August 2008 • Volume 107 • Issue 5

Wisconsin Medical Journal

Official publication of the Wisconsin Medical Society

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COVER THEME
Encouraging healthy habits in Wisconsin children

A US Preventive Services Task Force review recently concluded that evidence of effectiveness of interventions in overweight children is lacking. Two articles in this issue of the Wisconsin Medical Journal *examine this issue head on, looking at ways to encourage children to be more physically active, less sedentary and eat more fruits and vegetables at school and at home.*

Cover design by Mary Kay Adams-Edgette.

The mission of the *Wisconsin Medical Journal* is to provide a vehicle for professional communication and continuing education of Wisconsin physicians.

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The *Wisconsin Medical Journal* (the *Journal*) (ISSN 1098-1861) is the official publication of the Wisconsin Medical Society and is devoted to the interests of the medical profession and health care in Wisconsin. The managing editor is responsible for overseeing the production, business operation and contents of the *Journal*. The editorial board, chaired by the medical editor, solicits and peer reviews all scientific articles; it does not screen public health, socioeconomic, or organizational articles. Although letters to the editor are reviewed by the medical editor, all signed expressions of opinion belong to the author(s) for which neither the the *Journal* nor the Wisconsin Medical Society take responsibility. The *Journal* is indexed in Index Medicus, Hospital Literature Index, and Cambridge Scientific Abstracts.

Send manuscripts to the Wisconsin Medical Journal, 330 E Lakeside St, Madison, WI 53715. Instructions to authors are available at the Wisconsin Medical Society Web site: www.wisconsinmedicalsociety.org, call 866.442.3800, or e-mail wmj@wismed.org.

SUBSCRIPTION RATES
Members, $12.50 per year (included in membership dues); non-members, $89. Current year single copies, $12 each. Previous years single copies, when available, $10 each.

Periodical postage paid in Madison, Wis, and additional mailing offices

Published monthly except January, March, June, and November.
Acceptance for mailing at special rate of postage provided for in Section 1103, Act of October 3, 1917. Authorized August 7, 1918. Address all correspondence to the *Wisconsin Medical Journal*, PO Box 1109, Madison, WI 53701. Street address: 330 E Lakeside St, Madison, WI 53715; e-mail: WMJ@wismed.org

POSTMASTER
Send address changes to: *Wisconsin Medical Journal*, PO Box 1109, Madison, WI 53701.

ISSN 1098-1861
Established 1903

We are more than what we eat

John J. Frey, III, MD
Medical Editor, Wisconsin Medical Journal

When I returned to Wisconsin in 1993 after a 25-year professional exile in the wilds of Massachusetts and North Carolina, I remember going to a restaurant and being stunned at the size of the portions people were eating. I told my family that it was strange to be back where everyone had "Midwestern portions." Since that time, it appears from the data on obesity of the general US population, Midwestern portions have become the norm. The factors behind these changes are the source for many popular books in recent years that are well worth reading. *Fast Food Nation*; *The Omnivore's Dilemma; Animal, Vegetable, Miracle: A Year of Food Life*, and many others are making us read food labels from a new perspective. One will never look at a horizon full of corn plants with the same eyes as before reading these books, even before the gas price climb or world food shortages. And one never goes to the Wisconsin State Fair without being amazed at what people can eat in a single day.

In this issue of the *Journal*, 2 articles address strategies to change the way that children learn about eating. Clearly there is not, and never will be, a "silver bullet" approach to treating obesity. Jamelske and colleagues describe results from a statewide intervention to promote lower calorie fruits and vegetables in schools (Preliminary Findings from an Evaluation of the USDA Fresh Fruit and Vegetable Program in Wisconsin Schools. *WMJ*. 2008;107(5):225-230.) As my grandchildren are encouraged to follow the "one bite is nice" strategy to try new things, the children in the test schools are both educated and encouraged to see fruits and vegetables as acceptable and the study shows that their attitudes do change and their willingness to try these foods changes as well. One important finding was that children demonstrated a willingness to try new foods—but not at home. Parents, as in most things, are critical to any attempts to change behaviors. Children do not ignore parents and a variety of studies attempt to affect parents' attitudes and behaviors as well as children. Evidence-based studies of factors that affect the prevalence of childhood obesity repeatedly show that family behavior trumps almost any other attempts to intervene.[1]

In that regard, the study by Joose and colleagues attempts to approach entire families as the point of intervention. While their data are too small and too recent to look at long-term effects, their study shows that parents have a higher level of change in attitude than their children and that is a positive finding—in the long run. Sustaining those changes is the real task of community-wide interventions such as theirs. Supporting the efforts through school food choices and education can only be a good thing.

One of the larger problems of obesity in our society is that the forces that affect it are often at the societal level and are more resistant to changes.[2] Changing a culture is a slow process, changing factors such as poverty, neighborhood safety, and the influence of advertising—all of which have been shown to heavily influence the prevalence of obesity—are reasons for a national approach to causes as well as effects of obesity.[3]

As a society, we are good at finding something to blame: I blame sugar, I blame portions, I blame television, and I blame parents. While all of these may contribute to the problem, labeling childhood obesity as an "epidemic" doesn't really help either. Such a characterization carries the powerful message that obesity is something we "catch" rather than something

we do. The challenge is to take on the changes necessary to work with the forces that relate to obesity without stigmatizing either children or their families. Both of the articles in this issue of the *Journal* take positive approaches and realize that they—and we—are in it for the long run. We can all learn to be more tolerant of those among us who struggle with obesity through understanding, support, and encouragement while working to change the forces that affect the local and national cultures of consumption that we, collectively, have created and we, collectively and individually, can change.

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Right man, right time for reform

Society President Steve Bergin, MD, should be lauded for his audacity to take on the issue of health care system reform.

Addressing the problem of health care reform has not been influenced significantly by the previous piecemeal approach. Global goals must be established and pursued; this is my interpretation of Dr Bergin's approach.

We all know that one of the basic problems of the present health care system is that we have not empowered the individual to take personal responsibility for their own health. The health care industry has not found a way to get this done and—in spite of the great technical advances in emergency care, surgery, and diagnostic technology—chronic diseases have become epidemic. It is hard to avoid the criticism of the high cost of present day medical care, the increasing chronic disease epidemic, and patient dissatisfaction with treatment of their symptoms, with little attention paid to patient questions about their general health and wellness.

As a physician in practice since 1947, I have also been made aware of physician dissatisfaction and "burnout." The primary care physician often finds that the practice of medicine "just isn't fun anymore." My guess is that present emphasis on treatment of symptoms is not as satisfying as the practice of integrative medicine, which we don't do because of a lack of training and a feeling of not being competent in the subject.

Doctor Bergin may just be the right man at the right time to change the system, which I think will be done by integrating general medicine with other known health-promoting concepts such as the new science of cellular nutrition, and other alternative care modalities. Integrating our medical practices will legitimize the health and wellness concept and get the patient back as a player in the system.

Wisconsin's School of Medicine and Public Health will be a great asset for Dr Bergin in accomplishing his goal. It is one of our nations few medical schools training physician specialists in integrative medicine. It is my belief that this is the answer to changing our course and building a healthier and more effective medical system. It will also be the vehicle for changing our medical education so that doctors will learn the skills and competence to integrate our medical care system and to bring the fun and satisfaction back to patient care.

Walt Meyer, MD, CMD

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Preliminary Findings from an Evaluation of the USDA Fresh Fruit and Vegetable Program in Wisconsin Schools

Eric Jamelske, PhD; Lori A. Bica, PhD; Daniel J. McCarty, PhD; Amy Meinen, MPH, RD

ABSTRACT

Introduction: In 2002, the US Department of Agriculture (USDA) created the Fresh Fruit and Vegetable Program (FFVP) to improve nutrition and help reduce the prevalence of childhood overweight and obesity. The FFVP provides funding for students from selected schools in each participating state to receive a free fresh fruit or vegetable snack daily for an academic year. In November 2005, Wisconsin was added to this program. In this study, we evaluate whether the Wisconsin FFVP resulted in positive changes in children's attitudes and behavior related to eating fruits and vegetables.

Methods: In 2006, 25 Wisconsin schools were selected by the Wisconsin Department of Public Instruction for FFVP participation. Study measures included a pre-test and post-test survey given to 4th, 7th, and 9th graders in the intervention and controls schools. Post-test data from all 25 intervention schools were not yet available for analysis. Our sample, therefore, consisted of 1127 participants: 784 students in 10 intervention schools and 343 students in 10 control schools. Independent samples *t* tests and multivariate probit regression analyses were used to examine attitudinal and behavioral program effects.

Results: Compared to controls, intervention students reported an increased willingness to try new fruits (24.8% versus 12.8%, $P<0.01$) and vegetables (25.1% versus 18.4%, $P=0.01$) at school.

Conclusions: Findings indicate positive changes in attitudes and behavior among children participating in the Wisconsin FFVP.

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INTRODUCTION

Overweight and obesity is now the most common medical condition of childhood in the United States, with the prevalence more than doubling over the past 20 years.[1] Nationally, 15.3% of 6-11 year olds and 15.5% of 12-19 year olds are at or above the 95th percentile for Body Mass Index-for-Age.[2] In Wisconsin, nearly 24% of high school students are either obese or overweight.[3] The dramatic increase in the prevalence of childhood overweight and obesity and its resultant comorbidities are associated with significant health and financial burdens, thus warranting strong and comprehensive prevention efforts.[2]

Long considered one of the central causes of overweight and obesity, poor nutrition is prevalent among today's youth. Children and adolescents' food intake tends to be low in fruits, vegetables, and calcium-rich foods, and high in fat.[4] Current United States Department of Agriculture (USDA) guidelines recommend eating 6-13 servings of fruits and vegetables each day, however US children eat an average of only 3.5 servings daily.[5] Moreover, for the typical American adolescent, half of all vegetables consumed are french fries or other potatoes.[4] In Wisconsin, less than a third of high school students report eating ≥3 servings of fruit a day, while only 18% report eating ≥3 servings of vegetables.[3] Unhealthy dietary patterns developed during childhood and adolescence may create an increased risk for chronic diseases later in life.[6] Therefore, clearly focused efforts to improve the nutritional health of America's young people are needed, and schools, with their access to an estimated 95% of children and adolescents nationwide, are regarded as optimum settings for such efforts.[7]

There is a growing body of literature on the effectiveness of nutrition-related programs designed to

combat the rise in childhood overweight and obesity. A number of school-based interventions demonstrate that increasing children's fruit and vegetable intake is possible, even though effects are small and the long-term persistence of such changes is largely unknown.[9] Story et al found offering more and greater varieties of fruits and vegetables at lunch, combined with taste testing and skill building activities in the classroom, led to increased fruit and vegetable consumption at lunch.[10] Bere et al noted providing pupils with a piece of fruit or a vegetable at school at no cost to their parents is an effective strategy to increase school children's intake of fruit and vegetables.[11] Therefore, environmental interventions combined with educational approaches may be needed to effectively promote children's fruit and vegetable consumption at school.[5]

The USDA created the Fresh Fruit and Vegetable Program (FFVP) in 2002 to increase fruit and vegetable consumption in an effort to combat childhood overweight and obesity. In November 2005, Wisconsin was added to this program as an expansion state. Beginning in March 2006, approximately 13,500 students at 25 funded schools received daily fresh fruit and vegetable snacks for the remainder of the 2005-2006 school year and into the 2006-2007 school year. Additionally, the schools in the program incorporated into their curriculum nutrition education components designed to promote consumption of fresh fruits and vegetables.

In this study, we evaluated whether the Wisconsin FFVP is an effective method of introducing school-age children to fresh fruits and vegetables as a healthy food choice. Specifically, we sought to determine whether the program resulted in positive changes in attitude and behavior related to fruit and vegetable consumption.

METHODS

Participants

Students in the 4th, 7th, and 9th grade across 25 intervention schools and 10 matched control schools in Wisconsin participated in this study. A sample of 25 schools were selected as program sites by the Wisconsin Department of Public Instruction based on interest in the FFVP, geographic location, and number of students qualifying for free or reduced lunches. Ten control sites were selected based on characteristics similar to those of the intervention schools, including school size, geographic location, ethnic composition, and numbers of students qualifying for free or reduced lunches. Although these selection processes were not random, both the intervention and control schools were geographically diverse and, in general, reflected the characteristics of students in the state.

Our pre-test sample consisted of 2863 participants: 2287 students from the 25 intervention schools and 576 from the 10 control schools. Post-test data from all 25 intervention schools were not yet available for analysis, but we wished to report on a subset of 10 of the schools because, after interim analyses were performed, significant results emerged. Within this subset, analyses were further limited to only those students who provided both pre-test and post-test responses to the survey sections that are the focus of this study. Therefore, our final sample consisted of 1127 participants: 784 students in 10 intervention schools and 343 students in 10 control schools. Approximately equal numbers of girls (n=577) and boys (n=550) were represented in the sample, and just over 70% of the students were identified as white. Fourth grade students comprised 43.5% of the sample, while 33.8% were in 7th grade and 22.7% were in 9th grade.

Measures

The survey instruments used in this study were based on previously validated measures.[12-15] In addition to demographic items, the survey contained questions on lifestyle, including fast food consumption, physical exercise, parental limits on video game/TV time, and eating family dinners. The next section contained a series of questions measuring participants' willingness to try new fruits and vegetables at home and school, the frequency with which they ate the fruit or vegetable that came with school breakfast or lunch, and their willingness to choose fruits and vegetables as snacks over less healthy alternatives. Specifically, there were 2 items that asked if participants would try a new fruit offered at school and at home, respectively. There were 2 parallel items for vegetables. Two additional items asked whether participants would choose fruit or a vegetable, respectively, as a snack instead of chips or candy. Response options for all 6 items were 1=would not, 2=might, and 3=would.

The next section of the survey presented a series of pictures of 23 target fruits and vegetables and asked students to demonstrate their knowledge by correctly identifying specific items. Participants were also asked to indicate which items they had tried or would be willing to try. We selected the 23 fruits and vegetables for this section because they were most likely to be served to students in all 25 intervention schools. In the next section, students were given an expanded list of 68 fruits and vegetables and asked to identify the items they had tried and what items they liked. The final section of the survey contained a list of various food items, including 39 fruits and vegetables. Students indicated how many times (from 1 to 5) they had eaten each item in the last

24 hours. This dietary recall portion of the survey was administered to students over 3 consecutive days to calculate average daily fruit and vegetable consumption for each student over the 3-day period. The focus of this paper is on 2 sections of the survey: the dietary recall section (behavior) and the section measuring students' willingness to try new fruits and vegetables at home and school and willingness to choose fruits and vegetables as a snack over less healthy alternatives (attitude).

Procedure

Personnel in both intervention and control schools administered the pre-test to students during a regularly scheduled class period in March 2006 before the program began. All survey materials were approved by the University of Wisconsin-Madison Education Institutional Review Board. In addition, all persons administering the surveys completed the University of Wisconsin on-line tutorial on the use of human subjects in research and were given explicit instructions on how to administer the surveys. The post-test was given 3 months later at the end of the 2005-2006 school year following the same procedure. We surveyed the same students a third time as 5th, 8th, and 10th graders in March 2007 and also conducted teacher and parent surveys for 5th grade students in May 2007. Results from the first 2 sets of surveys, spanning approximately 3 months of program implementation, were analyzed for this study.

To compare changes in attitudes toward fruits and vegetables between the intervention and control schools, we generated an indicator variable =1 for those students with a positive change between the pre-test and post-test and 0 otherwise. A positive change was defined as a student response that changed from "would not" to either "might" or "would," or from "might" to "would" for a given item. The mean for each new variable measured the percent of students who increased their willingness to eat fruits and vegetables between the pre-test and post-test.

We used the dietary recall section of the survey to examine students' fruit and vegetable consumption. Students reported their eating patterns using a list of food items, including 39 fruits and vegetables, for 3 consecutive days. We then calculated each student's average daily fruit and vegetable intake for the 3-day period. To focus on students with very low fruit and vegetable intake, we restricted our analysis to a subset of students who reported eating fruits and vegetables an average of ≤1 times per day on the pre-test. To compare changes in behavior of fruit and vegetable intake between intervention and control groups, we generated an indicator variable =1 for those students with a positive change between the pre-test and post-test and 0 otherwise. A positive change was defined as an increase in student's average daily fruit and vegetable intake of at least 0.2 times from pre-test to post-test. The mean of this new variable measured the percent of students that increased their average daily fruit and vegetable consumption between the pre-test and post-test.

Table 1. Pre-test Data—Willingness to Try New Fruits/Vegetables and to Choose Fruits/Vegetables as Snacks

Variable	N	Willing (%)
Try new fruit at school	1120	33.8
Try new vegetable at school	1118	20.8
Try new fruit at home	1121	55.6
Try new vegetable at home	1121	32.9
Choose fruit as snack instead of chips/candy	1122	40.0
Choose vegetable as snack instead of chips/candy	1120	21.0

Note: The sample size varies due to non-response for some questions.

To investigate attitudinal and behavioral program effects, we first used SPSS 15.0 to calculate independent samples *t* tests to examine differences in mean responses between intervention and control participants. To explore the robustness of these results to the inclusion of control variables, we used Stata 6.0 to conduct multivariate probit regression analyses.

RESULTS

Pre-test data for the 6 items measuring students' willingness to eat fruits and vegetables are presented in Table 1. In terms of choosing fruits and vegetables as a snack instead of chips/candy, 40% indicated they would choose a fruit, but only 21% would choose a vegetable. Similarly, 33.8% of students said they would try a new fruit served in school, but only 20.8% would try a new vegetable. At home 55.6% of students indicated they would try a new fruit and 32.9% said they would try a new vegetable. Overall, students were more willing to eat fruits than vegetables and also more willing to try both fruits and vegetables at home versus at school. Of particular importance is that there was significant opportunity for students to move in a positive direction from either "would not" or "might" in terms of willingness eat fruits and vegetables.

Table 2 presents the change in student willingness to eat fruits and vegetables between the pre-test and post-test. In terms of trying a new fruit served at school, 24.8% of intervention school students reported an

Table 2. Pre-test/Post-test Comparison—Willingness to Try New Fruits/Vegetables and to Choose Fruits/Vegetables as Snacks

	Intervention		Control		
Variable	**N**	**Positive Change (%)**	**N**	**Positive Change (%)**	***P***
Try new fruit at school	741	24.8	337	12.8	<0.01
Try new vegetable at school	736	25.1	337	18.4	0.01
Try new fruit at home	741	15.4	336	13.1	0.31
Try new vegetable at home	740	18.2	339	17.4	0.74
Choose fruit as snack instead of chips/candy	742	18.1	339	15.0	0.21
Choose vegetable as snack instead of chips/candy	737	20.1	336	16.4	0.14

Note: The sample size varies due to missing data for some items.

Table 3. 4th Grade Student Pre-test/Post-test Comparison—Willingness to Try New Fruits/Vegetables and to Choose Fruits/Vegetables as Snacks

	Intervention		Control		
Variable	**N**	**Positive Change (%)**	**N**	**Positive Change (%)**	***P***
Try new fruit at school	347	25.1	117	11.1	<0.01
Try new vegetable at school	345	26.7	115	12.2	<0.01
Try new fruit at home	348	19.0	115	13.9	0.19
Try new vegetable at home	349	22.9	117	17.1	0.16
Choose fruit as snack instead of chips/candy	349	19.8	117	18.8	0.82
Choose vegetable as snack instead of chips/candy	346	24.3	115	14.8	0.02

Note: The sample size varies due to missing data for some items.

increased willingness compared to only 12.8% of control school students ($P<0.01$). Similarly, intervention school students were also more willing to try a new vegetable served at school, with 25.1% reporting an increase compared to 18.4% of control school students ($P=0.01$). Although no significant differences were found for the other comparisons, results are in the expected direction with intervention students demonstrating greater positive change than control students.

A multivariate probit regression model was used to explore if these simple differences in means were robust to the inclusion of control variables for gender, race/ethnicity, grade level, amount of physical activity, parental TV/video game limits, frequency of family dinners, and fast-food consumption. The model predicted that intervention students were 12.1 percentage points more likely to have experienced an increase in willingness to try a new fruit at school relative to control students ($P<0.01$), while the difference for a new vegetable was 6.7 percentage points ($P=0.02$).

We next looked at only 4th grade students' responses because we believe that school-based programs of this nature have the greatest potential to influence the behavior of younger children. Table 3 shows that the positive program effects were larger when we limited the analysis to just 4th grade students. Specifically, 25.1% of intervention students reported an increase in willingness to try a new fruit served at school compared to only 11.1% of control students ($P<0.01$). Intervention school 4th graders were also more willing to try a new vegetable at school, with 26.7% reporting an increase compared to 12.2% in control schools ($P<0.01$). Again, there were no statistically significant differences in willingness to try new fruits and vegetables at home, but the trends are in the expected direction. Unlike results from the full sample comparison, we do see a statistically significant difference in increased willingness to choose a vegetable as a snack instead of chips/candy for intervention students (24.3%) versus control students (14.8%) at $P=0.02$.

To determine if the FFVP had positively influenced those students most in need, we analyzed fruit and vegetable consumption patterns for students who reported eating these foods an average of ≤1 times per day on the pre-test. As shown in Table 4, over 32% of intervention school students with low initial consumption reported an increased willingness to eat both fruits and vegetables compared to only 15% of control school students ($P=0.03$ and 0.04, respectively). Table 4 also shows that 62.8% of intervention school students with low initial consumption reported increased fruit and vegetable intake compared to only 47.1% of control school students ($P=0.13$). A probit regression identical to that used above predicted that intervention school

Table 4. Low Consumption Student Pre-test/Post-test Comparison—Willingness to Try New Fruits/Vegetables and Intake

	Intervention		Control		
Variable	**N**	**Positive Change (%)**	**N**	**Positive Change (%)**	***P***
Try new fruit at school	83	32.5	33	15.2	0.04
Try new vegetable at school	82	32.9	33	15.2	0.03
Average daily fruit and vegetable intake	86	62.8	34	47.1	0.13

Note: The sample size varies due to missing data for some items.

students who reported low consumption initially were 19.5 percentage points more likely than control school students to have increased their average daily intake of fruits and vegetables (P=0.07). Again, the positive program effect was larger when the analysis was limited to just 4th grade students. Low consuming 4th grade students in intervention schools (n=40) were 29.7 percentage points more likely than control students (n=17) to have increased their average daily fruit and vegetable intake (P=0.05).

DISCUSSION

Preventing childhood overweight and obesity is a national pubic health priority. Childhood appears to be a critical time to target nutritional messages designed to influence food preferences.[15] Children's preferences for specific foods tend to increase with frequency of exposure to the food.[8] Frequency and exposure is influenced by the availability and accessibility of foods.[8] Moreover, studies show that consumption of fruits and vegetables, as a habit in childhood, is an important predictor of higher fruit and vegetable consumption as adults.[16] Also, lifetime food experiences, such as developing food preparation skills, developing specific preferences for healthy foods, and gardening, have been found to contribute to food choice.[17]

It is essential that the effects of school, district, or state policy changes regarding the school food environment are evaluated.[18] In this study, we determined whether the FFVP is an effective method of introducing school-age children to fresh fruits and vegetables as a healthy food choice. In particular, we examined whether the program resulted in positive changes in attitude and behavior related to fruit and vegetable consumption following 3 months of program implementation. We found that students in the FFVP intervention sites compared to students in the control schools were more willing to try new fruits and vegetables at school, but not at home. It is possible that differences in attitudes toward trying these foods at home will emerge following longer exposure to the program. Certainly, for the program to be considered a success, the effects must reach beyond school and into the home.

We recognize that there are certain limitations to the study. Participants were not selected at random and, although we feel they reflect the average characteristics of students in the state fairly well, it may be that our results are not generalizable to other samples of school-age children. We also recognize the limitations inherent in collecting data of this nature via self-report measures. We believe that the strengths of the study, including a large sample size, pre-test/post-test design, use of control schools, and comprehensive nature of the survey instruments provide informative and useful results.

In conclusion, this study indicates that the Wisconsin FFVP is having some beneficial short-term effects. Continued monitoring of this program will determine if healthier diets are being adopted by the students in the intervention schools and whether this in turn will eventually reduce the prevalence of childhood overweight and obesity.

Acknowledgments/Funding/Support: The authors would like to thank the University of Wisconsin-Eau Claire for funding support. They would also like to thank all students and staff at all participating schools; undergraduate student research assistants Anjali Anand, Emily Brown, Jason Haluska, Beth Lutz, John Rodgers, and others who assisted with data entry; Kirsten Austad and Jessica Zigman, Area Health Education Centers Interns, Wisconsin Department of Health and Family Services, for their contribution to the literature review; and the National Fruit and Vegetable Program, Centers for Disease Control and Prevention, for their suggestions for validated survey questions and review of the final student survey.

Financial Disclosures: Eric Jamelske is an employee of the University of Wisconsin-Eau Claire Economics Department. Amy Meinen is an employee of the Wisconsin Department of Health and Family Services.

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WISCONSIN MEDICAL JOURNAL

Fit Kids/Fit Families: A Report on a Countywide Effort to Promote Healthy Behaviors

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ABSTRACT

Introduction: Funded by the Wisconsin Partnership Fund for a Healthy Future and Aurora Health Care, Fit Kids/Fit Families (FKFF) is a multidisciplinary, family system approach to weight management that was developed and implemented by a community-academic partnership with the goal of reducing and preventing childhood overweight and obesity, increasing physical activity, and improving overall family health.

Program Description: A sample of Washington County children and their families participated in this 12-week program, which promoted healthy lifestyle changes. Data was collected pre- and post-intervention on age, height, weight, body mass index (BMI), body circumference measurements, child and family habits, and child self-esteem. A weekly nutrition, activity and behavioral log captured behaviors. Weekly 2-hour meetings in a community setting using a dietician, behaviorist, and exercise specialist addressed each of these areas.

Results: FKFF has served 68 children and their families. Two-thirds are female; the mean age is 10.4 years (age range, 5-16). Both parents (96%) and children (81%) demonstrated improved knowledge and attitudes regarding healthy lifestyle changes. Logs report that 59% of the children increased their physical activity and 32% reduced their sedentary activity. While 81% improved and 13% maintained BMI, 74% of the children showed decreased total body circumferences. Nearly two-thirds demonstrated improved self-esteem on the Rosenberg Self-Esteem Scale.

Conclusion: Preliminary results suggest FKFF has an effect on healthier nutritional choices, increased physical activity, decreased sedentary activity, overall healthier behaviors, and body circumference and BMI reductions.

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INTRODUCTION

Overweight and obesity are prevalent and associated with health problems in virtually all populations. Recent estimates from the National Center for Health Statistics suggest that 32% of US adults >20 years of age are obese, and an additional 34% are overweight.[1] The percentage of young people who are overweight has more than tripled since 1980, with 16% of children in the United States aged 6-19 years considered overweight.[2]

Wisconsin ranks as the 28th heaviest state in the United States.[3] The Washington County Health Department's "Healthy Washington County Health Improvement Plan, 2000-2005," indicates that 59% of adults in the county are at risk of becoming overweight, and 53% engage in insufficient physical activity. In addition, 55% consume fast food weekly, and only 29% of adults have sufficient intake of vegetables.[4] The Wisconsin Youth Risk Behavior Surveys (2001, 2003, and 2005) estimate that 24% of all students are at risk for overweight or are overweight based on their Body Mass Index (BMI.) Only one-third reported eating ≥3 servings of fruit, and 18% reported eating ≥3 servings of vegetables the day before the survey. Approximately 15% reported not eating breakfast at all in the last 7 days, and nearly 60% had gone without breakfast 2 or more days. In 2001, 64% of the students reported exercising or participating in vigorous physical activities that made them sweat or breathe hard for at least 20 minutes on ≥3 of the past 7 days. In 2005, the prevalence of students reporting vigorous activity increased significantly (67%); however, this reflects increases among males not females. Also, 26% of students reported watching ≥3 hours of television per day on an average

school day.[5] One of the 11 *Healthiest Wisconsin 2010* health priorities is to improve health status related to overweight, obesity, and lack of physical activity among Wisconsinites.[6]

According to a 2005 review by the US Preventive Services Task Force, childhood overweight is associated with a higher prevalence of risk factors for adverse health outcomes, such as insulin resistance, elevated blood lipids, increased blood pressure, and impaired glucose tolerance.[7] Severe childhood overweight is associated with immediate morbidity from conditions such as slipped capital femoral epiphysis, fatty liver, and sleep apnea. The Task Force also found fair evidence that BMI is a reasonable measure for identifying children and adolescents who are overweight or at risk of becoming overweight. At the same time, the US Preventive Services Task Force's 2005 review found insufficient evidence that behavioral or other preventive interventions are effective in treating overweight children—a knowledge gap that additional studies can address.

Fit Kids/Fit Families (FKFF) was developed and implemented to meet the needs of overweight youth in Washington County, Wis—a top priority of the county health improvement plan—and to evaluate the effectiveness of an evidence-based program tailored to this population.

PROGRAM DESCRIPTION

In 2004, Aurora Medical Center of Washington County expanded community nursing outreach services to address a *Healthiest Wisconsin 2010* health priority. Aurora and the Washington County Health Department, the YMCA Kettle Moraine, and the West Bend schools formed a multidisciplinary partnership that identified a common interest in developing and implementing a program designed to increase healthful behavior for overweight children. A local pediatrician and a University of Wisconsin School of Medicine and Public Health (UWSMPH) faculty member agreed to advise this coalition.

The FKFF project team established the following objectives: helping the children maintain or decrease BMI, increase physical activity, decrease sedentary activity, improve self-esteem, and increase overall knowledge about healthy lifestyle behaviors. This project advances a *Healthiest Wisconsin 2010* health priority through the promotion of good nutrition and increased physical activity for overweight children and their families by utilizing a multidisciplinary, community-based, family system approach that engages local health care professionals with community agencies.

Aurora Medical Center of Washington County applied for and received a 3-year grant in December 2004 from the UWSMPH's Wisconsin Partnership Fund for a Healthy Future to establish FKFF in Washington County. The project manager and the project coordinator were both Aurora employees, while the exercise component, specialized services, and project evaluation were subcontracted out. A project Advisory Committee, consisting of project partners and parents of participants, guided project design to meet the community needs and expectations. The Aurora Health Care Research Subjects Protection Program reviewed the project in January 2005 and determined that the intent was not research, and as such it was exempt from Institutional Review Board (IRB) oversight. Nevertheless, project leadership built in appropriate protection for the rights of participants, maintaining confidentiality and reporting data in the aggregate.

FKFF is based on the evidence-based pediatric weight management program Committed to Kids (CTK), now called the Trim Kids Program.[8-11] Developed and tested by Louisiana State University Health Sciences Center, under the direction of Melinda Sothern, PhD, this program has met the rigorous scientific review process and qualifications of the National Cancer Institute (NCI) and is now on the NCI's Research Tested Intervention Program (RTIP) Web site.[12] Select materials from a family-based program, SHAPEDOWN, which was developed by the University of California-San Francisco School of Medicine, were integrated into the CTK framework by the FKFF team.[13-15] The FKFF staff, consisting of a registered nurse, a registered dietician, an exercise specialist, and a behavior specialist, was trained by the originators of the CTK program.

FKFF is a 12-week program that focuses on the core objectives of nutrition, exercise, and behavioral components. Program participants are self-selected or referred by their physician. A child's weight is the criteria for participation, and all participants are overweight or at risk of obesity. Children with eating or mood disorders are excluded. The program was originally to be provided free of charge to participant families. However, the project Advisory Committee felt that some level of financial buy-in would enhance commitment to the program. The fee was set at $120 for the 12-week program ($10/week, an amount similar to that charged by commercial weight management programs). Families pay as much as they are able or have the opportunity to receive full scholarships. A maximum of 12 children is enrolled in each FKFF class.

FKFF has been offered 3 times per year with ses-

sions typically starting in the months of February, May, and September. During each 12-week session, the group meets 1 time per week for 2 hours. Sessions have been conducted in both a local school and at the YMCA. The FKFF curriculum consists of lessons equally divided between nutrition, exercise, and behavior. Each child receives a logbook and is asked to complete a section on each of these areas daily. Instructors review the logbooks weekly, providing stickers and comments to motivate and reinforce behavior change. During the weekly meetings, a dietician, behaviorist, and exercise specialist work with the children and families on strategies that promote lifestyle changes. Some sessions focus on the entire family, while others are dedicated specifically to the child or parent, in which case the groups meet separately. Due to the variability in the children's age, special consideration is given to address age-specific issues. FKFF does not promote weight loss through dieting. Rather, the program strives to help participants maintain or improve BMI scores through healthy lifestyle changes.

The FKFF dietician provides a nutrition plan appropriate for each child and parent (if desired). It is used as a guide as they learn about food groups. Lessons include identification of carbohydrates, proteins, and fats in various foods; portion sizes; label reading; beverage selection; and choices when dining out—including school lunches, holiday, and party eating. The children are involved in preparing a snack each week and sampling a variety of foods. Emphasis is placed on the importance of eating breakfast and regular meals including snacks, soda alternatives, and creative ways to prepare fruits and vegetables. Shopping with parents and eating family meals together are encouraged.

Two exercise specialists provided by the YMCA Kettle Moraine organize the activity portion of the FKFF. The children learn about core muscle groups and are given exercise bands to take home for practice. The games and activities provide fun aerobic exercise. The children exercise so their heart beats fast and they breathe hard for 30 minutes in each session. Parents and staff are encouraged to participate in the activities with the children. Goal setting is done weekly to increase the amount of time spent doing physical activity at home. The logbook requires monitoring sedentary activity by recording time spent watching TV, playing video games, and using the computer ("screen time"). One hour of physical activity is recommended each day, as well as families enjoying activities together. A list of Washington County recreational resources is provided to each family.

The behavioral lessons are provided by a specialist in disordered eating—a professional with expertise in distortions in growth caused by a disruption in the ability to regulate food intake. The key focus is the importance of self-care and self-esteem utilizing a team approach, with parents, kids, and staff working together and encouraging families to do the same. The program emphasizes awareness of feelings and using healthy coping skills to deal with them. The children are taught how to self-monitor food intake by becoming aware of feelings of hunger, appetite, and satiety. Practicing how to eat mindfully and handle relapses is demonstrated. The issue of power struggles between children and parents is addressed by providing guidelines about the division of responsibility in eating and feeding. Careful attention is paid to restrictive eating patterns.

Measures of Evaluation

In 2000, the Centers for Disease Control and Prevention (CDC) recommended use of body mass index (BMI) to describe the weight status of children and adolescents, designating BMI-for-Age of ≥95% as "overweight" and BMI-for-Age of ≥85% and <95% as "at risk for overweight."[16] For instance, if a child's BMI-for-Age falls at the 85th percentile, it means that he/she is at risk of being overweight, and there are only 15 out of 100 children of the same age and gender in the reference population who have a higher BMI-for-Age. For this study, data was collected, pre- and post-intervention, on age, height, weight, BMI, body circumference measurements, child and family habits, and child self-esteem. A FKFF weekly logbook captured behaviors, including foods eaten and amount of time spent in physical activity and sedentary activity. In week 2, pre-test measures were recorded (ie, height, weight, and body circumference) and BMI was calculated. Parents completed a family habit inventory, which is a 48-item scale that evaluated family food consumption, activity, and parenting. The children completed a child's habit inventory, a 36-item scale that reflected current eating, exercise, and other related habits. Each child also completed the Rosenberg Self-Esteem Scale in a 5-point Likert scale format, allowing for a score range of 0-50, with 50 being high self-esteem.[17] In week 11, the same inventories were completed and measurements were repeated.

Overwhelmingly, parents on the Advisory Committee did not want a program that focused solely on weight loss. Many indicated they tried different weight loss strategies with no success. The parents stressed the importance of wanting their children to learn healthy lifestyle changes; this sentiment greatly influenced the

development of the core measurements. Parents also expressed the desire for their children to feel better about themselves. Many of these children have experienced social isolation, strained peer relationships, and bullying. One child explicitly stated her goal was to wear a 2-piece bathing suit like her friends. Therefore, while BMI scores were calculated and used as a quantifiable measure, they were not overly emphasized. Each of the core evaluation measurements was linked back to 1 of the grant's objectives in order to measure the program's effectiveness.

Early Results

To date, FKFF has served 68 Washington County children and their families: 23 boys (34%) and 45 girls (66%.) The mean age was 10.4 years, with an age range of 5-16 years. All the participants were ≥85th percentile for BMI-for-Age, and as such overweight or at risk for overweight.[18] Approximately 40% of participants asked for scholarship assistance. The program yielded an 84% completion rate.

A primary FKFF objective was to promote and educate the families on healthy lifestyle changes. An analysis of pre- and post-session parent and child habit inventory data revealed that 96% of the parents and 81% of the children showed scores indicating improved knowledge and attitudes regarding healthy lifestyle changes. A paired-samples *t* test was calculated to compare the mean pre-test score to the mean post-test score for individual and family habits. The mean score on the child pre-test was 103.37 (SD=12.32), and the mean score on post-test was 114.27 (SD=12.8). A significant change from pre-test to post-test was found ($t(66)=-6.310$, $P<.0001$). Parent scores yielded similar findings.

Another project objective was to challenge the children to increase the amount of time they engaged in physical activity, at the same time reducing time spent in sedentary activities. While the children reported that maintaining a logbook was laborious, 89% of children consistently completed them. Parents were not asked to complete them. Based on the logs, 59% of the children increased their physical activity and 32% reduced their sedentary activity. The parents' estimates were higher, with 100% reporting a noticeable increase in their child's physical activity and 97% reporting decreased sedentary activity.

Maintaining or improving BMI by healthy lifestyle change is another project objective. Thus, BMI and body circumference measurements were taken pre- and post-program and results were analyzed. Eighty-one percent of the children improved, and 13% maintained their BMI. A paired-samples *t* test was calculated to compare the mean pre-test score to the mean post-test score for BMI. Pre-test mean was 30.00 (SD=6.533), and post-test mean was 29.14 (SD=6.193). A significant decrease from pre-test to post-test was found ($t(67)=7.710$, $P<.0001$). Seventy-four percent of the children showed decreases in total body circumferences. A paired-samples *t* test was calculated to compare the mean pre-test score to the mean post-test score for body circumferences. The pre-test mean was 370.06 cm (SD=64.63), and the post-test mean was 362.51 cm (SD=60.41). A significant decrease from pre-test to post-test was found ($t(64)=3.44$, $P<.0004$).

Improving the children's self-esteem was also a project objective. As measured with the Rosenberg Self-Esteem Scale, the results show that 65% of the children experienced improved self-esteem. A paired-samples *t* test was calculated. The pre-test mean was 36.31 (SD=7.147), and the post-test mean was 39.54 (SD=8.534). A significant increase from pre-test to post-test was found ($t(65)=2.961$, $P<.0004$).

Finally, the program promoted healthy food choices. The children reported data on healthy and unhealthy food choices in their daily logbooks. As noted previously, they reported that this exercise was laborious, which may lead to inaccuracies. Anecdotal evidence obtained through parent reports suggested many children tried new foods, reduced unhealthy food choices, and actually read labels.

DISCUSSION

FKFF was in its early stages, yet this pre- and post-analysis of participants in a youth healthy lifestyle program provides some evidence that such an intensive effort is effective in changing behaviors and intermediate outcomes, such as improved knowledge and attitudes about healthy behaviors, increased activity, maintained or decreased BMI, decreased total body circumference, and improved self-esteem.

Limitations to this project include the lack of a control group with which to compare the program's effects. Without such a comparison group, we cannot know if non-program effects were present, such as environmental influences. Another limitation is the reliance on self-recording of behavior as measures. Subjects relayed their perception that such recording was tedious, and therefore it is possible that not all behavior was diligently reported. This limitation may be why parents' estimates of their children's increases in physical activity were substantially greater than the children's own estimates. This project also does not include follow-up

measures beyond the 12-week FKFF curricular framework. Collecting measurements at 6 months and 12 months post-program would give some indication of the long-term effect of FKFF participation.

This project involved a community-academic partnership in developing a health improvement intervention for children and families in Washington County. Based on the information provided to the Aurora Health Care Institutional Review Boards at the onset of the project, a decision was made to exempt the project from IRB oversight because "the intent of the project is not research." However, as evidenced by this report, this community project, while not designed as a clinical study, does qualify as community-based participatory research.

This program is being replicated in Waukesha County, where local staff observed the Washington County program in action and received training using the video from the original FKFF training. Curriculum materials developed for Washington County participants are also being used. FKFF proved to be easily transportable. Interest in establishing a similar program has come from Marinette, Manitowoc, Green Bay, and Milwaukee, Wis.

Two modifications to the FKFF program have been developed based on the first 2½ years of experience. Project leadership participated in a sustainability planning process, based on the model developed by LaPelle et al.[19] This process calls for public health programs to redefine scope of services and more creatively use resources, by aligning goals and services, selecting appropriate and affordable services, finding new funding, adjusting staffing patterns, and creating demand for services—or some appropriate combination of these factors. To facilitate enrollment and make it less labor intensive, a referral network and outreach process is being further developed, including providing physicians with a screening tool and developing additional partnerships. A marketing plan provides for presentations at community events and to businesses. Other efficiencies include the following: (1) the project coordinator has received training in motivational interviewing and assumed the behavioral health duties, (2) staffing has been streamlined by sharing personnel between sites, and (3) intake assessment is being done during the interview time. To increase effectiveness, an aftercare and maintenance component has been added. After the completion of the program, participants and families move to the action stage and continue to meet weekly for another 12 weeks under the guidance of YMCA staff, practicing new skills through a variety of formats and involvement of both participant and family at different levels. Following the second 12 weeks, weeks 25-52 consist of the maintenance stage, with participant families meeting once a month at sponsored activities. Participants are invited to attend the YMCA's weekly Fun Family Fitness program for 1 year at no cost, and YMCA scholarships have been arranged.

FKFF has been allowed to carry over unspent funding from the Wisconsin Partnership Fund through 2008, while Aurora Medical Center and the YMCA are providing additional resources to support the program. During 2008, a total of 8 FKFF sessions will be completed, 4 each in Washington and Waukesha counties. With these additional results, a final evaluation of FKFF will be conducted.

CONCLUSION

While this nonexperimental design is inconclusive, the results are encouraging. In light of the recent US Preventive Services Task Force review concluding a lack of sufficient evidence of effectiveness of such interventions in overweight children, further experimental studies in this area are warranted and important to help guide clinicians and patients. Lessons learned from FKFF can be useful to others as this type of community health improvement intervention is modified and replicated in other areas. Obesity and overweight are serious health risks and require population health approaches to meet the challenge of improving health status in Wisconsin and the United States.

Funding/Support: Wisconsin Partnership Fund and Aurora Health Care.
Financial Disclosures: None declared.

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WISCONSIN MEDICAL JOURNAL

A Comparison of the Nicotine Lozenge and Nicotine Gum: An Effectiveness Randomized Controlled Trial

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ABSTRACT

Context: Both the nicotine gum and nicotine lozenge have been shown to increase smoking cessation rates, but no published trials have directly compared the two. Higher dose nicotine gum has been recommended as a treatment that may reduce cessation-related weight gain.

Design/Outcome: In a diverse urban setting, 408 participants were randomized to receive either the lozenge or the gum for 8 weeks of treatment. Seven-day point prevalence of smoking abstinence was biochemically confirmed by exhaled carbon monoxide levels of less than 10 ppm measured at 8 weeks with follow-up at 6 and 12 months.

Results: At 8 weeks, the lozenge quit rate was 15.1% and the gum quit rate was 11.3%, with an odds ratio of 1.39, 95% confidence interval (0.78-2.49) P=0.26. These rates compare favorably to a historical spontaneous quit rate of 5%. Quit rate comparisons were similarly non-significant at 6 and 12 months. At 8 weeks, successful quitters in the lozenge group gained 3.0±6.3 lbs compared to the gum group, which gained 8.4±9.2 lbs with t=-2.4, P=0.02, but this finding was not sustained at 6 and 12 months.

Conclusions: The gum and lozenge appear equally effective for smoking cessation; however, for patients concerned about preventing cessation related to immediate weight gain, the lozenge may be the better agent.

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INTRODUCTION

Tobacco use is the number 1 cause of overall preventable mortality in the United States, accounting for approximately 440,000 deaths each year.[1] Despite public health efforts to decrease tobacco use, 21% of the adult population still smokes.[2] Of these, 70% would like to quit, and 42.5% of smokers make a quit attempt each year.[2] The quit rate for those utilizing no form of treatment is approximately 5% per year, making the need to increase smoking cessation rates a top public health priority.[3]

Nicotine replacement therapy (NRT) has been shown to increase smoking cessation rates, relative to placebo. Both the nicotine gum and nicotine lozenge are US Food and Drug Administration (FDA) approved and have been shown to increase a smoker's chance of successfully quitting, with meta-analysis odds ratios (OR) of 1.66 (95% confidence interval [CI]: 1.52 to 1.81) and 2.05 (95% CI: 1.62 to 2.59) respectively.[4] The gum's efficacy is well established, but to date only 1 randomized controlled efficacy trial on the lozenge has been published.[5] In this trial, the lozenge showed efficacy among light smokers, heavy smokers, and smokers who had previously failed pharmacotherapy.[6-7] The lozenge is generally well tolerated, has a similar side effect profile to nicotine gum (mouth irritation, nausea, heartburn, hiccups, etc) without requiring a special technique for optimal use (park and chew).[8] It also delivers more nicotine than the equivalent dose of the gum.[9] These features suggest the lozenge may be a more effective method of oral nicotine replacement. The results of the single randomized controlled trial on the lozenge support this conjecture as the lozenge produced impressive abstinence rates at 6-month follow-up.[6]

In addition to examining the relative efficacy of these 2 pharmacotherapies, we also examined variables that might make these medications more or less appealing to smokers. Specifically, we examined weight gain and adverse events. Weight gain is a common and vexing side effect of smoking cessation. In the first year

after successfully quitting smoking, most patients typically gain 10-14 pounds.[10] Weight gain concerns are a significant barrier to some smokers.[11] Both the gum and the lozenge have been shown to delay, but not prevent, weight gain.[6,11] Nicotine gum in higher doses appears to reduce cessation-related weight gain[12] and has been recommended as a strategy to prevent it.

In addition, effectiveness of self-administered NRT appears to be more modest in "real world" effectiveness trials than in efficacy trials.[13] Thus, there is clear need to examine the performance of the nicotine lozenge in the effectiveness context as the existing efficacy trials may produce a relatively high estimate of clinic impact.

No trials directly comparing the nicotine lozenge and gum have been published to date. Lack of such information leaves patients and clinicians with little direction in choosing between the 2 treatments. Both are available over-the-counter and have the potential for widespread ad-lib use. Their cost per day is modest and can be less expensive than a pack of cigarettes. We therefore set out to compare the nicotine lozenge and gum in a direct "head to head" trial measuring quit rates, side effect profiles, and cessation-related weight gain in an urban setting with minimal controls, instructions, or reinforcements.

METHODS

Design

The study was conducted at the Aurora Sinai Medical Center in Milwaukee, Wis between June 2004 and July 2005. The present study was an effectiveness study with a 2 (medication conditions) x 2 (psychosocial interventions) design. Participants were randomized to receive either the nicotine lozenge or nicotine gum. They were also randomized to receive either 4 calls from the Wisconsin Tobacco Quit Line or a self-help brochure. Participants were treated with 8 weeks of NRT. Follow-up occurred at 8 weeks, 6 months, and 1-year post cessation attempt. Written informed consent was obtained from all participants and the University of Wisconsin Health Sciences Institutional Review Board approved consent forms and procedures. The study was conducted in compliance with ethical principles of the Declaration of Helsinki and the standards of good clinical practice developed by the International Conferences on Harmonization.

Screening and Eligibility

Participants were recruited by press release, newspaper and radio ads, flyers, and word of mouth to join the study. Men and women who were 18 years of age or older, smoked ≥10 cigarettes per day for the past 6 months, wanted to quit, had exhaled carbon monoxide (CO) levels of ≥10 ppm, had reliable access to a telephone, and planned to reside in the area for the next 12 months were eligible for enrollment. All interested participants were pre-screened by phone, and eligible participants made a clinic visit, at which, if they qualified for inclusion, they were immediately randomized to 1 of the 4 conditions previously mentioned.

A participant was considered ineligible if they were currently using another smoking cessation medication (ie, other forms of NRT, bupropion [Wellbutrin™, Zyban™]), had contraindication to the use of nicotine gum or nicotine lozenge (temporal mandibular joint disease, or other dental disease that would prevent safe gum chewing), had recent unstable cardiovascular disease (myocardial infarction, heart attack, or irregular heart beat/rhythm in the past 2 weeks), or had significant mental illness that would place the participant at risk (active depression with suicidality, or active psychotic symptoms). If female and premenopausal, the participant could not be pregnant and had to agree to use an effective birth control method during the treatment period.

Procedure

At randomization, baseline measurements were taken and included height, weight, demographics, smoking history, baseline carbon monoxide (CO) level, concurrent medications, and the Fägerstom Test of Nicotine Dependence questionnaire.[14] Randomization was done in 13 blocks of 36 participants, blocked by gender. Gender was used as a blocking variable because of hypothesized gender differences in response to nicotine replacement therapy.[15] Participants were given a 4-week supply of either nicotine gum or nicotine lozenge with instructions for use. At 4 weeks post-quit, participants could request additional medications for weeks 5-8 if desired.

If patients were randomized to the Wisconsin Tobacco Quit Line group, a baseline call to the Quit Line was made at the time of the initial enrollment, while in the office. During that phone call, cessation counseling was provided, and plans for future phone contacts were made. Specifically, plans were made for 3 follow-up calls: 1 call on or within 1-2 days of the Target Quit Date (TQD), a second phone call within 7-10 days of the TQD, and a third phone call within the next 30 days following the TQD. Patients could proactively call the Quit Line if desired; this was neither encouraged nor discouraged.

All participants were assessed via phone at 1 week post-TQD. Smoking status by self-report was assessed.

Table 1. Characteristics of Participants

	Quit Line and Lozenge	Quit Line and Gum	Self Help and Lozenge	Self Help and Gum
Number of participants	104	101	101	102
Average age in years (SD)	43.4 (12.7)	40.0 (12.0)	43.2 (13.1)	43.6 (10.9)
Men (% of participants)	45 (43.2)	45 (44.6)	45 (44.6)	44 (43.1)
Race (% of participants)				
White	75 (72.8)	65 (68.4)	65 (67.0)	74 (76.3)
Black	28 (27.2)	24 (25.3)	29 (29.9)	21 (21.6)
American Indian	0 (0)	2 (2.1)	0 (0)	1 (1.0)
Asian	0 (0)	0 (0)	1 (1.0)	0 (0.0)
Other	1 (1.0)	10 (9.9)	6 (5.9)	6 (5.9)
Number of years smoked (SD)	26.5 (12.2)	23.5 (11.6)	26.0 (12.6)	27.1 (11.2)
Average number of cigarettes per day in last month (SD)	23.8 (10.2)	22.3 (9.8)	23.3 (9.9)	22.9 (9.6)
Average Fagerstrom Test for Nicotine Dependence score (SD)	5.9 (2.2)	5.7 (2.3)	6.2 (2.1)	6.1 (2.1)
Number of prior quit attempts	3.4 (2.5)	4.2 (5.0)	4.4 (3.8)	3.9 (3.4)

SD=standard deviation

No counseling or advice was given during that or any other follow-up phone calls from the research center. At 8 weeks post-TQD, all participants attended a clinic visit. Smoking status, exhaled CO levels, adverse events, medication usage, and height and weight were assessed. Participants could request 4 additional weeks of NRT for tapering purposes if they desired, regardless of smoking status.

Further follow-up occurred by telephone at 6 months post-TQD and 12 months post-TQD. Only those who reported abstinence were invited for in-person clinic visits, at which time smoking status was confirmed with exhaled CO measurement and height and weight were measured.

Outcome Measures

The primary outcome measurement was 7-day point prevalent abstinence confirmed with exhaled CO of <10 ppm at 8 weeks post-TQD. Secondary outcomes were CO confirmed 7-day point prevalence at 6 and 12 months post-TQD as well as weight gain, and adverse events. Intensity of use of the Quit Line, use of NRT, gender, and race were used as variables for subgroup analysis. Participants lost to follow-up at any point were considered as relapsed and analyzed as continuing smokers using an intent-to-treat analysis.

Statistical Methods

All statistical tests were 2-sided with a Type I error rate of 0.05. Abstinence rates were expressed as binary data and were analyzed using a logistic regression model including main effects of treatment group.

A sample size of 100 participants per group was chosen to have 81% power to detect a difference between the lozenge versus gum assuming a 12% difference (29.5 for lozenge versus 17.5 for gum). Statistical significance was tested by comparing each individual condition against every other and then collapsing across treatment dimensions. For all analyses, data were collapsed across the counseling dimension, since this did not interact with the NRT condition.

RESULTS

Randomization

A total of 1155 people were screened for participation. One hundred forty-eight were excluded based on inclusion/exclusion criteria, 264 people declined further participation, and 335 were eligible, invited for a clinic visit, but never visited the clinic and were never enrolled into the study. Four hundred eight participants were randomized into 4 groups. Baseline characteristics are shown in Table 1. There were no significant baseline differences between groups.

Participant disposition is shown in Figure 1. Overall follow-up rates at 8 weeks, 6 months, and 12 months were 64.0%, 72.8%, and 69.9%, respectively, with little variation between groups. Of those reporting abstinence via phone follow-up who were subsequently invited for a clinic visit for CO confirmation at 6 and 12 months, 81.3% and 64.3% completed the clinic visit respectively, with little variation across the groups.

Participants were asked to return all unused NRT at the 8-week visit, but only approximately 60% of participants did so. Because of the limited response rate, NRT utilization estimates were considered unreliable enough to preclude further analyses.

Cessation Rates

To test the main effect of medication, we collapsed across the Quit Line and Self-Help conditions. It should be noted that there were no omnibus differ-

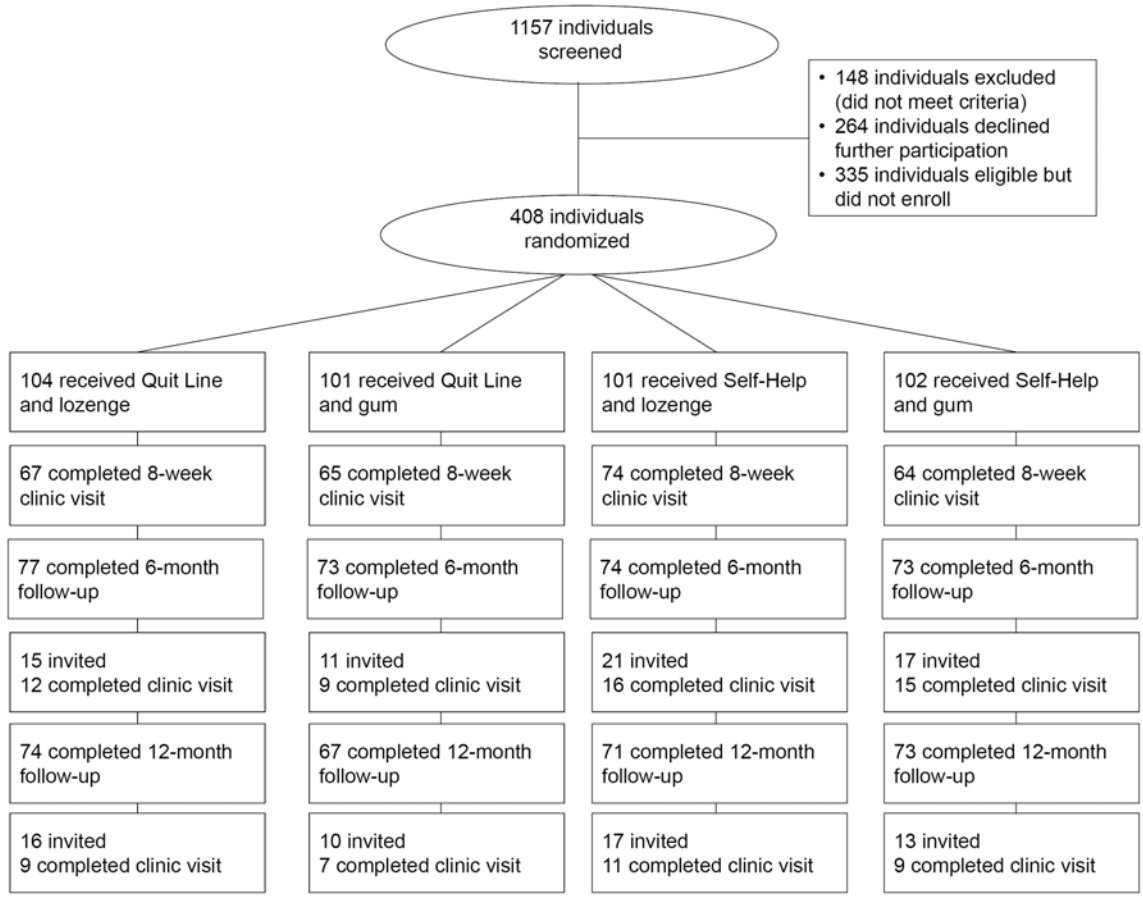

Figure 1. Consolidated Standard for Reporting Clinical Trials (CONSORT) diagram of participant disposition.

ences between counseling conditions and no interactions between groups. Results are shown in Table 2 and Figure 2. At 8 weeks, the lozenge quit rate was 15.1% and the gum quit rate was 11.3% with an OR of 1.39, 95% CI (0.78-2.49) *P*=0.26. At 6 months the OR was 1.24 (0.64-2.38) *P*=0.53. At 12 months the OR was 1.38 (0.67-2.83) *P*=0.38. Although slightly higher quit rates were observed at all time points among lozenge users, these differences were not statistically significant.

Because this effectiveness study was conducted with a diverse urban population, cessation rates were also examined for pre-defined demographic subpopulations. Among the 102 (25.0%) African Americans randomized, the overall quit rate across all conditions was 9.8% compared to the non-African American overall quit rate of 14.4% at 8 weeks, a non-significant difference. No difference was found between the lozenge and gum as a function of race.

Among the 223 (55.9%) women randomized, the overall quit rate was 11.7%, compared to men at 15.1%. This comparison was non-significant at all time points. However, among men, the lozenge trended toward being more effective than the gum at all time points. At 8 weeks, 6 months, and 12 months the quit rate, comparison rate, and odds ratios (with CI) were 18.5% versus 11.8%, OR 1.69 (0.74-3.84), 14.1% versus 6.5% OR 2.39 (0.86-6.58), and 13.0% versus 4.3%, OR 3.33 (1.03-10.7) respectively, reaching marginal significance at 12 months. Small cell sizes did not permit analysis of gender and racial/ethnic interactions.

Weight Outcomes

Weight outcomes are shown in Table 3 by type of nicotine replacement therapy and smoking status. At 8 weeks, successful quitters in the lozenge group gained 3.0±6.3 lbs compared to the gum group, which gained 8.4±9.2 lbs with *t*=-2.4, *P*=0.02. At 6 months no statistical difference was found with weight gain 8.7±11.6 versus 13.6±9.7, *t*=-1.5, *P*=0.13. At 12 months the difference was 6.3±27.4 versus 13.5±13.5 *t*=-1.0, *P*=0.32. Among participants who relapsed, weight gain was 0.9 lbs versus 1.8 lbs *t*=-1.1, *P*=0.27. At all time points, regardless of smoking status, the lozenge appeared to reduce weight gain compared to the gum, but this effect was only significant during the treatment phase among successful quitters.

Table 2. Seven-day Point Prevalence of CO-confirmed Abstinence for Lozenge vs Gum

Follow-up Period	Nicotine Lozenge n=205 (%)	Nicotine Gum n=203 (%)	OR (95% CI)	*P* value
8 weeks	31 (15.1)	23 (11.3)	1.39 (0.78-2.49)	0.26
6 months	22 (10.7)	18 (8.9)	1.24 (0.64-2.38)	0.53
12 months	19 (9.3)	14 (6.9)	1.38 (0.67-2.83)	0.38

OR=odds ratio; CI=confidence interval.

Side Effects/Adverse Events

Adverse Events are shown in Table 4. Total number of reported adverse events was 61 (43.3%) in the lozenge group and 42 (32.6%) in the gum group. The most common side effects were nausea, mouth/jaw/throat irritation, hiccups, and heartburn, with rates for the lozenge being 9.2, 8.5, 5.7, and 5.7 percent respectively. Rates for the gum were 6.2, 8.5, 3.1, and 0.8 percent respectively. Frequency of events was similar across groups with no statistical differences between the groups.

One death occurred 47 days after end of treatment and was determined to be from a post-operative complication following mitral valve replacement surgery and was not related to the study medication.

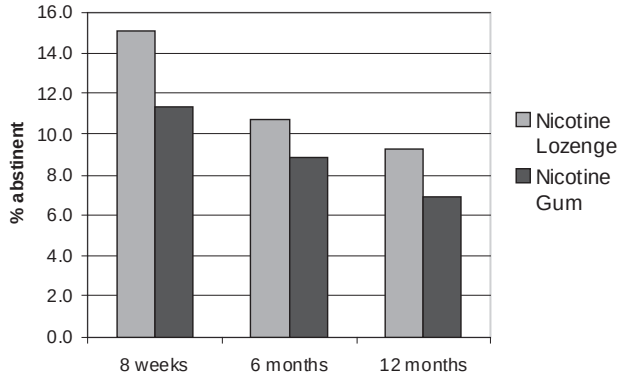

Figure 2. CO confirmed abstinence for lozenge versus gum (collapsed across groups).

DISCUSSION

The study demonstrated a nonsignificant trend toward increased effectiveness of the lozenge for smoking cessation. Subgroup analysis suggests the effect may have reflected a superior response among men. As originally suggested by Perkins et al,[15] a meta-analysis by Cepeda-Benito et al[16] found that among trials using all types of NRT compared to placebo, men had superior cessation rates over women at all time points but only reached statistical significance at 12-month follow-up. They concluded that NRT is more effective for men, and that women need more nonpharmacologic support to maintain abstinence long term. One critique of this theory was the discovery of a possible reporting bias, meaning that, when reviewing the literature for meta-analysis, only studies with positive gender associations were reported and published, while other trials with negative or insignificant associations never reported gender data. In addition, a meta-analysis by Munafo et al,[17] published essentially simultaneously with Cepeda-Benito's meta-analysis, found no meaningful differences in NRT response rates at all times points between men and women among trials of the nicotine patch compared to placebo. As a result, the issue remains unresolved.[18] We demonstrated a trend toward more effectiveness in men with the lozenge, but failed to find reliable statistical differences. Presumably, the lozenge might produce superior effects in men due to a higher delivered nicotine dose.

The statistically significant finding in this "real world" effectiveness study was the difference in weight gain among users of the lozenge compared to the gum. On average, those using the lozenge experienced 5.4 fewer pounds of post-cessation weight gain at 8 weeks. On average, all abstinent participants gained weight, but those in the lozenge group gained less weight. This effect also could reflect the more efficient nicotine delivery of the lozenge, compared to nicotine gum.[9] In addition, the side effect profiles of the gum and lozenge were quite similar, suggesting that either is a safe treatment option. As this study represents the first direct comparison of these 2 NRTs in an effectiveness trial, the results indicate that both therapies are similarly effective for cessation, but that the lozenge may confer significant benefit in terms of delaying post-cessation weight gain.

There are strengths and weaknesses to an effectiveness design. Notably, there was no placebo group in this study, so comparisons to an internal reference could not be made. However, both the lozenge and gum in this study compare favorably to unaided quit rates.[10,19] Due to the limited return of medication at week 8, it was not possible to reliably estimate gum or lozenge usage and the potential impact of rate of use on cessation. This occurred because participants were asked only once at randomization to return unused NRT at

Table 3. Weight Gain by Type of NRT and Smoking Status

	Lozenge group pounds gained (SD)	Gum group pounds gained (SD)	*t* value	*P* value
Abstinent				
8 weeks	3.0 (6.3)	8.4 (9.2)	-2.4	0.02
6 months	8.7 (11.6)	13.9 (9.7)	-1.5	0.13
12 months	6.3 (27.4)	13.6 (13.6)	-1.0	0.32
Relapsed				
8 weeks	0.9 (7.1)	1.8 (5.0)	-1.1	0.27

NRT=nicotine replacement therapy

Table 4. Reported Adverse Events

	Nicotine lozenge group n=141 (%)	Nicotine gum group n=129 (%)
Nausea[a]	13 (9.3)	8 (6.2)
Mouth irritation[b]	12 (8.5)	11 (8.5)
Heartburn[c]	8 (5.7)	4 (3.1)
Hiccups	8 (5.7)	1 (0.8)
Other adverse events	20 (14.2)	18 (14)
Total	61 (43.3)	42 (32.6)

[a] Nausea, stomach upset, stomach pain
[b] Mouth irritation, burning mouth, mouth sores, sore gums, jaw pain, dry mouth
[c] Heartburn, GERD, reflux

the 8-week clinic visit and many participants forgot. No other reminders were given and no aggressive NRT usage tracking was done, in keeping with the effectiveness study design. Since rates of use with ad lib NRTs may have a significant impact on success rates, this is a significant limitation compared to a highly-controlled efficacy study where rates of NRT use are typically tracked with more precision and are typically known in 90%-98% of participants.[5] Strengths of the study are that 25% of the population was African American and the education levels and socioeconomic status were diverse. Thus, the results may be generalizable to the current population of smokers, since smoking is becoming increasingly concentrated in low SES populations.[20] In addition, follow-up was consistent across all groups in the study, increasing confidence that the observed findings are reliable.

CONCLUSIONS

This effectiveness study, conducted with a diverse urban population, identified a significant benefit of the nicotine lozenge in reducing post-cessation weight gain relative to nicotine gum. It suggested a possible differential cessation benefit for male smokers, but this result was not consistently significant and would require replication. Further research is needed to clarify the optimal agent for smoking cessation in general populations of smokers.

Acknowledgments: We would like to thank Su Young Kim for his help with statistical analysis, Heather Vaughn for management of data entry and database, and the support staff at the Center for Tobacco Research and Intervention.
Funding/Support: This research was supported by the National Cancer Institute Grant P50CA084724 and the National Institute on Drug Abuse Grant #P50DA019706.
Financial Disclosures: Douglas E. Jorenby, PhD, has received research support from Pfizer and Nabi Biopharmaceutical. Michael C. Fiore, MD, MPH, reports that in the last 5 years, he has served as a consultant, given lectures, or conducted research sponsored by GlaxoSmithKline, Pharmacia, Pfizer, and SanofiSynthelabo. In 1998, the University of Wisconsin appointed him to a named chair made possible by an unrestricted gift from Glaxo Wellcome.

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WISCONSIN MEDICAL JOURNAL

Acute Thigh Compartment Syndrome Post Femoral Vein Catheterization: A Case Report

Mark W. Asplund, MD, FACS

ABSTRACT

This case report presents a previously unreported etiology of acute thigh compartment syndrome following ipsilateral femoral vein catheterization, including clinical results and a brief review of the literature.

INTRODUCTION

Acute thigh compartment syndrome is a rare event usually precipitated by trauma, severe ischemia/reperfusion injury, extreme overuse, burns, or compression. This report describes a case of thigh compartment syndrome as a complication of right heart venous catheterization for radiofrequency ablation of atrial arrhythmias.

METHODS AND RESULTS

A 53-year-old man presented 5 days after transvenous ablation of atrial arrhythmias through a right common femoral vein catheterization at an outside hospital. His past medical history was significant for atrial arrhythmias. He also had a right hipbone graft harvest site, an old tibia-fibula fracture to the right, and a right knee arthroplasty. He was on several medications, most notably subcutaneous Dalteparin twice a day and Warfarin, which were both started at the time of the ablation. He was taking 1 aspirin a day. Pre-ablation records and laboratory values were considered unreliable because they were done at an outside hospital. After his radiofrequency ablation, he did well and was converted to normal sinus rhythm.

The patient is a vigorous man who participated in outdoor activities, which he immediately resumed. Twenty-four to 36 hours prior to admission, which was 4 days after his ablation procedure, he developed progressive right groin pain and then right thigh pain. This progressed to numbness in his foot and an inability to walk. He presented to an outside emergency department (ED) where duplex of the femoral artery and vein failed to show any evidence of hematoma, deep vein thrombosis, arterial compromise, or pseudoaneurysm. Pulses were normal distally. The patient was discharged on oral analgesics. However, 3 hours later he sought care in our ED for progressive pain. A duplex was repeated with the same findings. The patient was again sent home with normal pulses, neurologically intact, and no specific diagnosis. However, after being discharged, he immediately returned from the parking lot unable to bear weight on his leg due to excruciating thigh pain and now-progressive paralysis. He returned to the ED and vascular surgery was consulted.

Examination at that time showed a pulse of 110, blood pressure of 140/80, and in sinus rhythm. There was a good Doppler pulse to the right foot. However, his foot now was becoming blue, somewhat edematous, and anesthetic. His thigh compartments were rock-hard anteriorly and posteriorly and exquisitely tender. His partial thromboplastin time (PTT) was 52, international normalized ratio (INR) was 1.62, hemoglobin was 9, and his potassium was 4. An immediate groin and thigh exploration was recommended for presumed acute hemorrhage into the thigh and groin.

The groin was explored under general anesthesia, and the femoral artery and vein were found to be normal-appearing with some perivenous edema and staining of the tissues, but no significant hematoma. The incision was carried down into the thigh, and edema seemed to be pushing the tissues from below upward as we continued down. The patient was deemed to have thigh compartment syndrome and, therefore, a complete fasciotomy was performed by both a lateral and medial approach to decompress the anterior, posterior, and medial thigh compartments. All compartments were hypertensive as evidenced by extreme bulging of the very edematous muscles, but the pressure posteriorly and laterally was

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so high that fluid tinged with blood sprayed out of the compartment 2-3 meters. The muscles protruded and we were unable to close the skin incisions (Figure 1). There was some bloodstaining but no marked hemorrhage or hematoma to the tissues. The fasciotomy was continued into the gluteal region superiorly, but this did not appear to be involved. The wounds were left open, and all anticoagulation stopped.

Postoperatively, the patient experienced immediate relief of all symptoms, and all neurologic function returned to the foot except for a moderate foot drop. His postoperative course was complicated by bleeding in the incisions and a return of his atrial fibrillation. The wounds necessitated plastic surgery closure approximately 1 week postoperatively. One year later, the patient has complete use of his right leg with no long-term sequelae.

Figure 1. Medial approach to thigh decompression with bulging quadriceps and adductor muscles.

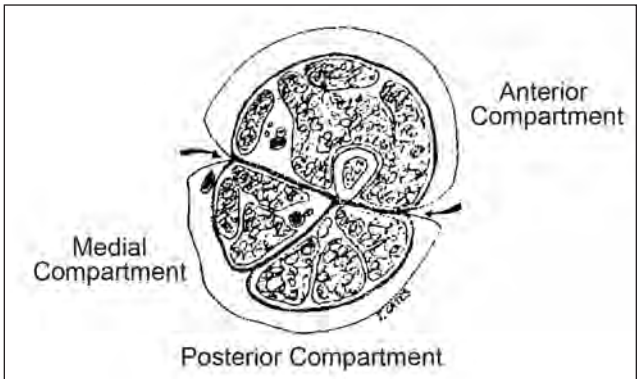

Figure 2. Anatomy of thigh compartments.[6]

DISCUSSION

Acute thigh compartment syndrome is a rare event and is typically caused by trauma, usually involving a femur fracture or severe contusion of the thigh.[2] Other etiologies include burns, severe ischemia/reperfusion injury, and extreme overuse. Rarely reported causes include cardiopulmonary bypass through the femoral artery and vein in a child.[1] There have been no previously reported cases caused by percutaneous puncture, either arterially or venous. This case involved only a venous puncture. The puncture was in the common femoral vein with no involvement of the profunda or superficial femoral vein.

This patient clearly had thigh compartment syndrome of the anterior, lateral, and posterior compartments, with an unknown cause. Of the known causes, ischemia/reperfusion was ruled out by the Duplex findings, normal pulses, and the operative findings. Likewise, deep vein thrombosis was ruled out by the Duplex findings and the operative findings. These are both known causes of thigh compartment syndrome.[3-5] There was no significant hemorrhage or hematoma. The patient was anticoagulated, which certainly could have contributed to bleeding as the cause for the compartment syndrome. However, his coagulation parameters were not excessive, nor was there significant bleeding discovered by Duplex or at the time of exploration. The tissue fluid encountered was edema that was blood-tinged.

The author believes this patient's compartment syndrome was caused by a relative outflow obstruction of the venous system due to the catheterization and perivenous edema and inflammation. This was significant in this patient because of his extreme vigorous activity, high pain threshold, and the fact that his leg compartments were somewhat rigid due to scarring from previous orthopedic injuries. This patient had a previous knee arthroplasty and a second large lateral thigh incision using the hipbone as a donor site for repair of a tibia-fibula fracture years ago. This then set up a vicious cycle where the rigid compartments became edematous due to exercise and relative venous obstruction causing more venous obstruction and more edema. This is a very unusual set of circumstances but is the only explanation for the patient's compartment syndrome, given the operative and Duplex findings.

Clinically, this patient presented with all the stigmata of thigh compartment syndrome with severe thigh pain, rock-hard thigh compartments on palpation, motor and neurologic dysfunction distally, and with complete relief of all his symptoms on the fasciotomy of the anterior, posterior, and lateral thigh compartments. This was particularly demonstrated by the force of the evacuation of the edema from the lateral approach (Figure 2).

CONCLUSION

This case is believed to be a previously unreported etiology of thigh compartment syndrome, successfully treated by fasciotomies. Previous orthopedic procedures to the thigh, vigorous activity, high pain threshold, and anticoagulation are believed to have led to acute thigh compartment syndrome. Contributing factors include recent venous catheterization with a relative venous obstruction. Health care professionals must be aware of such an event in the future.

Funding/Support: None declared.
Financial Disclosures: None declared.

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Proceedings from the 2007 Annual Meeting of the American College of Physicians, Wisconsin Chapter

INTRODUCTION

The Wisconsin Chapter of the American College of Physicians held its annual meeting in Wisconsin Dells, Wis, September 7-9, 2007. Internal Medicine residents from each of Wisconsin's 5 residency programs (Gundersen Lutheran Healthy System, Marshfield Clinic, the Medical College of Wisconsin, University of Wisconsin Hospital and Clinics, and University of Wisconsin Milwaukee Clinical Campus [Aurora Sinai Medical Center]) presented their research and/or unusual clinical experiences via posters and vignettes. Text versions of the research can be found below. The next Annual Meeting for the Chapter will be held September 12-14, 2008, at the Wilderness Resort in Wisconsin Dells, Wis.

PRESENTED POSTERS

Atraumatic Splenic Rupture

Vijay Aswani, MD, PhD, Maja Visekruna, MD; Marshfield Clinic, Marshfield, Wis

Case: Spontaneous splenic rupture is an extremely rare but life-threatening complication of Infectious Mononucleosis (IM) in young adults. A 25-year-old man presented to the emergency department (ED) with a 3-day history of fever and left-sided pleuritic chest pain. He denied any shortness of breath or recent trauma. Other than an oral temperature of 101.4ºF, his vitals signs were stable. His physical exam was significant for tenderness in the left lower chest wall on deep inspiration and tenderness to palpation in the left upper quadrant. Lab studies revealed leukopenia, thrombocytopenia, and lymphocytopenia. A mononucleosis test done in the ED was negative. D-dimer was elevated at 3.02. A computed tomography (CT) scan of the thorax and abdomen showed no evidence of pulmonary embolism but incidentally revealed an intraperitoneal hemorrhage into the abdomen and pelvis with an enlarged spleen. The patient was hospitalized for observation and remained hemodynamically stable. A CT scan repeated 4 days later revealed a splenic laceration. While Epstein-Barr Virus (EBV) IgG and IgM titers were negative, a polymerase chain reaction done 4 days after admission was positive. EBV IgM titers done 11 days following admission were positive. His fever, symptoms of pain and hematological abnormalities resolved. A CT done about a month later showed interval resolution of the hemoperitoneum and splenic laceration.

Discussion: Splenic rupture is a rare but known complication of IM. It is even more rare as the presenting sign of IM. The case illustrates the need for persistent clinical suspicion when investigating atypical presentations of common illnesses and keeping in mind the specificities and sensitivies of common screening tests.

Brain Drain

Vijay Bandhakavi, MD; Gundersen Lutheran Medical Center, La Crosse, Wis

Case: A 41-year-old woman presented with a 3-week history of occipital and bilateral temporal headaches following chiropractic manipulation of cervical spine for neck pain. The headache was relieved when she was recumbent but became worse when she stood up. She had no other systemic complaints. Her past medical history was significant for rheumatoid arthritis with ongoing Adalimumab therapy. Complete physical examination, including neurological examination, did not reveal any abnormal findings except for those of rheumatoid arthritis. A purified protein derivative test, Lyme serology, human immunodeficiency virus serology and VDRL serology were all negative. A CT scan of the head revealed small bilateral subdural hygromas. Magnetic resonance imaging (MRI) of the head revealed bilateral subdural effusions and diffuse enhancement of the dura, which was interpreted to be consistent with granulomatous meningitis. Multiple attempts to obtain cerebrospinal fluid (CSF), including eventually cisterna magna puncture, were unsuccessful despite appropriate positioning with fluoroscopy. MRI scan of the entire spine did not reveal any evidence of CSF leak. A right parietal burr hole was placed and subdural fluid was retrieved for further analysis. There was no evidence of mycobacterial, fungal, or bacterial infection on histopathology or culture. Histopathology was consistent with spontaneous intracranial hypotension. Her headaches resolved following treatment with lumbar epidural blood patch.

Discussion: We present a challenging case of spontaneous intracranial

hypotension in an immunocompromised patient with rheumatoid arthritis that radiographically mimicked granulomatous meningitis. Spontaneous intracranial hypotension is caused by single or multiple spinal CSF leaks. Women are affected more than men, with a peak around 40 years of age. In our patient, chiropractic manipulation of the cervical spine in combination with her underlying rheumatoid arthritis was felt to cause the CSF leak. An orthostatic headache is the typical manifestation. Associated symptoms include neck stiffness, tinnitus, photophobia, and nausea. Myelography is the study of choice to identify the spinal CSF leak. Typical MRI findings include subdural fluid collections and enhancement of the pachymeninges. Treatments include bed rest, epidural blood patching, and surgical CSF leak repair. Spontaneous intracranial hypotension is not rare but it remains underdiagnosed.

Neurofibromatosis Type I: A Case of Malignant Change

Tracy Brenner, MD; Aurora Sinai Medical Center, Milwaukee, Wis

Case: We present a 39-year-old man with a past medical history significant for Neurofibromatosis Type I (NF1), complaining of a 5-day history of progressive dyspnea on exertion and right-sided back pain. Pulmonary exam showed decreased breath sounds and dullness to percussion involving the entire right lung and at the left base. CT of the chest confirmed a large right pleural effusion and a complete collapse of the right lung. A thoracoscopy was performed that revealed multiple nodules blanketing the pleural space and a completely collapsed right lung in addition to a large effusion. A biopsy and subsequent histology revealed high-grade malignant peripheral fibromas with a confirmation of cell type as a sarcoma.

Two weeks after discharge the patient suffered recurrent, severe dyspnea. Emergency medical service found him to be in asystole. He was intubated and resuscitated and a chest CT was performed showing a complete opacification of the right hemithorax with significant mass effect, which appeared to be tumor burden on the left main stem bronchus, superior vena cava, and right atrium, along with a small right pleural effusion. Also seen was a pulmonary embolism in the left lower lobe. He died 2 days after admission.

Discussion: A recent international consensus statement on Malignant Peripheral Nerve Sheath Tumors (MPNSTs) in NF1 illuminated on the increased incidence of MPNSTs occurring with a significantly higher lifetime risk for the population diagnosed with NF1 versus the general population. MPNSTs are aggressive and potentially fatal soft tissue sarcomas that form in the outer layers of peripheral nerves, which may arise de novo, or from benign plexiform neurofibromas. MPNSTs are rare, with an expected incidence of 0.001% in the general population. However, about 40%-50% of MPNSTs are found in those individuals with a history of NF1. The lifetime risk of developing MPNST in patients with NF1 is documented to be as high as 10%-26%. To date, the only chance for survival is early detection and wide margin surgical resection. The goal of this discussion is to heighten awareness of MPNST in NF1 and thus, have a low threshold to work up any new symptoms.

When Dogs Are Not Man's Best Friend

Amberly Burger, MD; University of Wisconsin, Madison, Wis

Case: A 62-year-old immunocompetent woman presented with 2 days of constitutional symptoms followed by right upper quadrant (RUQ) abdominal pain radiating to the back. Blood cultures were obtained; she was started on broad spectrum antibiotics of ceftriaxone, ciprofloxacin, metronidazole, and ampicillin. Over the next 8 hours, the patient developed petechial rash of the trunk and extremities, purpura fulminans, and profound hypotension requiring 4 pressors. Early goal directed therapy was administered and she was transferred to the Intensive Care Unit at a tertiary care center. Due to RUQ tenderness, elevated liver function tests, and thickened gallbladder wall on ultrasound, digital vascular imaging was consulted and placed a percutaneous drain for control of the presumed source. Patient's illness progressed to septic shock with hypoxic respiratory and kidney failure. She was begun on a small dose of Recombinant Activated Protein C. Patient was given transfusions of blood products for disseminated intravascular coagulation. Patient developed multiple-organ dysfunction syndrome and died within 48 hours of presentation. Blood cultures from the original hospital grew out *Capnocytophaga canimorsus* and *Candida albicans* from her hospitalization in the tertiary care center. The patient owned 1 dog and had no history of dog bites or visible wounds on her body.

Discussion: Capnocytophaga canimorsus is well described in the literature of immunocompromised or asplenic hosts. In immunocompetent hosts it is associated with a known history of dog bite or workers at animal shelters. This disease course, although classic for *Capnocytophaga canimorsus* is rare in this population.

All Choked Up

Michael S. Harris; Medical College of Wisconsin, Milwaukee, Wis

Case: A 19-year-old female Division I swimmer with a history of essential hypertension presented with shortness of breath, chest tightness, and a choking sensation occurring primarily during exertion. She carried the diagnosis of exercise-induced asthma with a frequency of symptoms that placed her in the mild persistent category. Over the 4 years since this constellation of symptoms arose, she was treated unsuccessfully with a procession of bronchodilator and corticosteroid therapies. Management of her concomitant essential hyperten-

sion was complicated by frequent use of tachycardia-inducing beta-2-agonists and reluctance to initiate beta-1-blocker therapy in light of her reactive airway disease. Upon presentation, the patient's methylcholine bronchoprovocation tests were consistent with asthma. Flow volume loops, however, were suggestive not of small airway disease, but an intermittent variable extrathoracic obstructive process. Subsequent laryngoscopy with video stroboscopy revealed a paradoxical adduction of the true vocal cords during inspiration. With a correct diagnosis of Paradoxical Vocal Cord Dysfunction (PVCD), the patient began speech therapy, the mainstay of management for PVCD, and switched to a beta-1-blocker, bringing her blood pressures within normal limits.

Discussion: PVCD is a condition described by William Osler in 1902 in which the glottic space narrows during inspiration rather than demonstrating the normal vocal cord abduction to maximize inspiratory volume. Wheezing, shortness of breath, dyspnea, and stridor are common features of PVCD, and as such, it often masquerades as asthma. A number of etiologies of PVCD have been identified including neurologic, irritant-induced, and somatization/conversion disorder. The most common form, however, is exercise-associated PVCD. The condition has a striking predilection for young, competitive, athletic women, and it is often misdiagnosed as exercise-induced asthma, the treatments for which it is recalcitrant. The average time from presentation to correct diagnosis is 4½ years. In any patient with a history of poorly controlled or atypical asthma, particularly of an exercise-induced variety, PVCD should be considered in the differential diagnosis. Correct identification of PVCD based on subtleties in clinical presentation and volume-flow loops is important for early initiation of appropriate management and avoidance of untoward outcomes associated with unnecessary and ineffectual asthma treatments.

Severe Rhabdomyolysis and Death in a Man with Idiopathic Epilepsy

Aymen M. Khogali, MD; Aurora Sinai Medical Center, Milwaukee, Wis

Case: A 45-year-old African American man with human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS) and idiopathic epilepsy was admitted with severe metabolic acidosis and rhabdomyolysis in context of a 30-minute episode of witnessed seizure. He remained anuric, hypotensive, and hypoxic despite resuscitation with intravenous fluids and pressors. A striking increase in creatine phosphokinase (CPK) (265,000 u/L) and a phosphate of 17.7 mg/dl were noted along with hyperkalemia (7.5 mEq/L) that could not be managed with extra-corporeal therapy as he remained hemodynamically unstable. An autopsy was refused.

Discussion: Non-traumatic rhabdomyolysis has been reported in medical literature due to multiple etiologies. We were unable to find a series of cases in which severe rhabdomyolysis was associated with prolonged seizure.

An Octopus Trap

Gabrielle LeMarbre, MD; University of Wisconsin, Madison, Wis

Case: A 65-year-old woman presented with 1-day history of mild chest pressure. She was visiting her husband in the hospital when she became diaphoretic, nauseated, and short of breath. She experienced palpitations and her chest pressure increased to 6/10. On presentation, her troponin-I was elevated to 5.6. Her electrocardiogram (ECG) showed T-wave inversions in anterolateral leads suggestive of ischemia. Her coronary angiography was unremarkable. Her vetriculogram illustrated apical ballooning and decreased left ventricular function with an ejection fraction of 40%. Follow-up echocardiogram (ECHO) 2 days later demonstrated reduced ventricular function with apical ballooning, supporting a diagnosis of Takotsubo cardiomyopathy.

Discussion: In 1990, Japanese clinicians diagnosed a cardiomyopathy in which the left ventricle resembled the octopus trapping pot used by Japanese fisherman, known as a takotsubo. Takotsubo has been described in the United States population with increasing prevalence. In 1 series, 2.2 percent of patients presenting with ST-segment elevation acute coronary syndrome were diagnosed with Takotsubo. In 1 meta-analysis, 88.8% of patients were women, typically with a preceding psychological or physical stressor. Over 93% of patients were older than 50. Presentation mimics acute coronary syndrome. ECG in the disease can show ST-segment elevations or T-wave inversions. Troponin-I is typically mildly elevated, but does not predict the ventricular function or recovery. For diagnosis, ventriculography or echocardiography must show apical ballooning and akinesis without evidence of significant coronary artery stenosis or spasm. Patients commonly have reduced ejection fraction (20%-49%) that improves within days to weeks. Prognosis is favorable with an in-hospital mortality of 1.1%, but heart failure complicates the outcome in 17.7% of patients. One study suggests that treatment of Takotsubo with beta-blockers, aspirin, ace-inhibitors, and calcium-channel blockers does not improve the ejection fraction in patents at discharge or at 30-day follow-up. This lack of therapeutic benefit emphasizes the importance of prompt diagnosis and appropriate management.

Congratulations! It's a Neutrophil!

Swapna Narayana, MD; Gundersen Lutheran Medical Center, La Crosse, Wis

Case: A 27-year-old woman, 15 weeks primigravida, presented with a 3-day history of low-grade fevers, headache, joint pains, mouth sores, and malaise. She also had developed purple, vesicular skin lesions on her torso, back, and extremities. The skin lesions were initially noticed on

the abdomen and gradually spread towards the extremities. A recent trans-abdominal ultrasound revealed an age appropriate singleton pregnancy. She had a history of multiple sexual partners. She also had a history of multiple outbreaks of genital herpes simplex virus infections in the past. She had not taken any new medications. On physical examination, she had tender, purple, asymmetric, vesicular skin lesions involving the torso, back, and extremities. The physical examination was otherwise normal. Routine blood tests were significant for an elevated white count (14,000) and neutrophilia (90%). A comprehensive metabolic panel, including liver function tests, was normal. An erythrocyte sedimentation rate was 32 mm/hr. An exhaustive workup for infectious diseases including Tzanck smear, gram stain, fungal smear, viral culture and human immunodeficiency virus test was negative. In addition, CSF studies, blood cultures, urine cultures, VDRL, and tests for gonorrhea and chlamydia were all negative. She was empirically started on ceftriaxone and acyclovir. However, the patient's rash and pain clinically worsened despite this treatment. A punch biopsy of the skin lesions was then performed and revealed a superficial and deep, dense inflammatory infiltrate of neutrophils with focal spongiosis of upper dermis. No vasculitic changes were noted. This combination of perivascular neutrophilia with the absence of vasculitis or vascular thrombosis led to the diagnosis of Sweet's syndrome. She was then initiated on systemic steroids, and the skin lesions completely resolved after a week. Systemic steroids were tapered off after 6 weeks.

Discussion: Acute febrile neutrophilic dermatosis, or Sweet's syndrome, was described in 1964 by RD Sweet. It is a rare skin disorder that occurs mostly in women, 30-50 years of age. The importance of correctly identifying this disease lies in its association with other diseases. Pregnancy-induced Sweet's syndrome occurs in 2% of the cases and usually occurs during the first or second trimester. Diseases associated with Sweet's syndrome include inflammatory bowel disease, malignancy, and infections of the upper respiratory tract and the gastrointestinal tract. Treatment of Sweet's syndrome is with oral steroids and usually carries a good prognosis if the disease is not associated with malignancy.

More Than Weakness

Vipulkumar Rana, MD, Maria Delgado, Kurt Pfeifer, MD, FACP; Medical College of Wisconsin, Milwaukee, Wis

Case: A 47-year-old man with no past medical history presented with a 4-day history of proximal lower extremity weakness. Additionally, he reported a 25-pound weight loss over the past 4 months and a 2-month history of generalized weakness, fatigue, dizziness, and headaches. He was admitted to the neurology service, and evaluation revealed non-focal, 4 of 5, proximal, give-way weakness, with normal muscle bulk and tone. Electromyogram and head CT were also within normal limits, and infectious work-up was unremarkable. The patient was discharged with the diagnosis of fatigue of unknown etiology, only to return 5 days later with worsening of his previous symptoms, inability to bear weight, and mild diffuse abdominal pain. On initial evaluation, he had normal vitals signs and basic laboratory studies, and the symptoms were attributed to a psychological cause. However, after further work-up, adrenocorticotropic hormone stimulation test was performed and the diagnosis of adrenal insufficiency was made. Glucocorticoid and mineralocorticoid replacement was started with marked improvement of all symptoms.

Discussion: Adrenal insufficiency frequently presents with an insidious onset of weakness and fatigue that can dramatically progress to the point of disability. While a common presentation includes weakness, fatigue, and weight loss as seen in this patient, many physicians dismiss the diagnosis in a patient without hypotension or electrolyte abnormality. It is a common misconception among physicians that a patient cannot have adrenal insufficiency without hypotension and/or electrolyte abnormalities. Maintaining a high index of suspicion for the diagnosis of adrenal insufficiency in the absence of these findings may lead to earlier diagnosis, faster patient recovery, and avoidance of unnecessary testing and patient stress.

Unusual Etiology of Lung and Liver Nodules in a Smoker

Jason Ricco, BS, Anna Haemel, MD, David Feldstein, MD; University of Wisconsin, Madison, Wis

Case: A 60-year-old woman with a 30-pack-per-year smoking history presented to the ED with progressive fatigue, dyspnea on exertion, and mild hemoptysis. She also complained of anorexia, a 15-pound weight loss, small joint arthralgias, and decreased sensation in her lower extremities, all developing over 1 month. Examination revealed cachexia, crackles at the left lung base, and decreased light touch in the lower extremities. Initial laboratories included mild anemia and creatinine 1.9. Urinalysis showed proteinuria, hematuria, and granular casts. CT revealed numerous bilateral pulmonary nodules, some with cavitation, and several low attenuation liver lesions not amenable to biopsy. Biopsy of the most prominent lung lesion showed histiocytes and scattered giant cells with a necrotic background. Renal biopsy showed pauci-immune crescenteric glomerulonephritis and C-Anti-Neutrophil Cytoplasmic Antibody (ANCA) came back positive. The initiation of cyclophosphamide and prednisone resulted in improvement of her systemic complaints and kidney function.

Discussion: This patient was initially thought to have metastatic cancer due to her smoking history, pulmonary nodules and liver lesions consis-

tent with metastases. Her arthralgias and paresthesias raised the question of paraneoplastic syndrome. The granular casts on initial urinalysis misled the team to believe she had acute tubular necrosis. However, the unresponsiveness of her acute kidney injury to fluid resuscitation led to a unifying diagnosis of Wegener's granulomatosis.

Wegener's classically presents as granulomatous vasculitis of the small vessels of the respiratory tract with accompanying glomerulonephritis. The extent of disseminated vasculitis is variable. However, case reports of hepatic involvement are limited. Differential diagnosis of the nonspecific low attenuation liver lesions seen on CT includes metastases, abscesses, or granulomas. Although this patient's liver function remains within normal limits, the liver lesions may represent granulomas. This case exemplifies the diverse presentation of Wegener's and the high index of suspicion imperative in any patient with pulmonary nodules and renal dysfunction.

Phenytoin-Induced Dress Syndrome

Matthew A. Schmidt, MD, Kurt Pfeifer, MD, Amandeep Gill, MD; Medical College of Wisconsin, Milwaukee, Wis

Case: A 50-year-old man presented with nausea, vomiting, and abdominal pain after recently being admitted to an outside hospital for hypertensive emergency, hemorrhagic stroke, and seizure. He was treated in the intensive care unit, and started on phenytoin 900 mg 3 times daily for seizure prophylaxis. Following inpatient rehabilitation at the outside hospital, he was discharged home and then admitted to our hospital 1 day later. Initially, he was treated for suspected partial small bowel obstruction given radiographic findings of dilated loops of small bowel. The next day the patient developed a maculopapular rash on his chest and back, and phenytoin was discontinued as it was the suspected cause. His rash spread to his limbs, palms, soles and head, covering his entire body. At this time, he was also noted to have eosinophilia, and the diagnosis of Drug Reaction, Eosinophilia, and Systemic Symptoms (DRESS) was made. Following several doses of intravenous corticosteroids, his symptoms improved markedly, and his rash began to resolve. Levitiracetam was started in place of phenytoin for seizure prophylaxis, and he was discharged home on a tapering dose of steroids with dermatology follow-up.

Discussion: DRESS syndrome is associated with several antiepileptics including phenytoin, carbamazepine, and phenobarbital. The incidence with phenytoin is approximately 1 in 1000 to 1 in 10,000, and the hypersensitivity reaction usually occurs 2-6 weeks after the drug is first introduced. Patients typically have fever, rash, lymphadenopathy, and hepatitis, and less commonly interstitial nephritis, pulmonary involvement, and eosinophilia. When the viscera are involved, it can become potentially life-threatening. Standard treatment is discontinuation of the offending agent, intravenous hydration, antihistamines, and possibly corticosteroids, depending on the severity of reaction.

Hyperosmolar Therapy: The Good, the Bad, and the Ugly

Jayanth Vedre, MD, Jasjyot Nanra, MD, Anupama Inaganti, MD, Narayana, S. Murali, MD; Marshfield Clinic, Marshfield, Wis

Case: Mannitol, an osmotic diuretic, occupies a preeminent position in the therapeutic armamentarium of intracranial hypertension and acute angle closure glaucoma. Albeit uncommon, like all good therapies, this therapy too is not impervious to malevolent side effects. We report an 82-year-old man who presented with acute onset, painful right red eye with loss of vision, and elevated intraocular pressure with a subchoroidal hemorrhage. He was administered high dose intravenous mannitol in the inpatient setting. Baseline creatinine of 1.0 mg/dL (estimated glomerular filtration rate[GFR] 87.4ml/min) and sodium of 136 mmol/L. On day 3 of his treatment, he was noted to have mild hyponatremia (130 mmol/L) and lisinopril treatment was initiated to address hypertension (systolic blood pressure 170-180 mmHg). On day 4, he was slightly somnolent, profoundly bradycardic (27 bpm) with an ECG revealing a very slow ventricular response, peaked T waves, and was immediately addressed by temporary pacing. His laboratory investigations revealed marked hyponatremia (115 mmol/L), hyperkalemia with acute kidney injury that rapidly progressed to severe oliguric renal failure (creatinine, 2.6 to 4.5 mg/dL, eGFR 13.6 ml/min) over the next 12 hours. Measured serum osmolarity was 334 mOs/kg; calculated osmolality was 255, with an osmolar gap of 79. Mannitol and Lisinopril were immediately discontinued. He underwent Continuous Renal Peplacement Therapy (CRRT) to lower the serum levels of mannitol. CRRT was discontinued on Day 5, when measured serum osmolality was 309 mOs/kg. His urine output improved remarkably in less than 24 hours with prompt recovery of renal function. Cardiac rhythm returned to baseline and pacing was discontinued.

Discussion: This is the second such reported case in the English medical literature of acute reversible oliguric renal failure related to use of high-dose mannitol and Angiotensin Receptor Antagonists (ATRA). It illustrates not only the entire spectrum of complications of mannitol therapy ranging from severe hyperosmolar hyponatremia, acute oliguric renal failure, to atrioventricular block, but also showcases clinical prudence of avoiding ATRAs with hyperosmolar therapy on sound physiological principles. High dose mannitol incites intense vasoconstriction of afferent arterioles; decreasing GFR, which is compounded by concomitant ATRA-induced efferent arteriolar dilatation, further diminishing GFR leading to acute renal failure.

DISPLAYED POSTERS

Misleading Presentation of a Pulmonary Artery Arcoma

Muhammad Bakr Ghbeis, MD, William G. Hocking, MD; Marshfield Clinic, Marshfield, Wis

Case: We evaluated a 48-year-old woman who presented with increasing exertional breathlessness over 4 weeks. She had a persistent nagging dry cough 5 weeks earlier, following a slowly resolving cold. She reported right calf pain, 2 weeks earlier, for 2 to 3 days. She saw her primary care provider, who performed a chest CT scan, indicated by an elevated D-Dimer. The scan was interpreted as a "massive pulmonary arterial embolus." Subsequently, she was admitted to our critical care unit. There was no evidence of hemodynamic instability. A physical examination revealed no abnormalities except for obesity (body mass index of 41) and superficial varicosities in the lower extremities. The patient was started on anticoagulation therapy with unfractionated heparin and warfarin. She was discharged 6 days later, with instructions to continue low-molecular-weight heparin and warfarin.

One day after discharge, the patient returned to the ED for increasing breathlessness. A repeat CT scan was interpreted as persistent massive clot in the pulmonary arterial tree. There was no evidence of hemodynamic instability. Bilateral lower extremity venous Doppler ultrasonography showed no evidence of thrombosis. The abdominal and pelvic CT scan showed no evidence of malignancy or thrombosis. Despite active anticoagulation for 14 days, a repeat CT scan demonstrated no improvement, and the possibility of alternative diagnoses were considered. Positron emission tomography (PET)/CT imaging showed no evidence of hyper-metabolic lesion in neck, chest, abdomen or pelvis.

The patient underwent a thoracotomy via a midline sternotomy. A mass was found arising in main pulmonary artery, extending to both left and right pulmonary arteries. The pulmonary artery wall and the anterior pulmonary valve leaflet were grossly invaded by the tumor. A subtotal resection was performed with reconstruction of the pulmonary valve. Pathology showed a high-grade intimal sarcoma. The patient is recovering from surgery. Chemotherapy followed by radiation is planned.

Discussion: Pulmonary artery sarcomas are rare neoplasms and often cause symptoms suggestive of recurrent pulmonary emboli. A diagnosis of pulmonary artery sarcoma is virtually never considered initially. In patients with presumed thromboembolic disease, certain clinical and imaging characteristics may suggest the alternative diagnosis of pulmonary artery sarcoma.

Malaria

Mark Gaulke, MD, Matthew Hall, MD; Marshfield Clinic, Marshfield, Wis

Case: A 20-year-old man with no significant past medical history was transferred to our facility for management of malaria. He had presented 4 days prior to another facility with fever (103°F). He complained of having fever, headache, nausea, fatigue, and abdominal pain but denied weight loss, jaundice, diarrhea, or cough. He was treated overnight with intravenous fluids and doxycycline for a presumed tick borne illness (Lyme or Anaplasmosis). He returned within 24 hours of discharge with continued fever (106°F) and experiencing hallucinations. After 3 blood smears at the outside institution, a blood smear was found to have organisms consistent with malaria. On further questioning, the patient was noted to have traveled to New Guinea and Australia 2 months earlier with a traveling companion known to have contracted malaria. Prior to transfer, his platelet count was known to be anemic (11.5), thrombocytopenic (67,000) and to have splenomegaly. The patient was treated with 650 mg oral Quinine sulfate every 8 hours along with the doxycycline that he was already taking (100 mg twice a day). Upon discharge he was started on 15 mg Primaquine for 15 days. His follow up was scheduled 3 weeks later during the most likely time of reoccurrence. If needed treatment could be restarted. Otherwise the patient was to restrict activity until spleen size normalized. The patient was also educated to watch for relapses that are most likely the first 4 months and very unlikely after 1 year.

Discussion: Malaria is caused by *Plasmodia falciparum, P. ovale, P. malariae,* and *P. vivax. P. falciparum* is the most likely to kill due its unique vasooclusive characteristic. Symptoms begin 1-4 weeks after infection during the erythrocytic stage. *P. vivax* infect only early reticulocytes, approximately 2% of red blood cells and no microvascular sequestration occurs.

A Case of Cryptogenic Stroke in the Setting of a Patent Foramen Ovale (PFO) and Factor V Leiden Heterozygosity

Esayas Gebreyesus, MD; Aurora Sinai Medical Center, Milwaukee, Wis

Case: A 27-year-old man presented to our ED with an acute onset of vertical double vision and oscillopsia. Patient was driving when he suddenly experienced this. His past medical history includes history of 3 different eye muscle surgeries for correction of a head shift to the left, eyes right at the age of 9 or 10; gun shot wounds; recent history being dragged 4 blocks by a moving vehicle with scalp laceration and hand injury; and a back pain secondary to a motor vehicle accident a year ago. There is no past history of thromboembolic events. Upon admission, he had the following vital signs: temperature=99.1°F, rest rate=16/min, blood pressure=140/97mm/Hg, heart rate=82/min and pulse oximetry of 97% at room air. Physical examination showed a patch over the left eye. Upon removal of patch, patient had coarse horizontal nystagmus increased greatly in gaze left. Also on gaze right, he had gaze palsy to the right, which didn't improve on dolls-

head, and developed right hypotropia. Up gaze was impaired more than down gaze. Pupils were equally reactive. Visual acuity without correction was 20/25 each eye separately. Tonometry by applantation was 13/15. Fundoscopy examination was benign. Other motor/sensory examination was normal. Electrolytes, complete blood cell count, cardiac enzymes, and blood glucose were normal. Urine tox screening was negative. Coagulation workup revealed heterozygocity for Factor V Leiden (FVL) and low-normal AT 3 level. Magnetic resonance angiography of the head showed 2 areas of acute ischemia in the left thalamus and left brainstem. Transesophageal Echocardiography showed a Patent Foramen Ovale (PFO) and right-to-left shunt (RLS) on Valsalva maneuver. Patient was discharged to inpatient rehab with anti-platelets agents and his PFO was later closed.

Discussion: PFO is a frequent remnant of embryological development with clinical importance in thromboembolism, paradoxical embolism, and stroke. A meta-analysis of 9 studies showed a significantly higher prevalence of PFO in cryptogenic stroke (55.7%) as compared with stroke of known etiology (17.1%), giving a significant Odds Ratio of 6.0. Harvey et al made their first study of young patients with cryptogenic stroke and found evidence of RLS in 73% of cases. Some studies found FVL mutation in 7% of the patients with cryptogenic brain infarction and PFO, but in only 1% of the controls. Some studies estimate a 3-fold increase in the risk of thromboembolism with factor V heterozygosity.

Conclusion: A constellation of FVL heterozygosity and PFO with RLS on TEE could be an adequate explanation of this young patient with arterial embolism/cryptogenic stroke.

Painless, Acute Aortic Dissection Presenting as Seizures

Naga Grandhe, MD, Ravi Mareedu, MD, Kenneth P Madden, MD, Steven Gilbert, MD; Marshfield Clinic, Marshfield, Wis

Case: An apparently healthy 53-year-old man presented with recurrent episodes of witnessed seizures at 3 AM and was intubated for airway protection. Past medical history and social history was unremarkable except for reflux disease and occasional low back pain. Physical examination revealed stable vital signs but he was non-responsive to verbal commands. His neurological exam showed symmetrical reflexes and responsiveness to pain in all extremities except for the left lower extremity. Initial laboratory evaluation was unremarkable. CT of the head and cerebrospinal fluid analysis was unremarkable. Patient was loaded with phenytoin in the interim. Electronenceophalogram showed diffuse encephalopathy. MRI of the head showed multiple ischemic areas predominant on the right side. Stroke and infective endocarditis were considered in the differential at this time. CT abdomen done for evaluation of infectious source revealed aortic dissection extending from the aortic root through descending aorta and terminating at infra renal aorta. A 2-D ECHO confirmed the dissection and did not show any valvular vegetations. Carotid Dopplers showed a complete occlusion of the right carotids and mild stenosis on left side. A cardiothoracic surgeon evaluated the patient and recommended medical management because of the severe cerebral encephalopathy. As there was no improvement in neurological status after 72 hours of observation, patient was transferred to palliative care services per family wishes. Patient expired after withdrawing support. Autopsy did not show any evidence of infective endocarditis.

Discussion: Around 5%-15% of aortic dissections present without pain as per previous studies. Neurologic manifestations as a presenting symptom of acute aortic dissection without chest pain are uncommon. There have been case reports of seizures as one of the neurological manifestations of acute aortic dissection in literature. To our knowledge, there are no case reports of painless acute aortic dissection presenting as seizures. In our case, the occurrence of ischemic stroke could have precipitated the seizures.

Presentation of painless aortic dissection in an individual in their early 50s with no prior history of systemic diseases is also a unique feature in our case. Because of the absence of pain, the diagnosis of painless aortic dissection is usually delayed, as in our case. Even though isolated neurological manifestations are rare presentations of acute aortic dissection, physicians should always suspect this condition as it is associated with high mortality.

Pure Coincidence or Serendipitous Causality: Splenic Lymphoma and Hepatitis C Virus

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Background: Chronic Hepatitis C Virus (HCV) infection is the most common etiology of chronic viral hepatitis in the United States, afflicting 4 million in the United States alone. While everyday extra-hepatic manifestations of HCV are familiar to most physicians, the intriguing association with splenic lymphoma is poorly recognized largely due to its rarity. However, it is clinically important as it has provided valuable insight into lymphoma genesis and therapy.

Case: A 56-year-old woman presented with acute severe abdominal pain. Her history included chronic HCV genotype 1a, a recent bout of relapsing auricular polychondritis, coronary artery bypass surgery, stroke and end-stage renal disease on hemodialysis attributed to unusually rapid deterioration of diabetic nephropathy. Exam was notable for severe left hypogastric tenderness and massive splenomegaly with normal bowel sounds. CT revealed splenic enlargement to the pelvic brim, greater than 21 cm pole to pole (splenomegaly=10 cm), with a 3.5 cm decreased attenua-

tion consistent with splenic infarction and regional adenopathy. Doppler ultrasound revealed normal flow through hepatic vasculature without evidence of portal hypertension. A peripheral blood-flow cytometry was consistent with a B-cell lymphoproliferative disorder and a bone marrow biopsy was normal. HCV quantitative polymerase chain reaction titers were above the upper analytical limit of positivity. The diagnosis of splenic lymphoma was confirmed on excision biopsy, which revealed cyclin D1 positive mantle cell splenic lymphoma.

Discussion: Splenomegaly in the setting of HCV should trigger workup for splenic lymphoma—the clinical immediacy of such recognition is particularly relevant given recent compelling therapeutic evidence of remission with relatively benign antiviral therapy. The unusually rapid deterioration of biopsy proven Diabetic Nephropathy in the setting of well-controlled blood sugars (hemoglogin A1C less than 6) highlights not only the association of HCV to diabetes but also its documented role in accelerating diabetic kidney disease. Relapsing polychondritis in HCV, while very unusual, has been reported to have remitted with ribavirin and pegylated interferon therapy therapy and has been linked to the propensity of HCV to trigger or exacerbate autoimmune disorders.

The Clot is Just the Beginning of the Plot!

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Case: A 43-year-old woman was admitted with sepsis secondary to chronic non-healing ulcers. She had a history of profound diabetic peripheral vascular disease and underwent a below-the-knee amputation during her hospitalization. Three days later, she developed confusion and thrombosis of her central venous lines. Her past history was also notable for end-stage renal disease with a long history of hemodialysis and recurrent thromboses of her dialysis lines. A complete physical exam, at that point, was notable for a stump wound eschar along with palpable purpura involving both the lower extremities and the abdomen. She also had prominent swelling over her face and both upper extremities. Lab studies revealed an elevated parathyroid hormone at 91 pg/ml, an elevated thyroid stimulating hormone at 10.9 μ/ml, and an elevated ionized calcium at 1.4 mmol/L. She also had low platelet at 63 K/uL, low Protein C and S levels and activity at 24% and 21% respectively, an elevated prothrombin time (PT) at >8.0 and partial thromboplastin time (PTT) at >240 sec and abnormal PTT mixing study. A venous ultrasound of the upper extremities and neck revealed bilateral internal jugular vein thromboses.

Further evaluation for hypercoagulable states revealed the patient had lupus anticoagulant. A skin biopsy was performed and revealed epidermal and dermal necrosis associated with calcifications in the walls of the subcutaneous small blood vessels and neutrophilic vasculitis in the medium size blood vessels. This was felt to be consistent with calciphylaxis with a secondary autoimmune vasculitic process. Despite treatment, she eventually progressed into severe disseminated intravascular coagulation and sepsis along with multiorgan system failure and died within a month of her initial presentation.

Discussion: There have been several well-documented cases of lupus anticoagulant and calciphylaxis in patients with end-stage renal disease on hemodialysis. Having both of these conditions simultaneously poses a serious challenge for medical management. Calciphylaxis is a serious skin disorder characterized by small vessel calcification and necrosis in the dermis or subcutaneous fat. Ischemic changes often progress to necrotic ulcers that become superinfected with a resultant 60%-80% mortality. The incidence of calciphylaxis is only 1% in the dialysis population. However, there were multiple risk factors for calciphylaxis present in this patient, including an elevated ionized calcium, obesity, significant weight loss, low serum albumin, female sex, low protein C and S, multiple renal dialysis catheterizations, warfarin therapy, and calcium with Vitamin D supplementation.

Conclusion: This case points out the need for high clinical suspicion for the serious but preventable complications in dialysis patients and the awareness of various factors influencing management in this subset of patients.

Helicobacter Pylori Seropositivity in Patients with Both Negative Rapid Urease Test (CLO) and No Histopathological Evidence of Hp

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Purpose: Gastric biopsies are obtained routinely during esophogastroduodenoscopy (EGD) for campylobacter-like organism test (CLO) and histology; however, questions have been raised about a decreased diagnostic yield of CLO and histology in detecting this organism compared to the original published reports for several reasons, including a gradual decrease in *Helicobacter pylori* (Hp) infection over the past decade and increase in the use of acid-reducing medications. The aim of this study was to investigate the role of Hp serology in patients with negative CLO and no histological evidence of Hp.

Methods: Seven hundred seventy-six consecutive patients (age 18-95) who underwent a CLO test at a tertiary care center in the Midwest between July 2005-December 2006 were identified. Fifteen patients were excluded due to lack of CLO test verification and 5 due to lack of availability of EGD report. We reviewed the CLO results, EGD reports, available histology, and aspirin/nonsteroidal anti-imflammatory drug (NSAID) use. Serology was then compared to CLO and histology in the detection of Hp in patients with and without ulcers and erosions detected on EGD. The results were analyzed with the bino-

mial distribution using serology test specificity of 92% provided by the manufacturer (Meridian).

Results: A total of 756 patients were studied: 441 (58.3%) males and 315 (41.7%) females (mean age: males, 59.86 and females, 61.93 years). Most patients were caucasian (669; 88.5%) with more outpatients (411; 54.4%) than inpatients (345; 45.6%). CLO was positive in 52 (6.88%) patients and negative in 704 (93.12%) patients. Hp serology was available in 91 patients, of which 16 had it done more than 1 year prior to CLO. In the remaining 75 patients, no gastric biopsies were done on 25 patients. Of these 50, 49 patients had negative CLO and histopathology, but 9 (18.4%) had positive Hp serology. Exclusion of patients with Hp serology done >4 weeks before or after the CLO identified 26 patients of which 6 had positive Hp serology with this proportion (6/26) being significant, greater than the false positive rate ($p<0.05$).

Conclusion: CLO is positive in a small percentage of patients undergoing EGD. Negative CLO and histology may not be sufficient to exclude infection with Hp. Prospective studies assessing the role of Hp stool antigen testing and polymerase chain reaction for Hp16S ribosomal DNA on gastric tissue are warranted in this patient population.

PFO with Right to Left Shunt as a Cause of Hypoxia

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Case: A 58-year-old woman presented with a 9-month history of shortness of breath and a 1-month history of bilateral lower extremity pedal edema with baseline oxygen (O_2) saturation in the 60s to 70s. She exhibited central cyanosis and elevated jugular vein distension (JVD). The patient's O_2 saturation measured 66% on 2 liters of O_2 and increased to 73% on 5 liters of O_2. (ECHO) showed evidence of severely enlarged right atrium and right ventricle, depressed right ventricular systolic function, normal left ventricular systolic function, continuous flow to left atrium from an unknown source and pulmonary artery trunk (PA) pressure of around 40-45 mmHg. Transesophageal ECHO (TEE) showed marked right heart enlargement and right to left shunting across a probe patent foramen ovale (PFO). Catheterization confirmed presence of low femoral artery saturation (82%) with normal left atrial saturation (100%). PA pressure was moderately elevated at 40/20/28 mmHg with normal capillary wedge pressure at 8 mm Hg. To evaluate for tolerance of right heart after closure, temporary occlusion of the PFO with the sizing balloon was attempted, and after the patient was found to be stable, a 23 mm CardioSeal device was subsequently placed in the PFO without complications. The patient's O_2 saturation was ranging between 85%-93% on 5-6 liters of oxygen in the first 24 hours. At 1 month follow-up the patient showed significant improvement in functional status with O_2 saturations of 82% on room air. She continued to be stable at 6 months post procedure.

Discussion: Hypoxia secondary to right to left shunt (without Eisenmengers physiology or elevated Pulmonary Artery pressures) is an uncommon presentation. Initial diagnosis via transthoracic ECHO requires detection of a shunt with either color Doppler or agitated saline contrast with or without Valsalva maneuver. The agitated saline contrast study with TEE and the Valsalva maneuver is the gold standard test for detection of PFOs. It is sometimes simple to find the trigger for right to left shunt, but in patients such as ours in whom the PA pressures were not significantly elevated, there is no easily-identifiable single cause. Multiple theories have been postulated to explain severe shunting that can lead to hypoxia. Causes could be transient elevation of right atrial pressure in each cardiac cycle, or the flow of blood from the inferior vena cava preferentially towards the PFO (and inter-atrial septum), similar to the circulatory pattern in the fetus, or decreased compliance of the right ventricle in comparison to the left ventricle. Mechanical closure is clearly indicated in significantly hypoxic patients.

Lyme Meningitis

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Case: A 59-year-old woman presented with 1-week history of nonspecific complaints of fever, fatigue, and generalized weakness. There was no history of any headaches, neck stiffness, photophobia, dizziness, or changes in vision or hearing. She had slight nausea but denied any history of arthralgias, skin changes, or rashes. Patient was from rural Georgia and enjoyed gardening and being outdoors. She was visiting Milwaukee to see her children. She also denied any history of tick bite. Her physical examination was unremarkable, except for temperature of 103ºF. No evidence of any skin rashes. Complete blood cell count, blood cultures, urine analysis, and chest X-ray was unremarkable. Echocardiography was unremarkable. Patient continued to have high-grade fevers 103ºF-105ºF and had some episodic confusion with picking at clothes and medical equipment. Lumbar puncture and MRI of the brain were performed. CSF demonstrated white blood cell count 265 with 10% neutrophils, 81% lymphocytes, glucose 73 mg/dL and protein of 110 mg/dL. Gram stain and culture, viral cultures were negative. Enterovirus and herpes simplex virus in CSF were not detectable. Serum Lyme IgM antibody was positive but Lyme IgG antibody was negative. Diagnosis of Lyme meningitis and mild encephalopathy was established. Patient was treated with ceftriaxone 2 grams intravenously with resolution of fever and improvement of symptoms.

Discussion: Lyme disease is a multisystem infectious disease caused by tick-borne spirochete *Borrelia burgdorferi.* Clinical manifestations most often involve the skin, joints, nervous system, and heart. Extracutaneous manifestations are <10% of cases. When Lyme borreliosis affects the nervous system, it typically presents with (1) all or part of a

triad-meningitis, cranial neuritis, and radiculoneurirtis; (2) parenchymal inflammation of the brain or spinal cord; (3) mild radiculoneuropathy or (4) encephalopathy with or without evidence of brain infection. Lyme meningitis is a manifestation of the early-disseminated Lyme disease (2-10 weeks after tick bite). CSF has a lymphocytic pleocytosis, elevated protein, and normal glucose level. Diagnosis of Lyme disease requires confirmation by Western blot analysis after detection of a positive enzyme-linked immuosorbent assay. For adult with early Lyme disease and the acute meningitis, the use of ceftriaxone 2 g per day intravenously for 14 day (range, 10-28 days) is recommended.

Ca 19-9, a Pancreatic Tumor Marker?

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Case: A 61-year-old woman was brought to the ED for nausea, vomiting, and dizziness. She denied any abdominal pain, fever, diarrhea or hematemesis. She had no history of smoking or alcohol use. She reported a weight loss of around 18 pounds in last 2 months. Past medical history included diabetes mellitus, hypertension, and mild mental retardation. Physical examination revealed hemodynamically stable female with jaundice. Abdomen was non-tender with no peritoneal signs. Rest of the exam was normal. Initial laboratory evaluation revealed leukocytosis with bandemia, conjugated hyperbilirubinemia, and acute renal failure (presumed to be from biliary sepsis). Ultrasound of abdomen was suggestive of intra and extra hepatic biliary dilation. The gallbladder was non-tender, long and tortuous with debris and with very slight wall thickening. Acute renal failure precluded a CT examination. Due to the high suspicion of pancreatic-biliary malignancy, CA 19-9 level was checked and was found to be significantly elevated (8211). Further evaluation with endocopic retrograde cholangiopancreatography showed common bile duct stone and sphincterotomy was done. After her renal failure resolved, CT abdomen was done and did not suggest any malignancy. Colonoscopy and repeat liver function tests done during follow up were normal.

Discussion: CA 19-9 is considered a useful tumor marker for pancreatic cancer, and it has sensitivity of 70%-90% and specificity of around 90%. Higher levels of CA 19-9 (more than 1000) are associated with surgically unresectable cancer. Our case provides evidence that significantly elevated CA 19-9 level can be in benign biliary, pancreatic, and liver diseases. The non-malignant conditions associated with high Ca 19-9 reported are alcoholic liver disease, primary sclerosing cholangitis, primary biliary cirrhosis, hepatitis, acute cholangitis, and gallstones.

Familial Hypokalemic Periodic Paralysis

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Case: A 41-year-old woman was admitted with sudden onset of generalized muscle aches and weakness after recent sinus surgery. She had similar episodes in the past. Family history was unobtainable as patient was adopted. Examination was significant for generalized weakness with muscle tenderness. She had elevated muscle enzymes and slightly low potassium (3.2 mEq/L). A neurologist, psychiatrist and a rheumatologist reevaluated the patient. Head and spinal MRI along with antinuclear antibody, C3, C4, C-reactive protein, and Rheumatoid Factor were unremarkable. Patient continued to suffer similar episodes along with myoclonus involving the left upper extremity mostly accompanying asthma exacerbations. Due to uncertain diagnosis, patient was given trial of acetazolamide and muscle biopsy was performed, revealing muscle fibers with rimed vacuoles, some atrophic fibers and no inflammatory infiltrates. Biopsy along with clinical improvement confirmed hypokalemic periodic paralysis.

Discussion: Hypokalemic periodic paralysis is an uncommon but life threatening clinical syndrome. Most cases are familial. This disease usually presents in early childhood but may also present in the third decade. Paralysis results from ion channel mutations or channelopathies. Familial forms are associated with muscle calcium, potassium, or sodium channels defects. The mechanism during paralytic attacks is a transient membrane depolarization that inactivates the sodium channels along with K+ shift into the muscle cells. Severe attacks are usually precipitated in the morning, with strenuous exercise or with large carbohydrate diet. Weakness may occur with minimal hypokalemia. Creatine phosphokinase rises during episodes.

One of the most informative diagnostic tests is an exercise test. Compound Muscle Action Potential (CMAP) is usually measured during and after exercise. After a brief increase in CMAP amplitude, decrease of more than 40% is considered abnormal. This test is 98% sensitive.

Recent studies have shown that measuring Trans-tubular concentration gradient (TTKG) and potassium-creatinine ratio (Polymerace chain reaction) distinguishes primary from secondary causes of periodic paralysis. Most characteristic biopsy finding is the presence of vacuoles in muscle fibers and tubular aggregates. During attacks, the main objective is to normalize serum potassium levels. Oral potassium is preferable to intravenous. Continuous ECG monitoring and serum potassium measurements are mandatory. For prophylaxis, Acetazolamide is administered. Low sodium and low carbohydrate diet decreases the frequency of attacks.

Mycotic Aneurysm in a Patient With Infective Endocarditis

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Case: A 63-year-old man initially presented with a 2-month history of headaches, generalized malaise, decreased appetite, sweats, fevers, and weight loss. He had a history of

colon cancer with successful resection a number of years ago, a hemorrhagic stroke in 1973, and an ischemic stroke in 2003. In addition, his past medical history was significant for subacute bacterial endocarditis, for which he had failed to keep several follow-up appointments. A complete exam was performed and revealed no new neurological deficits. Initial studies revealed an elevated erythrocyte sedimentation rate of 49, white blood cell count elevation at 15,400 and hematuria. A CT scan of the head was performed and revealed an acute right hemorrhagic stroke. He then underwent cerebral angiography, which showed a new, lobulated irregular aneurysm of the distal right internal carotid artery, which was 9 mm in size. A left internal maxillary artery aneurysm was also seen. Blood cultures eventually grew *Streptococcus bovis.* Therefore, he underwent an ECHO, which demonstrated bileaflet mitral valve prolapse with posterior leaflet rupture and vegetations on mitral valve, consistent with endocarditis. He also developed acute renal failure, which was felt to be related to his infective endocarditis. It was determined that he had mycotic aneurysms, which were nonoperative in nature and therefore, medical management was initiated. However, the patient decompensated hemodynamically and required transfer to the intensive care unit for stabilization. Over the next several days, despite vigorous medical management, he had 2 grand mal seizures and a sudden loss of consciousness. A CT scan of the head was again performed and demonstrated an extensive new right basal ganglia and right frontal lobe intraparenchymal hemorrhage. At this point the family decided on comfort care and he died the same day.

Discussion: Mycotic aneurysms develop due to an infection in the arterial wall. They are extremely rare. One important predisposing factor is bacterial endocarditis. In fact, only about 2%-3% of intracranial aneurysms are mycotic in origin. Signs and symptoms of mycotic aneurysms may often be misleading during the early stages, resulting in misdiagnosis and delay in treatment. Mortality is greater than 90% in untreated patients. Subacute bacterial endocarditis can cause membranoproliferative glomerulonephritis from immune complex deposition. This patient had history of colon cancer with bacteremia due to *Streptococcus bovis.* This resulted in bacterial endocarditis, which eventually led to complications including mycotic aneurysms and acute renal failure.

Juvenile Rheumatoid Arthritis in an Adult?

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Case: Juvenile Rheumatoid Arthritis (JRA) is the most common form of persistent arthritis in children. It is also seen in adults, where it is known as Adult Onset Still's Disease. A 36-year-old man presented to his physician's office with episodic high fevers, weight loss, a sore throat, jaw pain, a stiff neck, and pleuritic pain. He did have rheumatic fever at age 17. At hospital admission he also had a non-migratory, persistent joint pain and swelling and intermittent nonpruritic macular rash. Imaging showed pleural effusion, pericarditis, and abdominal lymphadenopathy. Labs revealed leukocytosis, thrombocytosis, anemia, extreme elevated CRP, elevated anti-streptolysin o, and anti-Dnase B titers. Skin biopsy suggested erythema marginatum—seen in rheumatic fever and Still's disease. He was treated with indomethacin. He presented 3 weeks later with persistent thrombocytosis and joint flare. A tapering dose of prednisone was added to the indomethacin. Two months later, he improved significantly—showing weight gain, improved energy levels, no rash for several months, no joint flare, and a normal complete blood cell count, C-reactive protein, kidney and liver function on lab results. A year later the indomethacin was stopped and he did not have another flare.

Discussion: Features of this case that suggest a diagnosis of adult-onset JRA are the extreme leukocytosis and thrombocytosis, quotidian fevers, persistent joint pain lasting for more than a month, and the Still's rash. Additionally, the onset of the arthritis coexistent with a sore throat, pleural pericarditis, and extreme weight loss are also typical of this disease. This case illustrates the importance of considering JRA in the differential diagnosis of a multisystemic rheumatologic disorder in adults.

ORAL VIGNETTES

Hemolytic-Uremic Syndrome Complicated by Pulmonary Emboli and Heparin-Induced Thrombocytopenia

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Case: A 58-year-old man with no significant past medical history presented with acute kidney injury. Over the last 2 weeks, he had experienced symptoms consistent with a viral upper respiratory infection. Several days prior to admission, he developed low-grade fevers, malaise, nausea, watery stools, and oliguria. On admission, laboratory analysis revealed acute kidney injury with a blood urea nitrogen (BUN) of 127 and creatinine of 8.2, microangiopathic hemolytic anemia with a negative direct Coombs, thrombocytopenia with a platelet count of 98,000, and fibrinolysis. These findings, in combination with mild mental status changes, supported the diagnosis of hemolytic-uremic syndrome. Thrombotic thrombocytopenia purpura and antiphospholipid antibody syndrome were deemed less likely when his a disintegrin-like and metalloproteinase with thrombospondin (ADAMTS) 13 activity, lupus anticoagulant, and anticardiolipin antibodies returned within normal limits. The patient improved on hemodialysis and daily plasmapheresis. On day 6 of hospitalization, the patient became acutely hypoxemic and had a syncopal episode. Ventilation/Perfusion scan showed bilateral pulmonary emboli. Given his hemodynamic stability and normal echocardiogram, the patient was treated conservatively with heparin. He had not received prophylactic anticoagulation out of concern that it could exacerbate his preexisting thrombocytopenia.

Four days later, the patient's platelets dropped from 230,000 to 146,000. This was highly suspicious for heparin-induced thrombocytopenia (HIT), given his improving creatinine, decreasing lactic acid dehydrogenase and lack of schistocytes on peripheral blood smear. Heparin was discontinued and lepirudin started, as HIT can be a prothrombotic state. An enzyme-linked immunosorbent assay for HIT antibodies was positive, and a 14C-serotonin release assay subsequently confirmed HIT. The patient was bridged to warfarin when his platelets recovered.

Discussion: This case illustrates the relatively unusual occurrence of hemolytic-uremic syndrome in an adult patient, as well as the complexities of managing anticoagulation in such patients.

It's Not Just a Sore Throat—Lemierre's Syndrome

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Case: A 22-year-old previously healthy microbiology student currently doing research on *Haemophilus aphrophilus, Actinobacillus actinomycetemcomitans, Cardiobacterium hominis, Eikenella corrodens, and Kingella kingae (HACEK)* organisms came to the ED with complaints of a sore throat for 2 weeks. He was seen 1 week earlier at which time a rapid strep test and Monospot test were negative. He was given oral Ampicillin and sent home. He developed a rash resulting in a switch to Azithromycin the next day. He subsequently developed fevers, chills, increasing cough with pleuritic chest pain, worsening sore throat, dizziness, fatigue, and generalized malaise. A complete evaluation revealed tachycardia, fever, an erythematous oropharynx, and anterior cervical chain lymphadenopathy. Laboratory tests revealed an elevated white count, a left lower lobe infiltrate and positive Monospot test. He was admitted with possible community acquired Methicillin-Resistant *Staphylococcus aureus* and he was placed on Linezolid and levofloxacin intravenously. However, he rapidly deteriorated with acute respiratory failure requiring intubation. Chest CT showed worsening infiltrates bilaterally with cavitations and bilateral pleural effusions. Blood cultures grew anaerobic gram-negative rods and metronidazole was added to his antibiotic regimen. A CT of his neck and chest was then obtained to look for mediastinitis or neck abscess. It showed a questionable abscess on right side of neck. This was thought to be an inflammatory mass as interventional radiology was not able to drain any fluid. Due to bradycardia and pauses, a transthoracic echocardiogram was performed that was normal. His blood cultures were positive for *Fusobacterium necrophorum* and his antibiotics were changed to ertapenem. From this point he rapidly recovered with extubation a few days later and eventually was discharged home.

Discussion: Lemierre described Lemierre's syndrome as post anginal septicemia. It is an extremely rare, life-threatening septic thrombophlebitis of the jugular vein associated with anaerobic sepsis. It may arise from inflammatory lesions of oropharynx, otitis media, mastoiditis, genitourinary tract, or after gastrointestinal surgery. Immunocompromised patients are especially susceptible, but it is usually seen in young previously healthy patients with recent pharyngitis. Usual complications are posterior pharyngeal space infections with abscess formation, jugular vein phlebothrombosis, septic pulmonary emboli, and respiratory failure. Throat swabs, blood cultures, and imaging modalities like ultrasound and CT should guide in diagnosis. Early empiric treatment with good anaerobic coverage helps prevent fatal complications. Usually, 2 weeks to 3 months of antibiotic treatment is recommended. Surgical treatment is indicated in certain cases.

These Old Bones in My Young Body!

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Case: A 35-year-old Hispanic woman presented to the ED after waking with a swollen, erythematous right lower extremity associated with non-radiating pain and inability to bear weight. She was evaluated 1 week prior at another hospital for non-traumatic right lower fibular and tibial fracture for which the patient was treated with foot immobilization and referral to orthopedic surgery. Her past medical history was significant for diabetes mellitus type II, non-traumatic fractured femur and osteoporosis. On physical examination, vital signs were stable. The right lower extremity was swollen, tender to touch with erythema around the ankle up to the mid shaft region, decreased range of motion, inability to evert or invert the right foot secondary to pain. There was evidence of dentingenous imperfecta and onycholysis with a missing fingernail on the third left finger. Complete blood cell count and cytidine monophosphate were normal except for elevated alkaline phosphatase. X-ray showed evidence of fractured mid-shaft fibula and tibia and fracture of the third, fourth and fifth toes on the left foot. Osteoporosis of the hips bilaterally was seen. The limb was stabilized and patient was taken to surgery.

Discussion: Osteogenesis Imperfecta (OI) is an autosomal dominant mutation (sometime sporadic) that causes brittle bones, which are susceptible to fractures. The clinical range extends from mild symptoms to perinatal lethal disease (Type I-Type IV). The mutation occurs in the Type I collagen protein fibers, which are found in tendons, sclera, bones, organ capsules, fascia, dermis, and meninges. Two pro-alpha 1, and one pro-alpha 2 chains form this left-handed helical structure. Both chains have a primary structure of uninterrupted repeats of the tripeptide composed of glycine (Gly), proline (Pro), and hydroxyproline (Hyp), in that order. When Gly is substituted by another protein, OI occurs. Heterozygous mutations affecting the primary collagen structure cause moderate and severe osteogenesis imperfecta, whereas decreased collagen production causes mild osteogenesis imperfecta. The prevalence of OI is estimated to be 1 per 20,000 live births, the mild form is underdiagnosed, and the actual

prevalence may be higher. The diagnosis is mainly clinical, with a history of repeat non-traumatic fractures, osteoporosis in teens or early twenties usually exacerbated by childbirth in women, and a history of easy bruising during childhood. Confirmation is with elevated alkaline phosphatase, imaging, and genetic testing. This is a genetic disorder and there is no cure. The mainstay treatment is surgery with lifestyle modifications. Fractures heal normally in approximately 85% of patients.

Prevention is Always Better Than Cure!

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Case: A 78-year-old woman presented with a 48-hour history of progressive dysphagia, neck pain, and difficulty opening her mouth. Five days before presentation she accidentally stepped on a rusty nail and sustained a puncture wound extending to 1.5 cm into the plantar aspect of her right foot. She didn't seek medical attention until the day of admission. Past medical history is significant only for remote history of gout. She has not received primary medical care or tetanus immunization for many years.

Physical exam revealed an obese female in moderate distress with blood pressure=218/96, temperature=98.9ºF, heart rate=87, and Oxygen saturations of 95% on room air. She had inability to open her mouth beyond 3 cm, trismus, and risus sardonicus were noted. Neck exam revealed markedly restricted range of motion, tenderness to palpation, and trapezius spasm. Cardiopulmonary examination was significant only for II/VI aortic systolic murmur. Remaining neurological exam was normal. Initial labs showed normal cell counts with elevated creatine kinase and minimally elevated Troponin. Chest X-ray showed mild cardiomegaly and electrocardiogram with left ventricular hypertrophy. CT scan of soft tissues of neck showed no evidence of retropharyngeal abscess or cervical inflammatory process. Fiberoptic laryngoscopy showed no obvious airway compromise or edema. After initial clinical diagnosis of tetanus, patient was given 2000 IU of human tetanus immunoglobulin, started on metronidazole, diazepam, tetanus toxoid series, and admitted to ICU for airway monitoring. She developed hypoxemic respiratory failure 10 hours later and underwent emergent tracheostomy. After prolonged intensive care unit and hospital stay of 46 days, patient improved gradually and was discharged home after rehabilitation.

Discussion: Tetanus continues to be a major medical problem in the developing countries. Tetanus immunization dramatically reduced annual incidence in the United States. However, unvaccinated or inadequately vaccinated adults and intravenous drug abuser continue to be at risk.

Primary Hepatic Lymphoma With Hepatitis C

Saket Girotra, MD, Nitin Jain, MD, Christopher Hake, MD, Kurt Pfeifer, MD; Medical College of Wisconsin, Milwaukee, Wis

Case: A 41-year-old woman with a history of chronic hepatitis C without cirrhosis presented with a 2-week history of right-sided abdominal pain, nausea, vomiting, and 25-pound weight loss. Abdominal CT revealed multiple hypo-attenuating lesions in the liver suggestive of malignancy. Alpha-fetoprotein level was 8.7. No other site of a primary tumor could be found. A diagnosis of multifocal hepatocellular carcinoma was entertained; however an ultrasound-guided biopsy of the liver was consistent with diffuse large B-cell lymphoma. Serologic studies for human immunodeficiency virus were negative. Staging PET scan did not show any evidence of extra-hepatic disease confirming a diagnosis of primary hepatic lymphoma (PHL). Chemotherapy with rituximab, cyclophosphamide, adriamycin, vincristine, and prednisone (R-CHOP) was started, and she has since completed 3 cycles with a good clinical response.

Discussion: Non Hodgkin's lymphoma (NHL) is the fifth most common cancer in the United States. Primary hepatic lymphoma, however, is extremely rare, accounting for <0.05% of all NHL. This has been described more frequently in the setting of hepatitis C virus, HIV/acquired immune deficiency syndrome (AIDS) and other immunocompromised states. Available literature on the incidence of PHL is scant; some authorities believe that the incidence may be on the rise with the rising epidemic of HIV and hepatitis C. Diffuse large B-cell lymphoma is the most common subtype. Lymphomagenesis related to chronic hepatitis C continues to be an area of intense study. Treatment options include surgery, chemotherapy, and radiation, depending on the extent of the disease and histological subtype. Chronic hepatitis C infection confers a 20-fold increased risk of HCC; the risk of NHL is increased more modestly (20%-30%). The clinical and radiological features of PHL may overlap with those of HCC with biopsy being the only distinguishing test. While the prognosis of HCC is extremely poor with expected 6 month survival of <10%, the prognosis of PHL is quite favorable (70% 5 year survival with treatment). Therefore, pathologic confirmation of the diagnosis is crucial since treatment and prognosis differs considerably.

Migratory Poyarthralgia—Is it a Harbinger of Serious Systemic Illness?

Purnima Hirudayaraj, MD, MRCP, Monica Ziebert, MD, DDS, Neal Nygard, MD; Medical College of Wisconsin, Milwaukee, Wis

Case: A 37-year-old previously healthy woman was admitted from the rheumatology clinic with a 10-week history of migratory polyarthralgia, hemoptysis, dyspnea, morning stiffness, and bilateral earache and discharge. There was no associated erythema or joint swelling. She had minimal constitutional symptoms of low grade fever and fatigue. She had a strong family history of rheumatoid arthritis and Hashimoto's thyroiditis. She was evaluated 3 times in the ED

prior to this when migratory arthralgia was her only symptom with minor earache in the latter weeks. Her joint imaging was normal. Initial labwork in the ED showed mild anemia and microscopic hematuria with mildly elevated inflammatory markers. She received symptomatic treatment with opioid pain medications, empiric doxycycline therapy for possible Lyme's disease, and ciprofloxacin eardrops for earache. Examination on admission revealed crackles in her right lung base and dried secretions in both ear canals. Significant lab results on admission included hemoglobin 10.3 g/dl, sedimentation rate 120, C-reactive protein 22.9, and microscopic hematuria with red cell casts and proteinuria. Chest CT showed multiple cavitating lesions. Urgent renal biopsy showed necrotizing crescentic glomerulonephritis. She was diagnosed with Wegener's granulomatosis (WG) and was started immediately on cyclophosphamide and methylprednisone to which she responded very well. Antineutrophil cytoplasmic antibody (cANCA), especially the anti-proteinase 3 antibody, was elevated.

Discussion: WG is a necrotizing granulomatous vasculitis affecting small blood vessels with classic predilection for otolaryngeal and renopulmonary systems with a severe complication profile and high mortality. The American College of Rheumatology criteria for diagnosis include oral or nasal inflammation, abnormal chest radiograph (nodules, cavitary lesions, infiltrates), abnormal urinary sediment, and granulomatous inflammation on biopsy of an artery. Interestingly, musculoskeletal signs and symptoms are not part of the diagnostic criteria and yet joint symptoms are reported in more than 65% of the cases and can be inaugural in more than 20% of cases. Arthralgia is the most common symptom. Frank poly- and oligoarthritis, mostly nondeforming and nonerosive, have been reported in 25%-30% of cases. Effusion is rare and usually shows nonspecific inflammatory fluid. Migratory pattern is noted in about 5% of cases. Rheumatoid factor and antinuclear antibody can frequently be positive. Recognizing the atypical presentations of multisystem disorders is important, as these can often be a harbinger of potentially serious systemic illness. Looking diligently for further clues earlier in the illness can prevent potentially life-threatening complications.

Out of Africa

Jennifer Hsu, MD; University of Wisconsin, Madison, Wis

Case: A 62-year-old man presented with a 4-day history of pain, swelling, and erythema of the left leg, which was accompanied by fever, chills, malaise, diffuse myalgia, and headache. This illness began just prior to returning to the United States after hunting deer and impala in rural South Africa. He had no specific vaccinations or prophylaxis prior to travel. Physical exam was significant for temperature of 101.8°F, bilateral inguinal lymphadenopathy, and a black eschar at the base of the left first metatarsophalangeal joint with associated streaking erythema, warmth, and tenderness extending proximally to the knee. Initial laboratory testing revealed a normal complete blood cell count, but his C-reactive protien was elevated to 5.9 mg/dL and erythrocyte sedimentation rate to 47. Routine blood cultures and malaria smears were negative. Given the characteristic appearance of the eschar, or tache noir, a diagnosis of African tick bite fever was made. After treatment with doxycycline, he rapidly improved. Serum IgG for *Rickettsia africae* was negative likely due to the acuity of the infection.

Discussion: With increasing international travel, it becomes important to recognize diseases endemic to various regions. The incidence of African tick bite fever (ABTF) is estimated in up to 5.3% of travelers from sub-Saharan Africa and the eastern Caribbean. Infection with *R. africae* occurs via cattle ticks of the Amblyomma genus. ABTF commonly presents as an influenza-like illness accompanied by fever, regional lymphadenopathy, and an inoculation eschar, or tache noir. Risk factors include travel in endemic areas during the rainy season and contact with wild animals. Laboratory diagnosis consists of serologic tests, which become positive approximately 3 weeks after the onset of symptoms, as well as serum or tissue polymerase chain reaction and immunohistochemistry. The treatment of choice is doxycycline. Travelers should be counseled on prevention via application of DEET-containing products.

Drug Induced Sweet's Syndrome in Assosciation with Polychondritis and Multiple Autoantibodies

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Case: We present a case of drug-induced Sweet's Syndrome (SS) with polychondritis and multiple autoantibodies in an 86-year-old woman. She presented with a 5-day history of fever; conjunctivitis; painful tense vesicles on her ears, nose, and back; and painful digital lesions. She has a history of bipolar disorder and hypertension and was on multiple medications. Patient was on lithium for years, which was stopped 10 days prior to admission because of lack of efficacy and carbamazepine was started. She had been on hydralazine just over 1 year; dose was increased 8 months prior. Physical exam revealed fever, blepharoconjunctivitis, tense vesicles and bullae on the nose, superior aspect of the ears, and upper back, erosions on the post auricular crease, chondritis involving ear and nose, and oral ulcers. Hemorrhagic papulovesicles and bullae were noted on the distal finger pads and lateral fingers. Laboratory studies revealed elevated erythrocyte sedimentation rate and C-reactive protein, azotemia, microscopic hematuria, and proteinuria, antinuclear antibody positive (1:640), p-ANCA positive, MpoAb 200, Pr3 48.5, antihistone antibody positive, type II collagen antibody positive (47.6), lupus anticoagulant positive. Skin biopsies from the back and finger were consistent with neu-

trophilic dermatosis. A chest X-ray showed no infiltrates. Hydralazine and carbamazepine were discontinued. Cutaneous lesions and renal insufficiency rapidly improved on systemic corticosteroids.

Discussion: Sweet's syndrome (SS) is an acute febrile neutrophilic dermatosis. Association with infections, autoimmune diseases, inflammatory bowel disease, malignancy, and drugs are reported. There are few case reports of association between SS and relapsing polychondritis. Our patient had biopsy proven SS, clinical diagnosis of polychondritis supported by positive anti collagen antibodies, and multiple autoantibodies. She was on 3 drugs that have been associated with drug-induced SS, drug-induced lupus, and p-ANCA positive vasculitis.

The Lethal Giant

Vasthala Juvvigunta, MD; Gundersen Lutheran Medical Center, La Crosse, Wis

Case: A 34-year-old man presented with an acute onset of dyspnea, orthopnea and paroxysmal nocturnal dyspnea. He had no history of diabetes, hyperlipidemia, or coronary artery disease. Past medical history was notable for ulcerative colitis, primary sclerosing cholangitis, alcohol abuse, and smoking. Medications included flagyl, ibuprofen, and bupropion. A complete physical exam revealed hypotension, tachycardia, tachypnea, S3 gallop, bibasilar lung crackles, and mild hepatomegaly. A chest X-ray revealed marked pulmonary congestion, and ECG revealed low voltage QRS with a left posterior hemiblock, ST elevation from V1 to V6. Troponin-I was elevated to 2.09. With the initial impression of cardiogenic shock from acute myocardial infarction he was started on oxygen, heparin, pressors, and diuretics. However, a coronary angiogram was essentially normal. ECHO revealed EF of 31% with global left ventricle dysfunction, which later dropped to 15% on day 5 despite intra-aortic balloon pump. The transplant team was then contacted. However the patient went into ventricular tachycardia, and despite all efforts of resuscitation he remained unresponsive and died shortly thereafter. The autopsy revealed diffuse myocardial necrosis, inflammatory infiltrate with multinucleated giant cells consistent with the diagnosis of giant cell myocarditis.

Discussion: Giant cell myocarditis was first described in 1905. It is a rare but fatal myocarditis occurring in relatively young healthy adults. Etiology is unknown, but 20% of cases had autoimmune diseases. Evidence suggests potential autoimmune pathogenesis involving CD4 T lymphocytes. This disease frequently presents as acute heart failure. Endomyocardial biopsy is the standard diagnostic test with an 85% sensitivity. There is an average survival of 5.5 months, which is prolonged from 12.3 months with combined immunosuppressive treatment. Definitive treatment is heart transplant. Post transplant survival was noted to be roughly similar to patients receiving transplant for other etiologies. However, post transplant care involves close follow up as recurrence has been noted.

Conclusion: It is important to consider the possibility of giant cell myocarditis in otherwise healthy individuals who present with new onset, rapidly progressing left ventricular failure, especially in those with associated refractory ventricular tachycardias. Prompt pathological diagnosis will allow early pursuit of transplant and combined immunosuppressive therapy that can potentially improve survival.

Rapid Renal Ruins

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Case: A 57-year-old woman with a history of degloving extremity injuries and multiple reconstructive surgeries 6 years ago presented with bilateral leg swelling. The previous year she had several admissions for lower extremity cellulitis and was treated with ertapenem, amoxicillin-clavulanate, and cefazolin. Now her leg was mildly erythematous and edematous, and intravenous naficillin was started for presumptive cellulitis and furosemide for diuresis. Within 17 hours of the first doses, her creatinine more than doubled. She remained afebrile and hemodynamically stable. She had no prior renal problems and did not develop rashes, arthralgias, flank pain, malaise, anorexia, oliguria, or nausea. The medications were held, and a prerenal etiology was considered because her fractional excretion of urea was <35%. Despite intravenous fluids, her blood urea nitrogen (BUN) and creatinine increased every hour. No plasma or urine eosinophilia was found, and renal ultrasound was normal. Urinalysis showed no white blood cells/casts but had protein and blood. Proteinuria and hematuria in the setting of acute renal failure suggested glomerular disease; however, complement and antinuclear antibody levels were normal. Renal biopsy was performed to further elucidate the cause and revealed acute tubulointerstitial nephritis (AIN). Intravenous methylprednisolone was administered for 2 days and then switched to oral prednisone. Her creatinine and BUN returned to normal 2 weeks later.

Discussion: This case illustrates an atypical presentation of AIN. Although AIN usually manifests over several days, with average time to clinical development being 2 weeks after drug administration, her creatinine doubled within a few hours of receiving naficillin. Also, classic symptoms and signs such as rash, fever, arthralgias, urine and serum eosinophilia, and urine white blood cell casts were absent. No evidence has clearly demonstrated that corticosteroids are effective in AIN. Most patients respond to discontinuation of offending medications, but cyclophosphamide has been considered in refractory cases and dialysis for severe electrolyte and metabolic disturbances. Our case demonstrates the need to maintain a high suspicion for AIN even when the clinical picture is not entirely consistent with this common cause of renal failure.

Casting With Plastic!

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Case: A 60-year-old woman was evaluated for shortness of breath following repeat coronary artery bypass graft (CABG) surgery. She had CABG in 2002 with repeat in 2005 utilizing the right internal mammary artery. The dyspnea began shortly after hospital discharge in 2005. She also described a cough productive of firm, rubbery debris in the shape of some portion of the bronchial tree. She has a remote history of smoking and no prior lung disease. CT of the chest was normal. Pulmonary function testing demonstrated mild obstruction with good bronchodilator response. She underwent bronchoscopy with multiple bronchial casts extracted. Pathology demonstrated composition of blood, fibrin and mucin. Cytology and cultures were negative for infection and malignancy. Further work up was negative for cytomegalovirus, Aspergillosis, IgE, ANCA and angiotensin-converting enzyme. Hypersensitivity panels were negative as well. Initial treatment included inhaled corticosteroids and bronchodilators. As the disease progressed, she required courses of oral prednisone and was started on home oxygen and flutter valve therapy.

Over the course of 3 years, she has had multiple bronchoscopies for airway clearance. Her cast production has been increasing in frequency and severity, which has significantly affected her lifestyle. She produces 10-15 samples per day. The largest cast was 9.0 x 6.5 x 1.2 cm, taking her 13 hours to cough out. Treatment to date has been guided by case reports as the disease is rare and seen almost entirely in children. Azithromycin, as an anti-inflammatory agent, and dornase alfa, a rhDNase to reduce mucous viscosity, have given the most benefit to date.

Discussion: Plastic bronchitis is a rare disease most commonly seen in the pediatric population following the Fontan procedure as part of congenital heart defect repair. It is characterized by the formation of endobronchial casts thought to be formed secondary to damage of the lymphatic system. It has been reported to occur also in patients with allergic and inflammatory diseases including asthma, cystic fibrosis, pulmonary infections, and acute chest syndrome in sickle cell disease. These casts can cause pulmonary symptoms of wheezing, coughing, or respiratory distress. Diagnosis is made after expectoration of bronchial casts or by bronchoscopy. Multiple therapies have been trialed such as steroids, antibiotics, pulmonary vasodilators, and thoracic duct ligation with varied results.

Steroids for Parasites? A Case of Undifferentiated Hypereosinophilia

Elizabeth Wozniak, MD; University of Wisconsin, Madison, Wis

Case: A 29-year-old woman with a history of asthma presented to the hospital with progressive shortness of breath over several days. In addition to her respiratory symptoms, she described fatigue associated with a 20-pound unintentional weight loss. She also complained of pain and weakness in her right leg and left arm. She had a history of childhood asthma that recurred around the age of 21. Her symptoms were well controlled with a fluticasone/salmeterol inhaler, her only medication. She emigrated from India approximately 4 years prior and had returned there within the past year. She followed a healthy lifestyle and her family history was significant for coronary artery disease and diabetes. Pertinent exam findings included hypotension (92/67 mm Hg), tachycardia (100-120 bpm), right eyelid droop, bibasilar pulmonary crackles, normal S1 and S2 cardiac sounds with presence of S3, decreased muscle strength in her left arm and right leg, normal reflexes, and a macular rash on her lower extremities. Initial lab work was remarkable for a leukocytosis to 14,200 with an eosinophilic predominance of 5970. Her hemoglobin was normal at 11.7 g/dL and platelets normal at 322,000. Her chemistries were within normal limits including a blood urea nitrogen (BUN) of 13 and creatinine of 0.7. Her erythrocyte sedimentation rate was elevated at 50. A comprehensive work up for infectious diseases including parasites was negative. A chest CT revealed bilateral pleural effusions and patchy pulmonary infiltrates. An ECG was obtained which showed Q waves in leads V1-V4. Cardiac catheterization was without coronary artery disease. A transthoracic ECHO demonstrated severely reduced left ventricular function with an estimated ejection fraction of 20%. A myocardial biopsy similarly showed eosinophilic infiltrate.

Discussion: The constellation of her symptoms including asthma prodrome, eosinophilia, elevated inflammatory markers, cardiac infiltrate resulting in heart failure and mononeuritis multiplex suggested the diagnosis of Churg-Strauss Syndrome (CSS).

Wisconsin courts weaken physician non-compete agreements

Barbara J. Zabawa, JD

Many people learn best through example. Two recent cases in the Wisconsin Court of Appeals provide great examples of whether a physician's covenant not to compete might be enforceable.

In recent years, more and more physicians face the prospect of accepting employment tied to their willingness to sign a written employment contract containing restrictive covenants upon termination of the relationship. Wisconsin courts generally look with disfavor on unjustified or overly broad restrictions. The key term in determining whether a covenant not to compete is legally enforceable is whether the restriction is "reasonable."[1] A physician who is subject to a non-compete agreement with multiple restrictions, such as a geographic and time restriction, may find his or her entire agreement unenforceable if a court finds just 1 of those restrictions unreasonable. Two recent decisions from the Wisconsin Court of Appeals issued on the same day illustrate the uphill battle that employers of physicians have in enforcing their restrictive covenants.

Can a group practice restrict where a physician practices after the group loses an exclusive service contract?

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That was the question addressed recently in *Robert Davison, MD v Bay Area Nuclear Medicine* ("BANM"). The Court found the restrictive covenant unenforceable in Dr Davison's employment agreement with the BANM group practice. BANM's restrictive contract provision prohibited Dr Davison from practicing nuclear medicine at any entity within 35 miles of BANM's location and further required him to relinquish his clinical privileges at St Vincent's Hospital in Green Bay for 1 year after his termination from BANM. BANM lost its contract with St Vincent's Hospital, when St Vincent replaced BANM with Green Bay Radiology, SC. In response to the loss of the service contract, BANM terminated Dr Davison.

Green Bay Radiology hired Dr Davison with the condition that he free himself of any restrictive contract provisions. After BANM refused to release him from the restrictions, Dr Davison sued. The Court concluded that BANM did not have a protectable interest because it lost its contract with St Vincent's and therefore the covenant was not reasonably necessary to protect BANM. In a footnote, the Court also noted that both the 35 mile restriction and the provision requiring Davison's relinquishment of privileges at St Vincent's were overly broad. Therefore, Davison was free to take the offer with Green Bay Radiology.

Can employers limit a physician's practice in other specialties, consider a physician's duty of loyalty to his or her former group practice, or consider how his or her new practice will effect the marketplace?

In the case of *Fox Valley Thoracic Surgical Associates, SC v Robert J. Ferrante, MD*, the Court of Appeals examined the enforceability of another restrictive covenant. Dr Ferrante is a heart surgeon who left his group practice, Heart Surgeons, and became a competitor in the cardiac surgery market. Like Dr Davison, Dr Ferrante was subject to a covenant that prohibited him from engaging in heart surgery or thoracic medicine within the city limits of Appleton, Neenah, or Menasha—and also within a 30 mile radius of those cities—for 1 year after his termination with Heart Surgeons. After working with Heart Surgeons for 1 year, Dr Ferrante declined Heart Surgeon's offer to become a partner in the company and instead opened his own surgical practice. One cardiology group, Cardiology Associates, provided Dr Ferrante most of his referrals. Following Dr Ferrante's departure from Heart Surgeons, Cardiology Associates' referrals to Heart Surgeons slowed significantly. Heart Surgeons closed its practice and sued Dr Ferrante and others.

In this case, the Court of Appeals made several findings involving the conditions of the restrictive covenant, Dr Ferrante's duty of loyalty to Heart Surgeons, and anti-competitive issues. First, the Court concluded that Dr Ferrante's

restrictive covenant was unenforceable because it was overbroad. The Court determined that the covenant effectively prevented Dr Ferrante from practicing thoracic medicine and not just heart surgery. Further, the Court concluded that the geographic restraint was greater than reasonably necessary to protect the legitimate business interests of Heart Surgeons.

Second, the Court found that Dr Ferrante did not breach any duty of loyalty to Heart Surgeons by opening his own practice and receiving referrals from Cardiology Associates. The Court concluded that Dr Ferrante was not an "officer" of Heart Surgeons who owed the practice the fiduciary duty of loyalty, good faith and fair dealing, even though he was in control of his own surgical methods, had nurses working for him, maintained patient medical records and other documentation, and was privy to some of Heart Surgeons' financial information. Rather, the Court held that these are typical physician activities and therefore Dr Ferrante owed no special duty of loyalty to Heart Surgeons.

Finally, the Court did not find any evidence of a conspiracy between Dr Ferrante and Cardiology Associates to deny referrals to Heart Surgeons referrals. Heart Surgeons' case failed because it only offered evidence of the impact of the alleged conspiracy on the marketplace in general without offering sufficient proof of an illegal agreement.

Lessons learned

In the past decade, numerous Wisconsin Appeals Court decisions address the permissibility of restrictive covenants in employment and business relationships. These cases set forth fairly specific limitations on the enforceability of such provisions. Many agreements involving physicians in both clinic and hospital settings are now out of date and may not take into consideration recent case law decisions. The *Davison* and *Fox Valley* cases should encourage physicians, as well as their employers who are parties to employment or partnership agreements, to review those agreements for overly broad or unenforceable restrictions with a view towards crafting restrictions as narrowly as possible.

References

1. Wis. Stat. § 103.465.

Sridhar Vasudevan, MD

Medicare win in Congress shows power of physician voice

Sridhar Vasudevan, MD, WISMedPAC Chair

Congress's action to override President Bush's veto of HR 6331—the legislation preventing a 10.6 percent cut for physician Medicare reimbursement—shows how powerful the physicians' voice can be. It also reveals a disturbing corollary: physicians often only use their voice when a crisis arises, such as the Medicare issue, the state's raid on the Injured Patients and Families Compensation Fund, or the Supreme Court overturning the old cap on noneconomic damages in medical liability cases.

As recently as the end of June, conventional wisdom was that HR 6331 would not get enough votes to survive a procedural move to kill the bill in the US Senate. But the AMA's savvy combination of grassroots efforts and airing television ads in districts where senators face difficult reelection campaigns dovetailed perfectly with Sen Ted Kennedy's appearance on the Senate floor for a key vote. The confluence of physician effort and raw politics gave Medicare patients and their physicians the biggest win in years.

Unfortunately, the HR 6331 example is more the exception than the rule.

Physicians can do a better job of informing our policymakers on what's important, and how decisions made in the state and national capitols can dramatically influence how health care is practiced. One way is simple "grassroots" advocacy—having a critical number of physicians contacting legislators and others on a specific issue. It only takes a handful of phone calls to a state legislator to bring an issue to the forefront. The Wisconsin Medical Society has a "Key Contact" program to assist in this area—the Society's Government Relations team alerts physicians who are Key Contacts when grassroots efforts on an issue are timely. More information on this member program is available on the Society's Web site, www.wisconsinmedicalsociety.org.

Although the Key Contact program makes it easier for physicians to help educate policymakers, many of us still don't take the time to make the necessary contact. Physicians often fall into the trap of believing that the "right thing" will simply naturally happen on an issue in the Capitol; after all, once all the facts and data are examined, aren't the conclusions simple? Unfortunately, policy-making—especially in the health care arena—is far from simplistic. Most legislators do not have the depth of knowledge on the day-to-day provision of health care that we physicians understand, therefore confusing what physicians may see as "easy" conclusions.

Grassroots efforts are important, but are just part of the political scene. Political contributions—both in money and time—also alert policymakers that physicians are paying attention and need to be heard. This is another area where many physicians are uncomfortable: legislators shouldn't make their decisions based on who gave them money, should they? In reality, 21st century political campaigning in this country requires candidates to have dollars to spend on media advertising for election or reelection—the days of former US Senator William Proxmire spending less than 5 figures on a campaign are over. The math becomes simple: without a campaign war chest, a person will not likely have the opportunity to represent constituents in Madison or Washington, DC. Therefore, it is only natural that a candidate has a more generous ear for those who have made the investment to help a candidate win a political office.

The Wisconsin Medical Society has worked to enhance this area, providing an easy way for physicians to contribute to candidates: WIS*Med*PAC and WIS*Med*DIRECT programs. More information about both programs are on the Society's Web site, but in a nutshell they are organized methods to amplify the message that physicians pay attention to politics and policy.

This November's elections are likely historic, both in Wisconsin and nationally. Health care is a top issue. Physicians are a well-trusted group, but we have yet to maximize our potential for influence. As a physician who cares about your patients and about the health care system, please consider being a Society Key Contact, giving to WIS*Med*PAC and starting your own WIS*Med*DIRECT political contribution account. Let's not wait for the next crisis; instead, we can help prevent a crisis from happening by getting involved today.

Robert N. Golden, MD

Dean's Corner

NIH budgets, patient care, and health

Robert N. Golden, MD, Dean, University of Wisconsin School of Medicine and Public Health, Vice Chancellor for Medical Affairs, University of Wisconsin-Madison

Throughout the era of modern medicine, there has been a strong relationship between research and our evolving capacity to advance the health of the public. In the 1950s, for example, advancements in the fields of virology, immunology, and public health brought an end to the devastating scourge of polio. More recently, we were able to convert HIV/AIDS from a mysterious "death warrant" into a manageable (and even preventable) chronic disease in this country. This would not have been possible without our prior and ongoing investment in basic, clinical and translational research.

Who knows when the next pandemic threat will arrive, where it will come from, or what it will look like? Whether it is a new variant of an avian influenza virus or some unspeakable act of bioterrorism, the more experience we have in translating basic discovery into clinical- and population-based interventions, the better prepared we will be to tackle the newest health challenge.

From this perspective, every citizen should be extremely concerned about the insidious process that is attacking the very base of our research infrastructure: the deterioration of the National Institutes of Health budget. After a carefully planned and well executed period of growth in the NIH budget, 5 years ago this growth hit a brick wall when NIH was subjected to flat funding in all subsequent years. This means that over time, we have witnessed very serious erosion in the "purchasing power" of the NIH budget, due to substantial inflation in the costs of biomedical research. According to data from the American Association of Medical Colleges, we have lost more than $3.6 billion in real purchasing power for our country's NIH-supported research infrastructure.

Many of our patients do not understand that the vast majority of the NIH budget does not stay within the federal intramural research program in Bethesda. Most of it is distributed through the competitive peer-review process to investigators at leading research institutions throughout the country, including the Medical College of Wisconsin and the UW School of Medicine and Public Health. The faculty at both schools have been quite successful in competing for NIH research support, but as the NIH budget shrinks, the competition becomes unbearably intense. The overall success rate for first submissions has plummeted from 29% in 1999 to only 12% in 2007. We are at risk of losing the next generation of scientists, our "seed corn" for future crops of biomedical breakthrough discoveries.

The timing of this erosion of the NIH budget is ironic. Following the recent successful completion of the Human Genome Project, we are losing our capacity to take full advantage of the insights gained from that enormous effort. In the past decade, we have learned so much about the molecular basis of disease, and have begun to dramatically increase our capacity to translate this knowledge into clinical- and population-based interventions. There is a new emphasis on community-based translational research and effectiveness research, which builds connections between the "ivory tower" of universities and the "real world" of community-based clinical practice. Last year, for example, our school received a new NIH "Clinical and Translational Science Award," designed to support translational research in clinical practices and communities throughout the state. The decline in the purchasing power of the NIH budget means that our new pipelines for community-based translational research will run dry just as their construction nears completion. This will hamper our efforts to improve everyday clinical practice and health outcomes through the application of evidence-based medicine.

All of the hard work and investment of the past decade is at risk due to short-sighted budgetary decisions in Washington. The situation reminds me of the old joke about the fellow who set out to swim across the English Channel.

He got half way across and decided it would be too tough to finish, so he turned around and swam back. We must not turn back and relinquish the very real progress we have made in tackling the major illnesses that threaten the lives and well being of our patients.

Every day, whenever we provide care for a patient, we are utilizing the results of our past investments in basic, clinical and translational research. Every day, we are made painfully aware that we still have a long way to go in having access to the best possible tools for the diagnosis, treatment, and prevention of disease. Please join me in educating our patients, our elected representatives, and our neighbors on this important issue. Our patients' lives depend on it.

Maureen Hansen, CLU

Annuities: guarantee not worth cost

Maureen Hansen, CLU

"Annuities are never bought—they are sold," according to an old adage in the financial planning industry. In other words, people tend to see annuities as attractive investment options only when they are being sold annuities.

Life insurance companies sell annuities as tax-deferred investment contracts. Annuities are designed to provide a guaranteed income benefit over a defined period or over the buyer's lifetime. Annuities are invested in mutual funds and earnings are tax-deferred. Unlike a 401(k) or IRA, there is no annual contribution limit or a required minimum distribution at age 70½.

Too good to be true?

The objective of annuities is to protect income during market downturns. While income may be guaranteed, it is paid out at a very low rate. Like any insurance product, payments depend on the issuer's ability to pay claims. Commissions, administrative fees, and surrender charges can be prohibitive.

Annuity management fees can run as high as 3% per year, on top of the commissions that can run as high as 10% of your investment. Furthermore, the mutual funds in which the annuity is invested charge an additional management fee.

Most annuities charge a surrender penalty if excess amounts are withdrawn within the first 7-10 years of purchase. If you withdraw additional funds in the first year, you could pay a penalty of up to 7% of the value. If you withdraw funds from the annuity before age 59½, you will pay an early withdrawal tax penalty of 10%, unless you meet one of the exceptions to the rule.

One of the selling points of an annuity is a death benefit guarantee. At a minimum, your beneficiary will receive the amount invested. However, this benefit comes at a cost; mortality and expense charges can amount to 0.5% to 1% annually.

Earnings are tax deferred

Agents selling annuities often suggest rolling over a 401(k) account or an IRA into a tax-deferred annuity—an unnecessary step since the earnings are already tax deferred by virtue of the products. Furthermore, when the holder of a non-IRA annuity dies, his or her beneficiaries will pay taxes on the gains. Compare that to a non-IRA mutual fund, in which the basis is "stepped up," meaning beneficiaries do not pay income taxes on the earnings.

Other ways to protect income

If your objective is to protect income during a downward market cycle, talk with your investment advisor about other alternatives. For example:

- Diversify your investments. Standard advice, but it bears repeating. Greater diversity leads to greater resiliency and lower risk.
- Reallocate your assets. As you get closer to retirement, you will want to be more conservative in your investment choices. You don't have as many years to recover from a downturn in the market cycle.
- Evaluate your retirement income needs. Examine all of your sources of retirement income, including pension plans, investments, proceeds from the sale of a practice or home, and Social Security. Weigh that against your retirement plans. You may discover that an annuity adds very little value to the mix.

Conclusion

Think through the pros and cons and consider the alternatives before you are sold an annuity.

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The 5 Million Lives Campaign: Preventing medical harm in Wisconsin and the nation

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From December 2004 to June 2006, the Institute for Healthcare Improvement (IHI) along with many national organizations sponsored the 100,000 Lives Campaign. This campaign, which is described in a previous issue of the *Wisconsin Medical Journal*,[1] was aimed at preventing 100,000 unnecessary deaths over an 18-month period. Participating hospitals across the country implemented ≥1 of 6 interventions that were known to reduce mortality. Over 3100 hospitals joined the campaign, including 82 in Wisconsin. IHI estimated that the campaign prevented 122,300 unnecessary deaths; we estimated that about 2300 of these were in Wisconsin.

In December 2006, building on the 100,000 Lives Campaign, IHI and partner organizations announced the 5 Million Lives Campaign, with the aim of increasing patient safety and transforming the quality of care in America's hospitals.

The 5 Million Lives Campaign differs from the 100,000 Lives Campaign in several important ways.

- The duration of the campaign is 2 years from December 2006 to December 2008.
- The aim of the campaign is to prevent 5 million instances of medical harm during this period. Medical harm is defined as: unintended physical injury resulting from or contributed to by medical care (including the absence of indicated medical treatment), that requires additional monitoring, treatment or hospitalization, or that results in death. Such injury is considered medical harm whether or not it is considered preventable, whether or not it resulted from a medical error, and whether or not it occurred within a hospital.

  Note that by this definition, medical harm is not the same as medical error. Some errors do indeed result in medical harm, but many errors do not; conversely, many incidents of medical harm are not the result of any errors. IHI estimates approximately 15 million instances of medical harm occur each year in the United States.
- The types of interventions to be employed have expanded substantially. The 100,000 Lives Campaign limited itself to the following 6 interventions:
  - **Deploy rapid response teams**… at the first sign of patient decline.
  - **Deliver reliable, evidence-based care for acute myocardial infarction**… to prevent deaths from heart attack.
  - **Prevent adverse drug events (ADEs)**… by implementing medication reconciliation.
  - **Prevent central line infections**… by implementing a series of interdependent, scientifically grounded steps called the "Central Line Bundle."
  - **Prevent surgical site infections**… by reliably delivering the correct perioperative antibiotics at the proper time.
  - **Prevent ventilator-associated pneumonia**… by implementing a series of interdependent, scientifically grounded steps including the "Ventilator Bundle."

The 5 Million Lives Campaign has added an additional 6 interventions that hospitals may choose to employ:

- **Prevent pressure ulcers**… by reliably using science-based guidelines for prevention of this serious and common complication.
- **Reduce methicillin-resistant *Staphylococcus aureus* (MRSA) infection**... through basic changes in infection control processes throughout the hospital.
- **Prevent harm from high-alert medications**… starting with a focus on anticoagulants, sedatives, narcotics, and insulin.
- **Reduce surgical complications**… by reliably implementing the changes in care recommended by the Surgical Care Improvement Project (SCIP).[2]
- **Deliver reliable, evidence-based care for congestive heart failure**… to reduce readmission.

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- **Get Boards on board**… by defining and spreading new and leveraged processes for hospital Boards of Directors, so they can become far more effective in accelerating the improvement of care.

IHI has developed a tool—the *Global Trigger Tool*—that hospitals can use to perform a retrospective review of patient records to identify harm events. This tool will be used to measure the success of the campaign.

Physician leadership is critical to the success of the campaign. In November 2007, the 5 Million Lives Campaign conducted a Fall Harvest to collect and share ideas and improvement stories from hospitals and systems in every state.[3] Common themes were identified among the organizations most successful at improving quality and safety. In the most successful organizations, Boards, executives and clinician leaders set ambitious, system-level aims for improvement and closely track progress against those aims. Medical staff takes responsibility for clinical improvement, with physicians actively engaged in data review and the selection of improvement projects.

As of May 2008, over 3800 hospitals enrolled in the campaign nationwide. This includes 84 Wisconsin hospitals, two-thirds of the hospitals in the state. Of the 84, 50 are considered "fully committed"—that is, they submit profiles and monthly inpatient mortality data. The other 34 have access to all the campaign's resources despite not submitting data.

As with the 100,000 Lives Campaign, the 5 Million Lives Campaign is organized via a system of local "nodes" or field offices that disseminate improvement tools and provide support to participating organizations. Members of the Wisconsin node include MetaStar, the Wisconsin Medical Society, the Pharmacy Society of Wisconsin, the Rural Wisconsin Health Cooperative, the Wisconsin Hospital Association, the Wisconsin Nurses Association, the Wisconsin Organization of Executive Nurses, the Association for Professionals in Infection Control and Epidemiology Southeast Wisconsin Chapter, the American College of Healthcare Executives Wisconsin Chapter, and the Dahlen Company.

Even now, hospitals are continuing to join the 5 Million Lives Campaign. Results will be announced at the IHI Forum on Healthcare Improvement in December 2008. IHI and its partners are planning how to build on this campaign in 2009. The organizations that constitute the Wisconsin node will remain committed to continuing efforts with hospitals and physicians to accelerate the transformation of health care in Wisconsin.

References

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3. Bisognano M. Leadership's role in execution. *Healthcare Executive.* 2008:23;66-70.

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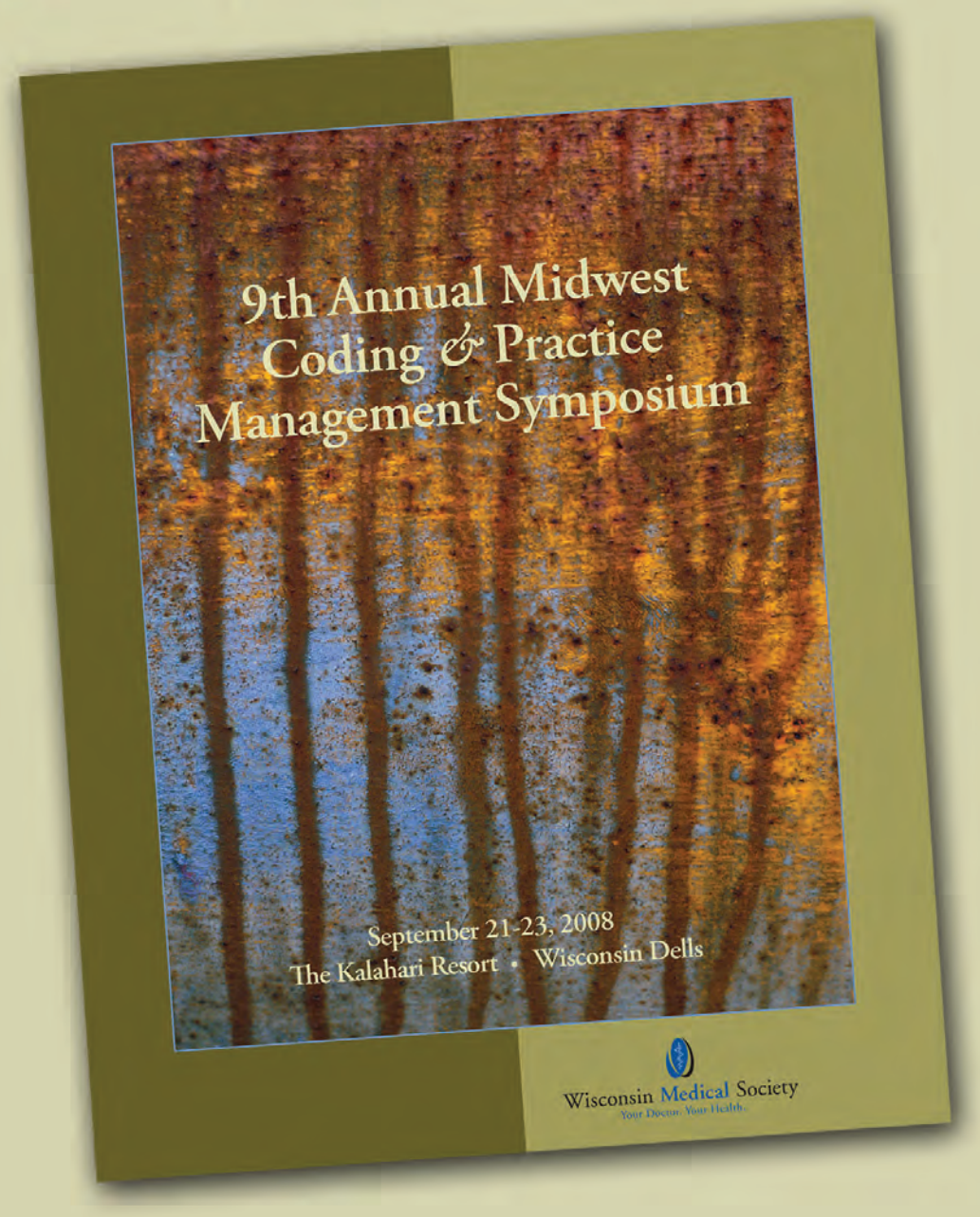

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