quacks.

— William Osler, MD, 1849-1919, Canadian physician and one of the four founding professors of Johns Hopkins Hospital
The internal mechanisms and figures of this clockspring-powered automaton are entirely handcrafted. (See it in action at: www.davestudiorama.com/the-snorer.html.) When wound up, the clockspring mounted into the side of this piece drives five cams, each of which manipulates the hand-painted figures much like strings on a marionette. One cam mechanism opens and closes the figures' eyes, another turns the heads or makes an arm swing, and yet another causes the wife to sit up. The result is the following scene: husband because of wife's snoring, pushes her, and goes back to sleep, and then she wakes up shocked before going back to sleep as well.

Mr Dumbrell is retired and lives in Vancouver, British Columbia, Canada. More of his work can be seen at: www.davestudiorama.com.
Most Common Dermatologic Topics Published in Five High-Impact General Medical Journals, 1970-2012: Melanoma, Psoriasis, Herpes Simplex, Herpes Zoster, and Acne

Young M Choi; Aram A Namavar, MS; Jashin J Wu, MD

Abstract

Context: General practitioners frequently encounter skin diseases and are accustomed to diagnosing the most common dermatologic conditions.

Objective: We sought to determine the most common dermatologic topics published in five high-impact general medical journals (New England Journal of Medicine, The Lancet, the Journal of the American Medical Association, British Medical Journal (now The BMJ), and Annals of Internal Medicine).

Design: We conducted an independent search of the Thomson Reuters' Science Citation Index for common dermatologic topics, limited to the period 1970 to 2012.

Main Outcome Measure: Total number of publications dealing with each dermatologic topic considered.

Results: The five most common dermatologic topics published were melanoma, psoriasis, herpes simplex, herpes zoster, and acne. Melanoma and psoriasis were the top two dermatologic topics published in each journal except for Annals of Internal Medicine.

Conclusions: Internists frequently diagnose herpes simplex, herpes zoster, and acne, which are also common dermatologic topics published. Although internists infrequently diagnose melanoma and psoriasis, they are major topics for general medical journals because of their increased community awareness, major advancements in therapeutic research, and their nondermatologic manifestations.

Introduction

Skin diseases are commonly encountered by general practitioners, and in today's health care system, most patients are evaluated first by their primary care physician before seeing a dermatologist. It is estimated that 6% of primary care outpatient visits are skin-related, and 60% of cutaneous diagnoses are made by nondermatologists.1 As the role of the general practitioner continues to grow, it remains imperative that these physicians are equipped to manage general dermatologic conditions.

To determine which skin diseases internists most commonly encounter, Feldman et al2 analyzed the National Ambulatory Medical Care Survey data from 1990 to 1994. The top five dermatologic diagnoses made by internists during this period were dermatitis, bacterial skin infections, tinea, acne vulgaris, and herpes zoster. By highlighting these common diagnoses, it was anticipated that skin disease educational programs for internists would be tailored to these diseases. Moreover, this study demonstrated that diagnoses such as psoriasis, actinic keratosis, seborrheic keratosis, skin cancer, and benign tumors were commonly made by dermatologists but not by internists. These findings elucidated the overlapping yet differing role of the dermatologist and the internist, espousing the need for further communication and alliance in diagnosing a wide range of skin diseases.

The purpose of our study was to determine the most common dermatologic topics published from 1970 to 2012 in five high-impact general medical journals. We sought to analyze whether these journals, having the largest readership in medicine, targeted the common dermatologic diagnoses made by internists or focused on skin diseases more commonly diagnosed by dermatologists.

Methods

We analyzed data from the Thomson Reuters Science Citation Index. The five high-impact general medical journals we considered, based on the highest impact factors, were the New England Journal of Medicine (NEJM), The Lancet, the Journal of the American Medical Association (JAMA), British Medical Journal (now The BMJ), and Annals of Internal Medicine. For each of these journals, we conducted an independent search for each of the dermatologic topics included in the study, limited to the years 1970 to 2012. The topics chosen were a modified list from the top dermatologic diagnoses made by internists and dermatologists.3 (Table 1).

Two independent reviewers analyzed search results to determine whether an article met the dermatologic topic under consideration. A consensus was achieved for all articles included. All types of publications (original research, case reports, review articles, meta-analyses, editorials, etc) were eligible for the study. If an article dealt with more than one possible topic, the topic that best fit the primary objective of the article was chosen. Topics without 20 or more papers in any of the 5 general medical journals were not mentioned.

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Results

A total of 2627 articles dealing with at least 1 of the 24 dermatologic topics mentioned in Table 1 were included in the study. From our combined data, the top 5 dermatologic topics published in the 5 high-impact general medical journals were melanoma (708 articles), psoriasis (455), herpes simplex (366), herpes zoster (253), and acne (165), as shown in Table 1. The Lancet had the highest total number of dermatologic publications (744), followed by British Medical Journal (661), NEJM (630), JAMA (419), and Annals of Internal Medicine (173).

Melanoma was overwhelmingly the most common dermatologic topic in each of the journals except for Annals of Internal Medicine (Figure 1). In NEJM, the second most common topic was psoriasis (100 articles), followed by herpes simplex (97) and herpes zoster (71). The other dermatologic topics were relatively uncommon in that journal. In The Lancet, the second most common topic was also psoriasis (144), followed by herpes simplex (102) and acne (49). There were also notable contributions to the dermatologic literature about herpes zoster (40), atopic dermatitis/eczema (40), urticaria (32), and abscess (28).

In JAMA, herpes simplex (with 68 articles) was the second most common dermatologic topic, followed by psoriasis (48) and herpes zoster (46). Acne (36), urticaria (30), and squamous cell carcinoma (22) followed in number of contributions. Melanoma (158) and psoriasis (134) were 2 greatly favored topics in the British Medical Journal. Herpes zoster (65), acne (60), and herpes simplex (56) made up the next highest proportion of topics, followed by abscess (35), urticaria (27), atopic dermatitis/eczema (26), and squamous cell carcinoma (22).

Annals of Internal Medicine was the only journal wherein melanoma (22) was not the most common dermatologic topic. In fact, melanoma was the fourth most prevalent. Preceding melanoma in prevalent articles was herpes simplex (45), herpes zoster (33), and psoriasis (29); see Figure 1.

Discussion

It has become customary for general practitioners to diagnose common skin conditions. For these physicians, primary sources for up-to-date information are general medical journals, namely the five high-impact journals (NEJM, The Lancet, JAMA, British Medical Journal, and Annals of Internal Medicine). By studying the prevalence of common dermatologic topics published in these journals, we attempted to provide insight into their emphasis on certain skin conditions.

Of the five high-impact general medical journals, we found that The Lancet and British Medical Journal, which have their foundation in the United Kingdom, published more articles on common dermatologic topics. In the United Kingdom, physicians must complete two years of foundation training and two years of core medical training before entering dermatology as a specialty.

This is in contrast to the US, where medical school graduates are required to complete only one year of internal medicine, general surgery, or pediatrics internship before entering dermatology residency. Perhaps in the United Kingdom, dermatology is integrated more with internal medicine, leading to a greater number of dermatologic publications in their general medical journals.

In our analysis, we found that herpes simplex, herpes zoster, and acne were three of the top five dermatologic topics published. This coincides with the fact that these topics were also among the top ten dermatologic diagnoses made by internists. Melanoma and psoriasis, on the other hand, were the top two dermatologic topics published but are diagnoses rarely made by internists.

As mentioned by Feldman et al., melanoma, despite being rarely diagnosed by internists, is important to internal medicine because of its serious nature. Some consider the early detection of melanoma, which has a 5-year survival rate of 98% if detected early and 15% with distant metastasis, to be the responsibility of primary care physicians. Furthermore, a “new era” of targeted and immune-based therapies for melanoma has been ushered in by recent advancements in melanoma research. Many of these findings have gained publication in prestigious general medical journals.

It is not surprising, therefore, that melanoma was the most common dermatologic topic published in 4 of the 5 high-impact general medical journals we studied.

Psoriasis, like melanoma, is another diagnosis infrequently made by internists but was found in our study to be the second most common dermatologic topic published. With a prevalence of 1% to 3%, psoriasis is likely to be encountered by general practitioners. Moreover, as a systemic inflammatory disease, psoriasis is compounded by psoriatic arthritis in 10% to 50% of cases. Psoriasis has also been associated with a significantly increased risk of myocardial infarction, stroke, and peripheral vascular disease, possibly because of accelerated atherosclerosis.

...certain dermatologic topics with increased relevance to internal medicine have greater numbers of publications.
Most Common Dermatologic Topics Published in Five High-Impact General Medical Journals, 1970-2012: Melanoma, Psoriasis, Herpes Simplex, Herpes Zoster, and Acne

in the setting of an inflammatory state. These systemic manifestations, as well as the increasing prevalence of this dermatologic condition, make psoriasis a very relevant disease to internal medicine and the general medical journals. We acknowledge limitations in our study. Access to journal articles may have been limited by our university’s subscriptions, but all resources available were used to obtain articles. Certain articles that addressed multiple topics were categorized under one topic, considered the best fit by the reviewer. We referenced a study by Feldman et al., who analyzed the National Ambulatory Medical Care Survey data from 1990 to 1994. Likely, diagnosing patterns of skin disease by internists may have changed since then, but to our knowledge, no similar analysis has yet been performed.

Conclusion
We believe our study achieved its primary purpose, to analyze the prevalence of common dermatologic topics published in high-impact general medical journals. We have demonstrated that certain dermatologic topics with increased relevance to internal medicine have greater numbers of publications. These findings are a testament to the value of these medical journals in providing relevant yet comprehensive information to general physicians, thus deserving the title of high-impact.

Disclosure Statement
Dr. Wu received research funding from AbbVie, North Chicago, IL; Amgen Inc, Thousand Oaks, CA; Coherus Biosciences, Redwood City, CA; Eli Lilly, Indianapolis, IN; Merck, Whitehouse Station, NJ; and Pfizer, New York, NY, which were not directly related to this study. He is a consultant for AbbVie, North Chicago, IL; DUSA Pharmaceuticals Inc, Wilmington, MA; Eli Lilly, Indianapolis, IN; and Pfizer, New York, NY; Mr. Choi and Mr. Namavar have no conflicts of interest to disclose. No funding was received for this study.

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

References
Introduction
Obesity among children and adolescents has continued to rise in epidemic proportions since the late 1970s. The prevalence of obesity among children and adolescents in the US has tripled between 1976 and 2008, with a 2012 prevalence of 19.7% (females) and 17.2% (males) among those aged 6 to 12 years, and 20.4% (females) and 21.4% (males) among those aged 12 to 19 years. Obesity rates in general have plateaued since 2008, but rates for obesity Class 2 (120% of the 95th percentile or a body mass index [BMI] > 35 kg/m²) and Class 3 (140% of 95th percentile or BMI > 40 kg/m²) continue to increase. The obesity prevalence among children is particularly alarming because obesity-related diseases, rarely seen in children in the past, are increasingly being diagnosed in pediatric patients; these obesity-associated conditions include obstructive sleep apnea, nonalcoholic fatty liver disease with resultant cirrhosis, and type 2 diabetes. In addition, obesity is related to hypovitaminosis D (vitamin D deficiency and insufficiency). Vitamin D is a fat-soluble vitamin and is naturally present in only a small number of foods. Vitamin D can be added to food, and it can be ingested as a dietary supplement. Vitamin D is produced endogenously when ultraviolet rays from sunlight strike the skin and trigger vitamin D synthesis. Groups of people at risk of vitamin D inadequacy include breastfed infants and older adults, as well as people with limited sun exposure, dark skin, or fat malabsorption, and those who are obese.

The serum concentration of 25-hydroxy-vitamin D (25(OH)D) is the best indicator of vitamin D status. The 25(OH)D that is produced cutaneously or obtained from food and supplements has a fairly long circulating half-life of 15 days. Vitamin D insufficiency is defined as a 25(OH)D level of 21 to 29 ng/mL and vitamin D deficiency as a 25(OH)D level below 20 ng/mL, according to an Institute of Medicine 2011 report.

Since the mid-1990s, mean serum 25(OH)D concentrations in the US have slightly declined among males but not females. This decline is probably caused by reduced milk intake, inadequate sun exposure, greater use of sun protection when outdoors, and simultaneous increases in body weight. Obesity does not affect the skin's capacity to synthesize vitamin D. Rather, greater amounts of subcutaneous fat sequester more of the vitamin, making it less bioavailable to the body.

Hypovitaminosis D has been considered a risk factor for glucose intolerance and decreased insulin sensitivity. Serum 25(OH)D levels below 20 ng/mL have been associated with decreased pancreatic β-cell function. It has also been found that insulin sensitivity is as much as 60% higher in individuals with serum 25(OH)D levels of 30 ng/mL vs those with levels of 10 ng/mL.

Along with glucose intolerance, vitamin D deficiency and insufficiency are associated with obesity-related health diseases. For instance, low vitamin D status may increase the risk of diabetes mellitus,
hypothesis, cardiovascular disease, \(^13\) and certain types of cancer \(^13,14\) and has been associated with greater severity of critical illness.\(^16\) Vitamin D also plays a role in the liver, skeletal muscles, \(^10\) and the immune system.\(^10,17,18\) In the present study, we report the prevalence of vitamin D insufficiency and deficiency in obese pediatric patients at Penn State Hershey Children’s Hospital in Hershey, PA, and the association of hypovitaminosis D with comorbidities of childhood obesity.

**Methods**

A retrospective chart review was conducted of 155 obese children and teenagers aged 5 to 19 years who attended the Penn State Hershey Children’s Hospital Pediatric Multidisciplinary Weight Loss Program from November 2009 through November 2010. Five children with missing or invalid birth dates were excluded from the study, leaving 150 children for analysis. We did not have a control group for comparison. This multidisciplinary program has physicians, nurses, and a dietitian who see children and adolescents referred by their

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>N</th>
<th>Vitamin D deficient, &lt; 20 ng/mL</th>
<th>Hypovitaminosis D, &lt; 30 ng/mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years (mean ± SD)</td>
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<td>14.5 ± 3.1</td>
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<tr>
<td>Age, years (%)</td>
<td></td>
<td></td>
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<tr>
<td>5-9</td>
<td>18</td>
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<td>10-14</td>
<td>79</td>
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<td>≥ 15</td>
<td>53</td>
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<td>26 (49.1)</td>
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</tr>
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<td>43 (43.9)</td>
<td>55 (56.1)</td>
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<tr>
<td>Male</td>
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</tr>
<tr>
<td>Race/ethnicity (%)</td>
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<td>6 (50.0)</td>
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<tr>
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<td>Spring</td>
<td>47</td>
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<td>Summer</td>
<td>48</td>
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<tr>
<td>Fall</td>
<td>31</td>
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<td>20 (64.5)</td>
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<tr>
<td>Winter/Spring</td>
<td>71</td>
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<td>35 (49.3)</td>
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<td>Summer/Fall</td>
<td>79</td>
<td>24 (30.4)</td>
<td>55 (69.6)</td>
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<td></td>
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<td>Diastolic</td>
<td>147</td>
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<td>64.8 ± 8.5</td>
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<tr>
<td>Systolic</td>
<td>147</td>
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<td>Total cholesterol, mg/dL</td>
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<td>HDL cholesterol, mg/dL</td>
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<td>LDL cholesterol, mg/dL</td>
<td>138</td>
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<td>Triglycerides, mg/dL</td>
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<td>ALT, IU/L</td>
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<td>Hemoglobin A(_1c), %</td>
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<td>Insulin, units</td>
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<td>Total comorbidities, no.</td>
<td>150</td>
<td>4.1 ± 1.4</td>
<td>4.2 ± 1.4</td>
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</table>

(continued on next page)
Prevalence of Hypovitaminosis D and Its Association with Comorbidities of Childhood Obesity

primary care provider who are obese as defined by BMI. In children, obesity is defined as having a BMI at or above the 95th percentile for age and sex. Most of our study population was at or above the 99th percentile.

Each patient underwent a complete history and physical examination, and data from the medical history were recorded. Screening laboratory tests were ordered on the basis of a full medical evaluation, which included a 25(OH)D level. Parents and/or patients provided the medical history by form and systematic questioning by the physician. The history included presence of asthma, attention-deficit/hyperactivity disorder, constipation, depression, eating disorders, gastroesophageal reflux disease, hypertension, polycystic ovary syndrome [PCOS], and snoring. Pulse and blood pressure (BP) were measured in the office and were deemed high if above the 95th percentile for age and sex. Laboratory values were obtained that included fasting lipid profile, insulin, glucose, aspartate aminotransferase, alanine aminotransferase, hemoglobin A1c (HbA1c), and 25(OH)D; reference values for age were used to determine if the results were abnormal.

Rural-urban commuting area code data were used to categorize the patient’s residence as either urban or rural on the basis of zip codes. These data were analyzed to determine the prevalence of vitamin D insufficiency/deficiency and to assess for its relationship to comorbidities. In addition to those from the history, comorbidities included acanthosis nigricans, hyperlipidemia, and abnormal liver function tests. Also assessed was the relationship between vitamin D insufficiency/deficiency and the total number of comorbidities, insulin level, elevation of systolic blood pressure, GERD, hyperinsulinemia, hypertension, and PCOS (female only), and snoring.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>N</th>
<th>Vitamin D deficient, &lt; 20 ng/mL</th>
<th>Hypovitaminosis D, &lt; 30 ng/mL</th>
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<tr>
<td></td>
<td></td>
<td>Yes, n = 60</td>
<td>No, n = 90</td>
</tr>
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<td>ADHD (%)</td>
<td></td>
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<td>No</td>
</tr>
<tr>
<td>Yes</td>
<td>17</td>
<td>7 (41.2)</td>
<td>10 (58.8)</td>
</tr>
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<td>No</td>
<td>133</td>
<td>53 (39.8)</td>
<td>80 (60.2)</td>
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<td>Acanthosis nigricans (%)</td>
<td></td>
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<td>No</td>
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<tr>
<td>Yes</td>
<td>89</td>
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<td>54 (60.7)</td>
</tr>
<tr>
<td>No</td>
<td>61</td>
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<td>36 (58.0)</td>
</tr>
<tr>
<td>Asthma (%)</td>
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<tr>
<td>Yes</td>
<td>24</td>
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<tr>
<td>No</td>
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<td>75 (59.5)</td>
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<td>No</td>
<td>131</td>
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<td>81 (61.8)</td>
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<td>Elevated systolic blood pressure (%)</td>
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<td>98</td>
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<td>58 (59.2)</td>
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<td>GERD (%)</td>
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<td>11 (68.8)</td>
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<td>No</td>
<td>134</td>
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<td>79 (59.0)</td>
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<td>Hyperinsulinemia (%)</td>
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<tr>
<td>Yes</td>
<td>61</td>
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<td>31 (50.8)</td>
</tr>
<tr>
<td>No</td>
<td>84</td>
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<td>Hyperlipidemia (high total cholesterol, LDL cholesterol, or triglycerides) (%)</td>
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<td>No</td>
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<tr>
<td>Yes</td>
<td>64</td>
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<td>45 (70.3)</td>
</tr>
<tr>
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<td>86</td>
<td>41 (47.7)</td>
<td>45 (52.3)</td>
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<td>Hypertension (%)</td>
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<td>No</td>
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<tr>
<td>Yes</td>
<td>17</td>
<td>7 (41.2)</td>
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<td>No</td>
<td>133</td>
<td>53 (39.8)</td>
<td>80 (60.2)</td>
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<td>PCOS (female only) (%)</td>
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<td>No</td>
</tr>
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<td>20</td>
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<td>7 (35.0)</td>
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<tr>
<td>No</td>
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<td>30 (38.5)</td>
<td>48 (61.5)</td>
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<td>Snoring (%)</td>
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<td>No</td>
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<td>35</td>
<td>12 (34.3)</td>
<td>23 (65.7)</td>
</tr>
<tr>
<td>No</td>
<td>115</td>
<td>48 (41.7)</td>
<td>67 (58.3)</td>
</tr>
</tbody>
</table>

* Logistic regression used for all comparisons, mean ± SD or no. (%). Boldface values indicate statistical significance.

ADHD = attention-deficit/hyperactivity disorder; ALT = alanine aminotransferase; AST = aspartate aminotransferase; GERD = gastroesophageal reflux disease; HDL = high-density lipoprotein; LDL = low-density lipoprotein; PCOS = polycystic ovary syndrome; SD = standard deviation.
sex, race, rural vs urban homestead, and season of the year. None of the patients were taking more than 400 IU/day of vitamin D (the recommended daily intake of vitamin D per the American Academy of Pediatrics\(^\text{20}\)). The study was conducted with the permission of the Penn State Hershey institutional review board.

**Statistical Analysis**

All analyses were carried out using SAS statistical software Version 9.3 (SAS Institute, Cary, NC). Descriptive statistics were generated for all variables using means, medians, and standard deviations for continuous variables and frequency tables for categorical variables. The season was defined by the laboratory date using the meteorologic definitions of the seasons by months. The outcome variables were defined in binary form for vitamin D insufficiency (< 30 ng/mL) and vitamin D deficiency (< 20 ng/mL). A bivariate analysis was performed to assess the association of these outcome variables with the various independent variables of interest using a logistic regression. This same analysis was stratified by categories: age, sex, race, and season to determine if any of the associations seen overall were manifested within 1 group more than in another. Because of a small number of children from a rural location, we were unable to stratify by location.

On the basis of results of the overall bivariate analysis, a subset of clinically and statistically significant independent variables was chosen to be considered in a multivariate logistic regression for each outcome. The starting subset of variables to be considered included age, sex, race, location, season, systolic BP, insulin level, hyperlipidemia, and total comorbidities as a surrogate for the collection of individual comorbidities. Before doing any modeling, this subset of independent variables was tested for multicollinearity using variance inflation factor. From this subset, a final reduced set of significant independent variables was chosen for each outcome using a backward process of elimination with an inclusion criterion of \( p = 0.10 \). Two-way interactions were tested for significance between all independent variables remaining as significant in the model after the backward elimination process, but none were found to be significant to the model for either outcome. The fit of the final logistic regression model was assessed using the Hosmer-Lemeshow goodness-of-fit test. Odds ratios were used to quantify the direction and magnitude of the association with the outcome of the independent variables remaining in the final model.

**Results**

The characteristics of our study sample are shown in Table 1. Our population was 65% female, 91% urban, 61% white, 19% African American, and 8% Hispanic. Their most common medical comorbidities included acanthosis nigricans (59%), hyperinsulinemia (42%), elevated systolic BP at first visit (35%), PCOS (20%), asthma (16%), attention-deficit/hyperactivity

![Figure 1](image1.png)

**Figure 1.** All season distribution of serum 25-hydroxyvitamin D levels (25[OH]D) (ng/mL).

![Figure 2](image2.png)

**Figure 2.** Distribution of serum 25-hydroxyvitamin D (25[OH]D) (ng/mL) in winter/spring collections.
disorder (11%), gastroesophageal reflux disease (11%), constipation (7%), autism (7%), and binge eating disorder (6%).

Vitamin D levels ranged from 5 to 60 ng/mL with a mean of 23 ng/mL. The prevalence of vitamin D deficiency (< 20 ng/mL) was 40% and insufficiency (20-30 ng/mL) was 38%; only 22% had a normal vitamin D level above 30 ng/mL (Figure 1). Stratifying these results by age group, 27.8% aged 5 to 9 years, 35.4% aged 10 to 14 years, and 50.9% aged 15 and older were vitamin D deficient.

In bivariate analyses, older age, African-American race, winter/spring season (Figures 2 and 3), higher insulin level, hyperlipidemia (elevated total cholesterol, low-density lipoprotein, or triglycerides levels), and PCOS (female only) were significantly associated with vitamin D deficiency (Table 1). Some of these associations were also found with overall hypovitaminosis D, including African-American race, winter/spring season, and higher insulin level. Higher systolic BP was significantly associated with hypovitaminosis D but not with vitamin D deficiency. Urban location was significantly associated with hypovitaminosis D and trended toward significance for vitamin D deficiency despite having a limited number of children from rural locations. In an unadjusted comparison, the total number of comorbidities was not associated with a low vitamin D level. However, when controlling for all other variables in our model, there was a significant association with vitamin D deficiency, and leaning toward a significant association with hypovitaminosis D. Sex; heart rate; diastolic BP; aspartate aminotransferase, alanine aminotransferase, and HbA1c levels; attention-deficit/hyperactivity disorder; asthma; depression; gastroesophageal reflux disease; and snoring were not associated with vitamin D deficiency or hypovitaminosis D. When the analysis was stratified by age category, sex, race, or season, several significant associations were stronger in 1 group than in another. For children age 10 to 14 years, girls were more likely to be vitamin D deficient than boys (43.4% vs 19.2%, p = 0.040). For children age 15 years and older, a higher insulin level was significantly associated with being vitamin D deficient (p = 0.007) or with having hypovitaminosis D (p = 0.026). A stronger association was seen in female subjects between urban location and vitamin D deficiency (p = 0.009) or hypovitaminosis D (p = 0.017), as well as between winter/spring season and vitamin D deficiency (p = 0.029) or hypovitaminosis D (p = 0.013).

Table 2. Final multivariate models for vitamin D deficiency and hypovitaminosis D

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Vitamin D deficient (&lt; 20 ng/mL)</th>
<th>Hypovitaminosis D (&lt; 30 ng/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Odds ratio (CI)</td>
<td>p value</td>
</tr>
<tr>
<td>Age (per 1-year increase)</td>
<td>1.24 (1.08-1.41)</td>
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</tr>
<tr>
<td>Sex (female vs male)</td>
<td>Eliminated</td>
<td>—</td>
</tr>
<tr>
<td>Race (nonwhite vs white)</td>
<td>4.96 (2.01-11.71)</td>
<td>&lt; 0.01</td>
</tr>
<tr>
<td>Location (urban vs rural)</td>
<td>5.91 (1.03-33.81)</td>
<td>0.05</td>
</tr>
<tr>
<td>Season (winter/spring vs summer/fall)</td>
<td>3.69 (1.55-8.78)</td>
<td>&lt; 0.01</td>
</tr>
<tr>
<td>Systolic blood pressure (per 1 mm Hg increase)</td>
<td>Eliminated</td>
<td>—</td>
</tr>
<tr>
<td>Insulin (per 1 µU/mL increase)</td>
<td>1.04 (1.01-1.07)</td>
<td>0.01</td>
</tr>
<tr>
<td>Total comorbidities (per 1 comorbidity decrease)</td>
<td>1.48 (1.06-2.08)</td>
<td>0.02</td>
</tr>
</tbody>
</table>

*All characteristics were considered for the final multivariate logistic regression model for both outcomes. The final set of variables for the model for each outcome was chosen using a backward process of elimination, and variables that were eliminated during this process are noted in the Table. Only variables with odds ratios and p values here are included in the final model. CI = confidence interval.
Male subjects tended to have a greater association between a higher insulin level and vitamin D deficiency ($p = 0.004$) or hypovitaminosis D ($p = 0.043$). In whites, female subjects were more likely to be vitamin D deficient than male subjects (31.7% vs 10.7%, $p = 0.043$), and winter/spring season had a more significant association with both vitamin D deficiency ($p = 0.038$) and hypovitaminosis D ($p = 0.028$). There was a more pronounced association between higher systolic BP and vitamin D deficiency ($p = 0.038$) or hypovitaminosis D ($p = 0.021$) in the summer/fall seasons.

**Discussion**

The etiology of hypovitaminosis D is likely multifactorial because it has been associated with several dietary factors as well as decreased sunlight exposure and poor vitamin D intake. Our Pennsylvania prevalence of 77.8% (insufficient and deficient) is less than that of a study in Texas that showed a prevalence of 92% of vitamin D insufficiency and deficiency in 6- to 16-year-old obese patients, and more than 90% in 17-year-old obese teens in Rhode Island. Our study did not look into milk intake or specific dietary sources of vitamin D consumption or sunlight exposure. We found that nonwhite race, elevated systolic BP, hyperinsulinemia, multiple comorbidities, urban location, and winter/spring collection of blood samples were associated with hypovitaminosis D.

Our findings suggest that older children and teenagers are most likely to be vitamin D deficient. Across age groups, urban patients are more likely than rural patients to be vitamin D deficient. In multivariate analysis, this was still significant for overall hypovitaminosis D. Diet and sunlight exposure probably played a role, but these data were not collected.

After multivariate analysis, we found a significant association with total number of comorbidities and vitamin D deficiency, and the association with hypovitaminosis D almost reached statistical significance. This may be an overall reflection of general health status. Vitamin D is part of many physiologic pathways, and its role in many illnesses is still not completely understood. These results may imply its cumulative involvement in obesity-related problems. The exact reason for this is unknown, and further study in this area may be warranted.

A few sex-based differences were noted. Female subjects showed a seasonal variation of being more likely to have low vitamin D in winter/spring. Male subjects showed no seasonal variation. Male subjects showed higher mean systolic BP and insulin levels as vitamin D levels dropped. This was not seen in female subjects. Obese 10- to 14-year-old girls are at higher risk of vitamin D deficiency compared with boys the same age. The exact relationship here is unknown. It may be related to more outdoor activity for the boys, but this was not directly measured.

Race played an important factor. African Americans had the lowest vitamin D levels, with 100% being insufficient and 79.3% being deficient. Whites had much lower prevalence. For those who were vitamin D sufficient, 85% were white. This is consistent with findings of previous studies looking at race. African Americans have skin pigmentation that reduces vitamin D production, and from about puberty onward, vitamin D intake is also generally below recommended levels. It has been recently shown that African Americans can have lower vitamin D and vitamin D binding protein levels, which may actually lead to similar levels of bioavailable vitamin D compared with whites. Thus, our current “normal” values for vitamin D may need to be adjusted for this population. Further study in this area is needed.

We found a strong link with seasonality in the winter and spring collections. There was a 3.7-fold greater likelihood of being vitamin D deficient and a 4.2-fold greater likelihood of having hypovitaminosis D in these seasons compared with summer and fall collections. This is probably secondary to decreasing sun exposure in late fall into winter and poor bioavailable Vitamin D stores. Vitamin D is fat soluble and is readily stored in adipose tissue, and may be sequestered in a larger body pool of fat of obese individuals. People obtain most of their vitamin D requirement from casual exposure to sunlight. It has been shown that there is more than 50% decreased bioavailability of cutaneous synthesized vitamin D in obese adult subjects, and this likely accounts for the consistent observation that obesity is associated with vitamin D deficiency. Insulin levels have been shown to have seasonal variation with the highest levels in spring compared with fall. This may explain why all of the vitamin D sufficient subjects had normal insulin levels in the winter/spring collection. Even with this seasonal variation, 69.6% had hypovitaminosis D and 30.4% were deficient in summer/fall collections. This may lead the practitioner to consider the season with borderline vitamin D results before supplementation recommendations are given. For example, if it is fall and the number is borderline, it will likely decrease over the winter/spring months.

Low vitamin D levels have been associated with risk factors for Type 2 diabetes mellitus (specifically insulin resistance but not HbA1c) in obese children. We also found this to be true in our population, as shown by its associations with overall BMI, hyperinsulinemia, and PCOS. Hyperinsulinemia was particularly predictive in the age group 15 years and older, in which 80% were vitamin D deficient (odds ratio = 10, $p < 0.001$). Insulin resistance is also part of PCOS, and we found associations with both. In another study, 72.8% of women with PCOS were vitamin D insufficient.

Serum triglyceride levels and systolic BPs have been linked to vitamin D deficiency. Our study overall showed that elevated systolic BP was predictive for hypovitaminosis D, but not deficiency. For male subjects, however, it was predictive of both, with higher systolic BPs in the deficiency group. We did not find an association with fasting triglycerides or cholesterol levels, but we did find an association with hypertriglyceridemia in general for any elevation in total cholesterol, LDL, or triglycerides levels.

It is difficult to precisely predict the exact amount of sunlight required to produce enough vitamin D for each individual, and there are some health concerns relating excessive sun exposure to skin cancer risks in adulthood. Therefore, it is important to encourage protected sun exposure for children and teenagers.
However, this practice may translate into insufficient endogenous vitamin D production. It is then necessary to encourage dietary supplementation of vitamin D. This is needed to normalize vitamin D levels and may temper insulin resistance, thus possibly delaying the onset of Type 2 diabetes mellitus (although this has not been demonstrated). Because most of our patients had hypovitaminosis D and vitamin D supplementation is relatively safe, the argument could be made to supplement all obese children with vitamin D and forego lab testing. This, however, would not pick up the vitamin D deficient children and would not adequately meet their replacement needs. In a study by Heaney et al. of response to oral dosing of vitamin D, it can be extrapolated from data in men older than age 20 years that to raise the serum vitamin D concentration by 1 ng/mL would require roughly 140 IU of cholecalciferol daily. There may be different responses to supplementation based on race, with whites normalizing quicker than Hispanics or African Americans.

Limitations of the present study are small sample sizes for age group comparisons and from rural homes. Data on dietary vitamin D (especially milk intake), sun exposure, and sunscreen use were not obtained as this was a retrospective study and these data were not routinely collected. In addition, data were not collected on parameters that could affect insulin levels, such as amount of physical activity, medication use, hours of sleep, or a family history of diabetes and PCOS. Our subjects were obese children from central Pennsylvania who were referred for weight management, which may not be representative of all obese children. Despite these limitations, these results show that there are multiple associations for hypovitaminosis D, and these findings are likely applicable to all obese children in the US. Our study looked only at associations and did not show causality.

**Conclusion**

Hypovitaminosis D has many extraskelatal associations, including cancer, cardiovascular disease, diabetes, and autoimmune disorders. Previous evidence has been inconsistent, inconclusive as to causality, and insufficient to inform nutritional requirements. In this study, African-American race, winter/spring season, urban location, and higher insulin level were significantly associated with vitamin D deficiency and overall hypovitaminosis D. These, along with elevated systolic BP, urban location, total number of comorbidities, and PCOS (in female subjects only) were also associated with hypovitaminosis D.

The American Academy of Pediatrics Expert Committee, regarding the assessment, prevention, and treatment of child and adolescent overweight and obesity, does not currently recommend assessing vitamin D status in obese children. Given the large percentage of children, even in our youngest age group who are vitamin D deficient, routine screening of vitamin D should be considered in obese children and supplementation when needed. Supplementation has been found helpful in patients with systemic lupus erythematosus and hypovitaminosis D, as it improved inflammatory markers and disease activity. Vitamin D screening is more likely to have abnormal results with any of the following: older age, nonwhite race, elevated systolic BP, hyperinsulinemia, multiple comorbidities, PCOS, urban location, or winter/spring collection of blood samples. Seasonal variations of vitamin D levels should also be considered when recommending supplementation. Further study is needed to see if vitamin D supplementation will have an impact on preventing further weight gain or preventing possible comorbidities such as hyperinsulinemia, diabetes, and PCOS.

**Disclosure Statement**

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

**Acknowledgment**

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**References**


Prevalence of Hypovitaminosis D and Its Association with Comorbidities of Childhood Obesity


Vitamins

It is now known that all these diseases, with the exception of pellagra, can be prevented and cured by the addition of a preventive substance; the deficient substances, which are of the nature of organic bases, we will call “vitamins.”

— Casimir Funk, 1884-1967, Polish biochemist who is generally credited to be among the first to formulate the concept of vitamins
A Pilot Study Comparing Anatomic Failure after Sacrocolpopexy with Absorbable or Permanent Sutures for Vaginal Mesh Attachment

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Abstract

Objectives: To describe anatomic failure rates for sacrocolpopexy in groups receiving either delayed absorbable or permanent monofilament suture for mesh attachment to the vagina.

Methods: We reviewed the medical records of 193 women who underwent sacrocolpopexy with 2 different types of sutures attaching polypropylene mesh to the vagina: delayed absorbable sutures (median follow-up, 43 weeks) and permanent sutures (median follow-up, 106 weeks). Vaginal apical failure was defined as Point C greater than or equal to half of the total vaginal length. Anterior-posterior compartmental failures were defined as Point Ba and/or Point Bp more than 0 cm. Fisher exact and chi² tests were used to compare failure rates. There were no documented suture erosions in the delayed absorbable monofilament suture group during the review period. Two patients in the permanent suture group were found to have permanent suture in the bladder more than 30 weeks after the index procedure.

Results: Failure rates for the 45 subjects in the delayed absorbable group and 148 subjects in the permanent suture group were similar (4.4% vs 3.4%, p = 0.74) and not statistically different in any compartment: apical (0% vs 1.4%, p = 0.43), anterior (4.4% vs 2%, p = 0.38), or posterior (0% vs 1.4%, p = 0.43).

Conclusions: Delayed absorbable monofilament suture appears to be a reasonable alternative to permanent suture for mesh attachment to the vagina during sacrocolpopexy. The use of delayed absorbable suture could potentially prevent complications of suture erosion into the bladder or vagina remote from the time of surgery.

Introduction

Sacrocolpopexy is a commonly performed technique for treating apical prolapse. Abdominal sacrocolpopexy was first described by Arthure and Savage in 1957. The basic principles of sacrocolpopexy involve the attachment of a graft or mesh to the vagina while affixing the proximal end of the mesh to the anterior longitudinal ligament overlying the sacrum at levels S1 to S2. A recent comprehensive review of sacrocolpopexy and 7-year follow-up data from a randomized trial of sacrocolpopexy with or without Burch urethropexy describe a reoperation rate for prolapse of only 2.2% to 5.1%.

Clinicians often use permanent suture to anchor the mesh to the vagina. Between our 2 institutions, during the previous 15 years, we are aware of at least 5 cases in which permanent monofilament suture has eroded into the bladder after sacrocolpopexy. These erosions presented many years after the index surgery despite the fact that intraoperative cystoscopic findings were noted to be normal.

Recent data suggest that permanent sutures may not be necessary. Porcine models demonstrate that 74% of the final strength of tissue ingrowth into polypropylene mesh is already achieved by 2 weeks after implantation, and maximum strength occurs by 3 months.

Delayed absorbable monofilament suture (polydioxanone or polyglyconate) loses 50% of its tensile strength by 4 weeks, 100% by 2 to 3 months, and complete mass absorption by 6 to 8 months. In a recent large series of sacrocolpopexy vaginal erosions, 3 of 20 erosions were suture only. Therefore, the use of absorbable sutures for mesh attachment during sacrocolpopexy is appealing because the risk of long-term suture exposure or knots eroding into the bladder would likely be eliminated. For these reasons, some of the surgeon authors (SAM and KML) began using delayed absorbable monofilament suture (polydioxanone [PDSII], Ethicon Inc, Somerville, NJ, or polyglyconate [Maxon], Covidien AG, Mansfield, MA) to attach, in 2008, Type 1 polypropylene mesh to the vagina.

The purpose of this study was to compare anatomic objective failure rates for minimally invasive sacrocolpopexy using delayed absorbable vs permanent monofilament suture for mesh attachment to the vagina. It was our hypothesis that the objective failure rates would not be significantly different between suture types because tissue ingrowth into mesh would occur by the time the delayed absorbable sutures lost their tensile strength.
Methods

This retrospective cohort study was approved by the institutional review board. The study included women who underwent minimally invasive sacrocolpopexy performed at the 2 institutions in our fellowship training program between November 2004 and January 2010. All subjects underwent sacrocolpopexy using either robotic-assisted laparoscopy or conventional laparoscopy. Details of our operative procedure have been published. In brief summary, our technique consisted of anterior and posterior leaflets of polypropylene mesh with at least 6 sutures placed on each leaflet to secure the mesh to the vaginal surface. Inclusion criteria were as follows: 1) operative report documentation of delayed absorbable monofilament (polydioxanone or polyglyconate) or permanent monofilament (polypropylene) sutures for mesh attachment to the vagina and 2) at least 1 follow-up visit with a pelvic organ prolapse quantification performed 12 weeks or more after surgery.

Data were extracted from the electronic medical record and hospital charts. Demographic data and baseline and postoperative pelvic organ prolapse quantification measures were collected from eligible subjects. Operative techniques and complications were abstracted from the hospital records. Postoperative follow-up visits, including pelvic organ prolapse quantification and the detection of suture complications, were also documented.

Our primary outcome was objective apical failure defined as Point C greater than or equal to half of the total vaginal length and/or objective failure of the anterior and posterior

<table>
<thead>
<tr>
<th>Demographic data</th>
<th>Delayed absorbable sutures, n = 45</th>
<th>Permanent sutures, n = 148</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age ± SD (years)</td>
<td>60 ± 9</td>
<td>61 ± 9</td>
<td>0.854*</td>
</tr>
<tr>
<td>Median (range) follow-up duration, in weeks</td>
<td>43 (12-272)</td>
<td>106 (12-372)</td>
<td>0.007*</td>
</tr>
<tr>
<td>Median (range) time to failure for primary or secondary outcomes, in weeks</td>
<td>58 (55-61)</td>
<td>6 (5-181)</td>
<td>0.143*</td>
</tr>
<tr>
<td>Median preoperative stage of prolapse (mean)</td>
<td>3 (3.0)</td>
<td>3 (2.8)</td>
<td>0.002*</td>
</tr>
<tr>
<td>Concomitant surgery, no. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procedure for repair of pelvic organ prolapse</td>
<td>16 (36.0)</td>
<td>36 (26.0)</td>
<td>0.196*</td>
</tr>
<tr>
<td>Anterior colporrhaphy</td>
<td>0 (0)</td>
<td>8 (5.1)</td>
<td>0.336*</td>
</tr>
<tr>
<td>Posterior colporrhaphy</td>
<td>13 (29.0)</td>
<td>28 (18.9)</td>
<td>0.152*</td>
</tr>
<tr>
<td>Paravaginal repair</td>
<td>5 (11.1)</td>
<td>12 (8.1)</td>
<td>0.534*</td>
</tr>
<tr>
<td>Hysterectomy</td>
<td>32 (71.9)</td>
<td>61 (41.2)</td>
<td>0.001*</td>
</tr>
</tbody>
</table>

* Student t test.
* Nonparametric testing.
* Chi-squared test.
SD = standard deviation.
compartments, which we defined as Point Ba and/or Point Bp more than 0 cm. We performed analysis using this definition of prolapse because it appears to be the most appropriate definition for surgical success. Barber et al. suggested that beyond the hymen might correlate more highly with subjective symptoms of surgical failure. This definition was used in the large randomized trial of sacrocolpopexy (Colpexy and Urinary Reduction Efforts, or CARE), whose results were published in 2013.

The records of subjects who were determined to have anatomic failures were further reviewed. Data were abstracted whether the patients reported being asymptomatic, being symptomatic but declining surgery, or if they underwent repeated operation for prolapse.

Chi squared tests and Fisher exact tests were used to evaluate dichotomous variables; Student’s t test was used for continuous, normally distributed data; and Wilcoxon rank tests were used to compare nonparametric variables. Odds ratios (ORs) and 95% confidence intervals (CIs) are reported. A p value of less than 0.05 was considered statistically significant. Statistical analysis was performed with PASW Statistics 18 (IBM, Armonk, NY).

Results
A total of 261 women underwent minimally invasive sacrocolpopexy at our institutions during the study period, and 74% had sufficient data to be included in the analysis (Figure 1). Of the 26% who were not included in the study, there were no significant differences in age, parity, body mass index, or preoperative stage of prolapse between the subjects included in the analysis (data not shown). Of those included, there were no differences in mean age, median follow-up duration (or range), median (or range) time to failure for primary or secondary outcomes, or rates of concomitant surgery for pelvic organ prolapse between the delayed absorbable and permanent suture groups (Table 1). On nonparametric testing, the delayed absorbable group had statistically but not clinically worse preoperative stage compared with the permanent suture group.

The anatomic objective failure rates for the different suture groups were similar and not statistically different for the participants with at least 12 weeks of follow-up (Table 2). No difference was seen in the objective failure rates in the robotic surgery group (3.4%, n = 2) vs the laparoscopic surgery group (3.7%, n = 5).

Of the 7 overall subjects with anatomic failure at the hymen or beyond, 3 (43%) were asymptomatic, 3 (43%) were symptomatic but declined reoperation (with 1 of them using a pessary), and 1 (14%) was scheduled for reoperation. The subject planning reoperation with an anterior colporrhaphy was in the permanent suture group.

There were no documented suture erosions in the delayed absorbable monofilament suture group during the review period. Two patients in the permanent suture group were later found to have permanent suture in the bladder. One patient presented at 47 weeks after her surgery with urinary frequency and nocturia. She was noted to have microscopic hematuria and underwent cystoscopy, revealing a suture in the bladder, which was removed cystoscopically. Urinary symptoms subsequently improved. The second patient presented 32 weeks after surgery with large-volume urinary leakage, which developed only immediately before presentation. She was noted to have a vesicovaginal fistula with polypropylene (Prolene) suture and mesh visible in the bladder. Two patients were noted to have polypropylene suture in the vagina remotely after surgery at postoperative weeks 30 and 279.

Vaginal mesh erosion rates were 17% in the permanent suture group and 13% in the delayed absorbable suture group, a difference that was not statistically significant (p = 0.385). Concomitant hysterectomy was performed in 41% of the permanent suture group and 72% of the delayed absorbable suture group (p = 0.001). There was a significant difference in the mesh erosion rate among participants receiving a concurrent hysterectomy vs the subjects who did not undergo a hysterectomy at the time of sacrocolpopexy (23% vs 10%, p = 0.014).

Discussion
In this preliminary analysis of the use of delayed absorbable monofilament suture (polydioxanone or polyglactonate) to secure polypropylene mesh to the vagina, apical failure rates were low, and we did not identify increases in objective failure rates compared with permanent monofilament suture in patients with more than 12 weeks of follow-up. On the basis of these data and the biochemical properties of the delayed absorbable suture, we believe that there is sufficient tissue ingrowth into the polypropylene mesh during the period of adequate suture tensile strength to prevent failure.

Table 2. Anatomic failures

<table>
<thead>
<tr>
<th>Anatomic failure</th>
<th>Delayed absorbable sutures, n = 45, no. (%)</th>
<th>Permanent sutures, n = 148, no. (%)</th>
<th>Odds ratio (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall failure by definition</td>
<td>2 (4.4)</td>
<td>5 (3.4)</td>
<td>1.33 (0.25-7.10)</td>
<td>0.738</td>
</tr>
<tr>
<td>Apical point (C ≥ half of total vaginal length)</td>
<td>0 (0)</td>
<td>2 (1.4)</td>
<td>—</td>
<td>0.433</td>
</tr>
<tr>
<td>Anterior compartment point (Ba &gt; 0 cm)</td>
<td>2 (4.4)</td>
<td>3 (2.0)</td>
<td>2.2 (0.36-13.80)</td>
<td>0.376</td>
</tr>
<tr>
<td>Posterior compartment point (Bp &gt; 0 cm)</td>
<td>0 (0)</td>
<td>2 (1.4)</td>
<td>—</td>
<td>0.433</td>
</tr>
</tbody>
</table>

a Three subjects in the permanent sutures group and 0 subjects in the delayed absorbable sutures group with simultaneous multicompartiment failure.

b Fisher exact test.

CI = confidence interval.
The choice of sutures and mesh material used during pelvic reconstruction is an important one. In a study of sacrospinous ligament suspensions, braided polyester permanent suture had an unacceptably high rate (36%) of suture-related complications such as suture erosion, persistent granulation tissue, and persistent vaginal bleeding that required suture removal in 70% of cases. Sacrocolpopexies with expanded polytetrafluoroethylene (Gore-Tex, WL Gore and Associates, Flagstaff, AZ) mesh were associated with a 4-fold higher risk of erosion, and most clinicians have opted not to use this material in their practices.6

Permanent monofilament suture has been widely used for securing mesh to the vagina during the sacrocolpopexy procedure. The rationale for the use of permanent suture is to secure the mesh to provide a durable repair with a theoretical lower rate of failure than that with absorbable suture. Vaginal suture erosions are often considered less morbid than mesh erosions; however, the etiology of vaginal mesh erosion is not completely understood, especially in the absence of a colpotomy. It has been postulated that if the sutures that secure the mesh to the vagina traverse the full thickness of the vagina, vaginal bacteria may travel along the suture to colonize the mesh.6 If this theory is true, the presence of permanent suture securing the mesh to vagina places patients at risk of erosion, even many years after surgery. We observed 2 permanent suture erosions into the bladder occurring more than 30 weeks after surgery.

There is very limited literature comparing the use of monofilament absorbable suture vs permanent suture when mesh is attached to the vagina. One study by Maher et al14 compared laparoscopic sacrocolpopexy with vaginal mesh-reinforced repairs. The laparoscopic sacrocolpopexy subjects (n = 53) had their mesh attached to the vagina using delayed absorbable monofilament suture and had a 77% objective success rate after 6-month follow-up. The study did not compare success rates for absorbable vs permanent sutures.11 One retrospective abdominal sacrocolpopexy study comparing the use of braided, permanent, polyester sutures (2-0 Ethibond Excel, Ethicon, Somerville, NJ) with monofilament delayed absorbable (2-0 polydioxanone, Ethicon) in mesh attachment to the vagina found that the use of monofilament absorbable suture appeared to reduce the risk of graft-suture erosion without increasing surgical failure.12 However, their study was limited by only 20% of patients having follow-up greater than 6 weeks. Our results confirm these short-term results, but also confirm the durability of the delayed absorbable monofilament suture technique after suture absorption.

Even more bothersome and more morbid than vaginal suture erosions are erosions of foreign material into the bladder. The presence of permanent suture in the bladder many years after sacrocolpopexy prompted 2 of the surgeons at our institution to begin using delayed absorbable sutures for mesh attachment to the vagina. In the cases involving permanent suture in the bladder, those women had normal cystoscopy results at the time of their sacrocolpopexy. We attribute the high rate of vaginal mesh erosions noted in this cohort to the high rate of concomitant hysterectomy (48%) overall. On the basis of a previous publication, we have determined that there is a 6-fold increase in vaginal mesh erosion when associated with hysterectomy.13 We noted a significant difference in the mesh erosion rate between patients receiving a concurrent hysterectomy (23%) and those who did not (10%).

Even though our absorbable mesh group had slightly worse preoperative median prolapse, which should have biased this group to more failures, this was not observed. Most of the failures were in the anterior and posterior compartments, which may not be related at all to surgical failure since these more distal compartments may not have received adequate support from the sacrocolpopexy.

The strengths of this study are its moderately large sample size, inclusion of 74% of subjects, use of the standardized pelvic organ prolapse quantification, a contemporaneous study period, and the long follow-up duration.

Limitations of this study are primarily related to its retrospective nature and nonstandardized follow-up intervals. This study took place at two institutions with seven different surgeons performing these procedures. All surgeons are fellowship-trained urogynecologists. There was substantial overlap in the study period, with permanent suture being used from 2004 to 2010, whereas the delayed absorbable suture was used by two of the seven surgeons from 2008 to 2010. More patients in the delayed absorbable suture group had a hysterectomy at the time of surgery, and this could potentially influence the results. Two different surgical modalities were used for the sacrocolpopexy, although there was no difference in failure rates between the robotic and laparoscopic groups. A further limitation of our study is that our results were purely objective, and we do not have reliable subjective symptoms for the anatomic success group. Subjective data were specifically collected from the patients if their operation failed.

Conclusion

We consider delayed absorbable polydioxanone or polyglyconate suture to be a reasonable alternative to permanent monofilament sutures to potentially prevent complications of suture erosion into the bladder or vagina remote from surgery. The findings from this study should be further confirmed in a randomized trial of delayed absorbable vs permanent suture. 

Disclosure Statement

Drs Tan-Kim, Metenee, Lippmann, Luber, and Nager have no relevant financial disclosures. Dr Lukacz is a consultant for Pfizer, Inc, a Scientific Medical Advisor for Med Edicus, and an Advisory Committee member for AMS. She receives grant support from Boston Scientific and the National Institutes of Health.

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References

A Pilot Study Comparing Anatomic Failure after Sacrocolpopexy with Absorbable or Permanent Sutures for Vaginal Mesh Attachment

Knowing

It is impossible to know perfectly the part, if one is not acquainted with the whole, even in a gross way (grosso modo); so it is impossible to be a good surgeon if one is not familiar with the foundations and generalizations of medicine. On the other hand, as it is impossible to know the whole perfectly if we are not acquainted in a certain measure with each of its parts, it is impossible for anyone to be a good physician who is absolutely ignorant of the art of surgery, with a knowledge of its possibilities and its limitations.

— *Cyrurgia*, Henri de Mondeville, 1260-1316, the “Father of French Surgery"
Differences in Perceived Difficulty in Print and Online Patient Education Materials

Michael Farnsworth, MA

Abstract

Context: Written patient education materials frequently exceed the reading ability of the general public. Patients are often intimidated by the task of reading patient education materials, perceiving the materials’ difficulty levels as prohibitive, even when they do not exceed the patients’ reading abilities. It is unclear how the delivery mechanism—print or a computer screen—affects a patient’s reading experience through his/her perception of its difficulty.

Objective: To determine whether first-year college students perceived online or print-based patient education materials as more difficult to read.

Design: Convenience sampling of first-year college students.

Results: Some first-year college students perceived online patient education materials to be more difficult to read than print-based ones—even when the reading level of the patient education materials was similar. Demographic information about this sample’s high levels of digital literacy suggests that other populations might also perceive online patient education materials as more difficult to read than print-based equivalents. Patients’ perceptions of the difficulty of patient education materials influenced their ability to effectively learn from those materials.

Conclusion: This article concludes with a call for more research into patients’ perceptions of difficulty of patient education materials in print vs on a screen.

Introduction

Effective patient education is a continuing objective in health care, and patient education materials provided in both print-based and online formats play important roles in this aim. Written patient education materials (both print-based and online) frequently exceed the reading ability of the general public.1,2 Perhaps more importantly, though, patients are often intimidated by the task of reading patient education materials, perceiving patient education materials’ difficulty levels as prohibitive, even in cases where the patient education materials are not written in excessively technical language and do not exceed the patients’ reading abilities.3

Research projects with a focus on patients’ perceptions of the readability levels of patient education materials may assist patient educators in the development of these educational materials. The purpose of this study was to explore readers’ understanding of health information in print vs on a computer screen by determining whether a convenience sample of first-year college students perceived online or print-based patient education materials as more difficult to read. The central concern of this article, then, is not a matter of reading levels or penetrability of the text, but of how the delivery mechanism interferes with or enhances a person’s reading experience through his/her perception of its difficulty.

To my knowledge, no published studies have compared levels of perceived difficulty between online and print-based patient education materials. Most researchers of patient education materials have focused on readability levels in print media2 or online media4 but have not yielded comparative analyses of either print or online formats. The measure of perceived difficulty has received comparatively little attention recently. An exception is the work by Leroy et al., who launched many promising investigations of perceived difficulty, although not through a comparison of print and online formats. The following section outlines the limitations of evaluating patient education materials with readability measures alone. Limitations of readability measures may demonstrate the promise of using perceived difficulty to more effectively evaluate patient education materials presented in both print-based and online media.

Readability-Based Improvements to Patient Education Materials

Historically, creators of patient education materials sought to lower levels of readability, where readability was measured by years of education necessary to comprehend a text. Levels of readability can be determined with a number of formulas, including the Simple Measure of Gobbledygook (SMOG), the Gunning Fog Index, and the Flesch-Kincaid grade-level formula, each of which is recommended by the Health Literacy Advisor (an interactive health literacy software tool from Health Literacy Innovations, Bethesda, MD). SMOG is also recommended by the US Centers for Medicare and Medicaid Services. These formulas are useful as basic guides for pairing patient education materials with appropriate audiences and for tracking attempts to improve the content of patient education material. Understanding readability-related problems identifies areas of need for alternative approaches to improvement of patient education materials, such as perceived difficulty measures.

Both print-based and online patient education materials are written at reading grade levels that exceed the reading ability of most patients. A recent study of
the readability of online health literature found a mean reading grade level of 12.30 from a sample of 352 Web sites using the readability tests SMOG, Gunning Fog, and Flesch-Kincaid. A similar study focused on readability of source material for patient education materials provided by private electronic health record vendors, as well as by the National Library of Medicine. The study found that these vendors' patient education materials had reading grade levels greater than the 5th through 6th grade recommendations provided by the European Commission and the Health Literacy Advisor in their codes of conduct for the readability of health information. The American Medical Association and the National Institutes of Health also recommended that readability levels not exceed the 6th-grade level, and the Maine Centers for Disease Control and Prevention recommended that consent forms be written at approximately the 6th-8th grade reading level, and preferably closer to the 6th grade level. These studies demonstrate that many patient education materials are largely inaccessible to general audiences because they are written at higher reading grade levels.

Complicating the readability landscape, the results of the various available readability formulas often vary greatly. Wang et al. found that readability varies by up to five reading grade levels, depending on which readability test is applied. The SMOG formula has a standard error of approximately one and one-half grade levels, whereas the Flesch-Kincaid has a standard error of up to two and one-half grade levels. Effectively, SMOG varies by up to three grade levels, or twice the standard error, whereas the Flesch-Kincaid varies by up to five grade levels. For this reason, the Journal of the Royal College of Physicians of Edinburgh stated, “SMOG should be the preferred measure of readability when evaluating consumer-oriented healthcare material.” These findings demonstrate the complexities involved in applying readability formulas to patient education materials. A potential exists for underestimating and overestimating patient education materials with the use of either formula, but SMOG produces more accurate approximations.

A related issue that can lead to variation in reported levels of readability is formatting. Often, readability tests fail to incorporate considerations involving overall passage length, individual paragraph length, as well as margin use and other formatting issues; however, these issues may play a major role in a reader’s comprehension of a document. Specifically, readability formulas are often difficult to apply to patient education materials written in outline formats; outlines, which often depend mainly on sentence fragments, do not clearly reflect sentence length—a primary factor in readability calculations.

Readability tests have entered many domains beyond those for which they were originally created. In these ill-suited contexts, they potentially fail to clearly represent the reading grade level or actual difficulty of health information. However, readability tests justifiably remain a popular tool for evaluating health information because they can rapidly provide gross approximations for establishing patient education materials’ difficulty, as measured through an estimation of reading grade level.

Applying Perceived Difficulty Measurements to Patient Education Materials

Several conceptual frameworks have been designed to explain why patients engage in or fail to engage in a variety of health-related behaviors; these measures attempt to account for why some patients are compliant and others are not. These frameworks examine the presence of possible impediments to successful completion of health-related behaviors. One barrier to health-related behavior is “perceived difficulty,” which impedes patients from engaging in health-related behaviors because of the belief that the difficulty of engaging in such behaviors is prohibitive. Leroy et al. state: “In the context of consumer education, perceived difficulty of the text is a barrier encountered by many consumers who are expected to read text and educate themselves.” Both the perceived and actual difficulty of patient education materials, then, might act as barriers to patient education by impeding patients from obtaining knowledge about their medical condition.

Levels of perceived difficulty can be altered through manipulations of surface-level grammar and term familiarity. Surface-level grammar manipulations include changes to sentence structure, noun phrase complexity, and function word density. Sentence structure manipulations include constructing a sentence with either an active voice or a passive voice. Overall sentence structure can also change by writing the sentence with an extraposed subject or a sentential subject. Complex sentences often have sentential subjects that contain the elements of sentences as subject terms. For example, a sentence with a sentential subject might read “the symptoms that were observed during intake were cough and fever.” On the other hand, extraposed subjects use “placeholders,” such as “it,” for more complex terms or descriptions. For instance, consider the sentential-subject sentence, such as “ACE inhibitors used to lower blood pressure can cause fatigue.” The subject of the preceding sentence could be extraposed to read: “They can cause fatigue.” This latter form may lower levels of perceived difficulty.

Function words, such as in, why, be, or the, also affect sentence structure and, in turn, perceived difficulty. Noun phrase complexity increases as the number of function words decreases. Finally, intuitive ease of reading decreases as the number of function words in a sentence decreases. Consequently, a liberal use of function words may lower levels of perceived difficulty. Each of the three methods described requires time commitments and writer expertise, and thus may prove prohibitive for many attempts to improve patient education materials.

Term familiarity is defined by the frequency of a term in the Google Web corpus, a database of more than a trillion words. The measure of term familiarity helps explain why words with fewer syllables (ie, more “readable” words) are sometimes more difficult to comprehend. For example, the corpus helps identify why certain shorter words, such as apnea, are actually more difficult for most readers than longer words like obesity. Term familiarity presents a hopeful direction for improvement of patient education materials because, similar to readability, term familiarity can be assigned by computational means with the use of algorithms.
The current study adds to this area of inquiry by evaluating whether the perceived difficulty of patient education materials is also a function of presentation media (eg, online or print). Acting as a hopeful launch for future research trajectories of greater scope, the following research suggests that patients may perceive online patient education materials to be more difficult than commensurate print-based patient education materials.

Methods

The purpose of this research project was to determine whether a convenience sample of first-year college students perceived online or print-based patient education materials as more difficult. The study additionally sought to measure the students’ perceived difficulty level of each patient education material, using a Likert-type scale.

The research was collected at James Madison University (JMU) in Harrisonburg, VA, during November 2012. This study was approved by the university’s institutional review board (IRB Protocol 13-0141, approved on November 8, 2012). The sampling method was convenience: participants were from 4 course sections of General Writing, Rhetoric, and Technical Communication (GWRTC 103), Critical Reading and Writing. Forty-one students participated in the research, which took place in JMU computer laboratories. Each laboratory had 21 computers with Windows 7 operating system (Microsoft, Redmond, WA) available for student use. All students voluntarily participated; none refused to participate.

Most JMU students take GWRTC 103 during their first year of college, meaning that they are probably members of the Millennenial Generation. Barring specific petitions for exemption, all students entering JMU are required to take GWRTC 103, which means that each group of students included a mix of academic majors from across the university. Thus, this sample should be generally representative of the university’s first-year class. Survey data from the JMU Office of Institutional Research shows that 83% of the Class of 2016 was 21 or younger at the time of the study. Therefore, these students were approximately 10 years younger than necessary for inclusion in the “digital native” classification, as stipulated by Prensky. Additionally, 87% of the Class of 2016 graduated in the top third of their high school class, and 65% came from a background with an estimated family income of $100,000 or more annually.

Each student received patient education materials about 2 of 4 possible topics that are familiar in student health contexts. Data were collected about 81 pairs of patient education materials. The topics included the following: conjunctivitis (“pink eye”); mononucleosis (“mono”); self-care for cuts, scrapes, and burns; and back exercises. Topics were paired in all possible combinations, resulting in 6 survey forms, A through F. The survey forms were as follows:

A. “Pink Eye” and “Mono”  
B. “Pink Eye” and “Cuts, Scrapes, and Burns”  
C. “Pink Eye” and “Back Exercises”  
D. “Mono” and “Cuts, Scrapes, and Burns”  
E. “Mono” and “Back Exercises”  
F. “Cuts, Scrapes, and Burns” and “Back Exercises.”

Survey forms were evenly distributed across participants. Each topic was presented in both online and print-based formats. Participants received four total readings: two print readings and two online readings. For example, a student in Survey Group C received a print patient education material on pink eye, an online patient education material on pink eye, a print patient education material on back exercises, and an online patient education material on back exercises. All patient education materials were used in actual practice, available at either a health center or a health education Web site.

The online readings were selected from popular search results from Google.com; each selection occurred on the first page of Google search results. These patient education materials were available at Web pages that the students accessed directly. The print-based readings were physical copies provided by the JMU Student Health Center (see Sidebar: Patient Education Materials). The SMOG test was used to construct an approximately equivalent reading grade-level difficulty between each set of patient education materials (eg, the online and print back exercises patient education materials). Materials in each set varied by approximately two reading grade levels. For examples of the text, see “So, You Have Mono: Taking the Next Step” from the American College Health Association and “Mononucleosis” from WebMD.

The online text from WebMD on mononucleosis was 2.3 grade levels lower than the printed brochure according to SMOG and 1.4 grades lower according to the Flesch-Kincaid measurement. On the basis of the expected standard error for these readability measures (the SMOG formula has a standard error of approximately 1.5 grade levels, and Flesch-Kincaid has a standard error of up to 2.5 grade levels), this sort of variation means that the texts may actually

Patient Education Materials

Online patient education materials included: “Pinkeye (Also called: Conjunctivitis)”: www.nlm.nih.gov/medlineplus/pinkeye.html (from the National Institutes of Health, Bethesda, MD); “Self-Care for Cuts, Scrapes, and Burns”: www.fairviewhealthservices.org/Article/84649 (from Fairview Health Services in Minnesota), whose content was created by Krames, now Krames Staywell; “Slide Show: Back Exercises in 15 Minutes a Day”: www.mayoclinic.com/health/back-pain/LB00001_D (from the Mayo Clinic’s Mayo Foundation for Medical Education and Research, Rochester, MN); and “Mononucleosis (Mono)”: www.webmd.com/a-to-z-guides/infectious-mononucleosis-topic-overview (from WebMD LLC, New York, NY).

Print-based patient education materials included “Conjunctivitis (‘Pink Eye’)” (from University Health Center); “Self-Care for Cuts, Scrapes and Burns” (Quality Health Care); “Back Exercises” (Brochure 7068 from Parlay International, Walnut Creek, CA); and “So, You Have Mono: Taking the Next Step” (Brochure HS21 from the American College Health Association, Hanover, MD).
ORIGINAL RESEARCH & CONTRIBUTIONS

Differences in Perceived Difficulty in Print and Online Patient Education Materials

Table 1. Chi-square test results

<table>
<thead>
<tr>
<th>Frequencies</th>
<th>Observed, n—perceived as more difficult</th>
<th>Expected, n</th>
<th>Residual</th>
</tr>
</thead>
<tbody>
<tr>
<td>Online</td>
<td>43</td>
<td>40</td>
<td>-3</td>
</tr>
<tr>
<td>Print</td>
<td>37</td>
<td>40</td>
<td>3</td>
</tr>
</tbody>
</table>

Test statistics

- Chi-square: 0.450
- Degrees of freedom: 1
- Asymptotic significance: 0.502

*(1 = print; 0 = online.)*

be almost identical reading grade levels or may vary by up to approximately 3.8 grade levels according to SMOG and approximately 3.9 grade levels according to Flesch-Kincaid. The WebMD example scored 4.7 for SMOG and 5.4 for Flesch-Kincaid, whereas the American College Health Association brochure scored 7.0 for SMOG and 6.8 for Flesch-Kincaid.

The survey was available for the participants at the same time they viewed the patient education materials, so that they could refer back to the readings for confirmation of their assigned levels of difficulty. All surveys were collected in Qualtrics Research Suite survey software (Qualtrics, Salt Lake City, UT). The survey questions asked the students to provide two kinds of difficulty rankings of the patient education materials. The first question asked the participant to decide whether the online or print-based education material was more difficult concerning the same subject matter (eg, the subject matter “pink eye”). This question requested an ordinal ranking from the student. An example of this kind of question follows: “Which was easier to read: the online material on conjunctivitis (‘pink eye’) or the paper material on conjunctivitis?” Three additional questions resulted from the other three subject matters in the respective patient education materials. The results for each subject matter (eg, mono, pink eye, back exercises) were combined to find an overall ranking for print patient education materials and an overall ranking for online patient education materials. The generalized, two-tailed hypothesis stated the following: the format (online or print) will produce a statistically significant difference in the resulting rankings.

The second survey question asked the participant to rank the difficulty of each type of patient education material, online and print-based, for both subject matters. These cardinal difficulty rankings were recorded on a seven-value Likert scale from “very difficult” to “very easy.” In this case, the generalized, two-tailed hypothesis stated: students will report significantly different rankings for online vs print-based patient education materials. The statistical tests were computed in the statistics program SPSS version 21.0 (IBM SPSS, Armonk, NY).

Results

The first hypothesis was analyzed with a χ² test, and the second hypothesis was analyzed with a t test. The first hypothesis did not reflect a statistically significant difference, whereas the second hypothesis did reflect a statistically significant finding.

Overall, participants ranked the print-based patient education materials as less difficult than online patient education materials in a test of Hypothesis 1. Across 80 difficulty rankings, participants ranked print-based materials as less difficult in 43 cases and more difficult in 37 cases, which did not reflect a statistically significant difference (p = 0.45; Table 1).

In the second hypothesis, participants reported an average ranking of 6.03, or “somewhat easy,” for the online patient education materials, whereas they reported an average ranking of 5.48, or “easy,” for the print patient education materials, which reflected a statistically significant difference (p = 0.000015; Tables 2a and b). In the Likert scale, “very easy” translated to a value of 7, “easy” to a value of 6, and so on.

Discussion

This study is possibly the first published research to compare levels of perceived difficulty between online and print-based patient education materials. The findings concluded that first-year students at JMU perceive print-based patient education materials as less difficult than online patient education materials. The students’ reports that online patient education materials were more difficult to comprehend may be further supported by the observation that the online materials were written at lower reading grade levels, as demonstrated in the SMOG and the Flesch-Kincaid measurements, described earlier.

Precisely why online patient education materials might be perceived as more difficult is beyond the scope of the current project. However, hypotheses include distractions in online environments (eg, advertisements or other applications), the cognitive difficulties associ-
Differences in Perceived Difficulty in Print and Online Patient Education Materials

...also perceive online patient education materials as more difficult than print-based patient education materials. Larger-scale studies of perceived difficulty rankings of patient education materials among additional demographics or in more randomized settings will help to produce more generalizable information about the differences between print-based and online patient education materials.

The decision to group four popular student health topics together may have affected the results, in that there may be important differences between the topics. For example, the online or print format may have led to a larger divide in reported perceived difficulty concerning an individual topic than is reflected by the pooled information that was analyzed in this study. Furthermore, student health topics, such as those examined here, may not be representative of other sorts of patient education materials. Subsequent work may wish to examine a wide range of health topics individually and with relevant populations to better understand, in each case, whether patient perception of difficulty is influenced by presentation media.

Finally, it may be argued that because mononucleosis may sometimes be associated with promiscuity—a potentially charged topic—health information seekers may experience additional difficulties when learning about this topic. Conversely, a topic that does not invoke similar emotional responses, such as back exercises designed to help stave off back pain, may not include similar impediments to learning.

Conclusion

This research presents a starting point for future research on the influence of the delivery medium on the perceived difficulty of patient education materials. Larger-scale studies with more randomized samples may more conclusively demonstrate that online patient education materials are more difficult to comprehend. This study underscores the topic's importance and offers a model for a relatively easy-to-follow protocol. That is, other researchers might select randomized samples from relevant populations, choose patient education materials for examination that cover topics relevant to the studied population, and use Qualtrics or other survey software to compile and analyze valuable information about the examined patient education materials. As well, clinicians could conduct their own small-scale inquiries like the author's own to learn more about the dispositions toward patient education materials in various media.

As health care systems move toward a preventive focus and patient-centered care, patient education may receive increased attention. Thus, the effectiveness of delivery of patient education materials may become an increasingly pressing concern. Although knowledge that the delivery medium affects delivery is important, knowledge of how the delivery medium affects patient understanding may also help patient educators better create and distribute patient education materials. In particular, investigators might attempt to understand why online patient education materials are perceived as more difficult.

Additionally, a content analysis of current online patient education materials' use of best practices in Web writing and Web design may highlight important differences between writing designed for online and print-based contexts. These and other possible factors deserve attention to better understand why online patient education materials are perceived as more difficult, should that tentative conclusion receive further confirmation.

Disclosure Statement

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

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So They Understand

Use familiar words—words that your readers will understand, and not words they will have to look up. No advice is more elementary, and no advice is more difficult to accept. When we feel an impulse to use a marvelously exotic word, let us lie down until the impulse goes away.

— James J Kilpatrick, 1920-2010, American columnist and grammarian
Morning Mist
photograph

Brad Christian McDowell, MD

This photograph was taken at sunrise on Long Lake in Rocky Mountain National Park in Colorado.

Dr McDowell is a Plastic Surgeon at the Denver Medical Office in CO. More of his photography can be viewed online at: www.DiversityofVision.com.
**Introduction**

Total Health is a vision for the future of health care. Total Health means health of mind (behavior health), body (physical health), and spirit. Total Health includes investing in the determinants of health by leveraging nonmedical impacts as a catalyst for public health and primary care integration. In addition, the current model of behavior and physical health care is better than treating either alone but is not sufficient to promote deeper healing of underlying trauma. The goal of Total Health is to treat the entire person and to have a deep understanding of how a patient’s emotional history and community may contribute to disease.

To achieve Total Health we will need healthy people in healthy communities and a system to make lives better. We hope to make lives better by 1) measuring vital signs of health, 2) promoting healthy behaviors, 3) monitoring and treating disease, 4) spreading leading practices, and 5) creating healthy environments with our community partners. Best practices, spread to the communities we serve, will make health care more affordable, prevent preventable diseases, and save lives.

The key to achieving our goal of Total Health is behavior change of people and behavior change of communities (Figure 1).

Primary care practice has adopted a generalist approach in which physicians are trained in the medical model and in solutions to problems that typically involve advice, medical interventions, medications, or a referral to a specialist. Appointment times are designed to maximize access and decrease appointment demand. However, we know many patients have behavior health needs whose symptoms may exacerbate, complicate, or masquerade a physical condition. In addition, the co-occurrence of a behavior health issue may prevent a front-line physician’s ability to effectively treat or prevent chronic diseases such as obesity, diabetes, or coronary artery disease. Additionally, owing to current appointment time constraints, physicians often do not have the time or the skill set to effectively manage change in patients with behavior health needs.

The future focus of health care will be on wellness and integrated care in a medical home. The National Committee for Quality Assurance has defined criteria for a medical home to be a clinic that include standards that apply to disease and case management activities that are beneficial to both physical and mental health. These criteria include patient registries, case management, evidence-based guidelines, self-management support, and access to specialists. If these standards are applied, then quality outcomes and cost of care should improve.

Cost-effective care will depend on our ability to prevent diseases such as diabetes through early detection and treatment. The key to a successful wellness program will be the ability to

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**Figure 1. Total Health and the behavior medicine specialist.**

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**Phillip Tuso, MD, FACP, FASN, is the Care Management Institute Physician Lead for Total Health. E-mail: phillip.j.tuso@kp.org.**
Behavior Medicine Specialist

The BMS concept is not new. Large health care systems across the country, including the Department of Defense, have added behavior change specialists into the medical home.2 Traditionally, the BMS is a psychologist who works side by side with all members of the health care team to enhance effective preventive and clinical care for all patients. The BMS role in primary care is different from his or her role in a mental health clinic (Table 1). As a member of the primary care team, the BMS mainly focuses on helping the primary care physician manage chronic diseases, primary care physicians may benefit from integrating a psychologist called a behavior medicine specialist (BMS) into the medical home where they provide direct patient care.

**Behavior Medicine Specialist**

The BMS role in primary care is different from his or her role in a mental health clinic. The key to achieving Total Health in the future may be integrating behavior health services into the medical home. In this model, healthy people will be able to receive physical health services and behavior health services in the clinic where they see their primary care physician. Currently most physicians focus on physical illness and refer patients to specialty behavior medicine for behavior health treatment. To be more effective and to obtain behavior change interventions to help the physician manage chronic diseases, primary care physicians may benefit from integrating a psychologist called a behavior medicine specialist (BMS) into the medical home where they provide direct patient care.

**Table 1. Behavior medicine specialist compared with mental health specialist**

<table>
<thead>
<tr>
<th>Dimensions</th>
<th>Behavior medicine specialist</th>
<th>Mental health specialist</th>
</tr>
</thead>
<tbody>
<tr>
<td>Model of Care</td>
<td>Population-based consultation</td>
<td>Patient-based specialty focus</td>
</tr>
<tr>
<td>Primary customer</td>
<td>Primary care physician</td>
<td>Patient</td>
</tr>
<tr>
<td>Direct report(s)</td>
<td>Primary care physician</td>
<td>Psychiatrist</td>
</tr>
<tr>
<td>Team structure</td>
<td>Primary care team member</td>
<td>Mental health team member</td>
</tr>
<tr>
<td>Location</td>
<td>Primary care clinic</td>
<td>Mental health clinic</td>
</tr>
<tr>
<td>Goal(s)</td>
<td>Measure vital signs of total health</td>
<td>Resolve patient’s mental health issues</td>
</tr>
</tbody>
</table>

**Measuring Vital Signs of Health**

Measuring vital signs of health will help the BMS and the medical home team identify patients who will benefit from upstream behavior change interventions before a disease progresses to a more serious level of care. Although consensus on vital signs of health has not been determined, some that may make the list are shown in the Sidebar: Proposed Vital Signs of Health. Vital signs of health should include measurements around healthy eating and active living as these have been shown to help improve biometrics or risk factors for health like blood pressure, cholesterol, and body mass index.6 Tobacco is a well-documented vital sign for health, and lowering tobacco smoking rates may be the single most important intervention we can do to save lives and reduce health care costs.7,8 Finally, mental health screening will be a very important means to help identify and treat patients with anxiety and depression. A new tool called the Treatment Progress Indicator measures anxiety, depression, and functional status.9,10 This tool can be used to monitor an individual patient’s therapy and response to interventions while seeing how care provided by one provider compares with care provided by many providers. This type of report could be used to identify and spread best practices. Once vital signs of health are agreed on, programs can be developed that promote healthy behaviors and improve health care outcomes.
**Promoting Healthy Behaviors**

The BMS is a culturally competent psychologist who provides treatment for a wide variety of mental health, psychosocial, motivational, and medical concerns, including management of anxiety,19 pain,19,33 depression,19,33 substance abuse, smoking cessation,18 insomnia,19 diabetes,20 medication adherence,14 and psychological trauma.21 The BMS also provides support and management for patients with severe and persistent mental illness and tends to be familiar with psychopharmacologic interventions.21 The BMS coordinates care of mental illness with the primary care physician and psychiatrist, which may decrease the need to refer patients to a psychiatrist, reducing overall cost of care,24 and alleviating the stigma of patients seen in the mental health clinic.35 Randomized controlled trials show that disease management models using care managers are both clinically effective and cost-effective. Meta-analyses indicate that there is a cost offset of 20% to 40% for primary care patients who receive behavior health services. Notably, fewer hospitalizations result in significant cost reductions for patients with chronic physical illness and those with psychiatric diagnoses.26

**Monitoring and Treating Disease**

Finally, the BMS may help primary care physicians differentiate symptoms from disease and prevent unnecessary tests and referral to specialists. Even though mind-body relationships may seem obvious, physical health problems may be masked by psychosocial concerns. Physicians are trained to deal with diseases, and they often must evaluate symptoms that are not associated with a disease.

A retrospective 3-year study of 1000 patients in a general medical clinic setting provided a comprehensive picture of symptoms in the outpatient setting. The investigators identified 14 common symptoms: chest pain, fatigue, dizziness, headache, edema, back pain, dyspnea, insomnia, abdominal pain, numbness, impotence, weight loss, cough, and constipation. They found that 38% of the patients reported at least one of these symptoms, but an organic cause for the symptoms was found only 16% of the time. Ten percent of the symptoms were believed to be psychological in origin and 74% were of unknown cause.27

As the physician focuses on helping his or her population achieve their health care goals, the BMS helps the physician by advising on the best way to successfully change the behavior of a single patient and a population of patients (eg, diabetics with kidney disease). To accomplish these goals, the BMS and physician must agree on a common strategy for management of patients with behavior health issues. An example of this model of care is known as stepped care.28

The BMS will help facilitate systemic change within a primary care population to improve measurable outcomes. The BMS typically collaborates with physicians as a consultant to develop treatment plans and monitor patient progress. The BMS is needed in primary care clinics because research has shown that approximately half of all mental health care services are provided solely by primary care providers.29 Furthermore, primary care practitioners prescribe about 70% of all psychotropic medications and 80% of antidepressants.30 Another reason to integrate the BMS into the medical home is that chronic disease can contribute to behavior health dysfunction, and behavior health dysfunction can contribute to chronic disease. An example is depression, which can coexist in diabetes, coronary artery disease, obesity, and chronic pain. Studies have shown effective treatment of depression in primary care clinics can improve quality of life and measurable outcomes31 and may improve treatment adherence in chronic disease.32

In stepped care, patients who do not improve through the usual course of care will move to the next level of care where the intensity of service is customized according to the patient’s response. This may include cognitive behavior therapy or psychotherapy. The key is to use a viable model and to have a strong, positive connection between provider and patient that occurs in a timely manner and over an appropriate period. Likewise, a patient who no longer needs a higher level of treatment can step down to a milder intervention. An example of stepped care is shown in Table 2. To diagnose a behavior health issue, primary care providers often use evidence-based behavior health screening tools. One such screening tool is the Patient Health Questionnaire (PHQ-9) that is used to identify adults with depression.35 This nine-item questionnaire can be quickly completed, usually in one to two minutes.

Ideally, the physician confirms the depressive symptomology and then uses brief intervention algorithms for treatment. Many medical homes have begun to integrate the screening of depression as a routine practice in caring for patients with chronic illnesses. This process may begin with a brief two-question screening, using the first two questions of the PHQ-9. Patients with depression, as determined by answers to the PHQ-9 tool, may need different types of care on the basis of the severity of their illness. Patients with mild depression

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**Table 2. Stepped care for depression**

<table>
<thead>
<tr>
<th>Stepped care</th>
<th>Step One</th>
<th>Step Two</th>
<th>Step Three</th>
<th>Step Four</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depression</td>
<td>Mild</td>
<td>Moderate</td>
<td>Moderate-Severe</td>
<td>Severe</td>
</tr>
<tr>
<td>PHQ-9 score</td>
<td>1-9</td>
<td>10-14</td>
<td>15-19</td>
<td>&gt; 20</td>
</tr>
<tr>
<td>Intervention</td>
<td>Very-low-intensity intervention</td>
<td>Low-intensity intervention</td>
<td>High-intensity intervention</td>
<td>Very-high-intensity intervention</td>
</tr>
<tr>
<td>Health education classes</td>
<td>Cognitive behavioral therapy</td>
<td>Group therapy, brief psychotherapeutic interventions</td>
<td>One-on-one therapy, intensive outpatient and inpatient programs</td>
<td></td>
</tr>
<tr>
<td>Wellness coaching</td>
<td>Care management</td>
<td>Care management</td>
<td>Care management</td>
<td></td>
</tr>
</tbody>
</table>

PHQ-9 = Patient Health Questionnaire-9.
(PHQ-9 score, 1-9) may need only mild intervention whereas a patient with severe depression (PHQ-9 score, > 20) may need significant intervention. Stepped care protocols can be used to help patients understand the different options of care available to them according to the severity of their illness. Stepped care may include referrals to wellness coaches, online programs, or community resources not provided in the medical home (eg, faith-based counseling).

Historically, subjective evaluations were used to determine when a patient’s condition had improved. Since it is hard to standardize outcomes and set goals for subjective measurable outcomes, it is also hard to determine when a patient could be repatriated back to the primary care physician and to identify and to share best practices in care. As a result, access to behavior health has been a challenge at a time when it appears demand for behavior health service has been increasing. In the future, physicians and the BMS will use objective tools to help manage behavior health conditions much like primary care physicians use objective measures to manage chronic disease such as diabetes, high blood pressure, and obesity.

Spreading Leading Practices

Healthy people and medical homes will be the foundation to a healthy community. Self-management tools will help individuals understand what they need to do to be healthy. To achieve Total Health in the future, we will need healthy communities to maintain health. Because patients spend very little time in the medical home, our communities need to be healthy to support work being done by healthy people and healthy medical homes. Healthy communities will help people thrive where they live, learn, work, play, and pray. To accomplish this goal healthy people and medical homes will need to interact with healthy communities. The BMS is an important team member coming into primary care clinics. The BMS will help stimulate change in our communities by identifying and sharing best practices while also identifying gaps in care.

Creating Healthy Environments

Another key responsibility of the BMS will be to integrate the patient with community resources. Every day thousands of our patients require assistance from our clinical social workers and other staff members for basic necessities like food, housing, transportation, medications, dental services, and support groups. And every day organizations in our local communities assist us to help our patients by providing these needed services. Currently there is no organized systematic Web-based approach to locate these services that also allows for community organizations to see the services previously accessed by a patient. In addition, there is currently no objective way to know if a service provided to a community improves health care outcomes.

In the future, the BMS will have access to Web-based resources (wellness resource locators) to help match up a particular patient need with a specific community resource where people live, learn, work, play, and pray (Figure 1). The BMS will have the ability to locate and interact quickly and effectively with all appropriate services in the local healthy communities. In addition, the BMS will have the ability to track referrals, services, visits, and program enrollment. Outcome-based reporting will have the potential to demonstrate community and individual patient results. This program will help the BMS to identify community care gaps and best practices. Many communities have a plethora of support and social services, but locating these resources can be time-consuming and frustrating. This new program can be incorporated into stepped care as part of a comprehensive care plan that includes referrals for required services. The coordination of social services with clinical services should result in a significant increase in patient compliance and improved outcomes.

Discussion

Since the 1980s, research has improved our ability to recognize, to diagnose, and to treat chronic disease. In fact, many studies have found correlations between physical and behavior health-related problems. Individuals with serious physical health problems often have comorbid behavior health problems. In addition, it is estimated that as many as 70% of primary care visits stem from behavior health issues. For these reasons it makes sense at this time to integrate the BMS into the primary care clinics and medical homes. Delivering behavior health services in primary care can help to 1) minimize the stigma and delay of seeing a behavior health specialist in another building, 2) increase opportunities to improve overall health care outcomes, and 3) improve access to psychiatry services.

The disease management model of the future will be a system of care and interventions designed to optimize wellness and actually prevent disease. Effective implementation of this concept will reduce the overall cost of care and disease burden. Prevention is forever a part of disorder management. Key to this shift in our paradigm will be a use of BMS-directed self-management tools needed to be healthy and thrive. This will involve developing Web-based tools to help people measure their biometrics and behavior health index as well as tools to help them meet their biometric and behavior goals. Web-based programs will be interlinked with the BMS and the medical home. The final part of this strategy is linking the care of patients to community resources. This last strategy will be more difficult because it will involve Kaiser Permanente partnering with key community leaders to align resources to help both the patient and the communities to achieve Total Health.

Finally, in addition to universal screening for vital signs of health, there should also be an awareness of an alternative paradigm that emphasizes a focus on health and protective factors as opposed to a focus on problems and risk factors. A recent article looked at estimated deaths attributable to social factors in the US. Results showed that approximately 245,000 deaths in the US in 2000 were attributable to low education, 176,000 to racial segregation, 162,000 to low social support, 133,000 to individual-level poverty, 119,000 to income unequal-
ity, and 39,000 to area-level poverty. The authors concluded that the estimated number of deaths attributable to social factors in the US is comparable with the number attributed to pathophysiologic and behavior causes. Therefore, regarding improving the Total Health of populations, social factors may play a role in determining why certain populations are not meeting their vital signs of health outcomes goals. For this reason, behavior health clinics that address social issues along with behavior health issues have been established into medical settings at Northwestern Memorial Hospital (www.nmh.org/nn/bluhm-specialists-cardiac-behavioral-medicine) and Boston Children’s Hospital (www.childrenshospital.org/centers-and-services/behavioral-medicine-clinic-program/overview).

Conclusion
In population-based care, the entire population is the target. Our strategy should be to use a “wide net” approach aimed at serving the entire primary care population with emphasis on prevention and improving outcomes with effective accountable interventions. By going upstream in care, health care clinics may dramatically improve health care outcomes while reducing cost of care. For example, the BMS may help to introduce trauma and stress reduction education to help everyone better understand the relationships between illness and wellness. It is important to recognize that the current health care environment is promoting and rewarding quality improvement and the concept of the patient-centered medical home. Medical groups that want to grow will need to focus on disease prevention to lower health care costs. To accomplish this goal, health care leaders will need to work closely with community leaders to create healthy environments.

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References

Behavior Medicine Specialist


Trinity

Man is a trinity composed of three elements: the body, the heart, and the mind.

To each of these elements corresponds some need. The satisfaction of these needs, in full measure, constitutes the science of life and assures the greatest sum of happiness, which we can enjoy.

— Joseph-François Malgaigne, 1806-1865, French surgeon and medical historian
Mindful Mood Balance: A Case Report of Web-Based Treatment of Residual Depressive Symptoms

Jennifer Felder, MA; Sona Dimidjian, PhD; Arne Beck, PhD; Jennifer M Boggs, MSW; Zindel Segal, PhD

Abstract
Residual depressive symptoms are associated with increased risk for relapse and impaired functioning. Although there is no definitive treatment for residual depressive symptoms, Mindfulness-Based Cognitive Therapy has been shown to be effective, but access is limited. Mindful Mood Balance (MMB), a Web-based adaptation of Mindfulness-Based Cognitive Therapy, was designed to address this care gap. In this case study, we describe a composite case that is representative of the course of intervention with MMB and its implementation in a large integrated delivery system. Specifically, we describe the content of each of eight weekly sessions, and the self-management skills developed by participating in this program. MMB may be a cost-effective and scalable option in primary care for increasing access to treatments for patients with residual depressive symptoms.

Introduction
Patients treated for depression who continue to experience residual depressive symptoms (RDS) may be at increased risk for relapse and impaired long-term functioning. RDS are highly prevalent, with research showing that 90% of individuals who remit from depression experience RDS up to 1 year later. Although there is no definitive treatment for RDS, the most common approach is antidepressant or psychotherapeutic monotherapy. Sequenced, phase-specific approaches are less commonly observed in practice but show increased effectiveness for treating RDS compared with monotherapy. These approaches usually involve treating patients to remission with pharmacotherapy and then providing psychotherapy for RDS. Mindfulness-Based Cognitive Therapy (MBCT) has a strong evidence base for prevention of depressive relapse among recurrently depressed patients and has recently been shown to be effective when sequenced with pharmacotherapy for treating RDS. However, access to MBCT groups is limited owing to a lack of trained clinicians as well as to other barriers impeding dissemination of psychological treatments for mood disorders.

Previous research has demonstrated the efficacy of Web-based cognitive behavioral approaches for preventing depressive relapse among individuals in partially remitted patients and the feasibility of Web-based mindfulness programs. Mindful Mood Balance (MMB) (Dimidjian S, Beck A, Felder JN, Boggs J, Gallop R, Segal ZV, unpublished data, 2014) is an eight-session self-guided, Web-based program that incorporates the core content of in-person MBCT. MMB aims, in part, to address the care gap for patients with RDS. Consistent with MBCT, MMB targets RDS by teaching specific emotion regulation and depression self-management skills. In each session, skill acquisition is enabled via experiential and didactic eLearning modules that use text, video, interactive programs, and reflection questions. Between weekly Web sessions, skill consolidation is developed from daily home practice of session content, including mindfulness meditation. Program support with a master’s level clinical psychology doctoral student who was part of the MMB research team was available via phone, e-mail, or text messaging and was intended to facilitate engagement with MMB as well as to troubleshoot barriers to completing weekly sessions and home practice. MMB patients were invited to contact the support person with any questions or challenges. Furthermore, the MMB support person contacted patients who had not logged on to the program in a week.

Qualitative data provided by MMB patients during a study exit interview suggest that the MMB program is feasible and acceptable. An open trial examination of MMB demonstrated that patients significantly improved in depressive severity, which was sustained over six months; improved on proximal markers of relapse such as rumination and mindfulness; and engaged with program sessions and daily mindfulness practice. MMB also was associated with significant reduction in RDS severity compared with the quasi-experimental propensity-matched control group (Dimidjian S, Beck A, Felder JN, Boggs J, Gallop R, Segal ZV, unpublished data, 2014). Although informative at the group level, these reports provide limited detail about both the nature of the MMB intervention and how patients engaged with the program.
and the specific experiences of patients as they complete the program curriculum. Such information may be valuable for primary care physicians considering MMB as an option for patients with RDS either following or combined with maintenance pharmacotherapy. The aim of this case study is to describe a composite case that is representative of the course of intervention with MMB and its implementation in a large integrated delivery system.

Case Report

Patient Identification

This report describes a composite case that is representative of the course of intervention with MMB and its implementation with patients referred from primary care clinics in a large integrated delivery system. The composite case is based on the experiences of patients enrolled in an open trial study of MMB who were recruited via physician referral and informational materials made available in clinics. All participants in the open trial study of MMB had a history of major depressive disorder and therefore were at elevated risk for depressive relapse. RDS were not an eligibility criterion for the open trial study, but the composite case described in this case report experienced RDS.

Before participation in the MMB program, the patient, a woman in her late 40s, was treated for her third episode of major depression by her primary care physician. Antidepressant medication was prescribed (citalopram, 40 mg/day), guided by the Sequenced Treatment Alternatives to Relieve Depression algorithm for sequential pharmacotherapy. When the patient continued to experience symptoms of insomnia, anhedonia, guilt, and functional impairment, her physician referred her to the study for augmentation because no in-person MBCT group was available. The patient reported that she was interested in MMB because she was an “introvert” and the opportunity to access treatment at home appealed to her more than attending a group with other patients.

Patient Use of Mindful Mood Balance

See Table 1 for a brief description of the objectives for each MMB session. In the first session of MMB, titled “Finding Your Place Beyond Blue,” the participant started by watching an introductory video from one of the two MMB facilitators that is featured throughout the program. She responded to a list of difficulties she hoped MMB would help, such as “being caught in my mind” and “taking things too personally,” and viewed video clips of participants from an in-person MBCT group discussing their experience with the MBCT program. The primary focus in this session was differentiating between “automatic pilot,” described as acting without awareness, and mindfulness. These concepts were conveyed through text, illustrations, videos, and mindfulness practices. For example, the patient streamed an audio recording of her first mindfulness practice, mindful eating, during which she was encouraged to direct her attention first to the sensations of sight, texture, smell, sound, and taste of eating a raisin. For all audio recordings, the patient chose to download the recording as an mp3 file to save on her phone, which she found more convenient than logging on to the program to listen to recordings. She often listened to the recordings while traveling on the bus to work. After this practice and all others, the participant answered reflection questions in a text box. These questions asked about what she noticed during the practice and how she thought the practice related to preventing depression and staying well. The patient reported that this was a helpful way to concretize what she had experienced in the practice and that it was useful to be able to return to her notes later. The session ended with a video of one of the MMB facilitators discussing the home practice for the week.

In session 2, “The Body Scan,” the patient watched a “welcome back” video and was provided brief instructions about how to prepare for her first formal meditation practice. The patient participated in a 30-minute body scan practice, during which she moved her attention to specific foci in her body. After the practice, she was invited to describe what she noticed during her body scan and to reflect on how intentional deployment of attention contrasted to automatic pilot. She was also presented with a list of videos of

<table>
<thead>
<tr>
<th>#</th>
<th>Session topic</th>
<th>Session objectives</th>
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<tbody>
<tr>
<td>1</td>
<td>Finding Your Place Beyond Blue</td>
<td>What is mindfulness; recognizing automatic patterns of reactivity associated with sad mood; integrating brief informal mindfulness practice into daily life.</td>
</tr>
<tr>
<td>2</td>
<td>The Body Scan</td>
<td>Paying attention to specific regions in the body to develop a foundation of mindfulness skill; identifying links between interpretations of interpersonal events and emotional responses.</td>
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<tr>
<td>3</td>
<td>The Breath</td>
<td>Increasing awareness of how often the mind is busy/scattered.</td>
</tr>
<tr>
<td>4</td>
<td>Exploring the Landscape of Depression</td>
<td>Recognizing experiential avoidance; practicing ways to stay present and attentive in the face of difficulty; identifying depression’s early warning signs.</td>
</tr>
<tr>
<td>5</td>
<td>Facing Difficulties</td>
<td>Using mindfulness as the first step in responding effectively to difficult experiences; increasing awareness of the experience of emotions in the body.</td>
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<tr>
<td>6</td>
<td>Thoughts Are Not Facts</td>
<td>Learning to “de-center” from difficult thoughts; recognizing one’s personal patterns of recurring thoughts.</td>
</tr>
<tr>
<td>7</td>
<td>Building Your Plan of Action</td>
<td>Identifying activities that improve or deteriorate mood; developing action plans to implement during periods of high risk; using mindfulness practice explicitly to guide taking action.</td>
</tr>
<tr>
<td>8</td>
<td>Supporting Your Practice in the World</td>
<td>Emphasizing the importance of regular self-care routines; reinforcing links between mindfulness practices, well-being, and mood balance.</td>
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MMB aims to help patients move from a pattern of getting “sucked into” negative thoughts and emotions to stepping back from and observing them.

the group participants responding to the same questions. The patient found it reassuring that group members experienced many of the same challenges as she did during the practice, such as feeling sleepy, or judging herself when her mind wandered from the practice to thinking about what to make for dinner that night. Next, the patient completed an exercise that highlighted the relationship between thoughts and feelings. She listened to a scenario in which she imagined seeing a friend, waving at the friend, and getting no response. The patient generated interpretations, such as “she’s mad at me” or “she didn’t notice me,” and resulting emotions, including sadness or feeling neutral. This practice was reinforced with a home practice assignment involving the development of one pleasant event each day and the accompanying thoughts, feelings, and sensations. The following week, the patient reported that she enjoyed bringing her attention to pleasant events because she noticed things she would usually miss, and it helped her stay present in the moment of her experiences. She planned to continue this practice, although it was not assigned for home practice again.

Session 3, “The Breath,” began with a video of a group leader describing the breath as another door to awareness. The patient reported feeling connected to the MMB facilitators, whom she described as warm and compassionate. In this session, the patient listened to an audio recording of a sitting meditation practice. She noted the physical sensations that were present during her practice and how busy her mind was. The patient participated in 2 additional mindfulness practices, including a mindful stretching exercise and a brief breathing practice called the 3-Minute Breathing Space (3MBS). The 3MBS was described as a “mini-meditation” to be used at any point during the day and as a first step in dealing with difficult situations. While reviewing the previous week’s home practice, the patient noted that it was difficult to make time to complete the Body Scan each day and that she was looking forward to having a brief meditation option. Additionally, she responded to an e-mail check-in from the program support person to let her know that she was struggling to complete the daily home practice. The program support person explained that home practice is often difficult for program participants, especially in the first few sessions of the program. Together, the patient and program support person identified some ideas to support her practice, including adding her practice time to her calendar to protect the time, recruiting her spouse’s assistance with childcare during her practice times, and adopting a compassionate attitude with herself when unexpected challenges arose. She also experimented with completing the longer practices on the weekends and briefer practices during busy workdays.

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In session 4, “Exploring the Landscape of Depression,” the patient learned that understanding depression is a vital step in learning how to recognize it and to prevent it from gathering momentum. The patient interacted with a “playlist” of negative automatic thoughts frequently reported by individuals with depression and, she created a personalized playlist of thoughts that accompany her depressive episodes, such as “I’m a loser.” She noticed that the mindfulness practices increased her ability to observe the presence of these thoughts without getting pulled into disputing them.

Over sessions 5 and 6, the patient practiced applying her mindfulness skills to face painful thoughts, emotions, and bodily sensations as they arose throughout the day. Session 5, “Facing Difficulties,” cultivated this practice in several ways, including a sitting meditation during which she invited a difficulty into the practice, the presentation of a poem, and the use of the 3MBS in reaction to a negative event. At first, the patient reported to the program support person that she was concerned that focusing on negative events might hasten the onset of depression. Over time, she found that they actually helped her feel prepared to deal with negative events in the moment. She also reported greater awareness of the patterns of her thoughts and emotions and an ability to notice that they ebb and flow. She described moments when she was able to stand back a bit from her thoughts and emotions instead of reacting to them, and say, “Oh, there’s sadness again, and thinking I am inadequate. Interesting that I am feeling that.” She contrasted this to times in the past where she would instead say, “I can’t handle this! I’m never going to feel better!” and her thoughts would spiral out of control from there, worsening her mood.

In session 6, “Thoughts Are Not Facts,” she learned how emotions affect thoughts—for example, by seeing the world “through rose-colored glasses” when happy and as “the glass half empty” when sad. This session described mindful attention as a first step in responding to difficulties. An animation of four doors illustrated potential options for when she notices negative thoughts, emotions, or sensations. The first door, “re-entry,” was described as the door to take when simply bringing awareness to a difficulty makes it less troubling. The “body door” invited her to attend to the ways in which difficult emotions and experiences can show up as physical sensations. The “thought door” suggested bringing fine-tuned awareness to observing her negative thoughts versus getting pulled into them. The “door of skillful action” highlighted that mindful awareness of difficult experiences does not require passivity. Instead, sometimes it is important to take action in ways that bring a sense of pleasure, nourishment, or accomplishment. The patient reported to the program support person that she was surprised to notice that sometimes a 3MBS was all she needed to deal with difficulties, such as a disagreement with a coworker. Other times, taking a bath, folding laundry, or watching a favorite movie at the end of a tough workday was needed.

In sessions 7 (“Building Your Plan of Action”) and 8 (“Supporting Your Practice in the World”), the patient reflected on actions she could take to look after herself in the areas of energy, pleasure, and mastery. She identified her personal
relapse signatures and wrote a letter to herself to catalog the strategies she learned in the program. Specific activities she included as part of her wellness plan were as follows: “Call your sister if you notice your mood is starting to drop,” “Do one nice thing for yourself each day like buying a magazine you’ll enjoy reading during lunch,” or “Make plans to go for dinner after work with a friend.” The patient kept her wellness plan in a file on her computer to revisit easily and reviewed it with her spouse so he could support her wellness plan. The patient reported really enjoying the practical suggestions in the last three sessions of the program.

The patient logged on to the program 73 times in 61 days over the course of completing the 8 sessions of MMB. In addition to online completion of each weekly program session, the patient logged on to submit logs that recorded the frequency and duration of each daily home practice assignment. The patient submitted 38 daily home practice logs, and reported completing brief informal mindfulness practices 54 times (194 minutes) and formal meditation practices 32 times (755 minutes) over the course of 9 weeks. The program support person provided an average of 55 minutes of phone, e-mail, and text support time per patient over the 9 weeks of enrollment.

Discussion
This case study, based on a composite of representative experiences of patients who have completed the MMB program, describes the specific learning goals, interventions, and trajectory of patients who use MMB as a component of a treatment approach to RDS. The case study illustrates that skills are learned over the course of the program that focus on new ways of relating to negative thoughts, emotions, and sensations. MMB aims to help patients move from a pattern of getting “sucked into” negative thoughts and emotions to stepping back from and observing them. Both the mindfulness meditation and the cognitive and behavioral techniques support this important learning.

Additionally, the MMB program includes key elements that are designed to strengthen a sense of interpersonal connection with the learning context; these include both the videotaped group participants and group facilitators and the access to a phone coach. As described in the composite case here, patients often find their personal concerns, questions, and challenges during the practices reflected in the experiences of members of the videotaped group. This both is validating and provides an opportunity to learn via modeling from how others coped with the challenge. The live phone coach also augments such asynchronous support through providing concrete feedback about technical questions and troubleshooting challenges with the home practice. Future research may seek to establish the appropriate training threshold for the program support person. For example, could trained health educators be effective in this role? Finally, the program includes an anonymous forum to post questions and receive responses from the group facilitators; although not all patients use this feature, it represents an additional option for patients to receive program support.

RDS represent an important intervention target to prevent relapse for at-risk individuals following treatment for acute depression. Physicians may find that MMB is a useful clinical adjunct for RDS that could be used sequentially with pharmacotherapy. Physicians might elect to refer patients who have been treated either pharmacologically or with psychotherapy for an acute episode of major depression and who are showing signs of treatment response, or patients with residual symptoms.

At present there are insufficient data to indicate which patients would be most suited for MMB, but an open trial described elsewhere indicated a relationship between the number of sessions completed and the amount of benefit experienced. The question of suitability merits further study. One possibility is the MMB might be viewed positively by patients for whom in-person MBCT is not available, for those who cannot travel regularly or do not feel comfortable attending in-person groups or individual psychotherapy, or for those who would prefer non-pharmacologic options to long-term depression care management. Because MMB can be easily sequenced with ongoing antidepressant treatment, it may be a cost-effective and scalable option in primary care for increasing access to comprehensive care for RDS.

Disclosure Statement
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Mindful Mood Balance: A Case Report of Web-Based Treatment of Residual Depressive Symptoms


The Storm of Murk

The madness of depression is … the antithesis of violence. It is a storm indeed, but a storm of murk. Soon evident are the slowed-down responses, near paralysis, psychic energy throttled back close to zero. Ultimately, the body is affected and feels sapped, drained.

— Darkness Visible, William Styron, 1925-2006, American novelist and essayist
This photograph was taken in Denali National Park in Alaska. Our national parks preserve some of our country’s most magnificent natural wonders, and we are incredibly fortunate to have them.

After more than 32 years practicing medicine, Dr Cullen retired in 2012 as Assistant Chief of Pediatrics at Kaiser Permanente Folsom in CA. She is passionate about protecting national parks and public spaces and uses photography to encourage others to celebrate our natural world. More of her photography can be viewed at: www.myparkphotos.com/property/SallyCullen.html.
Thinking about Thinking and Emotion: The Metacognitive Approach to the Medical Humanities that Integrates the Humanities with the Basic and Clinical Sciences

Quentin G Eichbaum, MD, PhD, MPH, MFA, MMHC, FCAP

Abstract
Medical knowledge in recent decades has grown prodigiously and has outstripped the capacity of the human brain to absorb and understand it all. This burgeoning of knowledge has created a dilemma for medical educators. We can no longer expect students to continue memorizing this large body of increasingly complex knowledge. Instead, our efforts should be redirected at developing in students a competency as flexible thinkers and agile learners so they can adeptly deal with new knowledge, complexity, and uncertainty in a rapidly changing world. Such a competency would entail not only cognitive but also emotional skills essential for the holistic development of their professional identity. This article will argue that metacognition—“thinking about thinking (and emotion)”—offers the most viable path toward developing this competency.

The overwhelming volume of medical knowledge has driven some medical schools to reduce the time allocated in their curricula to the “soft-option” humanities as they tend to consider them an expendable “luxury.” Vanderbilt University School of Medicine, Nashville, TN, has moved away from the traditional conception of the medical humanities as “the arts,” composed of art, music, and literature, toward an approach that integrates the humanities with the basic and clinical sciences, based on metacognition. This metacognitive approach to the humanities, described in this article, has three goals: 1) to develop students as flexible thinkers and agile learners and to provide them with essential cognitive and emotional skills for navigating medical complexity and uncertainty; 2) to elicit in students empathy and tolerance by making them aware of the immense diversity in human cognition (and emotion); and 3) to integrate the humanities with the basic and clinical sciences.

Through this metacognitive approach, students come to understand their patterns of cognition and emotions, and in the group setting, they learn to mindfully calibrate their thinking and emotions. They gain a humbling appreciation of the fallibility of the human mind/brain and how cognitive biases and misperceptions can lead to medical error. They come to appreciate the complex interplay between cognition and emotion, and the importance of cognitive monitoring and emotional regulation.

In the group setting, students also gain a sense of perspective of their thinking patterns and emotions in relation to those of their peers. Perspective taking and mindfulness engender tolerance and empathy, which ultimately serves as a platform for working collaboratively in teams as medical professionals. Students become aware of the social context in which thinking and learning occur, and this further shapes their professional identity. Thinking, learning, and interacting in the group setting ultimately induces a shift from self-preoccupation and an individualistic approach to knowledge toward an appreciation of collective cognition and empathy towards others.

In this article, I describe the metacognitive approach to the medical humanities at Vanderbilt University School of Medicine and how it is designed to develop students as agile learners and flexible thinkers with the mindful capacity for cognitive and emotional monitoring and regulation. Thinking and learning in the group setting of the colloquium ultimately also fosters the student’s professional identity.

Introduction
In a rapidly changing world of increased complexity, medical educators should direct efforts at developing in students a competency as flexible thinkers and agile learners with the capacity for navigating this complexity and its contingent uncertainties. Such a competency would entail not only cognitive but also emotional skills essential for the holistic development of the students’ professional identity.

This article will argue that metacognition—“thinking about thinking (and emotion)”—offers the most viable path toward developing this competency. In this article, I describe the metacognitive approach to the medical humanities at Vanderbilt University School of Medicine (VSUM), Nashville, TN, and how it is designed to develop students as agile learners and flexible thinkers with the mindful capacity for cognitive and emotional monitoring and regulation. Thinking and learning in the group setting of the colloquium ultimately also fosters the student’s professional identity.
The Conundrum of the Humanities in Medical Education

The germane role of the humanities in medical education remains a topic of ongoing controversy. As the volume and complexity of medical knowledge continues to surge, some educators may view the humanities as an expendable luxury and reduce the time in the medical curriculum allocated to these disciplines. Others may see a vital role for the humanities in eliciting and nurturing in students the essential Hippocratic qualities of caring and empathy. The humanities are frequently taught in medical schools to provide a rehumanizing counterbalance to the burdensome weight of scientific knowledge that students must memorize to pass their examinations, or as Bleakley¹ says: "as compensation for an overdose of science.” Be this as it may, the humanities and sciences are usually still taught in medical schools and universities as “silo” disciplines. Separating the sciences and humanities into what Snow² famously called “the two cultures” has, however, created a false dichotomy in knowledge.

The College Colloquium at VUSM seeks to integrate the sciences and humanities into a unified tapestry of knowledge. The colloquium is based on the premise that there are not “two cultures” but only a single “culture” of knowledge that is mediated through cognition and the human brain. The intellectual framework of the colloquium has its foundations in metacognition, a higher order of human cognition that is less formally referred to as “thinking about thinking.”³ Thinking and metacognition, or thinking about thinking (and emotion), happen in the brain, the physical manifestation of the mind, which is the epicenter of our cognitive processes, our consciousness, as well as our sense of morality.⁴ However, modern neuroscience now disputes whether the brain and mind are separate entities (a discussion beyond the scope of this article). Panksepp and Biven, in their landmark book The Archaeology of Mind: Neuroevolutionary Origins of Human Emotions, write that “modern neuroscience ... has revealed that it is no longer useful to distinguish between the mind and the brain, although we surely must distinguish between types of minds and types of brains.”⁵⁶

With the ongoing increase in knowledge, medical education will be impelled to abandon the clichéd fire hose image of filling students with factual information toward a competency-based approach that develops students into agile learners and flexible thinkers. Students possessing this competency will have a deeply enhanced understanding of how the mind works.⁸ They will come to have a keen sense of what they know and do not know, be more adept at navigating complexity and dealing with uncertainty, and they will be more skilled at asking the “right” questions. Moreover, with a sense of their own cognitive fallibility and of the brain as a fallible biologic organ, such students will likely be more circumspect and humble about their learned knowledge. They will be mindful of the context and the social setting of their learning, and (as will be argued) will also be more adept at regulating their own emotions. Such cognitive skills, monitoring, and mindfulness will have a positive impact on their well-being as well as their ethical sensibility and sense of professionalism. For these reasons, we at VUSM view metacognition as the foundation of the colloquium and as an emerging competency in which students should begin developing early in their medical education.

Structure and Rationale of the College Colloquium

I developed and innovated the College Colloquium in a more comprehensive form at a previous medical school and adapted it at VUSM as a course consistent with the goals of its new curriculum (Curriculum 2.0 introduced in 2013). Curriculum 2.0 at VUSM was designed in part to cope with the rapid growth in medical knowledge and complexity that can no longer be comprehensively accommodated in the curriculum, and instead to provide students with a more individualized and customized approach to their education. Curriculum 2.0 at VUSM reduces the basic science component of the traditional US medical curriculum from 2 years to about 15 months in length, and shifts the bulk of the clinical clerkships from third year to the second year of the curriculum. The third and fourth years are devised as an individualized learning plan in which students can tailor their education in the direction of their choice of medical specialty. The goal of the colloquium is to develop students to be more agile learners and flexible thinkers. In place of traditional rote memorization, students are taught to become competent conceptual thinkers and to develop a scientific and holistic understanding of how the mind works. The colloquium is situated in the 4 “colleges” that comprise the “learning communities.”

These “college” learning communities are designed to provide an environment in which students can interact in smaller groups, in a trusting space among peers and mentors, to hone their thinking and emotional skills and in which they can also develop and nurture their professional identity. Two college mentors oversee each college and serve as advisors to the students in their college and as facilitators during discussions in the colloquium. In the college community, students learn to trust one another and to develop their cognitive, emotional, and collaborative skills as medical professionals.

The College Colloquium meets for two to two-and-a-half hours each week. The first half hour is devoted to a “context talk,” a short talk delivered to the class by the course directors or associated faculty experts. The context talks are designed to provide a context around the required readings by placing the week’s colloquium topic in a broader learning and intellectual framework, and by posing challenging questions for discussion in the ensuing within-college discussions. Rather than leaving the context of learning implicit, the context talks situate the colloquium topics in the setting of their scientific and sociocultural/ethical interrelationships. The role of the expert teacher is not to provide answers, but to be challenging and to open up exploratory avenues for students to navigate in the participatory and trusting setting of their colleges.

After the talk, students break up into their separate colleges to discuss the assigned readings and possibly questions triggered by the context talk. The colloquium as a course starts with foundational readings and discussions on topics in metacognition
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Selected Readings in Meta/Neurocognition Assigned in the College Colloquium at Vanderbilt University School of Medicine

Books

Articles

and critical thinking, and in subsequent semesters proceeds to topics in professionalism, medical ethics, leadership, and health care systems. (See Sidebar: Selected Readings in Meta/Neurocognition Assigned in the College Colloquium at VUSM, which presents examples of the kinds of readings prescribed for the foundational colloquia on metacognition.)

For promoting open communication and for generating a sense of community, the seating arrangement of the student (and mentor) participants in the colloquium is important. The students sit together with their mentors in a circle facing each other across an open space. (No electronic devices or social media are allowed.) The college mentors facilitate the discussions. Students are required to submit and to disseminate a carefully considered question on each of the week’s readings to the college the evening before each colloquium, to drive discussions and to give the student practice in formulating creative questions.

Most medical humanities courses in the US, it appears, are not summatively assessed, and many are not even required courses. This is fairly well known among directors of medical humanities programs and is also frequently discussed at conferences on medicine humanities, such as the Project to Rebalance and Integrate Medical Education (PRIME) conference in 2012. Requiring attendance and assessing such courses, it is commonly thought, may further alienate students. Paradoxically, however, such tentativeness may compound the perception of the humanities as being a soft option and inferior to the basic science courses. Like the science courses at VUSM, the colloquium is a required, fully assessed, and evaluated course. Rather than having a separate examination, essay-style questions from the colloquium are integrated into the science end-block examinations. The questions are aimed at assessing whether students have intellectually integrated and assimilated the context (rather than just the content) of the readings into their own thinking and can communicate their thinking clearly. As attributed to William Osler, who spoke of absorbing readings: “It is much simpler to buy books than to read them and easier to read them than to absorb their contents.”

The Meta/Neurocognitive Approach Integration of the Humanities with the Basic and Clinical Sciences

The overemphasis on factual knowledge in medical education has a stifling effect on learning and thinking. Philosopher Nussbaum insists that education should teach us not to be just passive assimilators of facts but to be expert thinkers: “[E]ducation is not just about the passive assimilation of facts and cultural traditions, but about challenging the mind to become active, competent, and thoughtfully critical in a complex world.”

Medical students and trainees have a tendency to overemphasize and value the importance of factual knowledge. Many seem to consider a sound command of factual medical knowledge as the hallmark of the outstanding physician. From this perspective, students may perceive the humanities as subjective or a soft option compared with the objective sciences and therefore may relegate the humanities to an inferior standing.
The lopsidedness between the sciences and the humanities in the medical curriculum is antithetical to the notion of medicine as both a science and an art, and runs counter to a culture of producing well-rounded empathetic physicians. Bleakley et al argue that the humanities have a vital role to play in the process of learning the medical sciences: “[W]e see potential for learning medicine as imaginative and aesthetic science where medical humanities is reformulated as the process or perspective that creates the conditions of possibility for such learning of science to occur.”

Analogously, just as the humanities can have a vital role in creating the conditions for the effective learning of science, so too can the rigor of the scientific method be brought to enlighten the humanities. For example, investigators have used medical imaging to study how the brain processes stories and literature. Research shows that a group of neurons in the brain known as mirror neurons are involved in the processing of stories. These neurons also play a role in empathy. One therefore-sees that the sciences and humanities are part of an integral field of human knowledge. Harvard biologist Wilson refers to this integration of human knowledge as “consilience.”

The colloquium aims to redress this curricular imbalance between the sciences and humanities. The metacognitive approach—increasingly informed through neuroscience—provides the intellectual framework and focusing lens for integrating the sciences and humanities. The colloquium runs in parallel each week with the science curriculum allowing for a bidirectional integration of subject matter between the colloquium and science courses. For example, course content on the genetics of breast cancer may be included in a colloquium session, “How We Perceive,” to illustrate pitfalls in perception that can occur in reading a diagnostic mammogram. A science course on genetics conducted in parallel might include content from the colloquium about the ethics of genetic diagnosis and/or a discussion on how the mind navigates the kinds of cognitive complexity seen in genetics, such as the problems this complexity might pose for effective thinking and learning or the uncertainties entailed in genetic complexity that may result in mistakes and medical error.

The colloquium challenges the notion of the “two cultures” as separate cultures and instead attempts to integrate the humanities and sciences into a unified medical curriculum. Kulasegaram et al recently suggested that “cognitive science” (“cognitive activity occurring within learners”) should serve as the vehicle for integrating the basic and clinical sciences. The metacognitive approach, especially as informed by modern neuroscience, provides the most tenable approach to breaking down silos of knowledge in medicine and science, and to integrating the humanities and sciences in the medical curriculum.

Metacognition as an Interplay of Cognition and Emotion

Quirk defines metacognition as “the ability to think about one’s thinking and feelings and to predict what others are thinking.” A substantial body of literature from the neurosciences and cognitive sciences has challenged the assumption that cognition and emotions are processed along separate noninteracting pathways in the brain. Instead, there is a major interplay between cognition and emotions, and neither can be understood in isolation. Neurobiologist Damasio argues that “when emotion is entirely left out of the reasoning picture … reason turns out to be even more flawed than when emotion plays bad tricks on our decisions.”

Cognition affects emotion, and emotions in turn shape cognitive processes such as perception, memory, learning, and decision making. In medicine, we have underestimated the complex interplay between cognition and emotion in effective decision making and how this interplay underlies a sizable component of medical error.

The metacognitive approach of the colloquium therefore encompasses the study of not only cognition but also the emotions. At VUSM, we examine the complex interconnections between cognition and emotion with a focus on the role of emotions in the lives of patients and physicians. Thus, the metacognitive approach enhances not only students’ thinking and learning skills but also develops their professional identity by including topics that affect the students’ emotional lives, such as emotional regulation, coping and resilience, and empathy. Specific sessions in the colloquium are devoted to each of these and additional similar topics.

Metacognition, Neuroscience, and Cognitive Fallibility

The study of metacognition has traditionally fallen under the disciplines of philosophy and psychology. Advances in neuroscience and neuroimaging have more recently shed light on the biology of brain function during a variety of specific cognitive tasks, transforming the field of metacognition into neurocognition. Many of the topics and required readings in the colloquium therefore derive from writings and research in neurocognition. We at VUSM thus term this emerging field meta/neurocognition. A selection of readings is shown in the Sidebar: Selected Readings in Meta/Neurocognition Assigned in the College Colloquium at Vanderbilt University School of Medicine.

Modern neurobiology is providing the impetus for unifying previously disparate fields of knowledge. In The Marketplace of Ideas, Menand of Harvard University suggests:

“The most important intellectual development in the academy in the 21st century has to do with the relationship between the life sciences—particularly neurobiology, genetics, and psychology—to the fields outside the natural sciences, such as philosophy, economics, and literary studies. Neurobiology is integrating the sciences and humanities. Fields of investigation previously falling mostly in the realm of philosophy and psychology, such as perception, learning, and decision making, we can now examine using the rigorous methods of science.” To some, this reductionism may be unappealing, but as Wilson forcefully argues in his book...
Consilience: The Unity of Knowledge, science can actually enhance our appreciation of the humanities. As a further manifestation of how the metacognitive approach integrates the humanities with the basic and clinical sciences, students in the colloquium will simultaneously in the curriculum learn about brain anatomy and function as well as neuroscience and pathology.

Through the study of neurocognition, students become aware that the brain does not record reality like a camera. Instead, it constructs models of the world that are sufficiently effective for survival. As neuroscientist Eagleman states:

*One of the most pervasive mistakes is to believe that our visual system gives a faithful representation of what is “out there” in the same way that a movie camera would.*

... [Brains reach out into the world and actively extract the type of information they need.]

The brain doesn’t need a full model of the world because it merely needs to figure out, on the fly, where to look, and when.

Colloquium sessions on perception, learning, decision making, and medical error impress on students the brain's cognitive fallibility and proneness to error. Such an awareness of the brain’s cognitive fallibility is generally humbling. It instills in student learners a mindfulness about their own potential for being “wrong” about their beliefs, their perspectives on the world, and their decisions. For many students, this realization is initially unsettling. They begin to worry about their own potential for medical error as they progress to their clinical years. This realization, however, also impresses on them the relevance to their education of the colloquium's metacognitive approach and the importance of mindfulness and ongoing cognitive and emotional monitoring.

**Critical Thinking, Cognitive Flexibility, Learning Agility, and Mindfulness**

*Critical Thinking and the Shape of Thought*

Medical students in general are academic high achievers, having scored at the top of their class in college examinations and in medical school admission tests. Yet they are generally not trained as critical thinkers. Critical thinking as a discipline is seldom taught in US schools and colleges. Kuhn,

*in her book Education for Thinking,* writes:

Many students are unable to give evidence of more than a superficial understanding of the concepts and relationships that are fundamental to the subjects they have studied... It is possible to finish 12 or 13 years of public school education in the United States without developing much competence as a thinker.

Critical thinking is defined by Paul and Elder as “the art of analyzing and evaluating thinking with a view to improving it.” In the colloquium, we emphasize the “deliberate practice” (see Sidebar: Deliberate Practice) of critical thinking both as an intrinsically important skill, and to emphasize that the humanities are no less rigorous as intellectual disciplines than the sciences.

Sessions on critical thinking include topics on the pitfalls of logic and the analysis of various forms of cognitive heuristics and biases. Students learn to distinguish “straight” from “crooked” thinking, how to recognize the multifarious forms of cognitive bias, and how the quality of their thinking has an impact on medical error and the effective practice of medicine. Included in the readings for these sessions are seminal works by Kahneman, Kahneman and Tversky, Gardner, and de Bono, as well as physician-authors, such as Groopman and Montgomery, who discuss how physicians think and the kinds of cognitive errors physicians make.

Besides critical thinking, students are also taught about the uses and abuses of intelligence testing. The colloquium emphasizes that intelligence is not a monolithic human attribute but that there are “multiple intelligences” as described in Gardner’s Frames of Mind: The Theory of Multiple Intelligences. Having excelled in college examinations and in standardized tests, medical students frequently hold a monolithic view of intelligence—the fast and analytical type that Gardner terms analytical intelligence. They are surprised but often also encouraged to learn about Gardner’s other equally valid forms of intelligence that include kinesthetic, music, linguistic, intrapersonal, and interpersonal intelligences.

Students in the colloquium also discuss the pros and cons of group thinking and, in small groups, engage in exercises in creative thinking. One such creative thinking exercise is de Bono’s six thinking hats,” in which individuals in small groups assume different thinking roles according to the color of the hat they are given to wear.

As a further example of integration between the humanities and sciences, specific colloquium sessions focus on the biology of the brain and how specific neuropathologies can shape patterns of thinking. For instance, we assign readings on how brain stroke can distort thinking and personal identity (eg, Taylor, My Stroke of Insight); the effects of Alzheimer disease on memory and identity; and the biologic correlates of autism and other mental disorders. In addition, we explore the biologic basis of imagination and how imagination drives
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Cognitive Flexibility and Learning Agility

The concept of cognitive flexibility has been well studied, although there is no consensus on a precise definition. Dennis and Vander Wal\(^{29}\) posit a general definition of cognitive flexibility as the ability to “switch cognitive sets to adapt to changing environmental stimuli.” The authors developed an instrument, the Cognitive Flexibility Inventory, which is designed to measure three components of cognitive flexibility: 1) the tendency to perceive difficult situations as controllable; 2) the ability to perceive multiple alternative explanations for life occurrences and human behavior; and 3) the ability to generate multiple alternative solutions to difficult situations. Dennis and Vander Wal\(^{29}\) use this inventory to determine cognitive flexibility as a coping mechanism to assess the ability of individuals to “successfully challenge and replace maladaptive thoughts with more balanced and adaptive thinking.”

In the colloquium, we use cognitive flexibility to determine how rigidly students adhere to their beliefs and/or preconceived notions and ideas, as well as their capacity to gain new insights and willingness to change their mind. We have applied the Cognitive Flexibility Inventory to assess and monitor whether students change in their capacity to think more flexibly and adaptively (see the later section, Evaluation of the College Colloquium).

An analogous term, learning agility, pertaining to flexibility in learning, was coined by Lombardo and Eichinger\(^{10}\) to connote the “the willingness and ability to learn from experience, and subsequently apply that learning to perform successfully under new or first time conditions.” To function effectively in a world of uncertainty and complex medical knowledge, the physician of the future will, we at VSUM postulate, need to have the capacity for “cognitive flexibility” and be an “agile learner.” These skills are therefore deliberately cultivated and nurtured in the colloquium.

The discussion format of the colloquium encourages students to learn from the perspectives of their peers and mentors, and to integrate this learning into their own experience. The course impels students to develop the flexibility to adapt their own thinking and perspectives to the particular contexts (see Sidebar: Mobile Mind).

Cognitive flexibility includes such mental attributes as the capacity to see the world from different perspectives and the capacity to be sufficiently flexible to change one’s mind. It entails the ability to recognize one’s cognitive biases and to see how the subjectiveness of one’s beliefs can obfuscate clear thinking. Cognitive flexibility is also an inherent quality of agile learning that the colloquium promotes as an emerging competency in medical education.

As a consequence of the battery of tests medical students have taken, they may tend to overvalue factual knowledge over the nuanced, conditional, and contextual processes of thinking. Students in the colloquium may be perturbed to learn that “facts” are not immutable but that medical knowledge churns over and changes, and its veracity is constantly reevaluated. Robinson\(^{22}\) showed that medical knowledge doubles every 5 years and that approximately 90% of medical information becomes worthless and of little value in about 10 years from the date of publication.

The emphasis in medical education on factual information is misguided and can constrain cognitive flexibility and suppress curiosity. In her acclaimed essay, “Curiosity,” Fitzgerald suggests how the weight of factual knowledge in medical education can stifle student curiosity: “Medical education itself suppresses the expression of curiosity, emphasizing examinable facts rather than more ineffable thought processes in order to provide reproducible experiences for students.”

Mindfulness and Mindful Learning

The colloquium seeks to amend this static approach to knowledge. Instead, we encourage students to be flexible, skeptical, and curious. To this end, a key attribute cultivated in the colloquium is mindfulness. Siegel has defined mindfulness “in its most general sense [as being] about waking up from a life on automatic and being sensitive to novelty in our everyday experiences.”

Students in the colloquium discuss readings on mindfulness in medicine and the qualities of mindful learning.\(^{24,26}\) In contrast to the learning of static facts and absolutes, mindful learning encompasses the ability to think in terms of conditions and contexts. In his book, The Mindful Brain, Siegel describes this difference between mindful learning and the learning of factual knowledge as follows:

> When our minds lock onto something as being absolute, it enters our memory stores in a very different form from the way it would were we to be tentative about the contexts and conditions in which we learned. ...
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We can take a "fact" and create a rapidly accessible node of neural firing patterns ... but with conditional statement, that neural nodal point must have far more intricately established connections for it to meet the criteria for inclusion into the scaffold of knowledge. ... The conditional presentation of mindful learning engages a more complex set of neural associations, making it accessible in the future for retrieval in more flexible and adaptive ways.

Mindfulness and mindful learning are antidotes to the absolutes of factual learning and serve to sustain curiosity and cognitive flexibility. It would seem intrinsically valuable for physicians to cultivate these attributes of mind to effectively navigate the immense complexity of medical knowledge and the associated uncertainty in diagnosing and treating patients. The dynamism and flexibility associated with conditional, mindful learning in contrast to the rote learning of factual knowledge trains physicians to know what they do not know, to ask the right questions, and ultimately to make better-informed decisions.

Professionalism and Professional Identity

Medical educators have tended to view professionalism as being driven primarily by particular behaviors. As a result, the focus on improving professionalism in medical schools has been on identifying undesirable behaviors with the aim of eliminating these behaviors. Quirk146 points out that this focus on defining and evaluating behaviors associated with professionalism "does not adequately ensure the depth of understanding necessary to deal with the new professional challenges for generations of physicians to come." Whether this approach has been effective yet is doubtful because unprofessional behavior in medicine has not appreciably declined over the years.

Professionalism in medical schools is frequently approached in a manner that is static and prescriptive. What is needed instead is a dynamic mindset that is aimed at understanding the root causes of behavior and that encourages behavioral self-monitoring, reflection, and emotional regulation. Wear and Castellani57 propose a dynamic view of professionalism and suggest that professionalism should be viewed not as a series of isolated behaviors or personality character traits but instead as "an ongoing self-reflective process involving habits of thinking, feeling, and acting."

The understanding of professionalism has been problematic in part because of our incomplete understanding of the scientific underpinnings of behavior. Neurocognition offers a unique opportunity to understand the specific drivers of human behavior more accurately and scientifically, and it provides a more methodical and humanistic approach to modifying unprofessional behavior.

Professionalism: Respectful Disagreement and Perspective Taking

As individuals, we each hold differing perspectives of the world. As German philosopher Arthur Schopenhauer famously said, a danger of individuals rigidly adhering to their own perspectives, is "Every man takes the limits of his own field of vision for the limits of the world." A premise of the colloquium is that students and trainees will function more effectively in teams if they develop the capacity to view social contexts and medical situations from different perspectives. This ability to hold different and contrasting perspectives is an attribute of metacognitive capacity and skill.

The colloquium exposes students to the variegated perspectives of their mentors and peers.2 In addition, students receive ongoing explicit or implicit feedback on their own views and behaviors during colloquium sessions. The thoughts, opinions, and beliefs they express are further validated or negated in varying degrees by their college peers. Students will inevitably compare their perspectives with those of their peers and quite likely modulate or recalibrate their perspectives. (As argued later in the Mindfulness, Self-Monitoring, and Emotional Regulation section, this change in perspective also ultimately leads to behavior modification and emotional self-regulation.) Quirk refers to this capacity as "collective perspective taking" and associates this capacity with emotional self-regulation:

An essential capability of professionalism is acceptance of one's role and regulation of role-related behaviors within the group. ... Collective perspective-taking and self-regulation capabilities are often how high-profile professions are judged "from the outside" by the public.159-64

Collective perspective taking instills in students a respect for the views and opinions of their peers and others (see Sidebar: Mobile Mind). In the colloquium, we encourage students to engage in vigorous debate and to disagree with each other in a respectful manner. The term we use in the colloquium is respectful disagreement. Allowing students the intellectual and emotional space to respectfully disagree with each other's ideas and beliefs is essential for critical and creative thinking and is important in their development as medical professionals. In medical practice, these future physicians will find themselves disagreeing with colleagues, coworkers, and patients. Students therefore need to develop the skill to disagree in a professional and respectful manner and to calibrate their thinking against the thinking of their colleagues.

Professionalism: Identity and Leadership

Disagreeing with one's peers and going against the group can take courage. This topic is explored in the colloquium. In a session on "How We Perceive/Misperceive" we assign readings by neuroscientist Berns,3885-105 in which he describes imaging experiments based on the well-known findings of Solomon Asch in the 1950s. These studies showed how individuals, rather than disagreeing with the group about their own valid perceptions, will change their mind and adopt an incorrect perception to conform with the group opinion and allay their fears of opposing and being ostracized from the group. Challenging a group takes courage, a core quality of leadership. A leader would do best knowing when to conform with, and when to challenge, the group.47 Understanding, through neurocognition, the origins of the fear associated with
challenging the group can be empowering to the individual and works to diffuse such fears associated with courageous leadership. Thus, the neurocognitive approach of the colloquium is ultimately also an education in leadership. Such group skills are central to working in medical teams and to the student’s developing professional identity.

Cognitive Diversity, Empathy, Mindfulness, and Emotional Regulation

Cognitive Diversity and Empathy

A major objective of the colloquium is to make students aware of the immense diversity in human cognition (or cognitive “wiring”). The realization of such diversity triggers a mind shift in the individual’s self-centeredness toward an other-centeredness, leading to a deepening in tolerance and empathy.

In her book Not for Profit: Why Democracy Needs the Humanities, philosopher Nussbaum suggests how essential to the humanities is this ability to view the world from the perspective of a “person different from oneself”:

Citizens cannot relate well to the complex world around them by factual knowledge and logic alone. … [W]hat we can call the narrative imagination … means the ability to think what it might be like to be in the shoes of a person different from oneself, to be an intelligent reader of that person’s story, and to understand the emotions and wishes and desires that someone so placed might have. The cultivation of sympathy has been a key part of the best modern ideas of democratic education.1

A key function of the metacognitive approach to the humanities is therefore to help students relate to the world through the eyes, emotions, and perspectives of others. This capacity elicits and nurtures in medical students the essential professional quality of empathy. Students often remark on how their perspectives change during the colloquium, rendering them more tolerant to alternate viewpoints and empathic toward others.

Mindfulness, Self-Monitoring, and Emotional Regulation

Students in the colloquium receive from their peers and mentors direct and indirect feedback on the views and opinions they express in discussions, and on their general conduct. Such feedback from others can be a major impetus for behavior modification, but it is nonetheless usually sporadic and can also be misconstrued. For this reason, self-monitoring is an essential skill for effective behavior modification. Epstein et al define self-monitoring as “an ability to attend, moment to moment, to our actions; curiosity to examine the effects of those actions; and willingness to use those observations to improve behavior patterns and patterns of thinking in the future.”

Self-monitoring is, however, also susceptible to misjudgment. As Epstein et al write in their seminal article, “Self-Monitoring in Clinical Practice: A Challenge for Medical Educators”:

Self-monitoring requires the ability to distinguish high quality data from imagination and projection. The task is difficult because the mind is ultimately both the object and the instrument of assessment, and our mental processes embed idealization directly within our self perceptions. Nonetheless, Epstein et al suggest that self-monitoring provides a solution to the problem of integrating internal and external data to assess personal performance and improve learning. It enables physicians and trainees to follow and assess their own learning and mental processes for the purpose of improving clinical practice.

The deliberate practice of mindfulness that is nurtured and explored through readings in the colloquium is one of the main vehicles through which students accomplish such self-monitoring. Through mindful practice, as Epstein describes it, students learn to self-regulate their emotions by bringing to consciousness their deeply held values and knowledge, and then integrating these with new information and perspectives. Self-monitoring and emotional regulation are also essential components of the resilience that physicians may need to sustain them through the uncertainties and emotional vicissitudes of medical practice.

David and Congleton coined the term emotional agility to describe “the ability to manage one’s thoughts and feelings … in a mindful, value-driven and productive way … in a complex, fast-changing knowledge economy.” The authors expound this concept in the setting of business leadership to describe the ability to apply effective inner strategies to mindfully control negative thoughts and feelings that “sap important cognitive resources” during meetings and management experiences. For purposes of the colloquium, the term provides a helpful link with the concepts of cognitive flexibility and learning agility (discussed earlier) to suggest again how metacognition encompasses the capacity to monitor both cognition and emotion. Of note, Flavell does not use the terms emotional regulation and emotional agility but suggests a similar notion when he writes about “monitoring of … memory, comprehension and other cognitive enterprises.”

Reference


Narrative Medicine: A Metacognitive Tool for Eliciting and Nurturing Empathy

We introduce the topic of narrative medicine early in the colloquium to emphasize that medicine is not just about science but that the medical narrative is also important (and patients’ “stories matter”). Many students are perplexed, and some are irked, to hear that the patient’s “story” can at times have a
neurocognitive benefits. More recently, neuroscience has shed light on how the brain processes literature, a humanistic discipline. Such studies again demonstrate how the sciences and humanities should not be viewed as “silo” disciplines (“two cultures”) but as part of a unified field of human knowledge. Such a view validates the approach for integrating the humanities with the clinical and basic sciences in the medical curriculum.

**Reflective Writing: A Tool for Emotional Regulation and Professionalization**

We view the “deliberate practice” of writing personal and critical reflections as an integral component of the metacognitive approach (see Sidebar: Deliberate Practice). Similar to the recent scientific finding that reading literary fiction can elicit the reader an empathic response, evidence suggests the act of writing personal reflections can have neurocognitive benefits. We view the writing of personal reflections also as a way of connecting students with their inner voice and with their innate empathy. Shapiro et al argue that writing personal reflections increases provider well-being, which includes the enhancement of “emotional equilibrium, self-healing and reducing isolation/restoring a sense of community” (see Sidebar: Two Phases of Reflective Writing).

The reflective writing assignments in the colloquium are usually about a personal experience related to medicine, for instance, the experience of a medical error that occurred during the student’s own care or that of a close friend or family member. However, we also assign critical reflections that include topics on the ethics of specific clinical scenarios as a way of integrating the clinical sciences into the colloquium.

We have developed a specific writing format called APLC (Analysis, Perspectives, Critique, Learning) that jump-starts the creative writing process. The “Perspectives” section of this reflective writing format is in keeping with the colloquium notion of “perspective taking” (discussed in the section, Professionalism: Respectful Disagreement and Perspective Taking). The deliberate practice of writing personal reflections thus reinforces other metacognitive components of the colloquium.

**Evaluation of the College Colloquium**

Students express a high level of satisfaction with the College Colloquium. Results of an extensive (required) course evaluation demonstrate that 80% to 90% of students rated the College Colloquium as good to excellent. In particular, students valued hearing the perspectives of their peers in colloquium sessions and frequently commented on how this had caused them to reevaluate their own perspectives and beliefs. In addition, they valued hearing the “stories” of peers and mentors, and they commented on the trust that developed in their college
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over the course of the colloquium. Students valued the general clinical experience of their mentors and the willingness of their mentors to share their personal experiences from medical practice. The colloquium has therefore functioned as a true learning community.

The following are examples of some of the de-identified positive comments taken from the course evaluations:

• “Colloquium provides a welcome change from the rigorous science we learn and provokes interesting and relevant discussion. The assignments … challenge our class in important areas that are often overlooked in medical and premedical curricula.”

• “The readings were great. I saved many for future reference and shared them with friends and family.”

• “I loved colloquium discussions. I have always walked away with having heard a new perspective that I hadn’t considered before.”

Application of the Cognitive Flexibility Inventory, an instrument for determining student’s cognitive flexibility (as mentioned earlier), showed that most students enhanced their inventory score during colloquium. This indicated that they had learned to think more adaptively, to perceive problems from multiple perspectives, and to generate alternative solutions to complex situations. These pilot surveys suggest that the colloquium is achieving one of its major objectives of enhancing students’ cognitive flexibility.

Conclusion

In the setting of learning communities, the VUSM College Colloquium presents an innovative approach to teaching the humanities in medical school. Instead of viewing the humanities as separate and isolated from the sciences, the colloquium seeks to integrate these intellectual domains (the “two cultures”) into a unified medical curriculum. Starting with a foundation in meta/neurocognition, the colloquium aims to train students not only in critical thinking but also more broadly to engender the qualities of cognitive flexibility and mindfulness as well as the capacities for cognitive and emotional monitoring and regulation. These qualities, coupled with an awareness in students of the immense breadth of human cognitive diversity, serve to elicit and nurture tolerance and empathy, which are core attributes of the “good” physician.

Bleakley and Bligh contend the following:

“Learning is largely a meta-process concerning legitimate access to situated (context-linked) and distributed knowing. This is not to deny the value of one’s own store of knowledge, but to place this in the wider and more pressing context of learning how to learn or how to access knowledge.”

Metacognition is such a “meta-process” that takes account of this broader continuum of learning to include how we learn and access knowledge, as well as the context and social setting of such learning. The metacognitive approach at VUSM is deliberately situated in the social setting of the colleges (as described earlier) so that students come to appreciate the participatory and peer context of learning, in contrast to the individualistic acquisition of knowledge that mostly occurs in their basic and clinical science courses.

Some have suggested that the metacognitive approach may be too abstract and premature for first-year medical students. In the context of the personalized curriculum being implemented at VUSM, this approach seems to us highly appropriate for educating the physician of the future. Quirk concludes his treatise on Intuition and Metacognition in Medical Education with the following emphatic statement:

“The personalized curriculum that is the hallmark of the new paradigm begins in the first year of medical school with the establishment of an infrastructure for thinking that will impact learning, practice and teaching. New evaluation strategies must focus on the achievement of metacognitive as well as cognitive benchmarks and capabilities.”

Neuroeconomist Harris argues that our understanding of the world, of human well-being in the world, and the ethics for maximizing such well-being, should derive not from philosophy but from the scientific study of the brain: “Whatever can be known about maximizing well-being of conscious creatures—which … is the only thing we can reasonably value—must at some point translate into facts about brains and their interaction with the world at large.”

Wilson argues that this unification of knowledge is being spurred by the cognitive neurosciences: “As late as the 1970s most scientists thought the concept of mind a topic best left to philosophers. Now the issue has been joined where it belongs, at the juncture of biology and psychology. … The cutting edge of the endeavors is cognitive neuroscience.”

Siegel considers the connection between multiple perspectives and metacognition, as follows: “Embracing multiple perspectives has the quality of a metacognitive skill. In the study of how we come to think about thinking, there are acquired capacities called representational ‘diversity’ and ‘change’ that enable individuals to sense that each of us may have a different perspective, and that even the viewpoint we have at one time may change in the future. In this metacognitive view we can then see perspective as not only a changing frame of reference but also one that needs to be considered in viewing the situational embedded meaning of knowledge.”

Flavell refers to the “personal category” of metacognition as “thinking about cognitive differences within people, cognitive differences between people and cognitive similarities among all people.” He views this capacity as one of the “universal properties of human cognition.”

Ringleb and Rock describe this dilemma as follows: “[B]eing a good group member involves an awareness of one’s thinking, feelings, behavior, and emotions with the ability to alter any one of those to satisfy group standards or expectations. … Once the circuitry of the brain senses that the individual’s actions have or may violate group standards and that other group members are evaluating them negatively, the individual needs the self regulatory ability to rectify the situation and re-establish or maintain group status.”

“Mindful practitioners use a variety of means to enhance their ability to engage in moment-to-moment self-monitoring, bring to consciousness their tacit personal knowledge and deeply held values, use peripheral vision and subsidiary awareness to become aware of new information and perspectives, and adopt curiosity in both ordinary and novel situations.”

Disclosure Statement

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

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

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Thinking about Thinking and Emotion: The Metacognitive Approach to the Medical Humanities that Integrates the Humanities with the Basic and Clinical Sciences


Glossary

Cognitive diversity: A term indicating the immense differences in brain function and cognitive “wiring” that exists between individuals. It has been estimated that the human brain contains some 100 billion neurons with trillions of synapses interconnecting these neurons. These connections are unique to each brain, resulting in an immense diversity in the way we think and respond to the world. Moreover, these connections are constantly forming and reforming, resulting in enormous plasticity that furthers increases this diversity.

Cognitive flexibility: The ability to switch cognitive sets in order to adapt to changing environmental stimuli. Cognitive flexibility would determine how adaptively individuals can let go of preconceived and untenable ideas and beliefs, and their willingness to change their mind as new insights are gained.

Colloquium: Meaning “talking together” from the Latin co + loquare.

Deliberate practice: A concept advanced by Ericsson and colleagues, referring to a form of practice that is not just routinely repetitive but carefully (“deliberately”) and proactively designed to improve performance, entailing focused attention to detail and ongoing feedback (often with a teacher’s or coach’s help). Deliberate practice may be undertaken in intellectual domains such as chess or learning a language, in music, in business-related activities, or in physical activities such as sports.

Emotional agility: A mindful, values-driven, and productive way of managing one’s thoughts and feelings.

Emotional regulation: The ability to regulate changes in one’s emotions, control negative thoughts, and respond appropriately to a given context, and to modulate excitement, fear, and detachment in the face of challenge.

Learning agility: The willingness and ability to learn from experience and subsequently apply that learning to perform successfully under new or first-time conditions.

Metacognition: Flavell initially defined this term as “one’s knowledge concerning one’s own cognitive processes and products or anything related.” More broadly, the term refers to one’s ability to think about one’s thinking and emotions and, to some extent, predict what others are thinking and feeling. Flavell also uses another term, metacognitive knowledge, to describe knowledge that “consists primarily of knowledge or beliefs about what factors or variables act and interact in what ways to affect the course and outcome of cognitive enterprises.”

Meta/neurocognition: I use these terms interchangeably to indicate how the field of metacognition is increasingly being informed by scientific findings in neuroscience and neurocognition.

Mindful learning: A concept originally proposed by Langer in which learning is offered in a conditional format rather than as a series of absolute truths. [Mindful learning] consists of an openness to novelty; alertness to distinction; sensitivity to different contexts; [and] implicit, if not explicit, awareness of multiple perspectives; and orientation to the present.”

Mindfulness: Mindfulness in its most general sense is “about waking up from a condition of unreflective sleep to being fully present; wholly “in the moment.” It is this present moment awareness that is often used to describe mindfulness.”
Professionalism in that Integrates the Humanities with the Basic and Clinical Sciences

Thinking about Thinking and Emotion: The Metacognitive Approach to the Medical Humanities

41. Epstein RM, Siegel DJ, Silberman J. Self-monitoring in clinical practice: The “ability to attend, moment to moment, to our actions; curiosity to examine the effects of those actions; and willingness to use those observations to improve behavior patterns and patterns of thinking in the future.”


Professional identity: The values, commitments, responsibilities, and particular contextual behaviors that members of a profession share at the level of the self and the group, and that creates a sense of belonging to the same group. From a metacognitive perspective, Quirk defines professional identity as “collective metacognition [that] significantly influences professional behavior ... [and that] requires the capabilities to reflect on, assess, and modify one’s values, attitudes and behavior in relation to those of the profession.”

Perspective taking: A metacognitive capability that demands thinking about another’s thoughts and feelings. ... Expert perspective-takers control their interpersonal interactions and relationships through mastery of empathy, patient education, and negotiation.

Professionalism: Professionalism in medical education may be viewed as a competency entailing such attributes and behaviors as responsibility, accountability, honesty, and caring, as well as the appropriate and ethical application of knowledge, in the relationship between doctor and patient.
REVIEW ARTICLE

A Business Case for Tele-Intensive Care Units

Alberto Coustasse, DrPH, MD, MBA, MPH; Stacie Deslich, MA, MS;
Deanna Bailey, MS; Alesia Hairston, MS; David Paul, DDS, PhD

Abstract

Objectives: A tele-intensive care unit (tele-ICU) uses telemedicine in an intensive care unit (ICU) setting, applying technology to provide care to critically ill patients by off-site clinical resources. The purpose of this review was to examine the implementation, adoption, and utilization of tele-ICU systems by hospitals to determine their efficiency and efficacy as identified by cost savings and patient outcomes.

Methods: This literature review examined a large number of studies of implementation of tele-ICU systems in hospitals.

Results: The evidence supporting cost savings was mixed. Implementation of a tele-ICU system was associated with cost savings, shorter lengths of stay, and decreased mortality. However, two studies suggested increased hospital cost after implementation of tele-ICUs is initially expensive but eventually results in cost savings and better clinical outcomes.

Conclusions: Intensivists working these systems are able to more effectively treat ICU patients, providing better clinical outcomes for patients at lower costs compared with hospitals without a tele-ICU.

Introduction

Telemedicine is the use of medical information exchanged from one site to another via electronic communications to improve a patient’s clinical health status. Telemedicine includes a growing variety of applications and services using two-way video, smart phones, wireless tools, and other forms of telecommunications technology. A tele-intensive care unit (tele-ICU) involves the use of telemedicine in an intensive care unit (ICU), using technology to assist in providing care for critically ill patients by off-site clinical resources.

In the US, more than 4 million patients are admitted to ICUs each year; treatment of these critically ill patients has been estimated to account for 30% of costs of acute care hospitals. Patient safety concerns persist in the ICU, and serious medication errors account for 78% of all errors in the ICU. Hospital costs for critically ill patients have been estimated to be about $67 billion annually, with mortality rates ranging from 10% to 28%, or approximately 540,000 deaths each year.

Tele-ICUs may be effective by decreasing costs, decreasing ICU length of stay (LOS), decreasing medication errors, and increasing patient safety when adopted and implemented in hospitals. Two distinct types of tele-ICU have been identified. The decentralized tele-ICU is a medical facility or multiple medical facilities that can be accessed from remote sites such as office, home, or mobile. There is no distinct tele-ICU; rather there is a process of care having multiple sites of access to the patient, with intensivists monitoring the patients. A centralized tele-ICU program is often the tele-ICU system of choice. In the centralized system, one central ICU provides intensive care via telemedicine and remote monitoring to several satellite ICUs.

In the tele-ICU model, the tele-ICU is a definable entity providing continuous monitoring to sites with high levels of need via private, dedicated telecommunications lines. Networks of audiovisual communication and computer systems link hospital ICUs to intensivists and other critical care professionals, who are able to access patient data such as medical records, to conduct remote real-time monitoring of vital signs or chronic conditions, or to facilitate staff interactions via video, phone, or online computer. Video cameras located on the ceiling of an ICU patient room are situated to allow telemedicine practitioners to observe equipment and monitors in the patient’s room. Cameras often have an alert system to announce that the tele-ICU staff is in visual contact to share observations and care recommendations with bedside caregivers. These devices and elements are vital to the successful application of tele-ICUs. As has been noted, without appropriate electronic medical records and clinical decision support systems, or lacking patient-related data and information, clinicians may make inappropriate treatment recommendations.

Studies have demonstrated both clinical and economic benefits associated with adoption of tele-ICUs, including decreased mortality rate, decreased frequency of ICU complications, decreased ICU LOS and decreased ICU costs after a 16-week implementation of technology-enabled remote care. Additionally, it has been found that tele-ICU use can decrease medication errors and improve patient safety. A meta-analysis of non-severity-adjusted data from 11 studies confirmed these results and found the decrease of ICU mortality and ICU LOS, as well as hospital mortality and hospital...
LOS to be statistically significant. These outcomes are particularly important because studies that reported results on the basis of both severity-adjusted data and non-severity-adjusted data have found that the level of statistical significance of these outcome variables when using non-severity-adjusted data was higher than when using severity-adjusted data. These findings indicate that the benefits of tele-ICU implementation reach all populations of patients, regardless of severity of illness.

It has been estimated that full implementation of the tele-ICU standard in community hospitals could prevent between 5400 and 13,400 deaths and could potentially save $5.4 billion annually. One of the main barriers to adoption of tele-ICUs has been adoption and implementation cost: the cost of construction, installation, and training. The “command center” for a tele-ICU system has been estimated to cost between $2 and $5 million, with each additional tele-ICU added to the system costing $250,000. Such substantial financial outlays can be a challenge for hospitals and health systems that lack significant financial funds or borrowing capacity, especially with annual operating costs of about $2 million, including maintenance costs, licenses, staffing expenses, and additional upgrades. If the tele-ICU system is not fully compatible with the hardware or software systems of the physical ICU, additional software, hardware, and infrastructure may be required, which would require additional cost to the hospital.

Regardless of the need for upgrades, staff must overcome additional barriers such as computer issues, including difficulty logging on, short battery life, frequent rebooting, and other technical issues with computers or software. Some of the possible solutions for these problems include ensuring computers remain plugged in, confirming that passwords are able to be used in multiple programs, and providing information technology (IT) assistance by phone and on-site as required.

Although tele-ICUs are expensive to implement, with startup costs between $50,000 and $100,000 per bed, the benefits of tele-ICU utilization may far outweigh those costs for ICUs. Because ICU patients frequently have such complex medical and/or surgical conditions, intensive care provided via a tele-ICU system can provide this care and decrease hospital cost. The purpose of this review was to examine the implementation, adoption, and utilization of tele-ICU systems by hospitals to determine their efficiency and efficacy as identified by cost savings and patient outcomes.

**Methods**

The methods employed for this study were a literature review and a review of case studies. The research approach for the examination of the promotion factors and barriers to adoption of tele-ICUs was customized to this study following the conceptual framework used by Yao et al (Figure 1). Figure 1 depicts the process of IT adoption in health care, in this case, the tele-ICU. To research how tele-ICU can help improve health care practices in the ICU, it is first necessary to recognize the existing problems in the ICU and issues that drive and impede adoption of this technology by the hospital industry; then different applications can be identified to solve or partially unravel these challenges. By analyzing the literature, the benefits and barriers of tele-ICU utilization in health care can be identified (Figure 1).

The use of this framework in the current study is appropriate because the focus of this study, as in that by Yao et al, is to show how new technologies and IT systems can be applied to health care settings to enhance the care of patients. In addition, this conceptual approach has been successfully replicated in previous studies, including adoption of tele-ICU, radiofrequency identification, and electronic prescribing technologies, thus supporting its internal validity.

The review was conducted in stages, including: 1) determining the search strategy and establishing inclusion and exclusion criteria, 2) literature analysis, and 3) extracting and categorizing the findings.

**Step 1: Determining the Search Strategy and Establishing Inclusion and Exclusion Criteria**

When executing the search, the following terms were used: “tele-ICU” or “telemedicine ICU” or “virtual ICU” and “cost” or “benefits.” A mix of databases and online sources were used to compile a set of references covering both academic peer-reviewed research and practitioner literature. It was believed that this approach would help create the most comprehensive and up-to-date review. The following electronic databases and sources were used: PubMed, Academic Search Premier, Science Direct, ProQuest, and Google Scholar. The Web sites of the Society of Critical Care Medicine and the American Telemedicine Association also were searched.

**Step 2: Literature Analysis**

The literature review yielded 76 sources, which were assessed for information pertaining to this research project. Given the technology- and enterprise-oriented nature of the current study, literature was selected for review on the basis of financial, technological, and organizational impacts. References were reviewed and determined to have satisfied the inclusion criteria if the material provided accurate information about the tele-ICU with a particular focus on benefits and barriers.
to its implementation. Only articles that were written in English were included for review. Given the rapid changes in technology, studies that were published before 2001 were excluded from the search.

**Step 3: Literature Categorization**

In the third step, selected academic articles and practitioner health IT sources were analyzed, and relevant categories were identified. The findings are presented in the subsequent sections using the categories of cost of telemedicine technology in the ICU and several case studies. The use of brief case studies was thought to illustrate real cases of tele-ICU implementation.

**Results**

**How Tele-ICUs Can Be Cost-Effective**

According to the leading tele-ICU systems vendor, Philips VISICU in Baltimore, MD, tele-ICU implementation costs ranged from about $50,000 to $100,000 per bed, and the cost of equipping 100 beds was approximately $3 to $5 million.\(^{28,29}\) Annual operating costs (eg, overhead, maintenance, staffing) were estimated by Philips VISICU to be approximately 20% of the software costs, or about $300,000 for 100 beds.\(^{30}\) Staffing costs depended on hours in use and level of additional staff in the off-site center; typical staffing scenarios added approximately $1 to $2 million per year per 100 beds covered.\(^{31}\)

**Brief Case Study 1: Sentara Healthcare**

Sentara Healthcare in Norfolk, VA, was the nation’s first health system to establish a tele-ICU program in 2000 through the vendor VISICU (now Philips VISICU).\(^{32}\) Implementation of the tele-ICU at Sentara Norfolk General Hospital and Sentara Hampton General Hospital took 5 months and cost more than $1 million. In 2002, Sentara reported a reduction in hospital mortality of 26%, with a 17% decrease in ICU LOS (Table 1).\(^{33}\)

Findings from an independent evaluation by Cap Gemini Ernst & Young, London, United Kingdom, suggested a $2 million tele-ICU cost that was offset by $3 million in net savings annually.\(^{34}\) It reported extra revenue, approximately $460,000 per month, because of increased patient turnover resulting from decreased LOS.\(^{35}\) Table 2 displays the findings of the patient cost reduction of $2150 per stay based on reduced patient expenses and increased ICU capacity as well.

The centralized model has allowed optimization of time and services of intensivists without the requirement of staffing intensivists at multiple locations. The availability of intensivists in a single location also has given patients the opportunity to stay in location, instead of traveling and being transferred to a different hospital.\(^{36}\) As of 2010, more than 1 million ICU patients had been cared for using the strategy of frequent reassessment, alert-prompted evaluation, and rapid response to clinical needs.\(^{34}\)

**Brief Case Study 2: University of Massachusetts Memorial Medical Center**

The University of Massachusetts Memorial Medical Center in Worcester, MA, installed a tele-ICU command center in 2005 and extended the tele-ICU coverage to 2 Massachusetts community hospitals in 2007 and 2008. Over 3 years, 1 tele-ICU

### Table 1. Tele-intensive care unit cases studied, implementation costs, and outcomes

<table>
<thead>
<tr>
<th>Institution</th>
<th>Setting</th>
<th>Implementation costs (US dollars)</th>
<th>Major results/outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sentara Healthcare</td>
<td>Sentara Healthcare,(^{a}) academic tertiary care medical center with 5 ICUs, 130 critical care beds</td>
<td>1 million</td>
<td>Decreased ICU LOS by 17%; decreased hospital mortality by 26.4%(^{32,34})</td>
</tr>
<tr>
<td>New England Healthcare Institute and Massachusetts Technology Collaborative</td>
<td>University of Massachusetts Memorial Medical Center, academic hospital with 5 adult ICUs, 130 beds, 7000 ICU patients</td>
<td>7.12 million</td>
<td>Decreased ICU LOS (from 13.3 to 9.5 days); decreased mortality from 13.6% to 11.8%; recovered costs of implementation; lowered rates of complications(^{34})</td>
</tr>
<tr>
<td>Resurrection Health Care</td>
<td>Community hospitals with 14 ICUs, 182 critical care beds</td>
<td>7 million</td>
<td>6 months after implementation: 38% decrease in ICU LOS, approximately $3 million in cost savings(^{37,38})</td>
</tr>
</tbody>
</table>

\(^{a}\) Includes both Sentara Norfolk General Hospital and Sentara Hampton General Hospital.

ICU = intensive care unit; LOS = length of stay.

### Table 2. Sentara Healthcare and Resurrection Health Care tele-intensive care unit implementation savings

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Cost of implementation (US dollars)</th>
<th>Outcomes</th>
<th>Cost saving</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sentara Healthcare (savings from 2002 to 2010)</td>
<td>1 million</td>
<td>Reduction in mortality by 27%; decreased LOS of 17%</td>
<td>Reduced patient cost of $2150; average case contribution margin(^{a}) increased by 55.6%(^{33,36})</td>
</tr>
<tr>
<td>Resurrection Health Care (savings from 2007 to 2011)</td>
<td>7 million</td>
<td>Decreased LOS of 38%</td>
<td>7% reduction in blood transfusions ($11,200 in savings); estimated total cost savings of $11.5 million(^{37,38})</td>
</tr>
</tbody>
</table>

\(^{a}\) Average case contribution margin is the selling price per unit minus cost per unit. Contribution represents the portion of sales revenue that is not consumed by variable costs and so contributes to the coverage of fixed costs.

LOS = length of stay.
command center extended coverage to 9 adult ICUs covering 116 ICU beds in central Massachusetts. Figure 2 shows the initial expenses of implementation of a tele-ICU at the medical center. The total operating costs of $7.12 million also required an increment of annual operating cost of $3.15 million. Licensing and implementation fees accounted for 34% of the total expenses. Tele-ICU equipment costs and support center and servers accounted for $1.1 million and $1.19 million, respectively (Figure 2).

Figure 3 shows the operating costs and the continuous ongoing costs for the tele-ICU. The main ongoing cost was clinical salaries and benefits accounting for 72% or $2.27 million, followed by nonclinical salaries at 20% or $630,000 (Figure 3). The centralized tele-ICU program has been one of the most beneficial programs to the medical center. The positive net revenue produced a rapid payback such that total costs of implementation were recovered within 1 year.

**Brief Case Study 3:**

**Resurrection Health Care**

Covering 7 acute care hospitals and a long-term care facility, Resurrection Health Care in Des Plaines, IL (now part of Presence Health), introduced telemedicine into its 14 ICUs in 2007. The tele-ICU command center in Resurrection’s Holy Family Medical Center (now Presence Holy Family Medical Center) promoted proactive intervention, including trended alerts, which showed incremental changes in such factors as blood pressure, oxygen levels, and drip rates.

In the first 6 months after installation in 2007, a cost savings of $3 million was reported, including $11,200 from a 7% reduction in blood transfusions. The hospital found a 38% decrease in ICU LOS in 6 months, which totaled to approximately $3 million in savings (Table 2).

Resurrection Health Care leadership wanted to know how the system was going to prove its return on investment on the $7 million spent to set up all 14 ICU systems simultaneously. In 2011, it...
was reported that it had a $387,000 financial benefit: tele-ICU support for ICU patients across the health care system resulted in 9000 ICU days saved, for an estimated cost savings of $11.5 million. Also, it was reported that the reengineering of the existing tele-ICU infrastructure was expanded to support telestroke, telepsychiatry, telemedicine with skilled nursing facilities, and sepsis management initiatives.36

Brief Case Study 4: Six Intensive Care Units in Five Large Hospitals

A study by Franzini et al39 was conducted to determine the costs and cost-effectiveness of 6 ICUs in 5 large hospitals in the Gulf Coast region after the installation of a tele-ICU program. The sample included 4142 patients in the 6 different ICUs: 2034 patients were from the pretest period and 2108 were from the posttest period. Table 3 shows the ICU average daily cost before and after the tele-ICUs were implemented. The average daily costs and costs per case increased in all 6 ICUs after implementation (posttest period) from the period before implementation of the tele-ICU (pretest period). Overall, the daily average ICU cost increased from $2851 to $3653, or a 28% increase after tele-ICUs were installed, which was statistically significant. Two hospitals experienced cost increases greater than 30% (Table 3).

The floor daily average costs increased 16%, from $1451 to $1687, after tele-ICUs were installed. The overall ICU costs per case increased from $13,029 to $19,324 after tele-ICU installation.39

Costs per patient for hospitals increased, but the patient out-of-pocket expenses remained the same, causing hospitals to need to find some way to absorb the financial losses of tele-ICU implementation. Average ICU hospital cost per patient was $20,231 in the pretest period and $25,846 in the posttest period, which was financially and statistically significant (Table 4). Overall, the installation of the tele-ICU programs in the 6 ICUs was associated with higher costs not attributable to medical inflation. These researchers did note that sicker patients exhibited lower mortality; thus ICUs with high volumes of severely ill patients may gain more financial benefit with the utilization of tele-ICU technology. The researchers also noted that about two-thirds of ICU physicians in the study chose only minimal participation in the tele-ICU intervention.

Positive Outcomes of Tele-ICU Implementation

In terms of effectiveness, the literature on tele-ICUs demonstrated improved hospital financial performance, improved ICU financial performance, improved teamwork climate and safety climate, and improved patient care (Table 5). A tele-ICU program enhanced compliance to evidence-based practice bundles for severe sepsis. Between January 1, 2006, and December 31, 2008, antibiotic administration increased from 55% to 74%, serum lactate measurement increased from 50% to 66%, the initial fluid bolus of 20 mL/kg or greater increased from 23% to 70%, and central line placements increased from 33% to 50%. Higher rates of ICU staff adherence to critical care best practices, reduction of ICU LOS, and improved patient care were found in several studies (Table 5). Quality improvement and patient care have been improved by the implementation of the tele-ICU by increasing the use of evidence-based protocols for sepsis, ventilator-associated pneumonia, and blood transfusion (Table 5).

In 2013, Kumar et al53 combined a systematic review with cost data from the implementation of a tele-ICU program in 7 ICUs (74 beds) in the Veterans Health Administration to measure the cost of tele-ICU programs. According to the authors, it was estimated that the first-year costs of implementation ranged between $70,000 and $87,000 per ICU bed. The Veterans Health Administration also projected cost savings per 3000 patients across the health care system after the tele-ICUs were implemented. The floor daily average costs increased 16%, from $1451 to $1687, after tele-ICUs were installed. The overall ICU costs per case increased from $13,029 to $19,324 after tele-ICU installation.

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Discussion

This research study has examined potential benefits of implementing a centralized tele-ICU system. The evidence supporting cost savings is mixed. The

<table>
<thead>
<tr>
<th>Table 3. Average daily costs (US dollars) before and after tele-ICU installation in six intensive care units in 2010</th>
</tr>
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<tbody>
<tr>
<td>Costs</td>
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<tr>
<td>-------</td>
</tr>
<tr>
<td>Before tele-ICU period</td>
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<tr>
<td>After tele-ICU period</td>
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<tr>
<td>Change (%)</td>
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<td>ICU = intensive care unit.</td>
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<tr>
<th>Table 4. Intensive care unit costs per case (US dollars) before and after tele-ICU installation in six intensive care units in 2010</th>
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<tbody>
<tr>
<td>Costs</td>
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<tr>
<td>-------</td>
</tr>
<tr>
<td>Before tele-ICU period</td>
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<tr>
<td>After tele-ICU period</td>
</tr>
<tr>
<td>Change (%)</td>
</tr>
<tr>
<td>Average cost: before tele-ICU period vs after tele-ICU period</td>
</tr>
<tr>
<td>ICU = intensive care unit.</td>
</tr>
</tbody>
</table>
## Table 5. Studies addressing tele-ICU implementation and utilization

<table>
<thead>
<tr>
<th>Author, year</th>
<th>Study design</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aaronson et al, 2006&lt;sup&gt;40&lt;/sup&gt;</td>
<td>Literature review</td>
<td>Higher rates of ICU staff adherence to critical care best practices</td>
</tr>
<tr>
<td>Badawi et al, 2010&lt;sup&gt;41&lt;/sup&gt;</td>
<td>Pre/posttest of tele-ICU implementation</td>
<td>Higher rates of ICU staff adherence to critical care best practices</td>
</tr>
<tr>
<td>Badawi and Shemmeri, 2006&lt;sup&gt;42&lt;/sup&gt;</td>
<td>Pre/posttest of tele-ICU implementation</td>
<td>Higher rates of ICU staff adherence to critical care best practices</td>
</tr>
<tr>
<td>Berenson et al, 2009&lt;sup&gt;31&lt;/sup&gt;</td>
<td>Literature review</td>
<td>Improved patient care</td>
</tr>
<tr>
<td>Breslow et al, 2004&lt;sup&gt;43&lt;/sup&gt;</td>
<td>Pre/posttest of tele-ICU implementation across several hospitals</td>
<td>Improved hospital financial performance, improved ICU financial performance, improved patient care</td>
</tr>
<tr>
<td>Chu-Weininger et al, 2010&lt;sup&gt;44&lt;/sup&gt;</td>
<td>Pre/posttest of tele-ICU implementation and utilization in 3 ICUs</td>
<td>Improved teamwork and/or safety climate</td>
</tr>
<tr>
<td>Coletti et al, 2008&lt;sup&gt;45&lt;/sup&gt;</td>
<td>Cross-sectional survey of residents in ICU and tele-ICUs</td>
<td>Improved teamwork and/or safety climate</td>
</tr>
<tr>
<td>Dickhaus, 2006&lt;sup&gt;46&lt;/sup&gt;</td>
<td>Pre/posttest of tele-ICU implementation and utilization in a multistate hospital system</td>
<td>Lower ICU LOS</td>
</tr>
<tr>
<td>Giessele and Leedom, 2007&lt;sup&gt;47&lt;/sup&gt;</td>
<td>Pre/posttest of tele-ICU implementation and utilization in 3 ICUs</td>
<td>Improved teamwork and/or safety climate</td>
</tr>
<tr>
<td>Groves et al, 2008&lt;sup&gt;13&lt;/sup&gt;</td>
<td>Literature review</td>
<td>Lower ICU LOS</td>
</tr>
<tr>
<td>Howell et al, 2007&lt;sup&gt;48&lt;/sup&gt;</td>
<td>Pre/posttest of tele-ICU implementation and utilization</td>
<td>Lower ICU LOS</td>
</tr>
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<td>Ikeda et al, 2009&lt;sup&gt;50&lt;/sup&gt;</td>
<td>Pre/posttest of tele-ICU implementation and utilization</td>
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<td>Kohi et al, 2007&lt;sup&gt;51&lt;/sup&gt;</td>
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<td>Kohi et al, 2007&lt;sup&gt;52&lt;/sup&gt;</td>
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<td>Kohi et al, 2012&lt;sup&gt;53&lt;/sup&gt;</td>
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<td>Rincon et al, 2007&lt;sup&gt;60&lt;/sup&gt;</td>
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<td>Higher rates of ICU staff adherence to critical care best practices: • Antibiotic administration increased from 55% to 74% • Serum lactate measurement increased from 50% to 66% • Central line placements increased from 33% to 50%</td>
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<td>Zawada et al, 2009&lt;sup&gt;72&lt;/sup&gt;</td>
<td>Pre/posttest of tele-ICU implementation and utilization</td>
<td>Improved hospital financial performance</td>
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ICU = intensive care unit; LOS = length of stay.
hospitals in the first three cases experienced some benefit in terms of cost reduction, a decreased ICU LOS, or an overall improved efficiency.

The return on investment for hospitals implementing a tele-ICU system depends on how the system is used, as well as the number of patients the hospital ICU treats. If a hospital system wants to use a tele-ICU system for safety reasons or to make their workforce more efficient, the tele-ICU is a tool that could help. Another benefit of tele-ICU implementation has been an expansion of markets; the tele-ICU allows health care facilities to take care of more patients, which decreases geographic barriers and allows the provision of ICU services into previously inaccessible markets, such as those in rural areas.

In hospital tele-ICU systems examined by Franzini et al10 and Morrison et al,12 hospital costs rose after implementation. Both studies noted that costs associated with physicians choosing a low or nonexistent involvement with tele-intensivists rose more quickly than those costs associated with physicians choosing a higher level of tele-intensivist involvement. Additionally, Franzini et al10 noted that the tele-ICU system used in their study was not fully integrated with the hospitals’ electronic health record system, which may also have contributed to increased cost.

The LOS decreased because intensivists had more time to spend with the patient and were able to provide adequate intensive care. Franzini et al12 and Morrison et al12 noticed patients were being served more effectively than before the implementation of a tele-ICU system.

The large range of hospital costs per bed reported by Kumar et al13 stresses that each health care institution must do a careful cost-benefit analysis and should include vendors in the implementation process from the beginning. Many hospitals have demonstrated that a strong tele-ICU program can find payback in about a year, according to the New England Healthcare Institute (now the Network for Excellence in Health Innovation) in Cambridge, MA.16 In another study, with 10,000 patients, Advanced ICU Care in St Louis, MO, achieved a 40% reduction of mortality and a 25% reduction of ICU LOS.19 This finding concurred also with a study by Lilly et al14–17 of 28,000 patients across 8 states, supporting decreasing mortality and shorter LOS with increased cost savings for the hospitals implementing the tele-ICU programs.

Overall, hospitals have few research findings to help guide them when making a decision about whether to adopt and to use a tele-ICU program. The findings of this literature search suggest that the implementation of a centralized tele-ICU system can be cost-effective and can result in more efficient use of the hospital’s ICU staff, improvement in the quality of care provided, and a financial positive impact by reducing ICU LOS.

There were several limitations of this study review. Many articles documented the benefits of tele-ICUs but contained limited data on the actual financial savings or cost of implementing a tele-ICU. Other articles had cost data about the savings but did not have data on how much ICUs were costing them before a tele-ICU implementation. In addition, the excessively high fees presented may be peculiar to the location and hospital size, and so may not be as large elsewhere. This study also was limited by restrictions in the search strategy used, and publication and researcher’s bias may have limited the availability and quality of the research identified for review. Additionally, the review was limited to hospital organizations in the US, thus excluding many international providers of tele-ICU care.

The implication of this study is that the implementation of tele-ICU systems can be cost-effective and can improve patient outcomes. Future research should examine the results attributable to the implementation of a tele-ICU. A meta-analysis should be performed to have a more precise measurement of the effects (ie, cost and savings) of the implementation of a tele-ICU in practice. Other areas for study include how tele-ICUs affect different types of ICUs such as surgical vs nonsurgical ICUs, including tele-ICU vs a 24/7 in-house pulmonary model, and whether similar findings can be achieved in small and rural hospitals.

Conclusion

Although mixed results were found in the literature in terms of cost savings, the findings suggest that the implementation of tele-ICU systems have the potential to produce organizational change, with clinical and nonclinical ICU staff becoming more efficient and effective, and to decrease ICU LOS, hospital costs, and ICU mortality.دانشتنیهای دانشمندان در تحقیقات مربوط به بررسی تأثیر سیستم‌های دیجیتال در مرکز درمانی (Tele-ICU) نشان داد که این سیستم‌ها در بهبود کارکرد و بهبود کیفیت خدمات درمانی می‌توانند مؤثر باشند و هزینه‌های درمانی را کاهش دهند که می‌تواند بهبود در کیفیت خدمات درمانی در این مراکز را رقم بگیرد.

References


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Structure and Ability

The tasks assigned [to the physician] ... are determined primarily by the social and economic structure of society and by the technical and scientific means available to medicine at the time.

— Medicine and Human Welfare, Henry E Sigerist, 1891-1957, Swiss medical historian
CASE STUDY

Vasal Injury During Inguinal Herniorrhaphy: A Case Report and Review of the Literature

Lawrence Flechner, MD, PhD; James Smith, MD, MS; Patrick Treseler, MD, PhD; John Maa MD

Abstract

An injury to the vas deferens during inguinal herniorrhaphy from possible tethering of the vas has not, to our knowledge, previously been described in the surgical literature. We report a case of iatrogenic injury of the vas deferens that occurred during elective hernia repair in a 28-year-old man who had previously sustained blunt trauma to the abdomen and pelvis.

Introduction

Inguinal herniorrhaphy is among the most common surgical procedures performed in the US. An inguinal hernia develops from a weakness in either the abdominal wall fascia at the Hesselbach triangle or the internal inguinal ring. Any adjacent abdominal contents may be contained in or adherent to an inguinal hernia sac. The spermatic cord—consisting of the vas deferens, vessels, nerves, lymphatics, and tunica albuginea—is often involved in inguinal hernias, particularly of the indirect variety. Yet reports of injury to the spermatic cord and its contents are rare. We herein report a case of vas deferens injury during inguinal herniorrhaphy in a patient who had previously sustained extensive abdominal and pelvic trauma.

Case Study

A 28-year-old man with a history of pelvic fracture sought urologic evaluation because of erectile dysfunction and the desire to conceive a child. His medical and surgical history was notable for a pedestrian vs auto accident in 2005, in which he sustained fractures of the pelvis and right femur (Figure 1), and a partial urethral disruption. He required an emergency exploratory laparotomy, with a temporary colostomy because of a rectal laceration, and external fixation of his pelvic and femoral fractures. The urethral injury was treated with temporary Foley catheterization and a suprapubic cystostomy tube, after which normal voiding function eventually returned. After an initially unsuccessful attempt at colonic reanastomosis, the colostomy was later reversed. The patient’s medical history was otherwise unremarkable; he did not use prescription medications or smoke tobacco. He could obtain erections using phosphodiesterase Type 5 inhibitor therapy, suggesting a vasculogenic cause of his erectile dysfunction. He opted to attempt conception with his partner by natural means.

His urologic evaluation at our institution took place four years after his accident. At this time, a moderate right inguinal hernia was identified, prompting referral to the General Surgery Service. The hernia caused discomfort but was easily reducible, without evidence of incarceration or obstruction. The patient’s pelvic surface anatomy was heavily scarred from the prior external fixator placement. After an extensive discussion, the patient decided to undergo surgical...
repair of the hernia with polypropylene mesh. An open approach was selected, given the patient’s history of abdominal-pelvic surgery.

At the time of herniorrhaphy, extensive scarring was noted in the subcutaneous and fascial layers, possibly resulting from previous pelvic hemorrhage. The inguinal canal was exposed, and the iliohypogastric and ilioinguinal nerves and the spermatic cord were identified. A 5-cm-diameter direct hernia sac was identified medial to the epigastric vessels. The cord and hernia sac were densely adherent but could be separated, after which the spermatic cord was encircled using a Penrose drain. During retraction of the cord en masse to expose the pubic tubercle and floor of the inguinal canal, an audible snap was heard. Careful inspection revealed that the vas deferens had fractured, possibly because of extensive scarring and lack of mobility of the vas in particular.

An intraoperative urologic consultation indicated that the vas was firm and attenuated. The proximal and distal vasal ends were identified and were incised to expose fresh tissue in preparation for primary end-to-end anastomosis. The vas was approximated using 5 interrupted 7-0 polypropylene (Prolene) sutures in a tension-free manner. A metal clip was placed just lateral to the anastomosis to facilitate possible future localization. A Lichtenstein tension-free mesh herniorrhaphy was performed to repair the direct hernia, and the wound was closed.

The patient’s postoperative recovery was uncomplicated. Pathologic evaluation of a segment of the vas did not demonstrate ischemic changes or other underlying abnormalities (Figure 2).

A postoperative semen analysis revealed a low-normal sperm count of 20 million/mL with motility and morphologic characteristics within normal limits. Although the status of the vasal repair was unknown at the time of that analysis, these findings suggested that the contralateral vas was patent and functional, and likely would enable the patient to conceive a child. However, he underwent another urologic evaluation after 9 months of failing to achieve a pregnancy with his spouse. He chose to undergo vasography with contrast medium delivered by hemivasotomy proximal to the prior anastomotic site. The contrast agent did not pass beyond the level of the inguinal canal, saline injection revealed obstruction, and a 2-0 nylon suture did not pass the region of the inguinal canal, thus indicating vasal obstruction at the anastomotic site. The stricture was identified, excised, and reconstructed by vasovasostomy (Figure 3).

The patient had an uncomplicated recovery, and subsequent semen analysis findings 1 month and 4 months after surgery were equivalent to his preoperative values. After 2 attempts at intrauterine insemination, the patient and his wife were able to successfully conceive a child spontaneously.

**Discussion**

We believe that this case represents a novel and previously undescribed mechanism of injury to the vas deferens during open inguinal herniorrhaphy, in the setting of extensive scarring resulting from prior pelvic surgery. To determine whether there is a precedent for this scenario in the medical literature, we searched the MEDLINE electronic database for English-language articles by using the following key words: vas, hernia, injury, pelvis, scar. No reports were identified.

An iatrogenic injury to the vas deferens during adult open inguinal herniorrhaphy is rare. Mechanisms of vasal injury include partial or complete transection, fracture, thermal or crush injury, compression, and excessive tension from a foreign body such as mesh, leading to obstruction and ischemia. Injury to the vas deferens is thought to occur when it is adherent to the hernia sac. Although difficult to prove, chronic ischemia from our patient’s earlier pelvic vascular injury might have contributed to inherent weakness of the tissue, predisposing it to fracture despite careful handling of the cord. Furthermore, although the vasal injury may contribute to obstruction as a source of azoospermia, results of his physical examination demonstrated mild atrophy of the right testicle, suggesting that blood supply may have been compromised during one of his prior operations.

At the time of surgery, we hypothesized that either scar tissue was tethering the testicle and vas or that chronic ischemia contributed to the vasal injury and abnormal texture of the vas. Typically, the testicle can be delivered into the inguinal canal with gentle traction, but in this case, the testicle was immobile.
Vasal Injury During Inguinal Herniorrhaphy: A Case Report and Review of the Literature

The advent of laparoscopic inguinal herniorrhaphy has potentially increased the risk of iatrogenic injury to spermatic cord structures. Although an open approach is preferred, it does not preclude the possibility of injury. Intraoperatively, extra care should be taken during mobilization of the cord structures to prevent excess traction. If an injury is identified, urologic consultation is indicated, and a primary reanastomosis should be attempted, preferably with the aid of a surgical microscope. A metal clip and the vas fractured into two segments. The absence of chronic ischemic findings in the pathologic evaluation of the vas led us to conclude that scarring from the pelvic fracture and tethering of the testicle placed the vas on traction and resulted in the abnormal texture.

The true incidence of vas deferens injury during open hernia repair in adult men is likely underreported. This underreporting probably reflects that small injuries may be unrecognized intraoperatively, that improper mesh placement is difficult to appreciate, and that postsurgical symptoms are often absent. In the most common scenario, an unrecognized injury is revealed only years later in the evaluation of subfertile or azoospermic men who underwent hernia repair during childhood. Unlike in adults, inguinal hernia repair in children is the most common cause of injury to the vas deferens, which is more delicate and attenuated in infants. Early reports suggested that vasal injury occurs in 0.8% to 2% of pediatric hernia cases. However, an incidence as high as 26.7% has been reported in subfertile men with vasal obstruction.

There should be a high index of suspicion for iatrogenic vasal injury in azoospermic patients who have undergone bilateral inguinal herniorrhaphy. A review of 34 iatrogenic vasal injuries from a cohort of 472 patients who underwent vasovasostomy or epididymovasostomy indicated that 30 of the injuries were caused by inguinal herniorrhaphy. Ten of these were adult cases, supporting the argument that vasal injury is underreported after childhood. One reason for this underreporting may be that diagnosis of injury might be learned only from abnormal findings of semen analysis, a test obtained primarily for fertility evaluation. Additionally, perhaps because of delayed diagnosis, treatment outcomes for vasal injury repair are poor. Compared with vasectomy reversal, microsurgical repair of iatrogenic vasal injury was associated with a reduced success rate, longer length vasal defects, impaired blood supply, and longer duration of obstruction. Yet in our patient, the relatively brief duration of obstruction suggests a more favorable outcome. Because a microscopic repair of the vas requires additional expertise and equipment, the urgent nature of the intraoperative consultation at the time of injury precluded this approach initially in our patient.

The advent of laparoscopic inguinal herniorrhaphy has potentially increased the risk of vasal injury, given the precarious location of the abdominal vas and gonadal vessels as they converge onto the internal inguinal ring. The prominent location of the vas and gonadal vessels must be noted when placing the mesh, especially during bilateral herniorrhaphy. Longer-term follow-up of the fertility of young men who undergo bilateral laparoscopic hernia repair should be considered.

Special consideration should be made when obtaining preoperative consent for inguinal herniorrhaphy from men of childbearing age who have sustained previous pelvic trauma. In our case, an intraoperative alternative would have been to ligate the vas, with the expectation that if the contralateral vas were patent, the patient’s fertility would not be dramatically altered. We recognized, however, that the history of pelvic trauma might have predisposed the contralateral vas to ischemia or nonfunction, and to infertility if a repair had not been attempted. However, for patients who no longer wish to father children, the option of simple ligation of the vas deferens or unilateral orchiectomy could also be considered.

In the months after our patient’s vas deferens injury, he and his wife were initially unsuccessful in achieving spontaneous pregnancy. No symptoms of scrotal edema or pain developed, or any other suggestion of an obstruction of the vas deferens. He thus chose to undergo a repeated procedure to assess the patency of the initial repair and to increase the likelihood to conceive a child spontaneously.

**Conclusion**

To our knowledge, this is the first report of an unusual vas deferens injury during open inguinal herniorrhaphy in a patient with a history of extensive pelvic surgery. For patients with a history of pelvic trauma who are being considered for herniorrhaphy, our case suggests that there is a modestly increased risk of iatrogenic injury to spermatic cord structures. Although an open approach is preferred, it does not preclude the possibility of injury. Intraoperatively, extra care should be taken during mobilization of the cord structures to prevent excess traction. If an injury is identified, urologic consultation is indicated, and a primary reanastomosis should be attempted, preferably with the aid of a surgical microscope. A metal clip...
CASE STUDY

Vasal Injury During Inguinal Herniorrhaphy: A Case Report and Review of the Literature

placed adjacent to the site of repair may facilitate future procedures for repeated reconstruction if necessary. Finally, follow-up semen analyses may help guide fertility evaluation.

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

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References

Bassini’s Technique

This method reconstructs the inguinal canal as it is physiologically, with two rings, one abdominal, the other subcutaneous; and with two walls, one posterior and the other anterior, between which the spermatic cord passes obliquely.

— Attività di Congresso Associazione Medicina di Italia, Edoardo Bassini, MD, 1844-1924, Italian surgeon
EDITORIAL

Healthy Behavior Change in Practical Settings

Scott Young, MD

Abstract

The core principle of implementing healthy behavior change is making the healthy choice the easy choice. Putting this motto into practice requires us to remove the barriers that individuals face when trying to live a healthy lifestyle. It is important to look at the bigger picture when helping our patients reach optimal health, looking closely at exercise levels and home life. Environmental factors can cause strain and present challenges for people trying to develop and maintain good health. At the Care Management Institute and at Kaiser Permanente, we are making strides to change default behaviors so optimal lifestyles become the norm, rather than the exception.

The Healthy Choice

At the Care Management Institute, we pride ourselves on the work we do to “make the right thing easy to do.” One of the key tenets of putting this motto into practice is removing the barriers that make it difficult for us as an organization to initiate change—and a big part of that is looking at the whole picture. We’re not just trying to solve problems; we’re trying to identify the sources of the problems so that we can make necessary adjustments early on, and with greater success.

The same principles apply on an individual level. As a family practice physician, when I am sitting across from patients with high blood pressure, there are a number of questions I must ask. Their electronic health records (EHRs) prompt me with certain information about their family histories and body mass indexes and even remind me to measure exercise as a vital sign. However, there are so many more elements that I want to examine, beyond what the medical record can show me. To be successful in making my patients’ healthiest selves, I need to have effective and constructive conversations before providing any advice.

Behaviors and Social Practice

Our EHR system doesn’t necessarily prompt us to look at behaviors and social factors that may be obstacles to achieving optimal health. For my patients with hypertension, I’m going to care about aspects of their daily lives that prevent them from exercising healthier practices. I care about their environment—where they live, what they eat during the day, and how many hours they spend sitting each day. I care about whether there’s a grocery store in their neighborhoods where they can access fresh fruits and vegetables. The things I care about when I’m meeting with my patients look a lot different from the list of questions that pops up in the EHR. Yet these factors are equally, if not more, important than anything else when I’m looking at the causes of my patients’ medical conditions.

A Positive Conversation

Once I have a better understanding of the total picture of my patients, there is a second set of considerations I must examine. Will my patients make the lifestyle and behavior changes needed to positively affect their health? Yes, I can tell them to eat better and exercise more, but if they work two jobs and don’t have access to a grocery store in their neighborhoods, they’re going to have a tough time with this. At this point, I might think back to the motivational interviewing training I received and think about how to frame the conversation with patients in the most constructive way. Motivational interviewing involves four stages of dialogue to help orient patients toward success with their change-related goals using support, advice, affirmation, and empathetic conversation. These stages include engaging with patients to help build rapport, focusing on the changes they want to make while offering advice and support, evoking patients’ desires and what they possess within them to effect change, and planning to implement the goals and next steps patients identified through the encounter.1 Supporting my patients’ awareness about their current behavior patterns, helping them become aware of the skills they already have, and respecting any initial resistance will be crucial to conducting a positive conversation.

Healthy Lifestyle Changes

Traditionally, the ability to achieve total good health has been dependent on an individual’s willingness to implement change in his or her everyday life. Behavioral design ultimately helps people find useful tools and tactics for making healthy lifestyle changes. It also helps determine how able and ready a person is to make a change, and what triggers are most likely to instigate that change. At times, if I’m unable to motivate my patients to change, I might need to enlist the expertise of others on my team and provide a referral. What kind of resources or outside referrals will be beneficial in helping my patients accomplish their goals? I may need to go beyond the exam room and look to what the community can offer. There may be diet- and exercise-tracking apps, free nutritional and wellness counseling, cooking classes, sports clubs, and even community or church groups that could help my patients to make positive lifestyle changes once they leave my exam room.

For individuals to sustain healthy lifestyle changes, we must make the healthy choice the easy choice. Something as simple as having well-lit and well-main-

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Behavior Change Conversations

However, to sustain healthy lifestyle changes, we must address them not only in communities but also in clinical settings. Clinicians and physicians are a crucial element to bridging the gap between individuals knowing what needs to change and actually implementing those lifestyle changes. Physicians are in a position to help educate patients about the importance of healthy behavior change and to guide them to resources that may aid them in living healthier lives. Training in motivational interviewing is one useful tool that can aid clinicians to have productive conversations about behavior change with their patients. One resource used in Northern California is the Motivational Interviewing Toolkit: www.kphealtheducation.org; however, there are many ways to approach behavior change conversations with patients. Discussions about behavior change help individuals understand healthy living in the context of preexisting goals they may have and to view overall health as a community issue, rather than as a medical condition.

Unhealthy Habits

The prevalent and growing obesity epidemic in the US initially stemmed, in part, from negative systematic change. New communities today are frequently designed around unhealthy habits: Suburban housing developments require people to drive to everyday destinations, and fast food restaurants make unhealthy food the most convenient option. This has created an unmet need for systematic changes in the opposite direction—changes that will help us to climb out of the unhealthy routine and to redesign for optimal default behaviors. Since 1994, there has been a dramatic increase in obesity in the US. According to the Centers for Disease Control and Prevention, 35.7% of US adults and approximately 17%—or 12.5 million—of children and adolescents aged 2 to 19 years are obese. Obesity can lead to more serious chronic diseases such as heart disease and diabetes. Obesity is a problem that begins by affecting communities and eventually spreads to a national level. Awareness campaigns such as HBO’s The Weight of the Nation (developed in partnership with Kaiser Permanente) are attempting to reach individuals in their communities and warn them of the severe and adverse effects of being overweight or obese.

The Centers for Disease Control and Prevention also reports, through the Diabetes Prevention Program national study, that intensive lifestyle change and intervention can prevent diabetes caused by obesity. The multicenter clinical research study aimed to discover whether modest (5% to 7%) weight loss through...
dietary changes and increased physical activity (150 minutes/week) could prevent or delay the onset of type 2 diabetes in study participants. The Diabetes Prevention Program ultimately found that participants who lost a modest amount of weight through dietary changes and increased physical activity sharply reduced their chances of developing diabetes.4

Since Kaiser Permanente’s (KP’s) inception, the importance of prevention has always influenced our work and our values, and we have remained on the leading edge. Healthcare Effectiveness Data and Information Set (HEDIS) data show that KP’s Georgia and Southern California Regions are ranked first and second, respectively, in the nation for adult body mass index screening, with other KP Regions not far behind.5

**Exercise as Vital Sign**

Last year, we determined the validity of asking our patients how many minutes per week they exercise and recording this number as a vital sign. This was a progressive step toward achieving optimal behavior design in a clinical setting, and toward achieving total good health. It was also our first foray into creating a clinical measure that determines how a patient’s lifestyle can directly translate into the prevention of the leading causes of death in our country. According to a KP study published in the journal *Medicine and Science in Sports and Exercise*, establishing a systematic method for recording patients’ physical activity in their EHRs ultimately helps clinicians better treat and counsel patients about their lifestyles.6

**Healthy Habits**

Although recognizing exercise as a vital sign is a step in the right direction for healthy behavior change, there is still work to be done. Addressing exercise as a vital sign certainly opens the door to a larger conversation about healthy habits, but what keeps us from fully engaging with our patients is the fact that we don’t completely understand how to measure environmental determinants, or how to talk to patients about them. We must find a way to effectively relate to each patient individually to ascertain how they can fit healthy habits into their everyday routines. First, we must determine what changes each individual is willing to make. Then we must simplify these changes and guide patients through how to monitor their actions against an overall goal. We also must be aware that some patients may be initially resistant to change. Instead of challenging this resistance, we should respect it and encourage patients to drive toward their own goal-oriented solutions.

Karen J Coleman, PhD, research scientist at the KP Southern California Department of Research and Evaluation and lead author of the study examining exercise as a vital sign, stated, “Given that health care providers have contact with the majority of Americans, they have a unique opportunity to encourage physical activity among their patients through an assessment and brief counseling.”7 She added, “Embedding questions about physical activity in the electronic medical record provides an opportunity to counsel millions of patients during routine medical care regarding the importance of physical activity for health.”7

**Prescribing Success**

To focus on total health at a personal level with individuals, it is important to enlist the clinical community to help us prescribe success, rather than just prescribing medical interventions. A crucial question to ask ourselves is, “As a physician, am I equipped to prescribe success for my patient?” Although we, as physicians, have a role to play in the continued health of our patients, barriers to achieving this goal are inevitable.

We must incorporate behavior change as part of the total health framework that physicians advocate and model for their patients and that individuals implement in their lives and communities. As an integrated health care system, we should aim to change the course of how to approach and encourage healthier behaviors to prevent disease, as well as consider what fundamental elements encourage people to change their behavior, and sustain that change, understanding that personal behavior is a major contributor to overall health.

As the behavior change pyramid suggests, it is crucial to bridge the gap between the medical model of the physician’s office and the individual’s experience in the community (Figure 1). Because healthy behavior change begins at home, it’s important for primary care physicians to connect and engage patients on a personal level and to determine what matters the most to patients and what changes they are willing to make, so we can ultimately set them up for success in sustaining those changes. It’s equally important to reinforce ongoing successes once individuals do implement healthy habits in their everyday lives. Again, personal behavior is a major contributor to overall health.

One way to engage individuals in improving their health is to show them how healthy behavior changes can be major contributors to preventing or delaying the onset of disease or personal injury. Health care leaders are increasingly recognizing healthy behaviors as factors in the improvement of overall health. For example, studies indicate that there is a clear link between good emotional health and healthier behaviors.

In 1994, KP created the bone density screening program for osteoporosis prevention in Southern California. As part of this innovative initiative, we identified members with a higher risk of osteoporosis, and we performed bone density screenings on this population. We were also able to recommend calcium supplements, exercise, and other lifestyle changes that could help prevent fractures later on. By 2002, the fully integrated Healthy Bones program was in place at all Medical Centers in the organization’s Southern California Region. Since then, the Healthy Bones program has reduced the number of fragility fractures among Southern California members by 15%. The program has expanded to all KP Regions.8

This is just one example of how early intervention combined with lifestyle and behavior change successfully altered the course of health history for a significant number of our members with the potential for bone disease. With this example in mind, it seems logical that, as a delivery system, we should consider our role in addressing intensive lifestyle change to prevent other diseases such as diabetes, cardiovascular disease, and lung disease.
Mood and Sleep

Increased physical activity can directly and positively affect mood in individuals who experience depression. Physical activity has been examined as an adjunctive treatment strategy for major depressive disorder. This type of evidence can help patients see the positive effects of physical activity on not only their weight and blood pressure, but also on more serious emotional issues, such as depression and anxiety.

Similarly, lack of sleep has been directly linked to obesity. According to a new University of California, Berkeley study, something as simple as getting a good night’s sleep could be a habit that directly affects an individual’s weight. The study found that not only did sleep-deprived individuals crave unhealthy choices, but their behavior differed as well. Ultimately, the brain impairment that occurs when sleep deprivation occurs leads to unhealthy food choices and can eventually cause obesity. However, on the other side of the coin, this means that getting enough sleep is a factor that can help promote weight loss in overweight patients, as long as we can share relevant information with them and engage them to implement this healthy change.

Advertising Unhealthy Habits

Some environmental factors such as television advertising are beyond individual control, making it even more difficult to break unhealthy habits. Furthermore, advertisements also become a contributing factor to poor eating choices, creating a vicious cycle of bad behavior that is difficult to break. Advertisements are a telling example of environmental factors that individuals face in their daily lives that they cannot change or control. Television marketing increased by 8.3% for children ages 2 to 5 years and by 4.7% for children ages 6 to 11 years from 2009 to 2011, reversing declines in previous years, according to Lisa Powell, PhD, of the University of Illinois at Chicago School of Public Health, and colleagues. In addition, by examining television analytics data, the researchers found that teens’ exposure to food ads increased by 9.3%.

“Teens’ exposure to food-related TV advertising has continued to increase steadily since 2003, reaching almost 16 ads per day in 2011,” the authors wrote in the American Journal of Preventive Medicine. Challenges such as the advertising of unhealthy habits are an inherent problem for individual communities—which makes it more crucial for physicians to connect with individuals, better understand where they come from and the challenges they face, and effectively motivate them to change their lifestyles.

Invest in People in Community

In the end, for the medical community, including KP, to be successful in helping individuals implement healthy behavior change, it is crucial to approach prevention in a different way. To ultimately produce good health, we must make investments in the personal lives of our patients—understanding the communities they live in and what intersection is needed between the clinical system and changes that are easily supported by communities. As a health care system, we know that there is no more important relationship than the one between physician and patient. We have reached a point where we have an opportunity to help the primary care system prescribe success among individuals, empowering them to restore and maintain healthy lifestyles, and we have tools available to help us guide the necessary conversations to effect change. Recognizing exercise as a vital sign is one step forward in this process, and we will continue to engage physicians and patients to ultimately change the way healthy behavior change is approached and perceived.

Disclosure Statement

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

Acknowledgment

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References

Dear Editor,

Johna et al\(^1\) have offered an intriguing insight into reflective narratives written by medical learners. Although their study was small, they have succeeded in getting the learners to reflect on their practice, to express such reflections in a written narrative, and to express positive feelings about the experience. It will be interesting to see where their further research leads.

The first challenge in this field is that of taking a great idea, in this case reflective written narratives, and rolling it out to a wider group. Problems start to occur when reflection is made compulsory, which in itself sounds like an oxymoron. In the United Kingdom, many continuing professional development bodies require learners to reflect on every learning activity that they undertake. When you have to write 50 reflections on 50 hours of learning, what should be a life-affirming activity becomes a life-draining one. Learners repeat the same reflections or worse sometimes copy what they think is the “right answer” from another source. Reflection can be encouraged; reflective practice skills can be nurtured; a culture of reflecting on practice and on learning can be engendered, but reflection should not become a tick-box exercise. Another challenge is developing a system of assessment of reflective practice: the first test is to assess whether reflection has occurred or not—this is a simple binary choice for the assessor. However, assessing the quality of reflection is more challenging. But this has been done—sometimes in quite challenging domains. For example, Moon et al\(^2\) have analyzed reflective narratives to assess the ethical reasoning of pediatric residents. In their case too, the study was small and required substantial and expert input—however, feasibility was demonstrated. Assessment is vital: it drives learning, and it is incumbent on medical educators to ensure that assessment motivates the learners in the right way and moves them in the right direction—that is, so that they engage in real and meaningful reflection on their practice and that such reflection ultimately has an impact on their practice and their patients.

Yours Sincerely,

Kieran Walsh, MD, FRCP
clinical Director of BMJ Learning
BMJ Learning, London, UK

References

PLANT-BASED DIETS IN CROHN’S DISEASE


Dear Editor,

There are a lot of papers on plant-based diets by researchers, nutritionists, or specialists in the fields, but there is a paucity of comprehensive review for physicians. Therefore, we enjoyed greatly the article, “Nutritional update for physicians: plant-based diets.” Tuso et al. recommend a plant-based diet to all patients, especially those with hypertension, diabetes, cardiovascular disease, or obesity.

We want to comment on our experience of a plant-based diet in treating Crohn’s disease (CD). Symptoms of CD subside easily with total parenteral nutrition or total enteral nutrition. But CD is well known to flare up after the resumption of meals. Therefore, meals per se are thought to cause gut inflammation. Takagi et al. named their therapy “half elemental diet.” Generally, the more the amount of the elemental diet, the less the relapse rate is. Consequently, about half of the daily energy is provided by an elemental diet, which is a standard regimen in quiescent CD in Japan. Relapse rates with an “elemental diet” occur at the rate of 27% at one year, whereas the control group rate is 60% to 70% in the studies by Takagi et al. and Sandborn et al. When more than 30 kcal/kg ideal body weight/day of elemental diet is given, the remission rate at 1 year is about 95%. However, increasing the amount of elemental diet decreases the quality of life. We regard CD as a lifestyle-related disease mainly mediated by Westernized diets, which tend to cause dysbiosis in gut microflora. Namely, the greatest environmental factor in CD is diet-associated gut microflora. A design for increasing beneficial bacteria led us to a semivegetarian diet (SVD): lactovo-vegetarian with fish once a week and meat once every two weeks. SVD and infliximab induction therapy were initiated simultaneously. Patients were admitted until completion of standard induction therapy of infliximab. Patients were advised to continue the SVD after discharge. Relapse rates at 1 year and 2 years were 0% and 8% in patients on SVD and 33% and 75% in patients on an omnivorous diet. These results were obtained in the absence of scheduled infliximab maintenance therapy or immunosuppressants, and they are far better than the scheduled infliximab maintenance therapy. SVD is provided during hospitalization and is recommended not only in CD but also in other intestinal diseases including ulcerative colitis and cytomegalovirus enteritis. As Tuso et al. pointed out, current diseases are a reflection of our lifestyle, particularly a Westernized diet, in wealthy nations. Diet reviews recommend plant-based diets to treat and prevent a variety of common diseases. Inflammatory bowel disease (IBD) is not an exception. However, evidence level of our study is not enough to make gastroenterologists appreciate the efficacy of a plant-based diet in IBD. Clinical studies providing high levels of evidence showing the efficacy of a plant-based diet in IBD is eagerly awaited.

Yours sincerely,
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References
BOOK REVIEW

The Doctor Crisis
by Jack Cochran, MD, and Charles Kenney

In their book, The Doctor Crisis, Jack Cochran, MD, and Charles Kenney send a clear and compelling message to physicians and health care executives seeking to heal a health care system in need: to fix the health care crisis, we must first fix the doctor crisis.

Many physicians today are struggling under the burden of increased regulatory pressures, reduced reimbursements, and bureaucracy, all of which have contributed to levels of physician burnout of epic proportion. And yet, according to the authors, engaging physicians not only as healers, but as partners and leaders, creates a path forward that heals the system from the inside out.

Cochran states, “We can’t legislate our way out of the problem. We must learn our way out of the problem. Improved quality will ultimately be the most powerful force for controlling costs.”

Engaging physicians, Cochran and Kenney state, would be that powerful force to mobilize for change.

 Physicians by their very nature want to do what is right and best for their patients. And although physicians are often weighed down by the many challenges they face today, by addressing what holds them back, helping them to grow and to lead, they in turn will improve the health care system.

As Cochran states with such clarity, “… physicians must step up and solve the health care crisis. We must be part of the solution; we must be creative and bold and stand up for our patients.”

In making their case, Cochran and Kenney create an eloquent juxtaposition of data, biography, and leadership philosophy. The authors weave together stories of success and failure within the health care system, revealing its strengths and weaknesses. They note the relentless challenges negatively affecting the morale of hundreds of thousands of physicians who want nothing more than to “put their patients first, every step in the care process, every time.”

With a keen knack for storytelling, Cochran and Kenney tell powerful stories that touch our heads and our hearts: from opening the book with the inspiring story of a young boy with a cleft lip who convinced his anxious father to allow him to undergo reparative surgery, to the harrowing account of 22 surgeons and a large multidisciplinary team representing the best that medicine has to offer as they operate on conjoined twins, to Cochran’s experiences and challenges as the Executive Director, President, and Chairman of the Board of the Colorado Permanente Medical Group.

Each story demonstrates the challenges of health care and what remarkable things can be achieved when we are at our very best.

Cochran also outlines his leadership learning journey, which includes practical leadership tips and practices that have played a critical role in his development and in that of other physician leaders. Included among them are the importance of active listening, engaging and valuing physicians, and setting clear expectations. He discusses the impact key learnings from the book Play to Win had on the transformation of the Colorado Permanente Medical Group. Cochran believes that committing to the preservation and enhancement of physician careers frees physicians to focus on optimizing the patient care experience and streamlining the care process.

I strongly recommend The Doctor Crisis to physicians and to every leader in health care. Health care, at its heart, is a team sport. Success lies in bringing together all the compassionate, dedicated professionals who care for patients. Physicians have always played a critical role as leaders of our health care teams. By the very nature of their positions, they set the tone in every setting, influence every system, and are looked to by others as leaders. While asking them to engage, to value, and to listen to others, we also need to engage, to value, and to listen to them.

The Doctor Crisis is a valuable read for anyone seeking to understand the essential role physicians play in creating solutions for care delivery, and as a result, their critical involvement in making health care in the US all that we need it to be.

References

Edward Ellison, MD, is the Executive Medical Director and Chairman of the Board of the Southern California Permanente Medical Group. E-mail: edward.m.ellison@kp.org.
CME Evaluation Program

Section A.

Article 1. (page 4) Mindfulness-Based Stress Reduction in an Integrated Care Delivery System: One-Year Impacts on Patient-Centered Outcomes and Health Care Utilization

Which of the following core skills is not taught in Mindfulness-Based Stress Reduction?

- a. understanding of attitudes, perceptions, and unskilled thought patterns
- b. understanding and modulating one's reaction to stressors
- c. recognizing pleasant and unpleasant emotions, thoughts, and sensations
- d. meditation

Which of the patient-reported outcomes showed negative changes at 1 year, compared to 8 weeks following the Mindfulness-Based Stress Reduction intervention?

- a. mental composite score
- b. bodily pain
- c. self-efficacy
- d. depression

Article 2. (page 10) Improving Appropriate Use of Pulmonary Computed Tomography Angiography by Increasing the Serum D-Dimer Threshold and Assessing Clinical Probability

Based on the results of the three PIOPED trials, what should be the minimum prevalence of acute pulmonary embolism among patients undergoing evaluation for pulmonary embolism?

- a. 5%
- b. 10%
- c. 15%
- d. 20%
- e. 30%

Which of the following statements is true:

- a. the prevalence of acute pulmonary embolism in patients with a D-dimer < 1.0 μg/mL is no greater than the coincidental pulmonary embolism rate seen on computed tomography scans of the chest
- b. all patients with low clinical risk for pulmonary embolism should have their D-dimer level checked
- c. patients with intermediate clinical risk for pulmonary embolism do not need to have their D-dimer level checked
- d. patients with both high clinical risk and D-dimer level > 1.0 μg/mL should be treated for pulmonary embolism
- e. raising the D-dimer threshold to 1.0 μg/mL does not increase the prevalence of pulmonary embolism seen on pulmonary computed tomography angiographs

Article 3. (page 21) Impact of Implementing Glycated Hemoglobin Testing for Identification of Dysglycemia in Youth

The following American Diabetes Association recommendations for children are true except:

- a. screening at age 10 with any 2 risk factors as discussed in the study
- b. Body mass index (BMI) ≥ 85th percentile for age and sex with no other risk factors
- c. BMI ≥ 85th percentile for age and sex with any 2 risk factors
- d. onset of puberty with any 2 risk factors

The following are the main findings of the study except:

- a. glycated hemoglobin testing was more common in 2012
- b. the proportion of patients identified as at-risk for diabetes by either test (fasting plasma glucose or glycated hemoglobin) increased significantly in both sites from 2009 to 2012
- c. a significantly larger proportion of females were identified in 2012 in both sites
- d. the mean age for youth at risk for diabetes increased significantly between 2009 and 2012

Article 4. (page 89) Healthy Behavior Change in Practical Settings

Motivational interviewing involves which 4 stages of dialogue?

- a. assessing, level-setting, supporting, and motivating
- b. empathizing, balancing, orienting, and activating
- c. engaging, focusing, evoking, and planning
- d. understanding, rationalizing, processing, and materializing

The Bone Density Screening Program is an example of how combining early intervention with and can significantly alter the course of health history for patients.

- a. exercise and wellness coaching
- b. lifestyle and behavior change
- c. supplemental vitamins and physical therapy
- d. diet and health education

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?

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<td>Integrate learned knowledge and increase competence/confidence to support improvement and change in specific practices, behaviors, and performance.</td>
<td>Lead in further developing “Patient-Centered Care” activities by acquiring new skills and methods to overcome barriers, improve physician/patient relationships, better identify diagnosis and treatment of clinical conditions, as well as, efficiently stratify health needs of varying patient populations.</td>
<td>Implement changes and apply updates in services and practice/policy guidelines, incorporate systems and quality improvements, and effectively utilize evidence-based medicine to produce better patient outcomes.</td>
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Key
5 = highly likely
4 = likely
3 = unsure
2 = unlikely
1 = highly unlikely
0 = I already did this

Section C.

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

Section D. (Please print)

Name
Physician
Non-Physician

Title

E-mail

Address

Signature

Date

Please return completed form by December 30, 2014

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Reverse Pseudohyperkalemia in a Patient with Chronic Lymphocytic Leukemia

Taurino Avelar, MD

Abstract
A man, age 78 years, with a history of chronic lymphocytic leukemia presented to clinic for evaluation of a cough. On further evaluation, he was noted to have an elevated potassium level. This case report highlights the importance of distinguishing cases of true hyperkalemia from pseudohyperkalemia and reverse pseudohyperkalemia.

Introduction
Hyperkalemia can be challenging to manage. Differentiating true hyperkalemia from pseudohyperkalemia is often difficult. A less well-known condition that is thus challenging to identify is reverse pseudohyperkalemia. Here, I present an unusual case of reverse pseudohyperkalemia in an elderly man with a history of chronic lymphocytic leukemia (CLL).

Case Report
A man, age 78 years, with a history of CLL (not currently on treatment), chronic kidney disease 3A, coronary artery disease, and hypertension was initially seen in clinic reporting two days of coughing. He also reported one day of toe pain but was otherwise asymptomatic. There were no recent changes to his home medications, which included amiodipine, atenolol, aspirin, and pravastatin. Notably, he was not on an angiotensin-converting-enzyme inhibitor or an angiotensin receptor blocker, despite a history of coronary artery disease. Vital signs were within normal limits, and physical examination was unremarkable. Given his history of CLL, tumor lysis syndrome leading to gout was suspected. He was further evaluated, and laboratory results were significant for leukocytosis, 206 × 10³ cells/μL (95% lymphocytes) (normal 4.0 to 10.0 × 10³ cells/μL); plasma potassium, 8.4 mEq/L (nonhemolyzed; normal 3.5 to 5.0 mEq/L); calcium, 8.4 mg/dL (normal 9.0 to 10.5 mg/dL); phosphorus, 4.7 mg/dL (normal 3.0 to 4.5 mg/dL); uric acid, 10.6 mg/dL (normal 2.5 to 8.0 mg/dL); and glucose, 91 mg/dL (normal 70 to 100 mg/dL). Results were also significant for blood urea nitrogen, 36 mg/dL (normal 8.0 to 20 mg/dL); creatinine, 1.4 mg/dL (normal 0.7 to 1.3 mg/dL); and glomerular filtration rate of 49 mL/min/1.73 m². The patient’s baseline creatinine was 1.3 mg/dL, with a glomerular filtration rate of 53 mL/min/1.73 m². Given the profound leukocytosis, hyperkalemia, and hyperuricemia, tumor lysis syndrome seemed to have been confirmed. On the basis of the elevated plasma potassium level, the patient was subsequently referred to the Emergency Department for treatment.

Upon arrival, the patient’s repeat plasma potassium was 8.1 mEq/L. Electrocardiogram did not demonstrate peaked T waves, loss of P waves, prolonged QRS intervals, or evidence of high-grade block. He was treated with intravenous calcium gluconate, intravenous insulin, and oral sodium polystyrene sulfonate. Plasma potassium remained elevated at 8.1 mEq/L. A repeat electrocardiogram showed no change. With the exception of the cough and toe pain, he continued to be asymptomatic despite the persistently elevated plasma potassium, and he denied any weakness, fatigue, or palpitations. Given the apparent lack of improvement in potassium despite medical treatment, the decision was to proceed with emergent dialysis.

After partial dialysis, the possibility of reverse pseudohyperkalemia was considered. Potassium was rechecked, both the plasma and serum potassium, which were 7.9 mEq/L and 4.4 mEq/L, respectively. Given the patient’s history, hemodynamic stability, and lack of electrocardiogram findings and the fact that he was without improvement despite hemodialysis, it was suspected that the plasma potassium results did not represent the true in vivo potassium levels. Hemodialysis was subsequently discontinued, and repeat testing 4 hours later demonstrated similar results. The patient’s serum potassium was 4.4 mEq/L and 4.6 mEq/L on the day of discharge.

Discussion
Hyperkalemia is a life-threatening electrolyte abnormality that requires prompt diagnosis and treatment. In treating hyperkalemia, physicians have multiple therapeutic options at their disposal. In the case above, hemodialysis was felt to be an appropriate intervention because the patient’s plasma potassium level was not responding to medical management for severe hyperkalemia, a justifiable reason for emergent hemodialysis. Unfortunately, the inability to determine the patient’s true potassium level resulted in the implementation of interventions that could have led to significant morbidity and mortality. It was only after further clinical laboratory investigation that the true potassium level was identified (Table 1). Because there are various causes for falsely elevated potassium measurements, understanding the scenarios in which they may occur is crucial to a clinician’s decision making. The challenges in identifying this abnormality demand further discussion.
Potassium is normally measured from a sample of either plasma or serum. A sample of plasma is collected in a tube that contains heparin to serve as the anticoagulant (although it can also be collected with other additives, such as ethylenediamine tetra-acetic acid [EDTA] and citrate), whereas serum is collected in a tube that does not contain heparin or the other additives. In the clotting process, platelets undergo aggregation and degranulation while also releasing potassium. As a result, serum potassium is higher (0.36 ± 18 mEq/L) compared with a sample collected in plasma. This has also been noted in patients with significant erythrocytosis and leukocytosis. Such abnormalities can lead to what is known as pseudohyperkalemia, which is a phenomenon observed in vitro where the measured serum potassium is higher than the plasma potassium is normal. In addition to these patient-related causes, there are additional factors that can lead to this abnormality (Table 2). There have been attempts to define pseudohyperkalemia as a difference between serum and plasma potassium concentration of more than 0.4 mEq/L when the samples are obtained at the same time, remain at room temperature, and are tested within an hour of collection. Given the implications of basing medical decisions on falsely elevated levels, measuring potassium from plasma continues to be the preferred method.

In the case of reverse pseudohyperkalemia, the opposite is seen: plasma potassium is noted to be higher than serum potassium. It is a phenomenon that has been reported in patients with CLL. The mechanism of this phenomenon is yet to be clearly characterized, but several observations have been made. One possibility is increased sensitivity to heparin-mediated cell membrane damage during processing and centrifugation in the context of hematologic malignancy. In one study, the degree of increase in potassium was directly related to the amount of heparin contained within the tube into which the sample was collected. Mechanical stressors have also been implicated. Pneumatic tube transportation systems may lead to falsely elevated plasma potassium levels. These findings are not surprising given that the cells in patients with CLL are both fragile, and thus more susceptible to lysis, and more numerous, which can lead to significant abnormal laboratory results that may not otherwise be appreciated. This patient had a history of CLL with extreme leukocytosis, and the samples had been collected in heparin-containing tubes and transported via a pneumatic tube transportation system. No tested sample was transported manually for comparison.

There are ways laboratories may promptly identify cases of reverse pseudohyperkalemia. Consideration may be given to testing serum potassium if the plasma potassium is elevated in the context of leukocytosis. In addition, serum testing may include evaluating potassium in patients with CLL. Such testing may lead to prompt recognition of reverse pseudohyperkalemia. On further chart review, it was noted that the patient had not previously been started on an angiotensin-converting enzyme inhibitor or an angiotensin receptor blocker because of previously elevated potassium levels, further highlighting the importance of making the diagnosis.

Because of its cardiotoxic potential, hyperkalemia is a potentially fatal electrolyte abnormality. The ability to differentiate true hyperkalemia from pseudohyperkalemia and reverse pseudohyperkalemia is crucial for determining the appropriate interventions. The necessary treatments can only be determined by taking into account the clinical history, hemodynamics, appropriate clinical laboratory investigation, and echocardiogram findings.

**Disclosure Statement**

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

**Acknowledgment**

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**References**


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Reverse Pseudohyperkalemia in a Patient with Chronic Lymphocytic Leukemia


A 65-year-old man with a history of hyperplastic polyps underwent a surveillance colonoscopy, which revealed a large, smooth cystic bulge at the appendicular orifice (Figure 1). Subsequently, a computed tomography (CT) of the abdomen with contrast revealed an appendiceal mucocele measuring 13.3 x 4.5 cm (Figures 2a and 2b). Because of the abnormal imaging findings, an elective laparoscopic appendectomy and cecectomy was performed with minimal spillage. A gross specimen measuring 9 cm in length and 3 cm in diameter was collected with the appendiceal lumen, which was filled with yellow mucoid material. Histopathologic evaluation of the appendix revealed a low-grade appendiceal mucinous neoplasm (LAMN-I) (Figure 3). The patient had an uneventful recovery and was doing well at the time of writing. Repeat CT of the abdomen and pelvis was scheduled at 6 months and 12 months, and a colonoscopy at 1 year after surgery.

On endoscopic visualization of this 65-year-old patient, lipoma or mucocele were considered the differentials. On the basis of the CT of the abdomen and of the endoscopy, we considered LAMN, with the rare possibility of pseudomyxoma and peritoneal metastasis.

LAMN is a rare entity with an incidence ranging from 0.2% to 0.7% of all excised appendixes. Approximately 25% to 50% of LAMN are incidental findings with the initial discovery during radiologic or endoscopic examinations, or during surgery. Initial presentation can range from asymptomatic to right lower quadrant abdominal pain or a palpable abdominal mass. Initial clinical differentials include acute appendicitis, diverticulitis, ovarian mass (in women), large cecal mass, peritoneal carcinomatosis originating from colon cancer, peritoneal sarcomatosis, peritoneal mesothelioma, disseminated peritoneal fungal infections, pseudomyxoma peritonei, or retroperitoneal cyst.

LAMN is divided into two major classes. LAMN-I is found in a younger group of patients, with the tumor confined to the appendix lumen. LAMN-I is rarely progressive, so a “wait-and-watch” policy is recommended with measurement of tumor markers, CT of the abdomen and pelvis at six months, and an annual work-up. LAMN-II is usually found in older patients, with mucin and/or neoplastic epithelium in the submucosa, the intestinal wall, or in the area around the appendix with or without perforation. Recommended treatment for LAMN-II includes hyperthermic intraperitoneal chemotherapy, prophylactic cytoreductive surgery, greater omentectomy and splenectomy, left upper quadrant peritoneectomy, right upper quadrant peritoneectomy, right upper quadrant peritoneectomy.
An Incidental Discovery of Low-Grade Appendiceal Mucinous Neoplasm

CASE STUDY

An Incidental Discovery of Low-Grade Appendiceal Mucinous Neoplasm

quadrant peritonectomy, lesser omentectomy with cholecystectomy, pelvic peritonectomy with rectosigmoid resection, and anterectomy with a more aggressive follow-up. In women with concomitant peritoneum, ovarian, or appendix tumors, many authors believe that the appendix is the primary site with secondary involvement of ovary and peritoneum, whereas others believe that each tumor has an independent origin. The topic continues to be debated. Since intact mucocles are benign, the worst outcomes are perforation or spillage of the mucocles into the peritoneal cavity, causing pseudomyxoma peritonei to develop.

Disclosure Statement

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

Acknowledgements

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References


Figure 3. Histopathologic image (10x magnification) demonstrating villiform mucinous epithelium, glandular epithelium with tall columnar mucinous cells, and pseudostratified nuclei at the base.
Latrodectus Envenomation in Greece

Garyfallia Nikolaos Antoniou, MSc; Dimitrios Iliopoulos, PhD; Rania Kalkouni, MD; Sofia Iliopoulos, MSc; Giorgos Rigakos, MD; Agoritsa Baka, MD

Abstract

During the summer period 2011-2012, seven widow spider bites in Greece were reported to the Hellenic Center for Disease Control and Prevention. Widow spiders (in the genus Latrodectus) are found all over the world, including Europe, Asia, Africa, Australia, and the US. Alpha-latrotoxin (main mammalian toxin) causes the toxic effects observed in humans. Victims should receive timely medical care to avoid suffering. Latrodectus bites are very rarely fatal.

All the patients reported having an insect bite 30 minutes to 2 hours before they arrived at the Emergency Department of the local hospital. Severe muscle cramps, weakness, tremor, abdominal pain, and increased levels of creatinine phosphokinase were present in all patients. The Emergency Operation Center of the Hellenic Center for Disease Control and Prevention was informed immediately in all cases. Antivenin was administered to four patients upon the request of their physicians.

All patients recovered fully. It is essential that health care workers recognize early the symptoms and signs of Latrodectus bites to provide the necessary care. The management of mild to moderate Latrodectus envenomations is primarily supportive. Hospitalization and possibly antivenin should be reserved for patients exhibiting serious systemic symptoms or inadequate pain control. The most important thing for all of these patients is early pain relief.

Introduction

The spider genus Latrodectus, commonly called “widow spider,” is found all over the world, including Europe, Asia, Africa, Australia, North America, and South America. The genus includes the black widow spider common in North America: *L. mactans*.¹ The term widow spider is used because not all species in the genus Latrodectus are black. There are other widow spiders including the brown widow (*Latrodectus geometricus*), the red-legged widow (*Latrodectus bishopi*), the redback spider (*Latrodectus hasselti*), the button spider (*Latrodectus indistinctus*), *Latrodectus variolus*, and *Latrodectus hesperus*. Latrodectus tredecimguttatus is found in Europe (including Greece) and South America.² The adult female *L. mactans* is approximately 2 cm in length and is easily identified by its large, shiny, black abdomen with a red-orange hourglass or spot on the ventral abdomen. However, they can have variation in color and markings.³ *Latrodectus tredecimguttatus* is black in color, similar to most other *Latrodectus* species, and is identified by the 13 spots found on its dorsal abdomen. These spots are usually red in color but may also be yellow or orange. It is otherwise similar to other species in the genus *Latrodectus*. The male *L. tredecimguttatus* is smaller, brown, and incapable of envenomating humans. The female sometimes eats the male during or after copulation. Webs are irregular, low-lying, and commonly seen in dark environments such as garages, barns, outhouses, and foliage.⁴ Generally, *Latrodectus* bite if they are disturbed, so people should take care when reaching into dark areas to avoid spider bites.

Alpha-latrotoxin is the main mammalian toxin found in the *Latrodectus* venom, with predominantly neurologic and autonomic effects. The toxin opens presynaptic cation channels, causing a massive influx of calcium and increased release of multiple neurotransmitters (primarily acetylcholine). This results in excess stimulation of motor endplates with resultant clinical manifestations.

No deaths caused by *Latrodectus* envenomation have been reported to the American Association of Poison Control Centers since its first annual report in 1983 until 2004.⁵ Deaths caused by *Latrodectus* bites were reported in Spain (2001),⁶ Greece (2003),⁷ and Albania (2006).⁸

The spiders that bit the Greek victims during the summer period 2011-2012 were not caught, so it was not possible for the physicians to identify whether they were *Latrodectus* bites. However, the patients’ symptoms were indicative of bites from *Latrodectus* as determined by medical personnel and supported by the positive response to the antivenin, which the Hellenic Poison Information Centre and the medical staff agreed was indicated. The antivenin used (Aracmyn Plus; Instituto Bioclon; Mexico City, Mexico) possesses the necessary mix of antibodies to neutralize the various toxic components found in spider venom. It is produced by the antibodies developed by horses that are immunized with *Latrodectus* venom.⁹

Symptoms of spider envenomation (latrotoxic) may include initial localized reaction at the bite site, generally trivial, which may go unnoticed. Commonly, the bite is described as a pinch or pinprick; however, infants may present with unexplained
crying. Tiny fang marks may be visible, and local effects are usually limited to a small circle of redness, localized diaphoresis, and/or induration around the immediate bite site. A central red-dened fang puncture site surrounded by an area of blanching and an outer halo of redness is described as having a target appearance. Systemic symptoms begin within about one hour and may last for a few days.

Abdominal rigidity after the bite may mimic an acute abdomen regarding the symptom’s intensity. It is not a true surgical emergency. Neurologic effects, including mild weakness, fasciculations, and ptosis, have been described as well. *Latrodectus* facies, characterized by spasm of facial muscles, edematous eyelids, and lacrimation, may occur. This can be mistaken for an allergic reaction. Pain in the chest, back, and extremity muscles, depending on the bite site, may occur. Respiratory symptoms including chest pain/tightness, shortness of breath, grunting and respiratory distress, bronchorrhea, and pulmonary edema have been described in Europe and South Africa. Other reported symptoms include nausea, vomiting, headache, numbness, agitation, irritability, and priapism.

*Latrodectus* envenomations may be managed with opioid analgesics and sedative-hypnotics. Antivenin administration may be indicated for patients who have severe envenomation with pain refractory to these measures. Antivenin administration results in resolution of most symptoms half an hour after administration most of the time, and it has been shown to decrease the need for hospitalization. Calcium gluconate, though historically a treatment, has been shown to be less effective than benzodiazepines combined with opioids. Hospitalization and possibly antivenin administration should be reserved for patients exhibiting serious systemic symptoms or inadequate pain control. High-risk factors include age older than 60 years, severe envenomation, pediatric patient, or history of hypertension and coronary artery disease.

Latrodectism can be easily confused with steatodism. Steatodism is the envenomation caused by the spider species *Steatoda*. *Steatoda* resemble *Latrodectus* in size and physical form, owing to being members of the same family (Theridiidae). Although the bite of *Steatoda* spiders is not as serious as that of true widow spiders, several of these spiders do have medically

<table>
<thead>
<tr>
<th>Sex</th>
<th>Age, years</th>
<th>Pain</th>
<th>Cardiovascular system</th>
<th>Respiratory symptoms</th>
<th>Other reported symptoms</th>
<th>CPK</th>
<th>CRP</th>
<th>Level of white blood cells</th>
<th>Other</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>24</td>
<td>Acute abdominal pain</td>
<td>ECG: incomplete right bundle branch block</td>
<td>Tachypnea, pulmonary edema</td>
<td>Sweating, salivation, priapism</td>
<td>Elevated</td>
<td>Elevated</td>
<td>Elevated troponine (1.6 ng/mL)</td>
<td>Antivenin</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>70</td>
<td>Generalized muscle pain to back, chest, and abdomen</td>
<td>Mild hypertension (155/90 mm Hg)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Metabolic acidosis (pH: 7.23)</td>
<td>Opioid analgesics</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>49</td>
<td>Intense pain at the area of bite (inner surface of the arm), extension of pain to the chest and abdomen</td>
<td>Increased blood pressure (180 mm Hg)</td>
<td>Local swelling at the bite area</td>
<td>Elevated (1423 UI/L)</td>
<td>Mild leukocytosis</td>
<td>Oxygen, opioid analgesics, calcium and beta-adrenergic blockers, antivenin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>4</td>
<td>Intense pain at the area of bite</td>
<td>Local swelling at the bite area</td>
<td></td>
<td>Mild leukocytosis</td>
<td>Oxygen, opioid analgesics</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>21</td>
<td>Severe pain in the legs, thoracic pain</td>
<td>Myocardial ischemia augmentation in T-wave amplitude in leads V3 through V6 without reciprocal changes</td>
<td>General anxiety</td>
<td></td>
<td>Mild leukocytosis</td>
<td>Oxygen, opioid analgesics, antivenin</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

CPK = creatinine phosphokinase; CRP = C-reactive protein; ECG = electrocardiogram.
significant bites. Their bites cause symptoms that have been described as a very minor *Latrodectus* bite. Use of *Latrodectus* antivenin has been shown effective in treating steatodism.\(^2\)

**Case Presentations**

All patients reported having an insect bite 30 minutes to 2 hours before they arrived at the Emergency Department (ED) of the local hospital. The bite area looked like 2 small holes. Severe pain at the bite area, acute abdomen, severe muscle cramps, weakness, and mild leukocytosis were present in most patients. Respiratory symptoms including chest pain/tightness and tachypnea were present in 3 of them. Other reported symptoms were hypertension, sweating, priapism, elevated creatinine phosphokinase (CPK), elevated C-reactive protein (CRP), pulmonary edema, dyspnea, elevated troponin levels, and metabolic acidosis.

It is interesting that two young males (first and seventh cases) manifested cardiac toxicity. The first patient’s electrocardiogram (ECG) showed incomplete right bundle branch block, and he suffered elevated troponin levels; whereas the ECG of the seventh patient showed augmentation T-wave amplitude in leads V3 through V6 without reciprocal changes; he also had elevated troponin levels. Detailed information about each patient’s symptoms may be found in Table 1.

The antivenin (Aracmyn Plus) was administered to 4 patients upon the request of their physicians because of the severity of their situation or the presence of underlying diseases. One or 2 vials were administered to patients. The clinical improvement of the patients occurred after half an hour of the antivenin administration. Per the manufacturer, antivenin dose varies from 1 to 5 vials depending on severity of symptoms. The antivenin Aracmyn Plus has completed human Phase 3 trials. Aracmyn Plus has an equine-origin Fab2 product and is considered to be less likely to trigger an allergic reaction.\(^9\) One vial of the antivenin is mixed with 50 mL normal saline and is administered intravenously within 30 minutes.\(^9\)

All patients were administered opioid analgesics for the relief of their intense pain, which is the mainstay of therapy. Readers can find more information about patients’ cures in Table 1. We specifically describe here the case of the first victim, who suffered the most severe clinical signs.

**Patient A.** A man age 24 years came to the ED of our general hospital. The patient was sweating, with acute abdominal pain, salivation, priapism, palpitations, and reduced blood saturation. The ECG showed incomplete right bundle branch block and elevated troponin levels (1.6 ng/mL). CPK and amylase levels were elevated as well. CRP was normal, and the absolute value of white blood cells was 28,000/\(\mu\)L.

The patient reported experiencing intense back pain while he was sleeping, which was severe enough to wake him. After a few minutes, the symptoms appeared. On the basis of the symptoms and the statements and descriptions of the spider by the patient, it was determined that the patient was bitten by *L. tredecimguttatus*, one of the European species of *Latrodectus*.

During his hospitalization in the ED, the patient suffered pulmonary edema. He was intubated, sedated, and transferred to the intensive care unit (ICU) of the hospital. ICU physicians contacted the Emergency Operations Center of the Hellenic Center for Disease Control and Prevention to request the antivenin Aracmyn Plus, two vials of which were sent immediately. The first dose of antivenin was administered while the patient was sedated, and the second dose was administered while sedation was interrupted. Half an hour after the administration of the second dose of antivenin, the patient’s respiratory function significantly improved.

On the second day of hospitalization in the ICU, the patient was extubated. For his ventilation, a venturi mask was used. Initially, the patient’s pulse increased during effort, but this improved by the third day of hospitalization. Cardiovascular and pulmonary systems were in good condition, and he suffered mild fever. CPK and amylase were declining; whereas CRP was increasing. The white blood cells decreased by 21,000/mL. (On the first day of hospitalization, antibiotics were administered to avoid possible local bacterial infection.)

During the third day of hospitalization, CPK, CRP, and amylase remained elevated, whereas transaminases were normal (morning). In the afternoon, CPK increased significantly (4-digit number); amylase was declining. White blood cells declined to 17,000/mL. Twenty-four hours later, CPK was on a downward trend, owing to increasing hydration and diuresis. Amylase and transaminases were increased. The patient’s overall health condition was quite good, so he was moved from the ICU to the Internal Medicine Department of the hospital for further observation.

On the sixth day of hospitalization, the patient was discharged with complete recovery.

**Discussion**

In cases of *Latrodectus* envenomation, it is essential that health care practitioners recognize the signs and symptoms of envenomation as quickly as possible to begin the best care of patients.

To diagnose a *Latrodectus* envenomation, it is important for the physician to see the suspected spider. If this is not possible, *Latrodectus* bites are diagnosed through a bit of detective work. Evidence of the classic “target” lesion can aid the diagnosis. Additionally, other subtle findings on physical examination can be helpful. Physicians often must diagnose *Latrodectus* bites by asking patients about the onset of symptoms, how they discovered their bites, and whether they saw the spider.

*Latrodectus* bites are distinctive. The site of a bite develops a pale central area with surrounding erythema; often fang marks will be visible.\(^4\) There will probably also be some swelling and redness at the area of the bite.

In the case presented here, the spider was not available for identification, so the diagnosis was made by the clinical and laboratory findings that are reported extensively in Table 1. The victims of *Latrodectus* bites in Greece experienced the typical symptoms of the venomous spider bite. These symptoms were more severe than those caused by steatodism. Thus, physicians determined the identity of the insect that caused the bite and the type of the envenomation. The first case, described here, was the most severe compared with the others reported. It is interesting that the first and the last case reported (two young men) had positive troponins, ECG manifestations indicating that they suffered cardiac toxicity.
The elevated CPK levels in the other patients more likely originated in the skeletal muscle.

Antivenin use appears justified in severe envenomation. It is available and effective, but it is often withheld because of fear of acute hypersensitivity reactions. Because of these concerns about acute hypersensitivity reactions, physicians must weigh the benefits of treating with antivenin for a condition with limited mortality. This controversy stems from a single reported case of fatal hypersensitivity related to spider antivenin administration. Generally, antivenin provides rapid symptomatic improvement—mainly rapid pain relief—as demonstrated in the cases presented here.

Calcium therapy was once considered to be an antidote for *Latrodectus* envenomation. Calcium was thought to stabilize nerve membrane permeability, resulting in decreased neurotransmitter release. Although this effect was demonstrated in vitro and reported in some early clinical series, subsequent experience has not shown effectiveness. Therefore, calcium therapy has lost favor in the medical toxicology community. The traditional therapies for *Latrodectus* envenomation are aimed at providing symptomatic relief while venom effects resolve. Therapies include primarily opioid analgesics and muscle relaxants. In the majority of moderate to severe *Latrodectus* envenomation, patients treated with antivenin experienced a much shorter duration of symptoms and were less likely to be admitted to the hospital than those who did not receive antivenin. Relief of symptoms occurred within an average of 31 minutes of antivenin infusion. Administration of antivenin even late in the course of envenomation has been reported to be effective. Multiple allergies, asthma, or past reactions to equine-based products should be considered contraindications. Antivenin therapy is recommended in cases of envenomation during pregnancy because of the risk of venom-induced abortion or other possible harm to the fetus, although the risk is not known. Furthermore, it is not known whether *Latrodectus* antivenin passes into the breast milk. Although most medications pass into breast milk in small amounts, many of them may be used safely while breastfeeding.

Regarding the incidents in Greece, hospitalization was reserved for all patients, and antivenin was reserved for patients exhibiting serious systemic symptoms or inadequate pain control. All the patients who were administered the antivenin required hospitalization, but none of them suffered an allergic reaction. Four of seven symptomatic patients suffering *Latrodectus* envenomation were administered antivenin, and rapid resolution of symptoms was observed within about half an hour after the administration. These cases demonstrate the safe and effective use of *Latrodectus* antivenin. Antivenin is an important treatment for *Latrodectus* envenomation but has been less successful than those for snake envenomation, with concerns about their effectiveness for latrodectism.

**Conclusion**

It is very important that health care practitioners recognize the symptoms and signs of *Latrodectus* to provide immediate care to *Latrodectus* bite victims. The management of mild to moderate *Latrodectus* envenomations is primarily supportive. Hospitalization and possibly antivenin administration should be reserved for patients exhibiting serious systemic symptoms or inadequate pain control. Physicians should know that high-risk factors include age older than 60 years, severe envenomation, pediatric patient, or history of hypertension and coronary artery disease. People who report these factors should receive antivenin as soon as possible to avoid suffering envenomation complications (eg, cardiovascular collapse). Finally, the most important goal for all patients is early pain relief.

**Disclosure Statement**

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

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**References**


Helynda Uribe-Vivancos, PhD, Gregory A. Nichols, PhD
At both, Kaiser Permanente Hawaii and Kaiser Permanente Northwest, fasting plasma glucose testing was significantly more common in 2009 and 2010, testing was more common in 2012, but the characteristics of the overall population did not change. At both sites, the characteristics of youth at risk of diabetes changed substantially with a much greater proportion being female and children younger than age 10 years. The size and composition of the population of youth identified with diabetes was not affected.

Young Mi Cho, Aam A. Namasivayam, MS, Jasleen Myra, MD
Internists frequently diagnose herpes simplex, herpes zoster, and acne, which are also common dermatologic topics published. The authors conducted an independent search of the Thomson Reuters’ Science Citation Index for common dermatologic topics, limited to the period 1970 to 2012. The five most common dermatologic topics published in five high-impact general medical journals were melanoma, psoriasis, herpes simplex, herpes zoster, and acne.

22 Prevalence of Hypovitaminosis D and Its Association with Comorbidities of Childhood Obesity. Ronald Williams, MD, FAAP, FACP, Mandla Novick, MD, Erik Lehman, MS
We conducted a retrospective chart review from 155 obese children aged 5 to 19 years who attended the Penn State Children’s Hospital Pediatric Multidisciplinary Weight Loss Program from November 2009 through November 2010. Under the latest Institute of Medicine definitions, vitamin D deficiency (20-29 ng/mL) was present in 40% and 38% of children, respectively. African-American race, winter/spring season, hypothyroidism, elevated systolic blood pressure, urban location, and total number of comorbidities were significantly associated with hypovitaminosis D (0.035 ng/mL). Obese children should be considered for routine vitamin D screening.

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