THE GUNDERSEN MEDICAL JOURNAL

Contents–Volume 8, Issue 1

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SUPPLEMENT

Abstracts of presentations made by Gundersen staff in 2011-2012.
EDITOR’S MESSAGE

“If we knew what it was we were doing, it would not be called research, would it?”

---Albert Einstein (1879-1955)

Welcome to the Spring issue of the Gundersen Medical Journal! You’ll note that the title has changed to reflect the new name of the institution; the quality and scope of the publication remain the same, and again represent the interests and vigor of the authors. I wish to personally thank the reviewers who assisted us in seeing the current issue to fruition.

The GMJ remains an interdisciplinary and archival publication. More than 5000 print copies of the last issue were distributed to a variety of professionals, medical center libraries, and lay personnel. The Editorial Board continues to pursue indexing for the Journal in order to enhance recognition, circulation, and readership. Original research, case reports, vignettes, images with associated text, ethical reports, and position papers are encouraged. The guide for submissions can be found at http://www.gundersenhealth.org/research/medical-journal. Please feel free to contact me or Cathy Fischer, Managing Editor, if you have questions. I hope you enjoy this issue of the GMJ!

Original Research Articles

In the first article Ms Dawn Hoff and mentors from the University of Wisconsin-La Crosse studied the effects of Hatha yoga on several physiologic measures and found that regular training improved endurance, flexibility, balance, and muscle strength.

In the second paper, McHugh, Gundrum, and Ailiani present preliminary data for 12 patients and discuss the potential merits of using cardiac magnetic resonance imaging over transesophageal echocardiography for detection of left atrial/left atrial appendage thrombus.

In the third paper, Dr Sharma and colleagues found from examining the nature and outcomes from the Eastern Cooperative Oncology Group (ECOG) trials between 1977-2006 that concept approval to publication was protracted, and potentially taking up to a decade for completion. The authors argue for streamlining trial activation, accrual, and timely publication.

Dr Henry and colleagues, representing Gastroenterology, reported in the fourth article the effects of oral versus intravenous proton pump inhibitor therapy for patients admitted to hospital between 1997-2008 for gastric bleeding or duodenal ulcers. Interestingly, they found similar outcomes for the patients studied.

Case Reports

Case reports allow authors to discuss both interesting and atypical cases seen in the clinical environment and operatory.

Drs Hauck and Cole, representing Hematology-Oncology, present a patient with chronic disseminated intravascular coagulation (DIC) that decompensated following bone marrow biopsy, suggesting that the procedure itself may be a risk factor for more aggressive disease in patients with prostate cancer.

Drs Bassing, White, and Berg describe a patient who experienced cardiac tamponade in the context of adult-onset Still disease, a rare inflammatory disorder that potentially
can affect multiple organs. Cardiac tamponade has been reported for only 8 patients with this condition.

In the third report, Dr Berkseth and colleagues describe an unusual and potentially life-threatening situation in which a patient sustained penetrating cardiac trauma from an eyeglasses temple. Histology is frequently tantamount with accurate diagnoses. Drs Abraham and Schraith delineate this further in a case of a dermal lesion with unexpected histologic findings. Finally, Dr Adegboyega and colleagues present a rare case of cervical sympathetic chain schwannoma presenting as progressive dysphagia.

**Clinical Pearls**

This section is devoted to brief reports and “food for thought” that clinicians can store and retrieve from their acumen of differential diagnoses. To this end, Drs Agger and Brown discuss an unusual case of tick bite and management thereof.

**Ethical Considerations**

Clinicians are confronted with ethical issues on a regular basis and as an integral component of the practice of medicine. In this section Dr Harter discusses the decision-making process for a patient in a difficult end-of-life situation.

**Reprise**

In this section, previously published papers potentially of interest to a broad readership and covering a variety of topics are presented. The Wisconsin Network for Health Research (WiNHR) is a statewide, collaborative multidisciplinary group devoted to improving the health of citizens in Wisconsin. In an article appearing in the *Wisconsin Medical Journal* in 2009 by Howard Bailey, MD, and colleagues representing participating major medical institutions in the state, an overview of WiNHR is provided.

**Supplement**

Abstracts of presentations made by Gundersen staff in 2011 and 2012.

David E. Hartman, PhD, BC-ANCDS(A)
Editor
*Gundersen Medical Journal*
The Physiological Effects of 8 Weeks of Yoga Training

ABSTRACT

Background: Hatha yoga has been practiced for thousands of years and has become a popular form of exercise. Previous studies have focused on changes in ventilatory function and stress reduction consequent to yoga training. However, studies investigating the effects of yoga on muscular strength and endurance, flexibility, balance, and aerobic capacity are lacking.

Objective: This study was designed to investigate the effect of yoga training (50-minute sessions 3 times per week for 8 weeks) on VO2max, ventilation, maximal heart rate, muscular strength and endurance, flexibility, and balance.

Methods: Thirty-four subjects between the ages of 20 and 55 years were randomly assigned to either an experimental group (yoga) or a control group (non-yoga). Both groups were tested before and after the 8-week training period.

Results: Compared with the non-yoga group, the yoga group had significant (P<.05) improvements in trunk flexion (7°), trunk extension (8°), trunk rotation to the right (22°) and left (19°), ankle range of motion (6°), sit-and-reach (3 inches), back scratch on the right (1.2 inches) and left (1.2 inches), shoulder elevation (1.6 inches), trunk lift (1.9 inches), push-ups (6), curl-ups (14), and 1-legged stand (17 seconds). There were no significant improvements in maximal heart rate, VO2max, FVC, FEV1, or functional reach as a result of training.

Conclusions: When practiced regularly, Hatha yoga can significantly improve muscular strength and endurance, flexibility, and balance. However, the metabolic intensity of Hatha yoga does not appear to be sufficient to improve cardiorespiratory measures.
Treatment
Non-yoga group subjects were instructed to maintain their current lifestyle habits and were not to alter their activity or dietary patterns over the course of the study. The yoga group participated in 55 minutes of yoga training, 3 days per week, for 8 consecutive weeks. Make-up classes were also offered 1 day per week. Subjects were required to attend at least 21 classes to be included in the statistical analysis. The classes were led by a certified yoga instructor. Each class consisted of 5 minutes of relaxation and pranayama (yoga breathing). 10 minutes of warm-up exercises including sun salutations, 35 minutes of asanas (yoga postures), and 5 minutes of relaxation and pranayama (yoga breathing) in savasana (corpse pose).

Pranayama was practiced while sitting in the half-lotus position and consisted of angel breath and complete breath. The warm-up consisted of knee hugs, neck rolls, shoulder shrugs and circles, and cat (lower back) and cow (abdominal) stretches. Basic sun salutations (surya namaskar) were also included in the warm-up.

Each yoga session consisted of variations of standing and seated asanas (see Box).

Testing Procedures
All subjects were tested before and after the 8-week training period in the Human Performance Laboratory at the University of Wisconsin-La Crosse. The subjects participated in the following tests:

Modified Sit-and-Reach. Each subject sat with the buttocks, shoulders, and head in contact with a wall. The soles of the feet were against a 12-inch-high sit-and-reach box. The subject slowly reached as far forward as possible without stepping, lifting the heels, or touching any other surface. Three trials with each arm were executed. The best measurement from each side was recorded.

Functional Reach Test. Each subject reached one hand over the shoulder and down the back at the height of the box. The top hand was positioned with the palm facing the back and the bottom hand was placed with the palm facing away from the back. The amount of space between the fingertips was the subject's score. If the fingertips were not touching, a negative score was recorded. Three trials with each arm were executed, and the best score was recorded.

Back Scratch. Each subject reached one hand over the shoulder and down the back at the height of the box. The top hand was positioned with the palm facing the back and the bottom hand was placed with the palm facing away from the back. The amount of space between the fingertips was the subject's score. If the fingertips were not touching, a negative score was recorded. Three trials with each arm were executed, and the best score was recorded.

One-Legged Stand. Each subject stood on her dominant leg for as long as she could without moving the stationary leg or touching the opposite foot to the ground or the standing leg. The subject's arms remained stationary and crossed at the chest. The test was done with the eyes closed. Three trials were executed, and the average of the scores was recorded.

Trunk Rotation. Each subject stood with heels placed on a 180° plane. The subject held her left arm at 90° of flexion and was instructed to reach forward as far as possible without stepping, lifting the heels, or touching any other surface. Three trials were executed, and the best score was recorded.

Trunk Flexion and Extension. Inclinometers were placed on the subject's upper and lower back between T12/L1 and the posterior superior spine (sacrum). Trunk flexion was measured as the subject bent forward while keeping the hips and lower body stable. Trunk extension was measured as the subject leaned backwards while keeping the hips and lower body stable. The

<table>
<thead>
<tr>
<th>Standing Poses</th>
<th>Seated Poses</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>warrior</strong> (virabhadrasana)</td>
<td><strong>knee to head</strong> (janu sirsasana)</td>
</tr>
<tr>
<td><strong>side angle</strong> (utthita parsvakonasana)</td>
<td><strong>inclined plane</strong> (purvottanasana)</td>
</tr>
<tr>
<td><strong>twisting prayer</strong> (parivrtta parsvakonasana)</td>
<td><strong>spinal twist</strong> (matsyendrasana)</td>
</tr>
<tr>
<td><strong>half moon</strong> (ardha Chandrasana)</td>
<td><strong>archer</strong> (akarana dhanurasana)</td>
</tr>
<tr>
<td><strong>tree</strong> (vrksasana)</td>
<td><strong>cat</strong> (vidalasana)</td>
</tr>
<tr>
<td><strong>dancer</strong> (natarajasana)</td>
<td><strong>cow head</strong> (gomukhasana)</td>
</tr>
<tr>
<td><strong>eagle</strong> (garudasana)</td>
<td><strong>pigeon</strong> (eka pada rajakapotasana)</td>
</tr>
<tr>
<td><strong>mountain</strong> (tadasana)</td>
<td><strong>camel</strong> (ustrasana)</td>
</tr>
<tr>
<td><strong>triangle</strong> (trikonasana)</td>
<td><strong>cobra</strong> (bhujangasana)</td>
</tr>
<tr>
<td><strong>revolving triangle</strong> (parivrtta trikonasana)</td>
<td><strong>child's pose</strong> (garbhasana)</td>
</tr>
<tr>
<td><strong>pyramid</strong> (parsvottonasana)</td>
<td><strong>locust</strong> (salabhasana)</td>
</tr>
<tr>
<td><strong>chair</strong> (utkatasana)</td>
<td><strong>boat</strong> (ardha navasana)</td>
</tr>
<tr>
<td><strong>standing forward bend</strong> (uttanasana)</td>
<td><strong>plank</strong></td>
</tr>
<tr>
<td><strong>yoga mudra</strong></td>
<td><strong>bow</strong> (dhanurasana)</td>
</tr>
<tr>
<td><strong>extended hand and big toe</strong> (utthita hasta padangusthasana)</td>
<td><strong>bridge</strong> (setu bandhasana)</td>
</tr>
<tr>
<td><strong>plough</strong> (halasana)</td>
<td><strong>bound angle</strong> (baddha konasana)</td>
</tr>
<tr>
<td><strong>kneeling forward bend</strong> (paschimottanasana)</td>
<td><strong>seated forward bend</strong></td>
</tr>
</tbody>
</table>
difference between the inclinometers was the measurement in each case. The best score out of 3 trials for each movement was recorded.

**Trunk Lift.** Each subject lay in a prone position on the floor with toes pointed and hands behind the head. The subject lifted the upper body off the floor at a slow and controlled speed. The subject was required to hold in the upper position while the researcher obtained the measurement. The tester measured the distance from the subject’s chin to the floor. Three trials were executed, and the best score was recorded.

**Shoulder Elevation.** Each subject lay in a prone position with arms extended overhead, shoulder-width apart, while holding a meter stick. The subject then lifted the meter stick off the ground as far as possible without lifting her forehead off the ground. The distance between the ground and the bottom of the meter stick was the shoulder elevation score, and the best score out of 3 trials was recorded.

**ACSM Modified Push-up Test.** Each subject performed the bent knee push-up and began the test in the up position, kneeling with arms and back straight. Next, each subject lowered herself until her chest was 3 inches from the floor (a 3-inch foam block was placed under the subject’s chest to ensure accuracy) and then pushed back up to the starting position. Each subject performed as many push-ups as possible with no time limit. The number of push-ups executed correctly without stopping was recorded.

**ACSM Curl-up Test.** Each subject lay in a supine position with the knees bent at 90°. The arms were placed at the subject’s side, palms down on the mat. While lying in this position, the fingers were touching a piece of masking tape. A second piece of masking tape was placed 12 cm away from the original piece of tape. The subject curled up so the fingers moved from the first piece of tape to the second piece of tape. A cassette tape was played to ensure consistency in speed. Each beat on the tape was a separate movement and set at 40 beats per minute. The number of curl-ups the subject did correctly without stopping was recorded.

**Ankle Plantar Flexion and Dorsiflexion.** Each subject sat on a table with the feet off the floor and the knees and ankles positioned at 90°. A goniometer was placed on the axis at the lateral aspect of the malleolus. The stationary arm was placed on the lateral midline of the fibula, and the moving arm was parallel to the lateral aspect of the fifth metatarsal. The subject pointed the dominant foot 3 times in a row and then flexed the dominant foot 3 times in a row. The best score out of the 3 trials for total range of motion was recorded.

**Pulmonary Functions.** Forced vital capacity (FVC) and forced expiratory volume in the first second (FEV1) were measured using a QMC Quinton Industries spirometer. Following a deep inspiration, each subject exhaled and inhaled forcefully into a spirometer. Three trials were executed, and the best trial was recorded.

**VO2max Test.** This was done on a treadmill using the Modified Balke protocol. Each subject selected her own speed. The speed chosen for pretesting was kept constant for post-testing. The percent grade of the treadmill started at 0.0% and was increased by 2.5% every 2 minutes. The test ended when the subject was unable to continue. At each stage, heart rate was measured using a Polar heart rate monitor, ratings of perceived exertion were measured using the 6-20 Borg scale, and expired air was measured using the AEI Moxus Modular VO2 system. Maximum heart rate and maximum VO2 attained were recorded.

### Table 1. Descriptive Physical Characteristics of Subjects by Group

<table>
<thead>
<tr>
<th>Group</th>
<th>Age, y</th>
<th>Height, cm</th>
<th>Weight, kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yoga, n=19</td>
<td>33.2 ± 8.7</td>
<td>164.4 ± 5.0</td>
<td>72.7 ± 15.8</td>
</tr>
<tr>
<td>Non-Yoga, n=15</td>
<td>34.5 ± 12.3</td>
<td>163.6 ± 7.7</td>
<td>62.9 ± 13.7</td>
</tr>
</tbody>
</table>

* Data are presented as mean ± standard deviation.

### Table 2. Pretest and Post-test Flexibility Measures by Group

<table>
<thead>
<tr>
<th>Flexibility measure</th>
<th>Pretest</th>
<th>Post-test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trunk flexion, degrees</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yoga</td>
<td>49.2 ± 12.1</td>
<td>55.7 ± 10.3b</td>
</tr>
<tr>
<td>Non-Yoga</td>
<td>53.7 ± 9.7</td>
<td>53.1 ± 10.8</td>
</tr>
<tr>
<td>Trunk extension, degrees</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yoga</td>
<td>25.5 ± 11.1</td>
<td>34.3 ± 9.6b</td>
</tr>
<tr>
<td>Non-Yoga</td>
<td>27.3 ± 13.1</td>
<td>25.7 ± 11.6</td>
</tr>
<tr>
<td>Trunk rotation-right, degrees</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yoga</td>
<td>113.7 ± 15.9</td>
<td>136.3 ± 22.3b</td>
</tr>
<tr>
<td>Non-Yoga</td>
<td>116.7 ± 24.8</td>
<td>114.4 ± 21.2</td>
</tr>
<tr>
<td>Trunk rotation-left, degrees</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yoga</td>
<td>115.9 ± 20.7</td>
<td>134.9 ± 17.4b</td>
</tr>
<tr>
<td>Non-Yoga</td>
<td>119.2 ± 21.9</td>
<td>117.2 ± 21.9</td>
</tr>
<tr>
<td>Ankle ROM, degrees</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yoga</td>
<td>79.1 ± 9.5</td>
<td>84.8 ± 11.1b</td>
</tr>
<tr>
<td>Non-Yoga</td>
<td>82.1 ± 9.5</td>
<td>78.2 ± 11.6</td>
</tr>
<tr>
<td>Sit-and-reach, cm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yoga</td>
<td>30.7 ± 5.8</td>
<td>38.4 ± 6.9b</td>
</tr>
<tr>
<td>Non-Yoga</td>
<td>31.5 ± 9.7</td>
<td>32.5 ± 10.9</td>
</tr>
<tr>
<td>Back scratch-right, cm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yoga</td>
<td>3.6 ± 7.1</td>
<td>6.4 ± 6.1b</td>
</tr>
<tr>
<td>Non-Yoga</td>
<td>5.6 ± 6.4</td>
<td>4.3 ± 6.9</td>
</tr>
<tr>
<td>Back scratch-left, cm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yoga</td>
<td>-1.5 ± 10.7</td>
<td>1.5 ± 9.4b</td>
</tr>
<tr>
<td>Non-Yoga</td>
<td>0.5 ± 8.1</td>
<td>-1.0 ± 7.9</td>
</tr>
<tr>
<td>Shoulder elevation, cm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yoga</td>
<td>29.5 ± 10.7</td>
<td>33.3 ± 10.7b</td>
</tr>
<tr>
<td>Non-Yoga</td>
<td>28.4 ± 9.4</td>
<td>26.2 ± 9.9</td>
</tr>
<tr>
<td>Trunk lift, cm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yoga</td>
<td>21.1 ± 7.9</td>
<td>25.9 ± 8.4b</td>
</tr>
<tr>
<td>Non-Yoga</td>
<td>20.3 ± 7.9</td>
<td>20.8 ± 7.1</td>
</tr>
</tbody>
</table>

Abbreviation: ROM, range of motion.

* Data are presented as mean ± standard deviation.

# Statistical Analysis

Differences between pretest variables for the experimental and control groups were assessed using independent t tests. Repeated measures analysis of variance was used to determine differences between the pretest and post-test scores of the experimental and control groups. Tukey post-hoc tests were used to detect pairwise differences. Alpha was set at P<.05 for all analyses.
RESULTS

All 34 subjects completed the investigation. Descriptive statistics of the subjects are presented in Table 1. Average attendance for the yoga group was 21.6 sessions. The yoga and non-yoga groups were not significantly different with regard to any variable at the beginning of the study.

Flexibility

The results for all of the flexibility measurements are presented in Table 2. For all of the measurements, the yoga group had significant improvements in the flexibility scores, and their scores were significantly better than those of the non-yoga group.

Muscular Endurance

The results for push-ups and curl-ups are presented in Figures 1 and 2. The yoga group performed 6 more push-ups and 14 more curl-ups following the training period, which was significantly higher compared with the numbers performed in pretest. Pretest and post-test performance were similar in the non-yoga group.

Balance

The results for balance are presented in Table 3. The yoga group had a 17-second increase in 1-legged stand time, which was significantly longer than the pretest time. Neither group had a significant change in functional reach.

Pulmonary Function

The results for lung function are presented in Table 4. There were no significant changes in FVC or FEV₁ in either group over the course of the study.

Aerobic Capacity and Maximal Heart Rate

The results from the maximal treadmill test are presented in Table 5. There were no significant changes in VO₂max or maximal heart rate in the yoga or non-yoga group over the course of the study.

DISCUSSION

The purpose of this study was to determine whether 8 weeks of thrice-weekly Hatha yoga training results in significant improvements in flexibility, muscular strength and endurance, balance, lung function, and cardiorespiratory endurance. Prior studies have indirectly found improvements with yoga training; however, there is limited research that used direct measurements to support improvements in Hatha yoga practice. This study used direct measurements to evaluate the above-mentioned parameters.

This training study showed that regular practice of Hatha yoga improved a number of flexibility measurements. Trunk flexion increased by 13% and sit-and-reach scores increased by 25%. These increases were similar to the results of Tran et al., who found a 14% improvement in trunk flexion. Both studies utilized an 8-week training period and similar postures. Conversely, Gharote and Ganguly did not find significant changes in forward flexion following a 9-week yoga training program. The subjects in that study participated in both yoga practice and other routine workouts. It is possible that muscle tightness or range of motion may have been affected by the additional workouts.

Table 3. Pretest and Post-test Measures of Balance by Group

<table>
<thead>
<tr>
<th>Variable</th>
<th>Pretest</th>
<th>Post-test</th>
</tr>
</thead>
<tbody>
<tr>
<td>One-legged stand, s</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yoga</td>
<td>20.0 ± 20.9</td>
<td>36.8 ± 27.0b</td>
</tr>
<tr>
<td>Non-Yoga</td>
<td>23.0 ± 15.3</td>
<td>24.2 ± 19.7</td>
</tr>
<tr>
<td>Functional reach, cm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yoga</td>
<td>42.7 ± 5.3</td>
<td>46.0 ± 4.3</td>
</tr>
<tr>
<td>Non-Yoga</td>
<td>40.4 ± 5.1</td>
<td>41.4 ± 3.3</td>
</tr>
</tbody>
</table>

* Data are presented as mean ± standard deviation.

Table 4. Pretest and Post-test Measures of Lung Function by Group

<table>
<thead>
<tr>
<th>Variable</th>
<th>Pretest</th>
<th>Post-test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Forced vital capacity, L</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yoga</td>
<td>3.51 ± 0.5</td>
<td>3.47 ± 0.5</td>
</tr>
<tr>
<td>Non-Yoga</td>
<td>3.52 ± 0.6</td>
<td>3.50 ± 0.7</td>
</tr>
<tr>
<td>Forced expiratory volume in the first second, L</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yoga</td>
<td>2.71 ± 0.6</td>
<td>2.87 ± 0.4</td>
</tr>
<tr>
<td>Non-Yoga</td>
<td>2.82 ± 0.5</td>
<td>2.91 ± 0.4</td>
</tr>
</tbody>
</table>

* Data are presented as mean ± standard deviation.

* Significantly different from pretest (P<.05).
Physiological Effects of 8 Weeks of Yoga Training

Table 5. Pretest and Post-test Measures of Aerobic Capacity and Maximal Heart Rate by Group

<table>
<thead>
<tr>
<th>Variable</th>
<th>Pretest</th>
<th>Post-test</th>
</tr>
</thead>
<tbody>
<tr>
<td>VO2max, ml/kg/min</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yoga</td>
<td>32.8 ± 7.1</td>
<td>35.5 ± 7.2</td>
</tr>
<tr>
<td>Non-Yoga</td>
<td>33.4 ± 7.2</td>
<td>35.4 ± 8.3</td>
</tr>
<tr>
<td>Maximal heart rate, bpm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yoga</td>
<td>178.6 ± 11.3</td>
<td>179.7 ± 14.4</td>
</tr>
<tr>
<td>Non-Yoga</td>
<td>182.5 ± 11.9</td>
<td>181.3 ± 12.9</td>
</tr>
</tbody>
</table>

Abbreviation: bpm, beats per minute.
* Data are presented as mean ± standard deviation.

Trunk extension and trunk lift scores were found to increase by 35% and 23%, respectively, in the current study. Tran et al found a larger increase of 188% in trunk extension. Gharote and Ganguly found an increase of 15% in back extension, which is similar to that found in the current study. Different results could be due to the increased number of training sessions and the types of yoga asanas executed. The types of asanas used in Hatha yoga are similar, but the level of difficulty taught and the length of time each asana was held could influence the results. Trunk rotation to the right (20%) and left (16%) also increased significantly. Rotation may have increased because of the variety of twisting asanas that are involved in the Hatha yoga practice.

Ankle range of motion increased by 5.7º or 7%. Tran et al found an increase of 7.1º or 13%, which was slightly higher than, but comparable to, that of the current study. Gharote and Ganguly found a 110% increase in left ankle flexibility when compared to the control group. However, they did not find a significant change in ankle flexibility on the right side. Once again, the types of asanas that were executed or the types of measurements that were used to test ankle flexibility could have varied between studies. The current study and Tran et al measured the dominant ankle, and Gharote and Ganguly measured both ankles.

Shoulder flexibility improved as determined by 2 different tests. Back-scratch scores on the right and left increased by 2.8 cm and 3.0 cm, respectively. Shoulder elevation increased by 3.8 cm. Tran et al found an even larger increase of 20.3 cm in shoulder flexibility. The improvement may have been less in our study because our subjects had a higher level of shoulder flexibility at the beginning of the training period. The significant increases found in shoulder flexibility could be due to the vast amount of asanas that stretch and lengthen the shoulder and chest muscles.

Muscular endurance of both the chest and the abdomen were increased significantly as a result of yoga training. Subjects were able to perform 6 more push-ups and 14 more curl-ups at the conclusion of the study. The increase could be attributed to the asanas that used static muscle strength to hold the body in the correct position. Others have also found improvements in knee flexion as a result of yoga training. Conversely, Tran et al found no significant improvements in muscular endurance when measuring elbow extension, elbow flexion, and knee extension. This could have been because of the small sample size (n=10) in their study or the type of tests that were done to evaluate muscular endurance. Many of the postures require the use of the upper body to support the torso, which will result in increases in core strength. Examples of asanas that support the torso and were used in the current study include plank pose, half moon (ardha Chandrasana), boat (ardha navasana), twisting prayer (parivrtta Parsvakonasana), revolved triangle (parivrtta Trikonasana), camel (Ustrasana), chair (Utkatasana), triangle (Utthita Trikonasana), side plank (Vasisthasana), and incline plane (Purvottanasana).

In the current study, time for the 1-legged stand test increased by 84% (16.8 seconds). Balance may have improved during the 1-legged stand test because of the increased amount of pranayama (breathing exercises) that were practiced in those studies. Our study focused more on the physical asanas rather than elongated pranayama. Previous studies that found significant improvements in pulmonary function practiced pranayama (breathing exercises) for 30 to 90 minutes. The types of breathing exercises used active, fast, rhythmic breathing such as kriya pranayama. The current study and the study of Tran et al both practiced 5 to 10 minutes of slow, deep breathing. This type of breathing exercise focuses more on relaxation rather than the strengthening of the respiratory musculature.

The current study found no significant changes in pulmonary function. This is similar to the results of Tran et al who used a similar training regime. On the other hand, many previous studies have found significant improvements in FVC and FEV1. The current study found no significant changes in VO2max or maximal heart rate. The findings of the current study are consistent with previous studies that did not find significant changes in either VO2max or maximal heart rate after 4 weeks, 8 weeks, or 6 months of yoga training. Raju et al did not find significant improvements in submaximal VO2 or submaximal heart rate as a result of 90 days of yoga training. However, Balasubramanian found significant improvements in VO2max after 6 weeks of yoga practice, respectively. This could be due to the intensity at which they practiced yoga and the initial ability of the subjects. Also, VO2max values were predicted from a submaximal test, which may have influenced the accuracy.

Overall, this study found significant increases in a variety of flexibility measurements, balance, and strength measures. The nature of yoga involves holding, twisting, and balancing which lets one tailor his or her yoga practice any way he or she wants.
Increases in lung function were not found in this study, which could be attributed to the training regime, which focused mainly on physical asanas (postures) rather than pranayama (breathing exercises). Changes in aerobic capacity were not seen because Hatha yoga may not elicit a high enough intensity. However, the practice of power yoga, which is a more dynamic type of yoga practice, may improve aerobic capacity due to the increased intensity utilized to execute the movements.

ACKNOWLEDGMENT

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REFERENCES

16. Schuerman SE. Relationships between Pirtural Exercise and Risk Factors for Falling in Individuals with Osteopenia [dissertation]. Omaha, NE: University of Nebraska Medical Center; 1998.

Portaging a Canoe
Requires Good Footwear
ATRIAL FIBRILLATION (AF), the most common arrhythmia requiring therapy, affects 0.4% of the general population and 2% to 5% of persons older than 60 years.1,2 One current management strategy includes cardioversion. The use of anticoagulation to manage patients undergoing cardioversion is controversial, and the role of transesophageal echocardiography (TEE) is germane in evaluating patients with AF. It is crucial that patients with persistent AF of unknown duration or 48 hours or longer in duration be free of left atrial (LA) and/or left atrial appendage (LAA) thrombus at the time of cardioversion. To accomplish this, oral anticoagulation (international normalized ratio [INR] 2.0-3.0) is recommended for at least 3 weeks prior to cardioversion.1 As an alternative to anticoagulation prior to cardioversion of persistent AF, it is reasonable to perform TEE in search of LA or LAA thrombus.1 For patients with no identifiable thrombus on TEE, cardioversion is reasonable immediately after anticoagulation with unfractionated heparin bridged to anticoagulation with oral vitamin K antagonist (INR 2.0-3.0). For patients in whom thrombus is identified by TEE, cardioversion is deferred and oral anticoagulation (INR 2.0-3.0) for at least 3 weeks is recommended before cardioversion is again contemplated. Extended periods of postcardioversion oral anticoagulation may be appropriate even after apparent successful cardioversion because the risk of thromboembolism remains elevated in such cases.1

Thrombus in the LA/LAA is detected on TEE prior to elective cardioversion in 0.6% to 5.6% of cases.3-6 Thus far, TEE has been considered the clinical reference in detection of LA/LAA thrombus with high diagnostic accuracy; however, diagnosis and size estimation of LA/LAA thrombi remain challenging due to LAA’s complex anatomy. Thrombus on TEE is usually a well-circumscribed echoreflective mass of uniform consistency with a texture different from that of the atrial wall. To date, few studies have evaluated the role of TEE in patients with AF.

Accuracy of TEE for identifying LA thrombus was studied prospectively in comparison with direct intraoperative findings by Manning et al.4 Consecutive patients undergoing elective cardiac surgery (N=231) who required opening of the left atrium were studied; 56% of patients had a history of AF but were not necessarily in AF at the time of TEE or surgery. Transesophageal echocardiogram identified thrombi in 14 cases. Surgery confirmed 12 of 14 thrombi (9 in LAA) by direct inspection. Hence, the study showed a sensitivity of 100%, specificity of 99%, positive predictive value of 86%, and negative predictive value of 100% in a population with prevalence of 5.2%. Twelve confirmed

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thrombi were identified by 2 independent observers on TEE. Two thrombi on TEE that were not confirmed by direct inspection intraoperatively were identified by only 1 observer on TEE. This study indicates that TEE is highly accurate for identification of LA thrombi. However, the study was performed in the early days of TEE when single and biplane techniques were often used. Currently, TEE is performed almost exclusively with multiplane technique. Further, the prevailing rhythm at the time of the test affects quality of TEE images, especially for assessment of LAA; in this case, 36% of total study population and 82% of patients with identified thrombus were in AF. In practical terms, TEE is performed for assessment of LA thrombus while patients are in AF prior to cardioversion, with clinical decisions usually made based on the interpretation of a single observer without the luxury of a second opinion.

High negative predictive value is safer for the patients in this clinical situation where it is crucial not to miss a thrombus. The occasional downside of somewhat lower positive predictive value in this clinical situation is that otherwise deserving patients may be denied early expedited (nonemergent) cardioversion. According to the ACUTE trial, TEE-guided earlier approach versus prior 3-week anticoagulation approach had a higher initial rate of successful restoration of sinus rhythm (71% vs 65%, \( P = .03 \)).

Owing to these and other findings, TEE is commonly performed in AF patients who (1) require expedited (but nonemergent) cardioversion but for whom extended pre-cardioversion anticoagulation is not desirable; (2) who have had a cardioembolic event thought to be related to intra-atrial thrombus; for whom anticoagulation is contraindicated and for whom a decision about cardioversion will be influenced by TEE results; and (3) for whom intra-atrial thrombus has been demonstrated on previous imaging. TEE is semi-invasive and can be uncomfortable if not performed under adequate sedation. Although rare, complications can occur. In some cases, TEE is contraindicated. Hence, we sought to determine whether cardiac magnetic resonance imaging (CMRI), a noninvasive test, would serve as an alternative to obtain similar information.

To date, studies comparing TEE and CMRI have been few, and their results, conflicting. In one study, LA was readily visualized with CMRI using double- and triple-inversion recovery sequences, finding high concordance between detection of high-intensity mass with CMRI and thrombus with TEE. In another study utilizing 2D perfusion and turbo fast low-angle shot (FLASH) imaging, researchers concluded that contrast-enhanced CMRI lacked the diagnostic accuracy necessary to detect thrombi in the LAA. Conversely, other studies report that contrast-enhanced CMRI depicts LAA thrombi more accurately than TEE with similar sensitivity and can distinguish between subacute and organized thrombi.

**MATERIALS AND METHODS**

Our aim was to conduct a study in which both TEE and CMRI were done when the patient was in AF because, clinically, evaluation of LA/LAA for thrombus is performed while patients are in AF for decision regarding whether to proceed with cardioversion. The study was approved by our Institutional Review Board.

**Study population**

Patients with AF referred for TEE at a single institution between August 1, 2007, and October 26, 2009, were identified. Those seen to have a thrombus in LA/LAA on precardioversion TEE and had cardioversion deferred served as cases. Patients with AF referred for TEE for reasons other than cardioversion with a thrombus on TEE also served as cases. Patients with AF referred for TEE for reasons other than cardioversion who did not have a thrombus on TEE served as controls. Patients negative for thrombus in LA/LAA on precardioversion TEE and underwent cardioversion were excluded because sinus rhythm was restored right after TEE with cardioversion. Study population, including cases and controls, comprised 12 patients who were prospectively consented to CMRI within 24 hours of TEE. Four patients (controls) had no evidence of LA/LAA thrombus on TEE or CMRI, and 2 patients had incomplete data (1 did not return for CMRI, and 1 could not fit into the CMRI scanner). We report 6 cases with confirmed or suspected LA thrombus on TEE.

**TEE/MRI**

All patients underwent multplanar TEE performed in standard planes used to evaluate the LAA with patients under conscious sedation using the standard topical anesthetic and sedative medications. All patients also underwent an LAA Assessment CMRI Protocol (SIEMENS 1.5T Symphony MR system, Erlangen, Germany) within 24 hours of TEE, which included segmented balanced gradient echo (TrueFISP) cine images in 2-chamber, 4-chamber, 3-chamber and short-axis views; 2-chamber TrueFISP cine stack covering the entire LAA volume; TrueFISP cine stack of the LAA short-axis view covering the entire LAA volume; and TrueFISP gradient echo static localizers in 2-chamber and short-axis stack. If gadolinium could be used and was not contraindicated due to advanced renal failure, additional imaging was performed with time-resolved small-volume boluses in multiple (from 3 to 5) 2-chamber stack planes covering the LAA volume followed by 3D volume acquisition of the LAA angiogram after determining the scan delay time from the individual time-resolved small-volume boluses. This is a common off-label use of the contrast material. Cardiac magnetic resonance imaging protocol completion time in individual patients ranged from 30 to 60 minutes. An experienced cardiologist reviewer blinded to patient information interpreted the CMRI. After analysis was complete, patient identifiers were revealed and cases reviewed for patient characteristics, subsequent other imaging, and procedures performed. Individual findings were evaluated to investigate the differences between CMRI and TEE in the detection of LA/LAA thrombus.

**CASE SERIES**

**Case 1**

The patient was a 71-year-old man with known coronary artery disease and ischemic cardiomyopathy, left ventricular ejection fraction (LVEF) of 35%, history of past ethanol abuse, and previous complete recovery from a cerebrovascular event in the postoperative period following hernia surgery. Physical examination revealed stable vital signs, but a heart rate of 116 irregular beats per minute (bpm). Electrocardiogram (ECG) confirmed newly detected atrial
DETECTION OF LEFT ATRIAL APPENDAGE THROMBUS

flutter. Routine laboratory values, including complete blood count (CBC) and chemistry panel, were unremarkable. Results of a chest radiograph were normal. A chest computed tomography (CT) scan was negative for acute pulmonary embolism but positive for an incidental finding of splenic infarcts. Transesophageal echocardiogram was requested, which showed LAA thrombus (Figure 1A). The patient was placed on unfractionated heparin drip and warfarin. Within 24 hours, the patient underwent CMRI, which also showed LAA thrombus (Figure 1B).

**Case 2**

An 86-year-old gentleman with 2 previous bypass surgeries and 2 aortic valve replacement surgeries with LVEF 40%, moderate-to-severe biatrial enlargement and moderate resting pulmonary hypertension with recent congestive heart failure symptoms and newly detected atrial flutter with variable atrioventricular (AV) conduction was referred for TEE-guided cardioversion. He had been placed on oral anticoagulation with therapeutic INR 2 weeks earlier. Vital signs were stable, with a heart rate of 100 bpm. Telemetry confirmed atrial flutter with variable AV conduction. Cardioversion was deferred because TEE showed LAA thrombus (Figure 2A). The patient underwent CMRI the same day, which was negative for the presence of LAA thrombus (Figure 2B). Since this was per study protocol, management did not change based on CMRI findings, and the subject was discharged on rate control and anticoagulation medications.

**Case 3**

An 82-year-old man came to us with progressively worsening dyspnea for 2 days. He had no chest pain. He was significantly hypertensive on admission, with blood pressure of 194/110 mm Hg. His heart rate was 110 bpm, with oxygen saturation 97% on 2 L/min via nasal cannula. Results of the rest of the physical examination were noncontributory. Electrocardiogram revealed AF with ventricular rate of 110 bpm and new left bundle branch block (LBBB). He had positive cardiac biomarkers. Coronary
angiography revealed mid-to-distal left anterior descending (LAD) 70% stenosis with diffusely diseased LAD. LVEF was 33% on TEE. He was referred for TEE-guided cardioversion due to persistent heart failure symptoms after adequate treatment with antihypertensive and anti-ischemic medications. Transesophageal echocardiogram revealed a possible LAA thrombus (Figure 3A), and cardioversion was deferred. Cardiac magnetic resonance imaging performed within 24 hours also showed an LAA thrombus (Figure 3B). Patient was discharged home on rate control and anticoagulation medications.

**Case 4**

A 68-year-old woman with history of rheumatic valve disease and mitral valve replacement with 31-mm mechanical valve, moderate aortic stenosis, and moderate-to-severe aortic insufficiency was seen with new-onset heart failure symptoms. LV size and systolic function were normal, with LVEF of 62%. She also had newly detected AF with rapid ventricular rate despite adequate rate control medications. She was referred for TEE and cardioversion. Transesophageal echocardiogram showed normally functioning mitral prosthesis, mild-to-moderate aortic stenosis, and mild-to-moderate aortic insufficiency. Transesophageal echocardiogram also showed LAA thrombus (Figure 4A). Cardioversion was deferred, and patient was discharged on intensive oral anticoagulation with INR 3.0 to 4.0. Cardiac magnetic resonance imaging was performed the same day, which failed to reveal LAA thrombus (Figures 4B and 4C). Imaging of the entire LAA was difficult in this case due to susceptibility artifacts from the adjacent mechanical mitral prosthesis. In the interest of time, CMRI was performed without contrast. Five days later the patient underwent gated cardiac CT with additional delayed imaging, the results of which also strongly suggested an LAA thrombus due to persistence of the filling defect in the LAA, even in delayed postcontrast imaging performed 5 minutes after contrast administration (Figures 4D

![Figure 3A](image1.png) **Figure 3A.** Reported thrombus in left atrial appendage on transesophageal echocardiogram.

![Figure 4A](image2.png) **Figure 4A.** Thrombus present in left atrial appendage on transesophageal echocardiogram.

![Figure 3B](image3.png) **Figure 3B.** Muscle ridge and the actual thrombus in left atrial appendage on cardiac magnetic resonance imaging.

![Figure 4B](image4.png) **Figure 4B.** Cardiac magnetic resonance imaging, 2-chamber view, no thrombus seen in left atrial appendage.
DETECTION OF LEFT ATRIAL APPENDAGE THROMBUS

and 4E). The patient continued to have significant shortness of breath when evaluated 6 months later. She was still in AF, although with a well-controlled ventricular rate and consistent therapeutic oral anticoagulation. She was scheduled for TEE and cardioversion again. At this time, the LAA looked much different than it had on TEE 6 months earlier, with no visible thrombus (Figure 4F). Cardioversion was accomplished and sinus rhythm restored.

Case 5

A 68-year-old woman with history of hypertension, type 2 diabetes mellitus, obstructive sleep apnea, and peripheral arterial disease came to us with chest pain and dyspnea. She had clinical signs of biventricular heart failure. She was also in newly detected AF with rapid ventricular rate. Electrocardiogram showed AF with ventricular rate of 120 bpm. She was treated for heart failure and rate control medications for AF. Subsequent work-up included coronary angiography, which revealed severe triple-vessel disease. She was referred for TEE-guided cardioversion while awaiting coronary artery bypass grafting surgery. Transesophageal echocardiogram revealed LAA thrombus (Figure 5A), and cardioversion was deferred. That same day, the patient underwent CMRI, which showed LAA to be free of thrombus (Figure 5B). The next day, she underwent coronary artery bypass grafting, radiofrequency ablation with bilateral pulmonary vein isolation, along with automatic ganglion mapping, ablation of connecting lesions, and LAA amputation. Finding from an intraoperative TEE (Figure 5C) was similar to that of the preoperative TEE 2 days earlier, which was called a thrombus; however, no thrombus was seen in the LAA during surgery on direct visualization. No mural thrombus was reported on the histopathology report of the LAA surgical specimen.
Case 6

A 56-year-old man with a history of mitral valve prolapse without significant mitral insufficiency came to the emergency department with a history of intermittent palpitations for over 48 hours. He was found to be in AF, with ventricular rate of 136 bpm. Other vital signs and routine laboratory results, including CBC, chemistry, and TSH, were normal. There were no identifiable causes of AF. He was treated with diltiazem bolus and drip and referred for TEE and cardioversion. Transesophageal echocardiogram revealed mitral valve prolapse with mild mitral insufficiency, evidence of LAA thrombus, and an otherwise structurally normal heart (Figure 6A); cardioversion was deferred. He was discharged home on low molecular weight heparin, warfarin, and diltiazem. He underwent CMRI within 24 hours while still in AF, which revealed LAA to be free of thrombus (Figure 6B). At follow-up 48 hours later, he was in sinus rhythm without further episodes of palpitations. The patient elected to discontinue warfarin in favor of aspirin for anticoagulation. In the ensuing 14 months, he has remained free of any subsequent detected episodes of AF, palpitations, or embolic events.

DISCUSSION

Multiplane TEE has been traditionally used to assess LA/LAA for presence of thrombus prior to nonemergent cardioversion of AF in a subset of patients who require expedited cardioversion and in whom prolonged precardioversion anticoagulation is believed to be less desirable. Transesophageal echocardiogram has long been the gold standard for this indication—not because of a strong level of published evidence, but due to the long experience with TEE in clinical practice in the absence of an alternative imaging modality. The LAA is an anatomically complex structure and can be difficult to evaluate for thrombus. Transesophageal echocardiogram is a valuable tool with a high sensitivity and negative predictive value, but it can lack specificity and positive
predictive value in clinical practice. Pectinate muscles in the trough, muscle ridges at the orifice, and frequent multilobular morphology of the LAA contribute toward overdiagnosis of thrombus in the LAA. Occasional foreshortening of the LAA on 2D TEE views can contribute to overdiagnosis of thrombus in the trough, as well. Judgment regarding the presence of thrombus in the LAA frequently needs to be made quickly while the patient is sedated because, if performed, cardioversion usually proceeds immediately after the TEE in consideration of patient comfort, as well as facility throughput issues. Therefore, in such situations clinicians occasionally prefer to err for patient safety by overcalling the presence of thrombus.

We compared CMRI, a noninvasive imaging modality, with TEE for the diagnosis of LA/LAA thrombus in patients with AF. We believe that, unlike therapeutic trials, trials involving the performance of imaging modalities are heavily dependent upon operator. Additionally, in most clinical situations of LA/ LAA thrombus in patients with AF, a true gold standard does not exist. Hence, binary results, such as positive and negative alone, with subsequent computation of sensitivity, specificity, positive predictive value, and negative predictive value in comparison with a non–gold standard modality may be misleading. Therefore, we tried to study all possible clinical impacting aspects while comparing the modalities of TEE and CMRI for this indication. The presented results and attributes of individual cases bring to the fore some interesting discussion points.

In binary terms, the following conclusions could be drawn. First, the concordance for negativity was 100% when TEE is considered the reference imaging modality—that is, if TEE was negative for thrombus, so was CMRI. The concordance for positivity was also 100% when CMRI is considered the reference imaging modality: if CMRI was positive for thrombus, so was TEE. Discordance was mainly seen for positivity when TEE was considered the reference imaging modality, and for negativity when CMRI was considered the reference modality. Thus, either TEE was overdiagnosing or CMRI was underdiagnosing LAA thrombus. If TEE is considered the gold standard, in absolutely binary terms, CMRI appears to lack accuracy as a modality.

This case series is small and, therefore, the study lacks strength in terms of binary results; however, further examination of individual cases provides insight into the strengths and weaknesses of individual imaging modalities. After having been assigned positive or negative status in a blinded fashion by both TEE and CMRI, all cases were discussed at length by a group of experienced cardiologists. After presenting the data from the opposing imaging modality in some of the individual cases, the original reader of the reference modality believed that his/her diagnosis would have been different in retrospect. Review of the 6 cases reveals some interesting facts:

**Case 1.** Transesophageal echocardiogram and CMRI imaging were good quality, and there was agreement between the imaging modalities.

**Case 2.** Left atrial appendage was clearly visualized on CMRI in multiple planes with good image quality; in retrospect, the TEE finding was believed to be artifactual.

**Case 3.** Transesophageal echocardiogram and CMRI were in agreement regarding presence of LAA thrombus; however, the structure termed a mural thrombus on TEE was actually a muscle ridge at the LAA orifice. An additional, well-circumscribed thrombus seen in the LAA trough on CMRI was not called on TEE.

**Case 4.** In addition to comparing TEE and CMRI, this case emphasizes the role of cardiac CT, a modality less commonly used for this indication. We also have the advantage of a follow-up TEE, which aids in confirming that the finding of thrombus on the previous TEE was a true-positive finding and that CMRI was false negative, which is concerning. However, CMRI image quality was suboptimal due to the adjacent mechanical mitral valve causing artifacts, and to contrast not being used, which could have helped.

**Case 5.** This case has the advantage of having direct visualization and histopathology—the true gold standard—for comparison with TEE and CMRI. Initial TEE identified a thrombus unconfirmed by direct visualization. Interestingly, findings of the intraoperative TEE were similar to those of the initial TEE.

**Case 6.** Left atrial appendage was readily visualized on CMRI and unequivocally believed to be free of thrombus. In retrospect, the suspected thrombus on TEE was thought to be a pectinate ridge—hence, a false-positive finding.

In summary, while this study lacks sufficient power to determine equality, superiority, or noninferiority of CMRI compared with TEE for the diagnosis of LA/LAA thrombus in patients with AF, discussion points indicate that both modalities have advantages and disadvantages. No gold standard imaging modality exists for this indication. Advantages of TEE include its long track record, wide availability, relative safety, little or no patient cooperation required, few contraindications, high sensitivity, and high negative predictive value. Disadvantages of TEE include its semi-invasive nature, significant sedation required, short time during which to review the images before decision regarding cardioversion is made, and possible lower than ideal specificity and positive predictive value.

Advantages of CMRI include its noninvasive nature, true 3D capability, probable high sensitivity, specificity, positive predictive value and negative predictive value, and the opportunity to review the images for a longer period than is possible with TEE before a decision regarding cardioversion is made. The disadvantages...
include nonstandardized protocols, poor availability, short track record, contraindication in certain patients with metallic prostheses, claustrophobic or uncooperative patients, requirement of contrast in some cases for optimal image quality, and inability to use contrast in patients with advanced renal failure (glomerular filtration rate < 30 ml/min/1.73 m²).

Further research, possibly duplicating the design of the present study, is needed before CMRI can be recommended as a viable alternative to TEE.

REFERENCES
Nature and Outcome of Clinical Trials Conducted by the Eastern Cooperative Oncology Group: A 30-Year Study from 1977-2006

ABSTRACT

Purpose: We describe the nature and outcome of Eastern Cooperative Oncology Group (ECOG) trials.

Methods: We included therapeutic trials developed between 1977 and 2006 that were closed to accrual before January 19, 2008.

Results: We found 495 trials. Most were phase II (65%) and III (31%). The most common cancers studied were hematologic (24%), gastrointestinal (17%), genitourinary (15%), thoracic (14%), and breast (11%). Trial development peaked in 1982-1986 and bottomed in 2002-2006 (24 vs 10 trials/year). The median time from concept approval to activation was about a year for all trials. Overall, 73% completed accrual. Accrual completion rate was highest among those developed in 1977-1981 and lowest in 1997-2001 (88% vs 59%; P < .001). Of trials that completed accrual, results were 41% were positive, 50% negative, and 8% unavailable. The median accrual periods were 3.5, 2.4, and 3.7 years for phase I, II, and III trials, respectively. To date, 68% of all trials had been published. For trials that completed accrual, 86% were published, with 56% published within 5 years of study closure. Independent predictive factors for accrual completion were activation before 1987 (P = .009), non-hematological trials (P = .036), phase I or II trials (P = .036), and time from concept approval to activation within a year (P = .001).

Conclusions: The process of ECOG trial development from concept approval to publication was generally slow and could take up to a decade to complete. Equal efforts must be directed toward streamlining trial activation, promotion of accrual, and timely publication of results. Clinical trials are essential in providing high-quality evidence-based medicine for clinical practice. In order to achieve this purpose, not only must trials be activated and completed in a timely fashion, but the results also must be reported truthfully, published in full, and made publicly available within a short period of time. Only about half of phase I, II, and III oncology trials initially presented as abstracts subsequently get published in peer-reviewed journals. Furthermore, the results of fewer than 1 in 5 oncology trials registered with ClinicalTrials.gov are published. For trials that are eventually published, median time to publication after presentation at oncology meetings is approximately 3 years. Selective publication of trials with positive results, delay in publication, and non-publication of trials lead to bias in the evidence available for medical practice, hinder completion of systematic reviews or meta-analyses, and undermine evidence-based practice of medicine. Furthermore, it takes as
much or more time to develop and activate a clinical trial as it does to complete actual accrual.6

Data are emerging on the complex and time-consuming process of trial activation in the cancer cooperative group setting; however, limited data are available regarding what happens to trials after activation—that is, completion rate, time to completion, and rate of publication, as well as factors affecting these outcomes.6-9 Timely accrual of patients is perhaps the most crucial factor for trial success. Lack of availability of trials at community-based cancer centers remains a major barrier to clinical trial accrual among newly diagnosed adult cancer patients.10 If data regarding trial performance and outcome communication are available, we can learn how to better design, conduct, and report trials.

Although only about 6% of trials listed at the National Cancer Institute (NCI) website originate from the NCI-sponsored Clinical Trials Cooperative Group Program, the cooperative group trials recruit over 25,000 patients annually and comprise a substantial proportion of total cancer trial accrual in the United States.11,12 The Eastern Cooperative Oncology Group (ECOG), established in 1955, is 1 of 12 active Clinical Trials Cooperative Groups. It has evolved from a 5-member consortium of institutions on the East Coast to one of the largest clinical cancer research organizations in the United States, with almost 6000 physicians, nurses, pharmacists, statisticians, and clinical research associates. Institutional members include universities, medical centers, Community Clinical Oncology Programs, and Cooperative Group Outreach Programs. Currently, ECOG has more than 90 active clinical trials, with accrual of approximately 6000 patients annually and more than 20,000 patients in follow-up.13 Nationally, over 130,000 patients have been accrued into ECOG clinical trials to date, with about half of the accruals coming from community-based cancer centers.13 However, the nature and outcome of ECOG trials are not available to the public.

This study was conducted to systematically analyze the nature of all trials conducted by ECOG over the last 30 years and to determine the outcomes of these trials with respect to time to activation, accrual completion and duration, results, and publication rate. The trends of these outcomes over time and the variables affecting them were also evaluated.

METHODS

Study Selection

We obtained a list of all therapeutic trials from the NCI and ECOG websites. We included all trials developed from 1977 through 2006 that were coordinated by ECOG and terminated as of January 18, 2008, due either to study completion or poor accrual. We searched the ECOG and NCI websites, PubMed, EMBASE, and Google search engine for evidence of subsequent publication of the trials until September 1, 2008.

Data Extraction

The following data were collected for each trial: name of trial, type of cancer studied, date of study conception, study phase, date of activation, date of termination, accrual goal, number of patients accrued, accrual outcome, trial outcome, and date of full publication. Cancer types were classified as breast, gastrointestinal, genitourinary, head and neck, hematological (leukemia, lymphoma, and myeloma), thoracic, symptom management, and others (brain, gynecologic, melanoma, and sarcoma). Because we did not have access to data not published in the ECOG website (eg, date of trial concept approval), we arbitrarily used either January 1 or July 1 of the year specified under study nomenclature and at least 6 months before study activation as date of trial concept approval. For example, E2887 was activated on October 15, 1987. Hence, we used January 1, 1987, as the date of approval. Accrual was considered complete if the total number of patients enrolled was within 10% of trial target or if trial was closed early due to the futility stopping rule. Trial outcomes were classified as positive (phase I trials: treatment tolerated and recommended for phase II development; phase II trials: response rate ≥20%; phase III trials: primary endpoint met, ie, experimental arm statistically better), negative, or not available (trials terminated due to poor accrual, trials completing accrual but results unpublished, and trials just recently completed accrual: within 3 years for phases I and II and within 5 years for phase III).

Statistical Analyses

Mantel-Haenszel χ² test was used to assess time trends for data by disease sites, and logistic regression was used to determine factors predictive of time to accrual completion and publication. All variables with P values less than .20 were included in the multivariate model, with stepwise selection methods to determine the final model. A P value of less than .05 was considered statistically significant.

RESULTS

We found 495 therapeutic trials conducted by ECOG from 1977 through 2006 (Figure 1). Most of the trials (96.2%) were phases II and III. The number of phase II trials was slightly over twice the number of phase III trials. Trial development peaked in the years from 1982 through 1986, with an average of 24 new trials per year, but declined to an average of 10 new trials per year from 2002 through 2006. The top 5 cancers studied were hematologic (23.6%), gastrointestinal (16.8%), genitourinary (14.6%), thoracic (13.7%), and breast (10.7%) cancers (Figure 2). Symptom control trials comprised less than 1% of the studies. The number of trials activated for all disease sites proportionately decreased over time (Figure 3; P=.999).

Figure 1. Distribution of clinical trials according to year of development.
Overall, 73.3% of the trials completed accrual. The proportion of trials reaching their accrual goals over each 5-year period is shown in Figure 4. Accrual completion rate was highest among trials developed from 1977 through 1981 (87.8%) and lowest from 1997 through 2001 (58.3%; *P*<.001). The decline in accrual completion rate over time was most pronounced for phase II (*P*=.002) and III (*P*<.001) trials. Among the trials that completed accrual, results were positive in 41.3%, negative in 50.4%, and unavailable in 8.3%. For the latter group, results were unavailable either because the trials were unpublished (63.3%), completed recently and not enough time had elapsed for outcome reporting or publication (33.3%), or not applicable (3.3%).

Characteristics of trial development, accrual time, and time to publication are shown in the Table 1. The median time from concept approval to activation was about a year for all phases of trials. Phase I and III trials were open for enrollment for a median of about 3½ years, while phase II trials were open approximately 2½ years. At the time of our analysis, 67.7% of all trials had been published. The median follow-up time for unpublished trials was 95 months. Excluding trials that were developed more recently (from 2002 through 2006), the overall and phase-specific publication rates have declined over time (Figure 5). For trials that completed accrual, 86.3% were published, with 27.6% and 55.8% published within 3 and 5 years of study closure, respectively. The median time from trial closure to publication among trials that completed accrual and were eventually published did not change over time (Table 2).

Table 1. Characteristics of Clinical Trial Development, Accrual, and Publication

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Median time from concept approval, years</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>To activation</td>
</tr>
<tr>
<td>I</td>
<td>1.0</td>
</tr>
<tr>
<td>II</td>
<td>0.9</td>
</tr>
<tr>
<td>III</td>
<td>0.9</td>
</tr>
</tbody>
</table>

*Only published studies.

Table 2. Time from Clinical Trial Closure to Publication* by Trial Phase over Time

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>4-year intervals</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>–</td>
</tr>
<tr>
<td>II</td>
<td>2.7</td>
</tr>
<tr>
<td>III</td>
<td>3.7</td>
</tr>
</tbody>
</table>

*For trials that completed accrual and eventually published. All values presented as median years.
Using multivariate logistic regression, the independent predictive factors for accrual completion were activation prior to 1987 (odds ratio [OR]: 2.00; \( P = .009 \)), non-hematological studies (OR: 1.73; \( P = .036 \)), phase I or II trials (OR: 1.67; \( P = .036 \)), and time from concept approval to activation in less than 1 year (OR: 2.27; \( P = .001 \)). Independent predictive factors for full publication were time from concept approval to activation within a year (OR: 1.91; \( P = .011 \)) and completion of accrual (OR: 8.14; \( P = .001 \)).

**DISCUSSION**

Clinical trials form the essence upon which evidence-based medicine thrives; however, initiating, conducting, completing, and publishing trials are complex processes that consume significant amounts of time, money, and human resources, and involve logistical, ethical, and sometimes legal challenges. Our study showed that over the last 3 decades, ECOG conducted hundreds of trials, mostly phases II and III, targeting a variety of malignancies. In recent years, the number of trials developed annually had substantially declined. The process from trial development to publication was generally slow and, for phase III trials, could take up to a decade to complete. Over a quarter of the trials failed to achieve accrual goal, and almost a third were never published.

Similar to the trials conducted by the rest of the cooperative groups, over 90% of trials conducted by ECOG were later phase trials, with phase II trials outnumbering phase III trials by 2 to 1. This is in contrast to noncooperative group publicly funded trials, wherein over half of all therapeutic trials were phase I, and less than a tenth were phase III.\(^{14}\) Despite accounting for only 10% of all new cancer diagnoses in the United States, hematologic malignancies were studied in 24% of all ECOG trials. In contrast, lung cancer—which has been the annual leading cause of cancer deaths since 1954—was relatively underrepresented, with only 14% of trials devoted to this malignancy.\(^{15}\) This could be because specific trials for the various subtypes are required because of the heterogeneity of hematologic malignancies, and to the relative lack of promising agents discovered for lung cancer in the past 3 decades. Quite notable is the extremely limited attention given to supportive care trials, which comprised fewer than 1% of all ECOG studies; however, this is also true of the composition of most other publicly funded trial groups, whether they be cooperative groups or NCI-sponsored cancer centers, networks, or consortia.\(^{14}\) An exception is the NCI Community Clinical Oncology Program, which places equal emphasis on accrual to treatment and supportive care/prevention trials.\(^{16}\)

Our study shows that the median time from concept approval to trial activation was approximately 1 year for all phases of trials, but this is likely an underestimation for several reasons. First, because we did not have access to the actual dates of trial concept submission—18 and 24 months for phase II and III trials, respectively.\(^{15}\) In order to develop strategies to reduce the time required to activate NCI-sponsored cooperative group and early drug development trials, as well as NCI-designated cancer center investigator-initiated trials, the NCI Operational Efficiency Working Group was established in 2008 under the auspices of the Clinical Trials and Translational Research Advisory Committee. The result is a set of sweeping recommendations, the most notable of which is setting timelines by which protocols must be activated from the time of concept submission—18 and 24 months for phase II and III trials, respectively.\(^{17}\)

Accrual of patients is another rate-limiting step for a clinical trial. Of concern is that over a quarter of all ECOG trials did not complete accrual. For phase III trials, the accrual completion rate declined from 77% to 44% in the last 20 years. Failure to complete accrual is not a problem confined to ECOG or the United States. In a pilot study consisting of a subset of phase III therapeutic trials (N=82) conducted by 5 NCI-sponsored cooperative groups from 1998 through 2004, 58% were closed because of poor accrual. Unfortunately, the investigators found no features of the protocol (fewer exclusion criteria, shorter consent forms, treatment modality, absence of placebo or observation arm) or of the trial (simpler trial design, participation by other cooperative groups) that were predictive of successful accrual.\(^{18}\) Another study from the United Kingdom showed that of the 333 completed randomized oncology trials listed in the National Register of Cancer Trials conducted from 1971 through 2000, 52% did not meet accrual goal, and 20% recruited fewer than 25% of the planned number of patients.\(^{19}\) Recognizing this high accrual failure rate, in 2004 the Cancer Treatment Evaluation Program (CTEP) of the NCI implemented early stopping rules for all CTEP-sponsored cooperative group trials.\(^{20}\) However, early stopping rules do nothing to address the barriers to trial accrual—for example, those related to protocol design, trial implementation, and patient recruitment. Equally concerning is the slow rate of accrual for phase II and III ECOG trials (Table 1). For trials that completed accrual, median times from trial activation to termination for phase II and III trials were 2 and 3.7 years, respectively. A much speedier accrual is to be expected because most trials involve common cancers and ECOG membership is huge, comprising hundreds of cancer centers and thousands of oncologists across 6 countries.
Barriers to accrual into trials both in the academic and community settings have been studied extensively over the years. However, we would like to highlight 2 barriers less explored in previous studies. A crucial element to improve accrual to cooperative group trials is the adequacy of funding from the NCI. In a survey conducted by the American Society of Clinical Oncology in 2008, 41% of research sites were either planning or considering limiting participation in cooperative group trials, the majority (75%) citing insufficient NCI per-case reimbursement of $2000 as a reason for their decision. In 2005, the average actual cost (including labor and overhead) per enrolee in randomized government-sponsored trials was estimated to be about $6000. Another important factor that undermines trial accrual is the common practice of using drugs still undergoing evaluation in trials for a given indication but that are available for off-label use, or so-called off-protocol therapy. A recent survey of United States medical oncologists showed that a large majority reported ever discussing (93%) or ever prescribing (81%) off-protocol therapy. While 61% of respondents discouraged this practice, only 31% believed that it should not be available. A follow-up study from the same group revealed that most (63%) phase III oncology trials in the United States evaluated drugs that were available for off-protocol therapy. The time to accrual was much longer (41 vs 22 months) and less efficient (8.8 vs 22.7 patients/month) when off-protocol therapy was available.

Timely publication of oncology trials continues to be a major problem. Our study indicates that about a third (32%) of all ECOG trials and a substantial proportion (14%) of trials that completed accrual are never published. To our knowledge, this is the first available systematic analysis of the publication rate of trials sponsored by a cooperative group. Previous studies from our group and others showed that over a quarter of phase I, II, and III oncology trials presented at the American Society of Clinical Oncology annual meetings were not published. For those that were published, median time to publication was over 3 years, regardless of the phase of trial. Even more alarming is that the results of fewer than 1 in 5 oncology studies indexed at the National Institutes of Health Clinical Trials.gov registry are eventually published. The negative effects of publication bias, both from the scientific and ethical point of views, are well described. However, this is a difficult issue to address because most unpublished trials are more likely to have negative results and, as a consequence, less likely to be selected by journals for publication. Therefore, for both the investigators and journal editors, the incentive to publish is minimal. This inertia can be overcome only by a concerted effort coming from all stakeholders in clinical trial research to enforce publication. This should include the academic centers, institutional review boards, funding agencies, patient advocacy groups, and medical journals.

In order to accelerate the growth of evidence-based medicine in clinical oncology and maximize utilization of the data derived in this manner, equal efforts must be directed toward streamlining trial activation, promoting accrual, and publishing all trial results in a timely fashion. It is encouraging that progress is now being made to compress the timeline of trial activation and accrual; however, timely publication of all trials remains a major challenge and deserves more attention.


INTRODUCTION

Both oral1-3 and intravenous (IV)4-11 proton pump inhibitors (PPIs) have been shown to be beneficial in the management of acute peptic ulcer bleeding. There are, however, scant data comparing them in affected patients.12-14 Intravenous PPIs have evolved to become the standard of care in the medical management of peptic ulcer bleeding,15,16 despite the lack of comparative studies proving their superiority over oral agents. If oral PPIs could be shown to be associated with similar outcomes as IV PPIs, cost-effectiveness analysis would favor use of the oral agents.17 The 2013 Gundersen formulary PPI is pantoprazole, given as an 80-mg IV bolus, which costs $6, while a 250-ml IV bag lasting 10 hours costs $7.50, or $60 for a typical 3-day therapy. Oral pantoprazole 80 mg (two 40-mg tablets) twice daily, costs only $1.00 per day, representing a substantial savings versus IV bolus proving their superiority over oral agents. If oral PPIs could be shown to be associated with similar outcomes as IV PPIs, cost-effectiveness analysis would favor use of the oral agents.17

METHODS

Setting and Participants

The medical records of all patients admitted to a community hospital in a mid-sized western Wisconsin city from April 10, 1997, through October 16, 2008, with a discharge diagnosis of bleeding gastric, duodenal, or peptic ulcer were retrospectively reviewed. Candidates for study were identified by computer search using the hospital’s electronic medical record database. Inclusion criteria were as follows: age greater than 18 years; inpatient management; endoscopic findings of gastric or duodenal ulcer with active bleeding, a nonbleeding visible vessel in its base, adherent clot, or blood, eschar, or black particulate matter in its base that could not be washed away by vigorous irrigation; the presence of hemostasis after endoscopy; and treatment with high-risk endoscopic stigmata treated with IV bolus followed by infusion therapy. The purpose of this study was to compare clinical outcomes in endoscopically treated patients with bleeding ulcers having high-risk endoscopic stigmata treated with oral versus IV PPIs.

RESULTS

Records of 1299 hospitalizations were reviewed. Eighty-seven patients treated with oral PPIs and 87 managed with IV therapy were included. Outcomes in the orally and intravenously treated groups, respectively, were: hospitalization duration, 3.8 (95% confidence interval [CI], 3.2-4.3) and 3.8 (95% CI, 2.9-4.7) days; blood transfusions, 1.7 (95% CI, 1.2-2.2) and 1.3 (95% CI, 0.9-1.7) units; number of endoscopies, 1.1 (95% CI, 1.1-1.2) and 1.2 (95% CI, 1.1-1.2); rebleeding, 10% and 14% (P=.49); surgery, 3% and 5% (P=.99); readmission for bleeding, 5% and 1% (P=.21); and mortality, 5% and 1% (P=.37).

Conclusion: This study found similar outcomes in patients with bleeding peptic ulcers treated with high-dose, twice-daily oral versus bolus followed by infusion IV PPI therapy.

ABSTRACT

Introduction: Both oral and intravenous (IV) proton-pump inhibitors (PPIs) have been shown beneficial in management of bleeding peptic ulcers. The aim of this study was to compare outcomes of patients with bleeding ulcers treated with oral versus IV PPIs.

Methods: All patients hospitalized in a community hospital from 1997 to 2008 with bleeding gastric or duodenal ulcers were retrospectively identified. Patients with hemostasis after endoscopy and high-risk endoscopic stigmata treated with IV bolus followed by infusion or high-dose, twice-daily oral PPI therapy were studied.

Results: Records of 1299 hospitalizations were reviewed. Eighty-seven patients treated with oral PPIs and 87 managed with IV therapy were included. Outcomes in the orally and intravenously treated groups, respectively, were: hospitalization duration, 3.8 (95% confidence interval [CI], 3.2-4.3) and 3.8 (95% CI, 2.9-4.7) days; blood transfusions, 1.7 (95% CI, 1.2-2.2) and 1.3 (95% CI, 0.9-1.7) units; number of endoscopies, 1.1 (95% CI, 1.1-1.2) and 1.2 (95% CI, 1.1-1.2); rebleeding, 10% and 14% (P=.49); surgery, 3% and 5% (P=.99); readmission for bleeding, 5% and 1% (P=.21); and mortality, 5% and 1% (P=.37).

Conclusion: This study found similar outcomes in patients with bleeding peptic ulcers treated with high-dose, twice-daily oral versus bolus followed by infusion IV PPI therapy.

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All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none were reported.

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heparin, enoxaparin or clopidogrel; history of gastric bypass; ulcer intimately related to a fundoplication or gastrostomy tube; ulcer within a hiatal hernia; presence of a second bleeding site, such as a Mallory-Weiss tear; incomplete data due to transfer to another hospital; post-polypectomy ulcer; presence of a concomitant disorder not caused by the ulcer and affecting an outcome measurement; and failure to complete at least a 1-month course of oral PPI therapy after discharge.

Rebleeding was defined as any event prompting endoscopic or surgical intervention for management of suspected bleeding after initial endoscopy. The following data were recorded on individual data sheets for each subject: name; medical record number; age; sex; dates of admission and discharge; dates, times, findings, number, and therapeutic interventions of endoscopic examinations; presence or absence of hematemesis, melena, and hematochezia; previous history of peptic ulcer disease; smoking status; presence of cardiac, peripheral vascular, renal, cerebrovascular, pulmonary, or malignant disease; use of a nonsteroidal anti-inflammatory drug within 48 hours of admission; reasons for second and subsequent endoscopic examinations; dates and times of orders for PPI therapy; specific PPI and dose; ambulance or admitting nadir blood pressure and concomitant pulse; hemoglobin nadir in initial 24 hours; admission international normalized ratio (INR); presence of rebleeding during index hospitalization; need for surgery to control bleeding; units of transfused red blood cells; dates and times of transfusion orders and red blood cell unit issuance; re-admission for ulcer bleeding within 30 days of discharge; and in-hospital mortality. The study was approved by the Gundersen Clinic, Ltd. Human Subjects Committee/Institutional Review Board.

Statistical Analysis
Statistical analyses were completed using SAS software, version 9.2 (Cary, NC). Student t tests were used for comparison of continuous variables, while \( \chi^2 \) analyses were utilized for comparison of ordinal variables. Fisher exact tests replaced \( \chi^2 \) tests when low cell counts were present. \( P \) values less than or equal to .05 were considered significant.

RESULTS
Subjects, Baseline Characteristics, and Endoscopic Findings and Treatment
Records of 1299 patient hospitalizations meeting inclusion criteria were reviewed (Figure). One thousand one hundred twenty-five were excluded, leaving 174 study subjects, of whom 87 (59 men) had been treated with high-dose oral PPI therapy (PO group) and 87 (51 men) with IV PPI bolus followed by infusion (IV group).

The mean pulse in the PO group was significantly higher than in the IV group (\( P=.01 \)). Baseline characteristics, including comorbidities and clinical and endoscopic findings, were not significantly different between groups (Table 1).

Significantly more patients in the PO group were treated endoscopically with epinephrine alone. Significantly more patients in the IV group were treated with hemoclip application. There were no other significant differences with regard to endoscopic treatment (Table 2).

Rebleeding rates, mean number of units of red blood cells transfused, mean number of endoscopies, need for surgery, mean duration of hospitalization, rates of readmission within 30 days of discharge with gastrointestinal bleeding, and in-hospital mortality rates were not significantly different between the PO and IV groups (Table 3).

No significant differences were found in any of the 7 outcome parameters in patients in the PO group treated with pantoprazole (n=21) versus those treated with lansoprazole (n=38) versus those treated with omeprazole (n=27) (data not shown). One patient was treated with both omeprazole and lansoprazole.

Mortality
Four patients in the PO group died. An 81-year-old woman died of pneumonia and/or pulmonary edema without rebleeding. A 74-year-old woman died following surgery complicated by postoperative stroke, respiratory failure, sepsis, peritonitis, renal failure, and further gastrointestinal bleeding. An 84-year-old woman died following the abrupt onset of epigastric pain. Another 84-year-old woman died of respiratory failure following surgery.

There was 1 death in the IV group. A 92-year-old woman died following postoperative myocardial infarction, possibly of rebleeding and aspiration.
Table 1. Baseline Patient Characteristics by Route of Proton Pump Inhibitor Administration

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>PO Group n=87</th>
<th>IV Group n=87</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y, mean (SD)</td>
<td>71.6 (14.4)</td>
<td>69.4 (13.9)</td>
</tr>
<tr>
<td>Men</td>
<td>59 (68)</td>
<td>51 (59)</td>
</tr>
<tr>
<td>Smoker</td>
<td>15 (17)</td>
<td>23 (26)</td>
</tr>
<tr>
<td>Peptic ulcer history</td>
<td>30 (34)</td>
<td>20 (23)</td>
</tr>
<tr>
<td>Cardiac disease</td>
<td>34 (39)</td>
<td>32 (37)</td>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td>10 (11)</td>
<td>18 (21)</td>
</tr>
<tr>
<td>Peripheral vascular disease</td>
<td>6 (7)</td>
<td>12 (14)</td>
</tr>
<tr>
<td>Pulmonary disease</td>
<td>7 (8)</td>
<td>15 (17)</td>
</tr>
<tr>
<td>Renal disease</td>
<td>7 (8)</td>
<td>13 (15)</td>
</tr>
<tr>
<td>Malignancy</td>
<td>1 (1)</td>
<td>5 (6)</td>
</tr>
<tr>
<td>NSAID use</td>
<td>60 (69)</td>
<td>68 (78)</td>
</tr>
<tr>
<td>Hematemesis</td>
<td>29 (33)</td>
<td>33 (38)</td>
</tr>
<tr>
<td>Melena</td>
<td>66 (76)</td>
<td>66 (76)</td>
</tr>
<tr>
<td>Hematochezia</td>
<td>23 (26)</td>
<td>18 (21)</td>
</tr>
<tr>
<td>Systolic blood pressure, mm Hg, mean (SD)</td>
<td>114 (24.4)</td>
<td>113 (31.4)</td>
</tr>
<tr>
<td>Heart rate, beats/min, mean (SD)</td>
<td>95.2 (20.7)</td>
<td>87.1 (18.4)</td>
</tr>
<tr>
<td>Hemoglobin nadir, g/dL, mean (SD)</td>
<td>8.5 (1.7)</td>
<td>8.5 (1.7)</td>
</tr>
<tr>
<td>INR, mean (SD)</td>
<td>1.6 (1.4)</td>
<td>1.7 (1.7)</td>
</tr>
</tbody>
</table>

Endoscopic findings
- Ulcer in gastric fundus, body, or at incisura
- Ulcer in gastric antrum
- Pyloric ulcer
- Duodenal bulb ulcer
- Ulcer in second part of duodenum
- Active bleeding
- Non-bleeding visible vessel
- Adherent clot
- Adherent blood, eschar, or black particulate matter

Table 2. Endoscopic Treatment by Route of Proton Pump Inhibitor Administration

<table>
<thead>
<tr>
<th>Treatment</th>
<th>PO Group</th>
<th>IV Group</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epi and BICAP</td>
<td>38 (44)</td>
<td>40 (46)</td>
<td>.76</td>
</tr>
<tr>
<td>BICAP only</td>
<td>7 (8)</td>
<td>8 (9)</td>
<td>.79</td>
</tr>
<tr>
<td>Epi and banding</td>
<td>1 (1)</td>
<td>0 (0)</td>
<td>.99</td>
</tr>
<tr>
<td>Epi only</td>
<td>25 (29)</td>
<td>8 (9)</td>
<td>.99</td>
</tr>
<tr>
<td>Epi and BICAP and clips</td>
<td>0 (0)</td>
<td>16 (18)</td>
<td>.99</td>
</tr>
<tr>
<td>Epi and clips</td>
<td>0 (0)</td>
<td>1 (1)</td>
<td>.99</td>
</tr>
<tr>
<td>Clips only</td>
<td>0 (0)</td>
<td>1 (1)</td>
<td>.99</td>
</tr>
<tr>
<td>APC only</td>
<td>0 (0)</td>
<td>1 (1)</td>
<td>.99</td>
</tr>
<tr>
<td>Clips with or without other</td>
<td>0 (0)</td>
<td>18 (21)</td>
<td>.001</td>
</tr>
</tbody>
</table>

Abbreviations: PO, oral; IV, intravenous; Epi, epinephrine; BICAP, bipolar electrocautery; Clips, hemoclips; APC, argon plasma coagulator.

*Data are presented as number of patients (%).

Table 3. Outcomes Comparisons by Route of Proton Pump Inhibitor Administration

<table>
<thead>
<tr>
<th>Outcome</th>
<th>PO Group n=87</th>
<th>IV Group n=87</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of red blood cell units transfused, mean (95% CI)</td>
<td>1.7 (1.22-2.16)</td>
<td>1.3 (0.85-1.73)</td>
<td>.22</td>
</tr>
<tr>
<td>Rebleeding</td>
<td>9 (10)</td>
<td>12 (14)</td>
<td>.49</td>
</tr>
<tr>
<td>No. of endoscopies, mean (95% CI)</td>
<td>1.1 (1.06-1.22)</td>
<td>1.2 (1.06-1.24)</td>
<td>.85</td>
</tr>
<tr>
<td>Surgery</td>
<td>3 (3)</td>
<td>4 (5)</td>
<td>.99</td>
</tr>
<tr>
<td>Duration of hospitalization, mean days (95% CI)</td>
<td>3.8 (3.23-4.31)</td>
<td>3.8 (2.89-4.72)</td>
<td>.95</td>
</tr>
<tr>
<td>Readmission*</td>
<td>4 (5)</td>
<td>1 (1)</td>
<td>.21</td>
</tr>
<tr>
<td>Clips only</td>
<td>4 (5)</td>
<td>1 (1)</td>
<td>.37</td>
</tr>
</tbody>
</table>

Abbreviations: PO, oral; IV, intravenous; CI, confidence interval.

* Data are presented as number of patients (%) unless otherwise noted.

* The denominator includes only patients discharged alive.

Abbreviations: PO, oral; IV, intravenous; NSAID, nonsteroidal anti-inflammatory drug; INR, international normalized ratio.

*Data are presented as number of patients (%) unless otherwise noted.
DISCUSSION

In this retrospective analysis, patients with endoscopically treated bleeding peptic ulcers and high-risk endoscopic stigmata who were treated with high-dose oral PPIs had outcomes similar to those treated with IV bolus followed by infusion therapy. This suggests that oral therapy could safely replace the current standard, and more costly, IV therapy.

Function of the intrinsic and extrinsic blood clotting systems, as measured by the INR and activated partial thromboplastin time, respectively, and platelet aggregation are optimal at pH greater than 7. The platelet disaggregating effects of pepsin increase incrementally with decreasing pH below 7. Indeed, Curtis et al reported cessation of massive upper gastrointestinal bleeding in 23 of 25 (92%) patients treated with antacids administered via nasogastric tube to maintain a gastric pH of 7. The study, however, lacked a control group. PPIs are potent inhibitors of gastric acid secretion. Thus, it is not surprising that they have been found to be helpful in achieving and maintaining hemostasis in patients with upper gastrointestinal bleeding.

Intravenous PPIs given by bolus followed by continuous infusion are able to effect an increase in intragastric pH to 6 or greater by 20 to 138 minutes and to maintain the pH at this level for 28% to 100% (weighted mean, 64%) of the time in the ensuing hours to days. High-dose, twice-daily oral PPIs result in similar increases by 198 to 210 minutes and maintain intragastric pH at or above 6, 29% to 60% (weighted mean, 44%) of the time during continued administration. With oral PPIs, greater intragastric pH control attends initial administration of a high loading dose (eg, 90-120 mg lanoprazole) followed by administration every 3 hours (pH 6 reached at weighted mean of 170 minutes [range of means, 115-240 minutes] after loading dose, pH maintained at or above 6, 41% to 65% of the ensuing time [weighted mean, 56%]). Thus, IV bolus followed by infusion PPI therapy provides more rapid and more potent gastric acid secretory inhibition than high-dose oral administration. Despite slower and inferior intragastric pH control, however, high-dose, twice-daily oral PPI therapy seems to yield clinical outcomes similar to those associated with IV bolus/infusion therapy in endoscopically treated patients with bleeding peptic ulcers. One explanation is that endoscopically treated ulcers are sufficiently resistant to the lytic effects of acid to maintain clot/coagulum integrity in the first few hours following endoscopy before the intragastric pH has reached 6. Further, it may be unnecessary to maintain gastric pH above 6 to prevent clot/coagulum dissolution. In fact, Patchet et al found that “a rise in the pH…to 4 almost completely abolished the fibrinolytic activity in gastric juice.”

High-dose, twice-daily oral PPIs have been shown to maintain intragastric pH above 4 for 70% to 90% of the time administered (weighted mean, 83%). An English-language MEDLINE search to October, 2009 employing the terms proton pump inhibitor and oral and intravenous was used to discover published studies comparing oral and IV bolus followed by infusion PPI therapy in the management of bleeding peptic ulcers. Murthy et al retrospectively compared oral PPI therapy, at least 40 mg omeprazole or equivalent dose of another PPI daily, versus IV pantoprazole, and found no differences in the need for blood transfusions or time to discharge. Intravenously treated patients were significantly more likely to require surgery for bleeding control. In small prospective studies published in abstract form, Kim et al found no differences in duration of hospitalization, units of blood transfused, rebleeding, need for surgery or mortality in patients given oral rabeprazole, 20 mg twice daily, versus those treated with IV omeprazole; and Jang et al found treatment with oral pantoprazole, 40 mg twice daily, was associated with similar rates of rebleeding, endoscopy, mortality and blood transfusion as IV pantoprazole. Thus, none of the 4 studies comparing IV bolus followed by infusion and oral PPIs in patients with bleeding peptic ulcers found an outcome advantage of IV therapy (Table 4).

The study has a number of limitations. Salient is its retrospective design. There are no prospective comparisons of oral versus IV bolus followed by infusion PPI therapy in patients with bleeding peptic ulcers published in full, peer-reviewed form. The most important limitation of the study is its suboptimal power, because of which its findings cannot justify a change in clinical practice. The findings do, however, suggest that a large, prospective comparison of oral and IV PPIs in patients with peptic ulcers is warranted. In the present study, patients in the PO and IV groups were managed noncontemporaneously. Those in the PO group were hospitalized between 1997 and 2005. Those in the IV group were admitted between 2002 and 2008. Any advancements in the management of patients with gastrointestinal bleeding during the patient accrual period would bias the study in favor of the more recently managed IV group. Significantly more patients in the PO group were treated endoscopically with epinephrine injection only. Epinephrine injection alone has been found to be associated with higher rebleeding rates than combination treatment with epinephrine and hemoclip or bipolar electrocautery application. Lo et al also found a higher rate of emergency surgery in patients treated with epinephrine alone. More utilization of the less effective epinephrine injection alone in the PO group biases the present study in favor of the IV group. Hemoclips were used significantly more often in the IV group in this study. In fact, hemoclips were unavailable for the entire time period from which data for the PO group were collected. Studies have shown the hemoclip to be a useful tool in achieving and maintaining hemostasis in patients with bleeding peptic ulcers. Availability and utilization of an additional tool to achieve permanent hemostasis also biases the present study in favor of the IV group.

A large scale and adequately powered prospective prospective, randomized clinical trial would be helpful to verify the findings of this study.

Using outcomes data reported in 6 previously published studies of oral or IV PPI therapy in patients with bleeding peptic ulcers, Erstad found therapeutic endoscopy coupled with IV therapy marginally more cost-effective than therapeutic endoscopy coupled with oral therapy. However, none of the studies from which data were gleaned were head-to-head comparisons of IV versus oral therapy. Thus, IV and PO groups were from disparate and, therefore not necessarily comparable, populations. Further, since the studies were carried out in various parts of the world, differences in medical care may well have been confounding. Finally, Erstad’s conclusion was the direct result of assumptions that the probabilities of recurrent bleeding and need for surgery were greater with oral than IV therapy, assumptions
### Table 4. Studies of Oral (PO) versus Intravenous (IV) Proton Pump Inhibitors (PPIs) in Endoscopically Treated Patients with Bleeding Peptic Ulcers

<table>
<thead>
<tr>
<th>Study Characteristic</th>
<th>Murthy et al(^1) 12  n=162</th>
<th>Kim et al(^3) 13 n=45</th>
<th>Jang et al(^4) 14 n=40</th>
<th>Henry et al</th>
</tr>
</thead>
<tbody>
<tr>
<td>Design</td>
<td>retrospective</td>
<td>prospective</td>
<td>prospective</td>
<td>retrospective</td>
</tr>
<tr>
<td>Patients, n</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PO group</td>
<td>72</td>
<td>23</td>
<td>20</td>
<td>87</td>
</tr>
<tr>
<td>IV group</td>
<td>90</td>
<td>22</td>
<td>20</td>
<td>87</td>
</tr>
<tr>
<td>PPI and dose</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PO group</td>
<td>Omeprazole, ≥40 mg/day or equivalent</td>
<td>Rabeprazole (n=82) 20 mg BID</td>
<td>pantoprazole 40 mg BID</td>
<td>pantoprazole 80 mg BID or lansoprazole 60 mg BID or omeprazole 40 mg BID</td>
</tr>
<tr>
<td>IV group(^a)</td>
<td>pantoprazole (n=82) other (n=8)</td>
<td>omeprazole</td>
<td>pantoprazole</td>
<td>pantoprazole (n=86) esomeprazole (n=1)</td>
</tr>
<tr>
<td>Rebleeding, (%)</td>
<td>not given</td>
<td>not given</td>
<td>1.1</td>
<td>1.1</td>
</tr>
<tr>
<td>P Value</td>
<td>N/A</td>
<td>N/A</td>
<td>not significant</td>
<td>.85</td>
</tr>
<tr>
<td>Red-cell transfusions, mean units</td>
<td>not given</td>
<td>2.4</td>
<td>1.9</td>
<td>1.7</td>
</tr>
<tr>
<td>P Value</td>
<td>N/A</td>
<td>.58</td>
<td>not significant</td>
<td>.22</td>
</tr>
<tr>
<td>No of endoscopies, mean</td>
<td>not given</td>
<td>not given</td>
<td>1.8</td>
<td>1.1</td>
</tr>
<tr>
<td>P Value</td>
<td>N/A</td>
<td>N/A</td>
<td>not significant</td>
<td>.85</td>
</tr>
<tr>
<td>Surgery, (%)</td>
<td>2</td>
<td>4</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>P Value</td>
<td>.23</td>
<td>1.0</td>
<td>1.0</td>
<td>.99</td>
</tr>
<tr>
<td>Duration of hospitalization, mean days</td>
<td>not given</td>
<td>8.3</td>
<td>not given</td>
<td>3.8</td>
</tr>
<tr>
<td>P Value</td>
<td>N/A</td>
<td>.2</td>
<td>N/A</td>
<td>.85</td>
</tr>
<tr>
<td>Readmission for bleeding, (%)</td>
<td>5</td>
<td>not given</td>
<td>not given</td>
<td>5</td>
</tr>
<tr>
<td>P Value</td>
<td>&gt;.2</td>
<td>N/A</td>
<td>N/A</td>
<td>.21</td>
</tr>
<tr>
<td>Mortality, (%)</td>
<td>2</td>
<td>4</td>
<td>5.9</td>
<td>5</td>
</tr>
<tr>
<td>P Value</td>
<td>&gt;.2</td>
<td>1.0</td>
<td>not significant</td>
<td>.37</td>
</tr>
</tbody>
</table>

Abbreviations: BID, twice daily; N/A, Not Applicable.

\(^a\) IV PPI dose = 80-mg bolus followed by 8 mg/hour infusion.
In a more recent cost-effectiveness modeling analysis Spiegel et al found similar rebleding rates reported in the literature in endoscopically treated patients given oral (2% to 27%) and IV (6% to 24%) PPIs, but used expert opinion derived rebleding estimates of 13% and 6% for patients treated with PO, and IV PPIs, respectively, in their comparative calculations. They found that using IV instead of oral PPI therapy would cost $708 735 to gain 1 quality-adjusted life-year and concluded, “The higher effectiveness of IV PPI therapy may not offset its increased costs...” and, “The... budget impact of IV PPIs exceeds most benchmarks.” Had the authors assumed similar rebleeding rates for IV and oral PPIs, as might be suggested by the literature, oral therapy would have been decisively more cost-effective.

In conclusion, the findings of the present study, coupled with those of three smaller, congruent studies, suggest that high-dose, twice-daily oral PPI therapy could safely replace IV bolus followed by infusion therapy in endoscopically treated patients with bleeding peptic ulcers. Prospective comparison in a large study is called for.

REFERENCES

Acute Disseminated Intravascular Coagulation Following Bone Marrow Biopsy in Metastatic Prostate Cancer: A Case Report

ABSTRACT

Conversion of chronic disseminated intravascular coagulation (DIC) to acute, high-grade DIC has been reported after biopsy of primary or metastatic prostate cancer sites. It has been postulated that this occurs due to the thromboplastic substances released into the bloodstream following biopsy, which has prompted consideration of alternative means of diagnosis, such as bone marrow biopsy. We describe a case in which chronic DIC became acutely decompensated following bone marrow biopsy, suggesting that biopsy of any involved tissue in chronic DIC patients can lead to the immediate release of coagulation mediators that are capable of overwhelming the compensatory mechanisms maintaining a subclinical level of DIC, and that diagnostic bone marrow biopsy, performed in the context of known or unknown metastatic prostate cancer, may also confer the risk of conversion to fulminant DIC.

CASE REPORT

A 90-year-old man with multiple chronic medical issues and a known prostate nodule, presumed malignant on examination 7 years prior, visited his primary care provider for evaluation of recent-onset anorexia, fatigue, substantial weight loss, and general decline. The patient had previously declined pursuit of diagnosis or therapy because he remained asymptomatic despite nodule enlargement. The patient was admitted to the hospital, and preliminary testing revealed new, significant thrombocytopenia (platelet count 65 × 10^3/µL) and hypoproliferative anemia (hemoglobin 7.9 g/dL, reticulocyte count 68.6 × 10^3/µL, immature fraction 37.3%). Système International (SI) conversion factors for all relevant analytes to which this article refers are provided after the conclusion.

Upon admission, the patient denied any pain but was noted to have several ecchymoses scattered about his limbs and appeared dehydrated and generally unwell. Secondary investigations of the

Table. Summary of Laboratory Values before and after Procedural Intervention

<table>
<thead>
<tr>
<th>Analyte</th>
<th>4 hours prebiopsy</th>
<th>2.5 hours postbiopsy</th>
<th>11.5 hours postbiopsy, following transfusion therapy</th>
<th>~24 hours postbiopsy</th>
</tr>
</thead>
<tbody>
<tr>
<td>APTT, s</td>
<td>35.7</td>
<td>59.5</td>
<td>37.8</td>
<td>34.7</td>
</tr>
<tr>
<td>Fibrinogen, mg/dL</td>
<td>149</td>
<td>&lt;35</td>
<td>98</td>
<td>182</td>
</tr>
<tr>
<td>Hemoglobin, g/dL</td>
<td>9.3</td>
<td>7.2</td>
<td>8.1</td>
<td>10.6</td>
</tr>
<tr>
<td>INR</td>
<td>1.2</td>
<td>2.0</td>
<td>1.3</td>
<td>NA</td>
</tr>
<tr>
<td>Platelets, ×10^9/µL</td>
<td>45</td>
<td>30</td>
<td>42</td>
<td>68</td>
</tr>
</tbody>
</table>

Abbreviations: APTT, activated partial thromboplastin time; INR, international normalized ratio; NA, not available.

SI conversion factors: To convert fibrinogen to μmol/L, multiply values by 0.0294. To convert hemoglobin to g/L, multiply values by 10. To convert platelet count to ×10^9/L, multiply values by 1.
anemia and thrombocytopenia demonstrated no evidence for substrate deficiency, hemolysis, monoclonal gammopathy, or JAK-2 mutation. Additional testing showed fibrinogen concentration was low-normal (216 mg/dL), and D-dimer concentration was elevated at >4.5 µg/mL.

Initial coagulation markers were within reference range (activated partial thromboplastin time [aPTT], 27.6 seconds; international normalized ratio [INR], 1.0). Prostate-specific antigen (PSA) and carcinoembryonic antigen (CEA) measurements were ordered. Platelet count dropped further (nadir of 45 × 10^3/µL the day after admission), but then stabilized. Hemoglobin concentration had stabilized following transfusion (appropriate post-transfusion concentration of 10.0 g/dL and subsequent range between 9.1-9.8 g/dL).

It was posited that the patient had a chronic, compensated DIC, with prostate cancer as the likely causative agent. Hypoproliferative anemia was suspected owing to a combination of decreased erythropoietin production from renal insufficiency, chronic disease and inflammation, and consumption due to the compensated DIC. Upon stabilization, bone marrow biopsy was scheduled.

Four hours prior to the biopsy, laboratory tests found low fibrinogen concentration, mildly prolonged aPTT of 35.7 seconds, and an INR of 1.2. Hemoglobin concentration and platelet count remained low but stable. A summary of laboratory results at 4 hours before biopsy and at 2.5, 11.5, and 24 hours after biopsy is provided in the Table. PSA and CEA results were still pending.

The patient was feeling well and had no further development of ecchymoses or other evidence of bleeding. At 9:30 AM, a bone marrow biopsy was performed, with tissue obtained from the posterior iliac crest. A “moderate amount” of bleeding was noted with the procedure, which subsided with standard manual pressure application.

At 11:57 AM, the Medical Response Team was alerted to the patient's bedside due to the abrupt onset of copious bleeding. A scheduled wound check had revealed the biopsy site bandage to be saturated with blood. Removal of the dressing induced immediate and significant blood loss, resulting in a rapid decline of the patient's systolic blood pressure from 150 to 90 mm Hg over minutes. As fluid boluses were administered, the hematologist was contacted. The hematologist suspected decompensated DIC and ordered corresponding laboratory testing and blood bank products. The hematopathology service was contacted and reported initial findings of metastatic adenocarcinoma within the bone marrow aspirate.

Immediate laboratory results revealed a dramatic drop in fibrinogen and platelet concentrations, with a sudden prolongation of the aPTT. A single donor unit of platelets, 6 units of fresh frozen plasma, and a 10-pack of cryoprecipitate were administered over the ensuing hours. Hemoglobin concentration dropped to 7.2 g/dL, prompting transfusion of 2 additional units of packed red blood cells. Results of laboratory tests obtained later that afternoon showed an improvement in fibrinogen, platelet, and aPTT values. The patient continued to improve and had no further bleeding. Over the following 24 hours, fibrinogen concentration continued to increase, and platelet, hemoglobin, and aPTT stabilized at values compatible with those from pre-biopsy (49-68 × 10^3/µL, 10-10.6 g/dL, and 34.6-35.2 seconds, respectively).

In the following days, the diagnosis of metastatic prostate adenocarcinoma was confirmed by pathology (Figures 1 and 2). PSA concentration result was markedly elevated at 717 ng/mL. Medical Oncology initiated treatment. The patient continued to recover and was discharged to a nursing home with a fibrinogen concentration of 192 mg/dL, platelet count of 70 × 10^3/µL, and aPTT of 36 seconds. Nearly 1 month after hospitalization, following the resolution of acute decompensated DIC and initiation of palliative therapy for malignancy, the patient's fibrinogen (563 mg/dL), platelet (189 × 10^3/µL), and aPTT (25.5 seconds) values had normalized.

**DISCUSSION**

There appears to be a direct correlation between the conversion of this patient's chronic/compensated DIC to a fulminant DIC and the timing of the diagnostic bone marrow biopsy. The acute DIC...
resolved after the inciting procedural insult was completed and the initial therapeutic interventions had corrected the deranged hematologic parameters. The patient returned to his baseline level of chronic/compensated DIC more quickly than would be expected given the minimal amount of blood products that he received. The chronic DIC also improved with the initiation of treatment for the prostate malignancy, which was the presumed impetus for this pathology.

Acute DIC has been precipitated by direct manipulation of prostate tumor tissue during biopsy of the prostate gland, believed due to the release of increased amounts of thromboplastic agents produced by the cancer cells.1,2,7-9 Previous literature has suggested that to avoid precipitating acute DIC, less invasive diagnostic procedures should be considered, including fine-needle aspiration or bone marrow biopsy with the utilization of PSA immunohistochemical staining.1 In the case of our patient, chronic DIC became acutely decompensated following bone marrow biopsy, suggesting that biopsy of any involved tissue can lead to the immediate release of coagulation mediators capable of overwhelming the compensatory mechanisms maintaining a subclinical level of DIC.

Our experience demonstrates that close observation and the anticipation of adverse bleeding or clotting events in the periprocedural period is warranted in chronic DIC patients, particularly those with prostate cancer as the underlying diagnosis. It also suggests that bone marrow biopsy should not be considered an alternative diagnostic means that will minimize the risk of developing fulminant DIC in this patient population.

Further study is needed to elucidate the exact mechanisms behind the acute transition from subclinical to overwhelming DIC, and to identify other precipitating factors/markers for optimal monitoring and management of possible complications in these patients.

**Système International Conversion Factors**

Carcinoembryonic antigen: to convert to μg/L, multiply by 1.0.

D-dimer: to convert to nmol/L, multiply by 5.476.

Fibrinogen: to convert to μmol/L, multiply by 0.0294.

Hemoglobin: to convert to g/L, multiply by 10.0.

Platelet count: to convert to ×10⁹/L, multiply by 1.0.

Prostate-specific antigen: to convert to μg/L, multiply by 1.0.

Reticulocyte count: to convert to ×10⁹/L, multiply by 1.0.

**REFERENCES**


An Unusual Case of Cardiac Tamponade

ABSTRACT

Adult-onset Still disease (AOSD) is a rare inflammatory disorder that affects multiple organs. Pericarditis is described in approximately 20% to 40% of cases. However, cardiac tamponade is a rare complication of AOSD, with only 8 cases reported in the literature. We describe the case of a 19-year-old man with cardiac tamponade and acute respiratory failure requiring intubation and emergent pericardiostomy. His diagnosis, clinical course, and response to therapy are discussed followed by a review of the literature with an emphasis on therapeutic options.

A 19-year-old man came to us with a 1-week history of diffuse myalgias, arthralgias, and subjective fevers and chills. At the onset of his symptoms, he also had a sore throat. By the time he sought medical attention, he had developed left-sided chest pain and dyspnea on exertion. He was previously healthy with no known chronic medical conditions and no daily medications. Examination revealed a pericardial rub, sinus tachycardia, and a palpable hepatic margin. Arterial blood gas testing on room air revealed a pH of 7.44, PCO₂ of 31 mm Hg, and PO₂ of 55 mm Hg. Additional laboratory findings included leukocytosis, anemia, and thrombocytopenia (Table). Chest radiograph was significant for a left lower lobe infiltrate. Transsthoracic echocardiogram revealed a trivial pericardial effusion without tamponade. The patient was admitted, and therapy with ibuprofen 800 mg 3 times daily for pericarditis and intravenous ceftriaxone and azithromycin for presumed community-acquired pneumonia was initiated.

On hospital day 3, the patient developed increased chest pain and dyspnea. Chest radiograph revealed diffuse infiltrates. Repeat transthoracic echocardiogram was remarkable for a moderate circumferential pericardial effusion and signs of tamponade physiology including greater than 25% respiratory variation of mitral and tricuspid inflow and early diastolic inversion of the right and left atria. The patient was intubated in preparation for emergency surgery due to hemodynamic instability. Emergent pericardiostomy was performed with drainage of 750 mL of serosanguinous fluid from the pericardial space. The patient was then extubated though almost immediately re-intubated due to persistent hypoxia and respiratory failure. Bronchoscopy with bronchoalveolar lavage was then performed. No fungi or pneumocysts were seen on Gomori-Grocott methenamine silver (GMS) stain. Numerous neutrophils and macrophages were seen on Wright stain. No malignant cells were identified. Histopathologic examination of the pericardium revealed chronic fibrinous pericarditis. Aerobic, anaerobic, fungal, and acid-fast bacillus cultures of blood, fluid from bronchoalveolar lavage, and

ALT; 57 U/L) concentrations were slightly elevated, and lactate dehydrogenase (LDH) concentration was elevated at 479 U/L. Système International (SI) conversion factors for all relevant analytes to which this article refers are provided after the conclusion.

On hospital day 3, the patient developed increased chest pain and dyspnea. Chest radiograph revealed diffuse infiltrates. Repeat transthoracic echocardiogram was remarkable for a moderate circumferential pericardial effusion and signs of tamponade physiology including greater than 25% respiratory variation of mitral and tricuspid inflow and early diastolic inversion of the right and left atria. The patient was intubated in preparation for emergency surgery due to hemodynamic instability. Emergent pericardiostomy was performed with drainage of 750 mL of serosanguinous fluid from the pericardial space. The patient was then extubated though almost immediately re-intubated due to persistent hypoxia and respiratory failure. Bronchoscopy with bronchoalveolar lavage was then performed. No fungi or pneumocysts were seen on Gomori-Grocott methenamine silver (GMS) stain. Numerous neutrophils and macrophages were seen on Wright stain. No malignant cells were identified. Histopathologic examination of the pericardium revealed chronic fibrinous pericarditis. Aerobic, anaerobic, fungal, and acid-fast bacillus cultures of blood, fluid from bronchoalveolar lavage,
pericardial fluid were negative for growth. Following this infectious work-up, the pulmonary infiltrates were believed to be secondary to congestive heart failure.

The patient was transferred to the intensive care unit. Over the course of hospital days 4 through 6, the patient was diuresed and was extubated on hospital day 6. However, over this time he developed fevers to a maximum temperature of 39.1°C (Figure). An erythematous macular rash most prominent during febrile episodes was noted on the trunk and proximal lower extremities. An infectious disease physician was consulted, and testing for human immunodeficiency virus, Epstein-Barr virus, cytomegalovirus, influenza, enterovirus/coxsackie, adenovirus, parvovirus, Lyme disease, anaplasmosis/rickettsial panel, tularemia, chlamydia, brucellosis, Q fever, and fungal antibody panel returned negative. Only Histoplasma total antibody testing by enzyme immunoassay (EIA) was positive. Subsequent complement fixation/immunodiffusion immunoglobulin G (IgG) and immunoglobulin M (IgM) for Histoplasma returned negative, indicating that the result of the first test was a false positive.

The rheumatology service was consulted on hospital day 6. An antinuclear antibody (ANA) test returned weakly positive with a 1:40 titer. Anti-dsDNA antibody, extractable nuclear antigen antibodies (ENA) panel (anti-Smith, SSA, SSB, and RNP antibodies), rheumatoid factor, cytoplasmic antineutrophil cytoplasmic antibodies (c-ANCA), and perinuclear antineutrophil cytoplasmic antibodies (p-ANCA) returned negative. Ferritin returned significantly elevated at 11,888 ng/mL, as did the patient’s C-reactive protein concentration (295 mg/L) and erythrocyte sedimentation rate (ESR; 83 mm/hr). A diagnosis of adult-onset Still disease (AOSD) was made. The patient was started on intravenous methylprednisolone 80 mg every 8 hours and began to improve, with resolution of myalgias, arthralgias, and fevers. By hospital day 11, the patient was discharged home on prednisone 20 mg 3 times daily and ibuprofen 800 mg 3 times daily.

As part of an evaluation for a possible reactive hemophagocytic syndrome, the patient’s triglyceride concentration was noted to be slightly elevated at 208 mg/dL. The level of soluble interleukin-2 receptor (sIL-2R) was elevated at 3729 units/mL (reference range 45-1105 units/mL), and the natural killer (NK) cell activity was depressed at 2% (reference range >20%). Given the patient’s favorable clinical response as above to glucocorticoids and the absence of significant cytopenias (Table), a bone marrow biopsy was not performed.

### Table. Trend of Laboratory Values by Hospital Day a,b

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Reference Range</th>
<th>Hospital Day</th>
<th>2-month Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1 2 3 4 5 6 7 8 9 10 11</td>
<td></td>
</tr>
<tr>
<td>White blood cell count, /μL</td>
<td>3700-10 400</td>
<td>19 360 24 180 29 330 26 920 23 540 23 530 35 690 25 220 23 480 22 910 43 700</td>
<td>11 950</td>
</tr>
<tr>
<td>Neutrophils-segmented</td>
<td>44-79</td>
<td>66 34 52 60</td>
<td>75</td>
</tr>
<tr>
<td>Neutrophils-bands</td>
<td>0-11</td>
<td>21 61 38 25</td>
<td>31</td>
</tr>
<tr>
<td>Lymphocytes</td>
<td>19-45</td>
<td>6 6 3 4</td>
<td>1</td>
</tr>
<tr>
<td>Monocytes</td>
<td>0-11</td>
<td>2 1 1 2</td>
<td>1</td>
</tr>
<tr>
<td>Eosinophils</td>
<td>0-5</td>
<td>0 0 0 1</td>
<td>0</td>
</tr>
<tr>
<td>Hemoglobin, g/dL</td>
<td>13.6-16.7</td>
<td>11.1 11.1 10.1 10.0 9.8 9.9 10.3 10.8 10.4 11.1 11.9 11.6</td>
<td></td>
</tr>
<tr>
<td>Platelet count, ×10^5/μL</td>
<td>140-385</td>
<td>163 123 123 96 95 151 233 352 417 449 505 229</td>
<td></td>
</tr>
<tr>
<td>Ferritin, ng/mL</td>
<td>29-322</td>
<td>11 888</td>
<td>1920 2285 278</td>
</tr>
<tr>
<td>ESR, mm/h</td>
<td>0-15</td>
<td>83 58 53</td>
<td>46 27</td>
</tr>
<tr>
<td>CRP, mg/dL</td>
<td>0.0-8.0</td>
<td>295 231</td>
<td>89</td>
</tr>
</tbody>
</table>

Abbreviations: ESR, erythrocyte sedimentation rate; CRP, C-reactive protein.

SI conversion factors: To convert white blood cell count to ×10^9/L, multiply values by 0.001. To convert polymorphonuclear leukocytes, bands, lymphocytes, monocytes, and eosinophils to proportion of 1.0, multiply values by 0.01. To convert hemoglobin to g/L, multiply values by 10.0. To convert platelet count to ×10^9/L, multiply values by 1.0. To convert ferritin to pmol/L, multiply values by 2.247. To convert CRP to nmol/L, multiply values by 9.524.

Data are presented as % unless otherwise indicated.

Blank cells indicate that laboratory test results were not available for that day.
However, the patient was readmitted within 24 hours due to worsening diffuse myalgias, arthralgias, and pleuritic chest pain. He was treated with intravenous methylprednisolone 1 g daily for 3 days. The patient was discharged home on hospital day 5 on a regimen of prednisone 40 mg twice daily and ibuprofen 800 mg 3 times daily. His prednisone and ibuprofen doses were tapered over the next 3 months; however, the patient developed a recurrence of fever, sore throat, and diffuse myalgias when his prednisone dose reached 5 mg daily. His dose of prednisone was increased to 40 mg daily, and ibuprofen was increased to 800 mg 3 times daily. Subcutaneous etanercept 50 mg weekly was initiated shortly thereafter and prednisone again tapered.

Since that time, the patient has done well, with the exception of a hospitalization for acute pericarditis requiring the restart of prednisone and nonsteroidal anti-inflammatory drugs (NSAIDs). During the hospitalization, the patient did report myalgias and arthralgias, but he did not develop fever or rash. Transthoracic echocardiogram at that time revealed interventricular septal bounce and a fixed appearance of the apical portion of the right ventricle consistent with early constriction. Continued observation was recommended given the subclinical nature of the findings; however, pericardiectomy may be required in the future if the patient becomes symptomatic. At present, nearly 2 years since he came to us, the patient has tapered off prednisone and NSAIDs and is asymptomatic on etanercept monotherapy.

**DISCUSSION**

Adult-onset Still disease is a rare systemic inflammatory disorder. This syndrome was first described by Sir George Still in children in 1897 and nearly a century later in adults. The estimated prevalence is 1 to 10 cases per million. Predominant disease onset is between the ages of 16 and 35 years, although a bimodal distribution has also been noted with a second peak between the ages of 36 to 45 years.

The cardinal symptoms of AOSD include quotidian fevers typically of 39°C or greater (seen in 82%-100%), arthralgias (95%-100%), and an evanescent, salmon-colored rash more prominent during febrile episodes (77%-100%). These symptoms may be preceded by other constitutional symptoms and sore throat. Pericarditis among AOSD patients has been described in approximately 20% to 40% of cases. However, cardiac tamponade remains a rare complication of AOSD, with only 8 cases reported in the literature.

Adult-onset Still disease remains a diagnosis of exclusion. The most widely validated criteria for AOSD are the Yamaguchi criteria, which have a 93.5% sensitivity and 92.1% specificity for the diagnosis of AOSD based on a comparative study of 6 sets of criteria by Masson et al. The major criteria include intermittent fever of at least 39°C for 1 week or longer, arthralgias for 2 weeks or longer, characteristic skin rash, and leukocytosis with at least 80% granulocytes. The minor criteria include sore throat, lymphadenopathy, hepatosplenomegaly, elevated AST, ALT, and LDH, and negative antinuclear antibodies/rheumatoid factor (ANA/RF). Diagnosis requires the presence of 5 criteria including 2 major criteria.

Laboratory evaluation reveals markedly elevated inflammatory markers. Serum ferritin concentrations of 3000 to 30 000 ng/mL are not uncommon. Increased release of ferritin from the histiocyte-macrophage system and from damaged hepatocytes as well as increased production induced by the cytokine milieu are...
thought to be responsible for the elevated ferritin levels. Although an elevated ferritin of 1000 ng/ml or greater has an 80% sensitivity for AOSD, it carries only a 41% specificity. In a retrospective review by Lee et al., 6.7% of the 1826 serum ferritin assays performed over a 1-year period in a hospital setting were ≥1000 ng/ml. Associated clinical syndromes included liver disease, renal disease, malignancy, HIV, non-HIV systemic infections, chronic transfusions, and sickle cell syndromes.

A reduction in the fraction of glycosylated ferritin is also seen in AOSD. This commonly falls below 20% (normal 50%-80%) in patients with AOSD due to saturation of glycosylation mechanisms and lower clearance of non-glycosylated proteins. A newer set of diagnostic criteria including the glycosylated fraction of ferritin has been proposed by Fautrel et al.; however, further validation and greater availability of the test will be required before widespread use can be adopted.

Other laboratory abnormalities in AOSD include marked leukocytosis secondary to bone marrow granulocyte hyperplasia, normocytic anemia, reactive thrombocytosis, and elevated AST, ALT, and LDH. In contrast, cytopenias in the setting of pronounced hyperferritinemia should raise concern for reactive hemophagocytic syndrome (RHS) which not uncommonly presents concomitantly with AOSD. Reactive hemophagocytic syndrome is characterized by NK cell dysfunction and uncontrolled immune activation with proliferation of activated T lymphocytes and macrophages and resultant hemophagocytosis and cytokine storm. It has been proposed that evidence of depressed NK cell activity can help to identify patients at risk of developing RHS. The levels of sIL-2R and CD163 are also often elevated due to shedding from the surface of activated T cells and macrophages. Although these may be useful markers, the diagnosis of RHS is usually based on evidence of hemophagocytosis on bone marrow biopsy. However, published data regarding AOSD-associated RHS remains limited, and there are not validated diagnostic criteria at this time.

In a retrospective study by Hot et al., 8 of 52 patients with AOSD (15.3%) developed RHS. Cases of AOSD-associated RHS were diagnosed based on unexplained progressive cytopenia involving at least 2 cell lines, identification of hemophagocytic histiocytes on examination of bone marrow, liver, or lymph nodes, occurrence during an active phase of AOSD, and effective treatment with agents targeted at AOSD. The clinical and laboratory findings in AOSD patients with and without RHS were also compared. Statistically significant findings in the RHS group included more frequent splenomegaly and lymphadenopathy, pancytopenia, lower fibrinogen and haptoglobin levels, and higher transaminases, triglycerides, and ferritin.

The clinical course of AOSD tends to follow 1 of 3 patterns, with approximately a third of patients falling into each group. The self-limited pattern manifests with a single disease episode and a median time to remission of 9 months. The polycyclic pattern is marked by recurrent disease flares. The chronic articular pattern is characterized by prolonged periods of active disease eventually resulting in ankylosing (often carpal) arthritis.

Uncertainty surrounding the pathogenesis of AOSD remains. Some studies have demonstrated an association between AOSD and certain human leukocyte antigen (HLA) alleles, suggesting a potential genetic predisposition. Infectious agents acting as a trigger have been proposed, although none has been substantiated to date. What has been repeatedly demonstrated is that patients with AOSD have significantly elevated levels of interleukin (IL)-1, -6, and -18, tumor necrosis factor (TNF), and Type II interferon (IFN-γ) in the serum.

Recommendations for treatment of AOSD are largely based on observational studies because no randomized, double-blind, placebo-controlled trials have been completed. First-line therapies include NSAIDs and corticosteroids, which yield 10% to 20% and 60% to 80% response rates respectively. Second-line therapy includes disease-modifying antirheumatic drugs (DMARDs), primarily methotrexate. Third-line therapy includes biologic agents that target TNF, IL-1, and IL-6.

The utility of anti-TNF agents in refractory AOSD was investigated in a retrospective review by Fautrel and colleagues. Twenty patients were identified, 10 of whom received infliximab and 5 of whom received etanercept. Five patients received both agents in succession. All of the patients had previously been treated with prednisone and methotrexate. Eighteen patients continued on prednisone during the study period, and 17 remained on a DMARD. Complete remission, which was defined as resolution of all clinical AOSD-related symptoms, was achieved in 5 patients. Failure to respond was observed in 4 patients. The remainder achieved partial remission. However, upon final follow-up at 13 months, the anti-TNF agent had been withdrawn in nearly 70% of cases, predominantly due to lack or loss of efficacy. Increased optimism with regard to the anti-TNF agents was raised in an open-label trial by Husni et al. of 12 patients with refractory AOSD treated with etanercept. The mean number of prior DMARDs used in this cohort was 2.5. Five patients continued on a DMARD during the study period, and 9 continued on prednisone. Of the 10 patients who completed the study, clinical response based on the ACR20 scoring system indicating 20% improvement in arthritis and inflammatory scores as defined by the American College of Rheumatology was achieved in 70%.

Therapy with the IL-1 receptor antagonist anakinra is also being explored. In a retrospective review by Lequerre et al. of 15 patients, all of whom had previously been treated with corticosteroids and methotrexate and 10 of whom had been treated with anti-TNF agents, 73% achieved a significant response defined by the ACR20 to anakinra. In a report by Naumann et al., 8 of 8 patients with refractory AOSD achieved sustained remission (minimum follow-up of 9 months) with anakinra. Four of these patients required continued concomitant therapy with DMARDs. Investigation into longer-acting IL-1 blockers is also underway with the emergence of rilonacept, a soluble decoy receptor that binds IL-1β and IL-1α and has a half-life of 8.6 days, and canakinumab, a monoclonal antibody against IL-1β with a half-life of 26 days that is effective in juvenile inflammatory arthritis.

Therapy with tocilizumab (TCZ), a humanized monoclonal antibody against the IL-6 receptor, has also been found to be of benefit in refractory cases of AOSD. Puechal and colleagues reported their experience with 14 patients with refractory AOSD treated with TCZ. In 4 of the patients, TCZ was used as monotherapy. All of the patients had previously been treated with corticosteroids, methotrexate, and anakinra, and 12 had also been treated with anti-TNF agents. European League Against Rheumatism (EULAR) remission, defined as a Disease Activity
Score in 28 joints (DAS28) less than 2.6, was achieved in 36% of patients at 3 months, and in 57% at 6 months. Systemic symptoms resolved in 86% of patients.

The above investigations support a role for biologic therapy in the treatment of refractory AOSD. Evidence-based determinations of which patients are most likely to benefit from biologic therapy as well as the appropriate timing of biologic therapy will require further investigation.

**CONCLUSION**

Adult-onset Still disease is a rare disorder and presentation with cardiac tamponade is even less common. Diagnosis in our patient was guided by the Yamaguchi criteria after infectious and neoplastic processes had been ruled out. Our patient’s sustained response to TNF blockade illustrates the potential usefulness of this approach even in the setting of AOSD associated with life-threatening complications.

**Système International Conversion Factors**

- Alanine aminotransferase: to convert to $\mu$kat/L, multiply value by 0.0167.
- Alkaline phosphatase: to convert to $\mu$kat/L, multiply value by 0.0167.
- Aspartate aminotransferase: to convert to $\mu$kat/L, multiply value by 0.0167.
- C-reactive protein: to convert to nmol/L, multiply value by 9.524.
- Ferritin: to convert to pmol/L, multiply value by 2.247.
- Lactate dehydrogenase: to convert to $\mu$kat/L, multiply value by 0.0167.
- Triglycerides: to convert to mmol/L, multiply value by 0.0113.

**REFERENCES**

Right Ventricle Stab Wound from Eyeglass Sidearm

ABSTRACT
Penetrating cardiac trauma is usually caused by stabbing or gunshot. These injuries are extremely serious and have a high mortality rate. We describe a case of penetrating cardiac trauma with an unusual cause.

The incidence of penetrating cardiac injury in the National Trauma Data Bank is 0.16%. The overwhelming majority of these injuries result from gunshot wounds and stab wounds. Penetrating cardiac trauma is a highly lethal injury, with relatively few victims surviving long enough to reach the hospital. In the case report to follow, we present an unusual mechanism of penetrating cardiac injury.

CASE REPORT
A 55-year-old prison inmate came to us as a trauma activation with foreign body impalement to the anterior chest. He reportedly rolled out of bed and fell onto his eyeglasses. He complained of chest pain but denied shortness of breath. Upon arrival, he was alert and talking, had clear breath sounds bilaterally, and had a blood pressure of 160/98 mm Hg and pulse of 52 beats per minute. There was no external hemorrhage or jugular venous distention. A thin, metallic object protruded from the anterior chest just to the left of midline and cephalad to the xiphoid (Figure 1). Computed tomography (CT) scan demonstrated penetration of the right ventricle with moderate pericardial effusion (Figure 2). He was transferred to the operating room and underwent subxiphoid pericardial window with evacuation of 100 cc of clotted blood. The foreign body penetrated the right ventricular wall and was removed under direct vision. There was no bleeding after extraction. A 24 French Blake drain was placed in the pericardial space. The foreign body was a metal eyeglass sidearm measuring 11.7 cm in length by 0.1 cm in diameter, and the penetrating end had been sharpened to a point (Figure 3). The postoperative course was unremarkable. An echocardiogram on postoperative day (POD) 2 demonstrated scant pericardial effusion with normal ventricular function. The pericardial drain was removed on POD 2, and the patient was discharged the following day.

Figure 1. Photograph of foreign body protruding from the anterior chest.
Figure 2. Sagittal (A) and axial (B) views from a CT scan demonstrating foreign body penetration of the right ventricle with moderate pericardial effusion.

Figure 3. Foreign body (gross pathology) removed from right ventricle.
DISCUSSION
Most penetrating cardiac trauma is the result of stab wounds and gunshot wounds. In a review of 711 patients with penetrating cardiac trauma, Wall et al reported 54% stab wounds and 42% gunshot wounds, with an overall mortality rate of 47%. Several unusual mechanisms of penetrating cardiac injury have previously been reported, including those resulting from nail guns, hammer splinters, and spectacles.

The potential danger of ordinarily benign items in a person’s possession must be considered, especially in psychiatric hospitals and correctional facilities. A case similar to our case involved a 53-year-old inmate with a self-inflicted laceration to the right ventricle using the broken sidearm of the frame of his eyeglasses. He presented with unstable vital signs and clinical signs of cardiac tamponade; he underwent successful median sternotomy for right ventricular repair.

Our case of right ventricular penetration from a thin, sharp, metallic object is similar to nail gun injuries to the heart. Penetrating cardiac injuries from nail guns are not uncommon in the construction industry. Nail guns first came into use in 1959 and found widespread acceptance in the 1960s. They can be subdivided into high- and low-velocity types (> or <150 m/s, respectively). High-velocity nail guns require an explosive cartridge to directly propel the nail. Low-velocity nail guns accelerate the nail indirectly through a piston powered by a compressed air cartridge. The right ventricle is the most commonly injured cardiac chamber owing to its anterior location in the thorax. Treatment of these injuries has most often required operative exploration. A 25% mortality rate was reported in a series of 16 patients who sustained cardiac nail gun injuries.

Although caused by projectiles, nail gun injuries behave more like stab wounds than gunshot wounds for 2 reasons. First, the radial kinetic energy of a nail is minimal compared with that of a bullet, so the blast effect and surrounding tissue damage are limited. Second, due to their elongated form, nails have a very small frontal cross-sectional area, which focuses their impact force on a small region. Thus, the reported mortality from cardiac nail gun injuries is closer to that of stab wounds than gunshot wounds. Nail gun safety mechanisms have been developed to reduce the rate of inadvertent injury. A force greater than 22 newtons above the weight of the tool must be applied to the firing surface of the nail gun in order for it to fire. In addition, an angle of less than 8 degrees must exist between the firing surface and receiving surface.

Management of unusual mechanisms of penetrating chest trauma, as described in our case report, may require diagnostic evaluation not typical of most mechanisms of penetrating chest trauma. Computed tomography of the chest is rarely needed in the acute management of penetrating chest trauma from gunshot wounds or stab wounds; however, in the context of a hemodynamically normal patient with foreign body impalement to the anterior chest, the chest CT may be valuable to determine the depth of penetration of the foreign body. This information becomes important in choosing the ideal setting in which to remove the foreign body. With evidence of penetration of a cardiac chamber, the foreign body should be removed in the operating room, where equipment is readily available for median sternotomy and cardiac repair if necessary. In contrast, if the chest CT reveals that penetration of the foreign body is limited to the chest wall, removal in the emergency department setting is appropriate.

CONCLUSION
We have presented a case of cardiac penetrating trauma from an unusual mechanism. The patient was hemodynamically stable, allowing for a diagnostic chest CT scan, which clearly demonstrated a moderate amount of pericardial fluid and foreign body penetration of the right ventricle. This foreign body was able to be removed under direct vision through an open subxiphoid pericardial window in the operating room. Had the patient experienced significant ongoing hemorrhage, a median sternotomy would have been necessary for control and repair of the cardiac injury. In this case, there was no active hemorrhage after foreign body removal, and no right ventricular repair was necessary.

REFERENCES
Patients are often referred to the general surgeon for the excision of presumed benign skin lesions. Primary care providers and surgeons are generally quite adept at identifying lesions that have a risk for malignancy; however, a histologic review frequently reveals an unexpected diagnosis leading to the need for further intervention. This case illustrates an example of chondroid syringoma (CS), typically referred to as mixed tumor of the skin (MTS). The mixed tumor designation is derived from the cellular admixture of epithelioid and stromal components as seen histologically. Most commonly, it arises in the head and neck but can occur anywhere in the body. Malignant transformation has been described.

**CASE REPORT**

A 66-year-old man was seen in consultation in our institution’s general surgery clinic on a referral from his primary care provider for a lesion on his medial right lower leg. The patient had noted the presence of this lesion for 1 year, over which time he has had an intentional 30-pound weight loss, making it more prominent. The lesion was asymptomatic, aside from some discomfort when kneeling. He had a history of a benign lipoma removed from his back a decade prior. Review of symptoms and history were otherwise unremarkable. Upon examination, the lesion was freely mobile, non-tender, and had no associated skin changes. Regional adenopathy was not present. Excision was recommended, with dermal cyst as the presumed diagnosis.

A 20 × 4-mm ellipse of skin and a firm cutaneous nodule were shelled out en bloc, aside from one deep extending pedicle that was ligated. The specimen consisted of a 2.4 × 2.0 × 1.3-cm rubbery, pink-white, nodular mass with a solid, glistening, tan-white cut surface. Histologic examination demonstrated well-circumscribed, lobulated proliferation of mixed epithelial and spindle cells with myxoid and focally chondroid background, without cytologic atypia or necrosis (Figures 1 and 2). The neoplasm extended focally to the specimen edges. The diagnosis was benign MTS.

Re-excision for margins was discussed with the patient given the low potential for malignancy. He opted for close clinical follow-up. At 6-month follow-up there had been no clinical sign of regrowth of the lesion or adenopathy.

**Figure 1.** Low-magnification view of MTS showing a well circumscribed fibrous capsule (arrow) surrounding mixed cellular components.
The incidence of MTS is 0.098% of skin nodules excised based upon a review of histopathologic diagnosis of all skin lesions submitted to one institution over a 17-year period. This revealed a woman-to-man ratio of 0.6 and an average age of 42.8 years. Of the 16 MTS identified, 1 was on an upper extremity, and the remaining were in the head and neck region. The differential diagnosis for similarly presenting skin lesions is protean, but does include dermal or sebaceous cysts, dermatofibroma, neurofibroma, hystiocytoma, pylomatricomas, and various carcinomas, such as basal cell. The most certain way to confirm diagnosis is with histopathologic examination. At our institution, approximately 10 to 12 excised skin lesions clinically thought to be benign are upgraded to a malignant diagnosis each year. An important aspect to making this diagnosis and assessing margin status is delivering a specimen that has intact architecture to allow for complete histopathologic examination. Certain biopsy techniques, such as curettage or shave, do not allow for this, as opposed to the ellipse technique used in this instance.

The histopathologic diagnosis, along with specific lesion type and indications for further therapy, should be reviewed with the patient. In the case of MTS, it is generally benign if cytologic atypia or necrosis are not present. Given the low potential for malignant transformation, excision to negative margins is recommended. Conversely, malignant MTS requires tumor resection and regional nodal dissection.

**CONCLUSION**

Mixed tumor of the skin is a rare lesion with low malignant potential. Histopathology can reveal features that indicate worse prognosis and guide clinicians and patients in the decision for further therapies. The malignant potential of MTS and numerous other skin lesions is difficult to ascertain grossly, underscoring the need for histopathologic examination of an intact specimen in order to separate those with malignant potential from benign lesions. This information will allow the clinician to have a more informed discussion with the patient in order to guide treatment options.

**REFERENCES**

A Case of a Cervical Sympathetic Chain Schwannoma

ABSTRACT

Importance: Schwannomas are uncommon benign neoplasms arising from Schwann cells, which make up the nerve sheath. They can involve peripheral, cranial, or autonomic nerves throughout the body. Most patients are asymptomatic or have vague complaints. There are few reports on the presentation and management of cervical chain schwannoma.

Observations: We describe the case of a patient with a cervical sympathetic chain schwannoma who came to us with progressive dysphagia.

Conclusion: Cervical sympathetic chain schwannomas are rare tumors that can be managed surgically and should be considered as part of the differential diagnosis in patients presenting with a neck mass and Horner syndrome.

A schwannoma is a benign neoplasm arising from Schwann cells, which make up the nerve sheath. With the exception of the olfactory and optic nerves, they can involve peripheral, cranial or autonomic nerves throughout the body. Although schwannomas are an uncommon source of neck masses, 25% to 45% of schwannomas are found in the head and neck region. Studies have reported involvement of cranial nerves IX, X, XI, and XII, and the cervical sympathetic chain (CSC). Schwannomas are often benign, slow growing, and well encapsulated. Most begin as an asymptomatic mass; however, pain, dysphagia, hoarseness, and dyspnea have been reported. Various imaging studies, such as ultrasonogram, computed tomography (CT) scan, and magnetic resonance imaging (MRI) scan, may be utilized in evaluation and diagnosis. Surgical excision is the treatment of choice. We present a case of CSC schwannoma with progressive dysphagia as the initial symptom.

CASE REPORT

A 54-year-old woman with a longstanding history of gastroesophageal reflux disease came to us with a 1-year history of progressive solid food dysphagia. She had been on proton pump inhibitors intermittently for her reflux. Her past medical history was significant for coronary artery disease, atrial fibrillation, non–insulin-dependent diabetes mellitus, and obesity. Her medications included aspirin, digoxin, glyburide, hydrochlorothiazide, metoprolol, omeprazole, simvastatin, warfarin, and paroxetine. Her only prior surgeries were tubal ligation and cholecystectomy. She had a 15 pack-year smoking history and had quit 3 years prior to her visit. She had no family history of dysphagia, malignancies, or thyroid pathology.

Physical examination revealed a nontender, mobile mass in the right paratracheal region with no regional lymphadenopathy. Results of a flexible fiberoptic examination of the nasopharynx,

Figure 1. Esophagram showing extraluminal compression of the esophagus by the thyroid mass.
oropharynx, hypopharynx, supraglottis, and glottis were normal. A standard esophagram showed extraluminal compression of the cervical esophagus resulting in approximately 50% stenosis of lumen (Figure 1). A CT scan showed a 2.7 × 3.1 × 4.1-cm mass in the right tracheoesophageal groove (Figure 2). An ultrasonogram showed similar findings, with the mass adjacent to but distinct from the right thyroid gland.

Fine-needle aspiration (FNA) of the lesion revealed spindle cell proliferation of varying degrees of cellularity, mild nuclear enlargement, and pleomorphism consistent with schwannoma. The mass was removed via an oblique incision at the anterior border of the sternocleidomastoid muscle on the right. It was dissected off the esophagus and posterior aspect of the right thyroid lobe medially and the common carotid artery and internal jugular vein laterally (Figure 3).

Intraoperative monitoring of the recurrent laryngeal nerve on the right was used during the procedure. The nerve was preserved (Figure 4). The mass was noted to originate from the sympathetic trunk and was resected without transecting the nerve.

The patient's postoperative course was uneventful, and she was discharged on postoperative day 1 without any complications.

**DISCUSSION**

Schwannoma of the CSC is rare, with fewer than 50 cases reported, and most patients have an asymptomatic or vague presentation. Although neurological symptoms are uncommon, Horner syndrome (ptosis, miosis, and anhydrosis) is the most common for CSC schwannomas. In a study of 28 patients with benign solitary schwannomas, 57% (4 of 7) with CSC schwannomas had Horner syndrome. In another study of 4 patients with CSC schwannomas reported by Wax et al, 1 patient had Horner syndrome. Our patient's primary symptom was progressive dysphagia, which has not been reported in the literature as the symptom first prompting patients with CSC schwannomas to seek care.

Various radiographic modalities have been used for diagnosis of schwannomas, with MRI scans reported as the most reliable and consistent. The role of FNA is controversial because the accuracy of its results depends upon an adequate tissue sample and the expertise of the pathologist. In a retrospective study of 21 patients with head and neck schwannomas conducted by Langner et al, FNA gave an inconclusive diagnosis in 75% of cases and a different diagnosis from the final surgical specimen in the remaining 25%. In another study, FNA provided a definite diagnosis in 20% of patients and suggested the diagnosis in another 30% based on the presence of spindle cells. For our patient, the FNA and the results of immunohistochemistry testing were helpful and provided a diagnosis preoperatively.
CERVICAL SYMPATHETIC CHAIN SCHWANNOMA

The location of the CSC in relation to other structures in the neck can help differentiate it from a schwannoma originating from the vagus nerve, thus aiding in the differential diagnosis.2,8 The CSC is in the parapharyngeal space and is posterior to the carotid sheath. A CSC schwannoma will displace the common carotid artery and internal jugular vein laterally, unlike a schwannoma arising from the vagus nerve, which will grow between the common carotid artery and internal jugular vein, thus causing a separation between these vascular structures.8

The most common postoperative neurological sequela from resection of a CSC schwannoma is Horner syndrome. Even with careful preservation of the CSC intraoperatively, patients may still have symptoms. Valentino et al reported a 64% permanent deficit (11 of 17) and 29% transient deficit (5 of 17) among patients who underwent nerve-preserving excision of tumor. Among the 19 patients with sympathetic chain as the origin of tumor, Horner syndrome (including transient and incomplete) was reported in 9 patients. Seven of the 19 patients did not have reporting on deficits, and 1 patient suffered cord paralysis.9 Other postoperative neurological deficits reported included mild facial weakness (cranial nerve VII), tongue weakness (cranial nerve XII), hoarseness (cranial nerve X), and temporomandibular joint and preauricular pain (great auricular nerve).7 Our patient had no neurological sequelae or evidence of Horner syndrome immediately after surgery or on 6-month follow-up.

CONCLUSION

Cervical sympathetic chain schwannomas are rare tumors. Surgical excision is the treatment of choice. In addition to imaging studies, FNA can be helpful in attaining a preoperative diagnosis. Horner syndrome is a common postoperative complication; however, it is not always present when the CSC is spared.

REFERENCES


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A 7-year-old girl living in rural western Wisconsin was seen in urgent care in early June after complaining of a bubbly-crackling sensation in her left ear of 2 days’ duration. Otoscopic evaluation revealed a tick embedded in her tympanic membrane in a small amount of fibrinous debris (Figure 1). Two days later, using surgical microscopy, an otolaryngologist extracted the tick. After tick removal, the patient was observed for symptoms and signs of possible infections.

Figure 2 shows the tick under 4× magnification. This tick had black legs, a black rostrum, and a reddish abdomen typical of a female adult *Ixodes scapularis* (the white on Figure 1 is due to reflected glare). Definitive identification of the *Ixodes* genera can be accomplished by direct observation of a U-shaped anogenital groove (arrow on Figure 2), which is especially helpful for identification of this species during its larval and nymph phases.

**DISCUSSION**

Unlike other mammals, we humans, owing to our upright posture, rarely experience tick bites in or around our ears. This was a rare case of a bite of the tympanic membrane by a deer tick, also called the black-legged tick (*Ixodes scapularis*), which emphasizes...
that ticks can attach in difficult-to-observe body areas, especially in children with long hair.

The United States has multiple species of hard ticks, the bites of which can result in various sequelae, both infectious and noninfectious. One noninfectious complication caused by toxins in hard tick saliva is tick paralysis. This rare paralysis occurs after prolonged attachment, more common with a Dermacentor species than with *Ixodes* species, and usually in children with long hair that obscures the biting tick.

In brief, wood and dog ticks of the *Dermacentor* genera, which in recent years are less commonly seen in the La Crosse area than *Ixodes* ticks, can also transmit a variety of infections—Colorado tick fever, tularemia, and Rocky Mountain spotted fever (RMSF), among others. And, found to the south of our area, lone star ticks of the *Amblyomma* genera can transmit Southern Tick Associated Rash Illness (STARI), tularemia, and the newly described heartland virus. Fortunately, all these tick-borne illnesses are extremely rare in the tristate area.

The tick in this case, *Ixodes scapularis*, and the similar West Coast *Ixodes pacificus* are vectors for *Borrelia burgdorferi* and a relapsing fever caused by *Borrelia miyamotoi*. In addition, the same ticks can transmit babesiosis and human granulocytic anaplasmosis.

Tick removal can be achieved by grabbing the tick with a forceps near the head at skin level and pulling directly backwards without stripping the patient's skin, as was done in this case. Any remaining hypostome (mouth parts) is inert chiton, which is usually spontaneously extruded by the epidermis and does not need to be removed.

If an *Ixodes* tick has been attached longer than 36 hours, and if prophylaxis can be started within 72 hours of a bite, one dose of doxycycline 200 mg can be considered for patients older than 8 years to prevent Lyme disease. However, due to our patient's age and a direct fluorescent antibody test of this tick's midgut that was negative for *Borrelia burgdorferi*, she was not given such prophylaxis.

One of history's first naturalists, Pliny the Elder, proclaimed ticks "the foulest and nastiest creatures that be," but prompt checking for and removal of ticks after exposure will prevent most tick-borne diseases.

**REFERENCES**


4. Pliny the Elder, circa AD 79.
What a Pickle!

AUTHOR'S NOTE:

My colleague, Dr. Jennifer Mattingley, inspired the Ethical Considerations section of the Gundersen Medical Journal (GMJ) and this column's inaugural title, “What a Pickle.” Dr. Mattingley and I recently worked together on an ethically challenging and emotionally taxing case. When we debriefed about the case, she suggested that I begin a new column in the GMJ to discuss some of my most difficult and distressing ethics consults. With that idea in mind, the purpose of this column is to create an additional ethics-based learning opportunity for readers by choosing a single case in which I provide narrative, insight, self-reflection, and analysis.

It was a late Tuesday afternoon when I received a request for consultation for a middle-aged pedestrian who had been struck by a motor vehicle as he crossed an intersection. He was emergently taken to surgery for a splenectomy. After surgery, an electroencephalogram showed minimal brain activity. Radiographs confirmed that his brain had detached from the rest of his body, which was considered a nonsurvivable injury.

I was called by the attending trauma surgeon to help determine who could consent to organ donation. Specifically, I was asked if a coroner could consent to organ donation for a deceased patient. As an out-of-state newcomer to our institution, I checked our hospital policy and called our legal department for assistance.

Wisconsin law specifies a hierarchical list of 10 classes of individuals who may consent to organ donation for a patient who has died or is near death (2007 Wisconsin Act 106). In order, they are: the patient himself or herself, spouse, adult children, parents, adult siblings, adult grandchildren, grandparents, adults who exhibit special care or concern for the individual except the patient's compensated health care provider(s), guardians at or near the time of death, and any other persons with authority to dispose of the patient's body.

A coroner responsible for a deceased patient falls into the last category. Therefore, the technical answer to the surgeon's question was "yes," a corner may consent to organ donation for a deceased patient; however, this answer does not actually resolve the ethical issue that the surgeon brought to my attention. Our professional obligations as clinicians dictate that we attempt to honor a patient's treatment preferences, including a patient's antemortem obligations as clinicians dictate that we attempt to honor a patient's compensated health care provider(s), guardians at or near the time of death, and any other persons with authority to dispose of the patient's body.

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Ethically I had to attempt to identify this patient's preferences regarding organ donation and the possibility of withdrawing of life-sustaining treatment. Although a coroner could consent to organ donation, there is a bona fide reason why the category of persons with authority to dispose of deceased bodies is last on the list of consenting options; it would be unlikely that a coroner would know the patient or his preferences regarding organ donation. I set out to answer whether this patient had anything to indicate what he would have wanted in a state of permanent unconsciousness: an advance directive, a power of attorney for health care, conversations with family or friends, even a driver's license with a donor status listed.

I was informed by the unit social worker that a large number of people had been calling the hospital claiming to be "cousins" of the patient. I was also told that the patient had two friends who had come to see him and that one of them was still at the hospital.

When I got to the patient's room, a friend of the patient, Cameron, was sitting by the his bed crying. She told me that she had known the patient for 8 years. I mistook her for the patient's girlfriend and she quickly corrected me. She told me that she and the patient were good friends but not romantically involved. Cameron credited the patient with getting her on an exercise program to lose weight and get fit. As she put it, "He saved my life."

I asked Cameron if she knew of any family members who could be contacted. She gave me a brief social history; some of it was helpful, but most of it was not. The patient had moved to the area about 14 years ago. He was blind in one eye and had severe glaucoma in the other. To her knowledge he did not have a driver's license. Although he attended a local college, he was financially destitute and lived in a seedy motel. He was not married. He had a daughter who he had not seen since she was 5; they had reconnected through social media a few years ago; however, he apparently insulted the girl's deceased mother so she stopped communicating with him altogether. Cameron did not know the daughter's name or age. The patient's parents were deceased. He had 3 adult siblings—2 brothers and sister—but they reportedly wanted nothing to do with him after they alleged he stole money from them. Cameron did not know their names or where they live. Cameron did not know if the patient had any other living relatives
but confirmed the “cousins” calling the hospital were not really his cousins; they were acquaintances who for whatever reasons did not want to disclose their real names to hospital staff when they called or visited. I had no reason to doubt Cameron about this because earlier in the day a known local prostitute claiming to be the patient’s sister came to visit him and was asked to leave after exhibiting bizarre behavior in the waiting room.

Still, we had Cameron. She was there and knew the patient. She seemed to meet the criteria for an adult exhibiting special concern who is not a compensated care provider. I asked Cameron if she would be willing and able to meet with the patient’s care providers in the morning. She agreed.

The next morning I was paged to the care conference. Cameron was there, along with the patient’s other friend, Will. Cameron and Will looked slightly uncomfortable being surrounded by such a large number of staff. Several services were represented at the meeting: Pulmonary, Neurology, Surgery, Social Work, Ethics, and Spiritual Care. I actually found the meeting slightly unusual. Cameron and Will were friends of the patient, not family and not legally appointed representatives either by the patient or the county. The extent of their decision-making authority about the patient’s medical care began and ended with the question about organ donation. Without any known family or legally appointed representative, decisions about provision or abstention of treatment for this patient fell to his care providers, including the withdrawal of life-sustaining treatment.

As the care conference proceeded, a brief medical update was given, and Cameron and Will were told that the patient would not survive. They were asked if the patient had ever had any end-of-life conversations with them. They both replied “no.” They were asked if they thought the patient would want to donate his organs after he dies. Cameron and Will paused, then together responded that the patient was a Christian and believed that he would enter heaven with his body intact. Both took this to mean the patient would not want his organs donated . . . unless we could guarantee that his organs would be donated to a child, which we could not.

Had the patient been an organ donor, life-sustaining treatment would have continued until his organs were assessed for donor viability. With organ donation now off the table, the other ethics issue needing to be addressed—an issue I had intentionally delayed until the organ donation question was settled—accelerated to the forefront. I was no longer advising on who could consent to organ donation; rather, I was advising on whether, and when, we should stop life-sustaining treatment.

Some ethics literature suggests the terms futile or futility should never be used in clinical settings to describe certain medical interventions or a patient’s overall medical condition. This is because these terms are considered value-laden and carry noxious stigmas among the general public. They are often associated with giving up on a patient. Despite this being a wrong assumption—since the former refers to objective limits of medical treatment while the latter refers to a conscious choice about stopping medical treatment—I agree that the underlying force of these terms in clinical settings can be ethically problematic and they should be minimally used. In this case, though, there was no other reasonable, tactful way to describe current or future medical interventions offered to this patient. No treatments exist that could cure or reverse the patient’s underlying neurological devastation. As one care provider explained to me, the patient suffered a decapitation in which the head stayed attached.

Based on the medical judgments of the patient’s care providers that his condition was irreversible and not conducive to life, I made four recommendations. First, withdrawal of life-sustaining treatment was ethically permissible on the grounds that its continuation would be physiologically ineffective. Second, it was ethical to change the patient’s code status so that we would not attempt resuscitation when his heart or lungs stopped working. It was unlikely that a resuscitative effort would have caused the patient any pain or suffering given the extent of his neurological devastation, but because we could not reverse his medical condition, prolonging his death by attempting resuscitation could not be ethically justified. Third, escalation of treatment should be avoided for the same reasons why it was unethical to offer or perform resuscitation on this patient. Lastly, I stated that the time between a decision and the actual removal of life-sustaining treatment should not be subject to delays—that is, once the decision to withdraw was made, it should occur as soon as possible.

Even now I shudder a little at how strongly worded this fourth recommendation is, and I wonder whether others perceive this recommendation as move toward hastening this patient’s death. Sometimes delaying the withdrawal of life-sustaining treatment can be ethically permissible, such as when family members are en route to see the patient before the patient dies. There are two reasons why I made this recommendation for this patient.

First, as with the other 3 recommendations, once the decision to withdraw life-sustaining treatment is made, delays do nothing more than subject the patient to unnecessary interventions. Justice—a standard principle in medicine and ethics—requires providers to be good stewards of medical resources. Providing or offering treatments or interventions that cannot reasonably benefit a patient, but would merely prolong the patient’s death, is akin to poor resource management and stewardship. This notion is further grounded in the idea that prolonging a patient’s death by providing nonbeneficial treatments or interventions is disrespectful and dehumanizing because the patient is consequently treated merely as a body to be kept alive by whatever means necessary.

My second reason was contextually specific to the unusual circumstances of this case. Cameron asked us not to withdraw life support until she could speak with someone related to the patient. Leads identifying persons related to this patient were virtually nonexistent. The few leads we had were exhausted by our unit social worker without success. A previous effort by Cameron to contact someone she believed was the patient’s daughter was met with silence. I was concerned that honoring Cameron’s request would have given her far more decision-making authority than she was ethically and legally entitled to, and that we potentially would have dug ourselves into a rut of indefinitely delaying treatment withdrawal without a clear plan for stopping. In short, the fourth recommendation was my attempt to reiterate that the decision about when to withdraw life-sustaining treatment for this patient was ours to bear.

Recommendations are not meant to dictate behavior. In this case, a decision was made by the patient’s primary care provider to delay withdrawal until the unit social worker had a chance to discuss with Cameron her attempts to notify the patient’s family of his situation. As a friend of the patient, and as someone who
had become a stakeholder in the patient’s care, giving Cameron the opportunity to further speak with the unit social worker was humane and ethical.

Within an hour of the end of the conversation between Cameron and the unit social worker, the patient’s life support was withdrawn. A nearly 3-day ordeal ended peacefully 20 minutes later with me, Dr. Jennifer Mattingley, the primary attending physician, the unit chaplain, and Cameron and Will by the patient’s side.

At the end of the case, Dr. Mattingley offered some sage advice to her medical residents: when involved with a tough case, try to find something that amuses you. As one might guess, the title of this essay was inspired by what she found humorous in our case. I’ll spare the details except to say that this was the first time I was involved in a care conference in which an invited participant proceeded to eat a bagged pickle sopping in vinegar.

However, the title is not just a reference to this case. It is a play on the common phrase “in a pickle.” My research suggests that the origin of this phrase dates back almost 5 centuries and describes a situation with no clear way out, akin to a pickle in a jar being soured by a spicy, vinegary brine. Some cases are medically bleak and socially murky. They can sour us and the care we provide to patients. I have no great wisdom to offer for how to help address or resolve those feelings. But taking a moment to pause and reflect on our toughest patients and finding something lighthearted in the midst of the situation seems like a promising starting point.
Reprise is intended to recognize and reprint significant articles published by Gundersen staff in leading journals. This issue’s Reprise article is “The Wisconsin Network for Health Research (WiNHR): A Statewide, Collaborative, Multi-disciplinary, Research Group,” an article published by the Wisconsin Medical Journal and reprinted here with permission.
The Wisconsin Network for Health Research (WiNHR): A Statewide, Collaborative, Multi-disciplinary, Research Group

Howard Bailey, MD; William Agger, MD; Dennis Baumgardner, MD; James K. Burmester, PhD; Ron A. Cisler, PhD; Jennifer Evertsen, MS; Ingrid Glurich, PhD; David Hartman, PhD; Steven H. Yale, MD; David DeMets, PhD

ABSTRACT
In response to the goals of the Wisconsin Partnership Program and the National Institutes of Health (NIH) Initiatives to Improve Healthcare, the Wisconsin Network for Health Research (WiNHR) was formed. As a collaborative, multi-disciplinary statewide research network, WiNHR encourages and fosters the discovery and application of scientific knowledge for researchers and practitioners throughout Wisconsin. The 4 founding institutions—Aurora Health Care/Center for Urban Population Health (CUPH), Gundersen Lutheran Medical Foundation, Marshfield Clinic Research Foundation, and the University of Wisconsin-Madison—representing geographically diverse areas of the state, are optimistic and committed to WiNHR’s success. This optimism is based on the relevance of its goals to public health, the quality of statewide health care research, and, most importantly, the residents of Wisconsin who recognize the value of health research.

BACKGROUND AND OVERVIEW
Wisconsin has a long history of innovative health care research leading to changes in clinical practice. A few examples include the Wisconsin Longitudinal Study, which collected extensive health and social information from a random sample of 10,317 people; the Wisconsin Epidemiological Study of Diabetic Retinopathy, which described the frequency, incidence, and risk factors for complications associated with diabetes; the Wisconsin Cystic Fibrosis Neonatal Screening Project, which screened more than 1 million Wisconsin infants; and, more recently, the Marshfield Clinic Research Foundation’s Personalized Medicine Research Project, which resulted in one of the largest (approximately 20,000 participants) health care genetics databases in the world.

The value of clinical research to foster medical discovery and to confirm best medical practice is self-evident. The National Institutes of Health (NIH) Roadmap Initiatives propose “re-engineering the clinical research enterprise” to increase the efficiency and effectiveness of clinical research and the pace of discovery. The societal imperative behind the desire to improve the efficiency of clinical research comes from 3 main premises about the future: (1) a rapid increase in the scope and rate of biomedical discovery, (2) growing public demand for clinical applications of biomedical discoveries, and (3) increasing calls to ensure equity in the availability of improvements in health care. The ability of clinical research to promote equity in health care availability is frequently underappreciated. Most evidence-based improvements in health care are implemented slowly and inconsistently; however, clinicians who participate in health care-related studies are most likely to incorporate evidence-based improvements more rapidly into their clinical practice.

Improving the efficiency of clinical research is an important goal. One proposed way to increase efficiency is through more effective “regionalization” of research (more cooperative efforts among multiple regional medical facilities).
clinical practice has become increasingly reliant on evidence-based medicine. This evidence comes from a variety of sources, including observational studies, but the most definitive evidence comes from clinical trials, especially multi-center, randomized clinical trials. To facilitate clinical trials, many interested clinicians formed regional or national groups (cooperative groups within a disease/discipline or groups of clinical research centers organized for a specific trial). However, these research groups were often subspecialty-specific or transient. As a result, centers interested in research had either a varied portfolio of research options from different sponsors with different policies, standards, and data management requirements, or no portfolio at all. Increasing regulatory requirements, system redundancies, and the lack of wider availability/participation contribute to the inefficiencies of this ad hoc approach. Thus, there is a compelling need for more effective regionalization of research.

Wisconsin is an ideal arena for evaluating health care strategies. This is exemplified by the Cancer Intervention and Surveillance Network’s examination of modeling data collected from various states, which found that Wisconsin data closely represented composite data from across the country. Wisconsin citizens are traditionally interested in health, health care, and disease prevention, as shown by high research participation rates. Moreover, the Wisconsin population is very stable, with small out-migration, which allows more accurate monitoring and follow-up of study participants.

The above social and demographic factors, coupled with the excellent health care facilities and outstanding research institutions in Wisconsin, led us to pursue building a statewide health care research network. Four large, multi-specialty health care groups united to form WiNHR in 2005 as an initial step toward establishing a statewide research network. These 4 institutions provided significant coverage of the state both in terms of population (>3 million residents) and geographically (>50 counties). Additional financial support was provided by the Wisconsin Partnership Program and the University of Wisconsin (UW) Institute for Clinical and Translational Research. WiNHR has the following goals:

- **Improve health in Wisconsin.**
- **Improve consumer and physician access to state-of-the-art therapeutics/preventive care and up-to-date knowledge through clinical trials and web-based resources.**
- **Improve health care professional and researcher access to larger academic center resources.**
- **Enhance ability for evaluating new health care interventions.**
- **Establish new or improved collaborative relationships among medical centers throughout the state.**
- **Increase cross-discipline exploration and discovery.**
- **Facilitate trainee education in health-related sciences at sites across the state.**
- **Format a multi-disciplinary, statewide research infrastructure that researchers could use as needed.**

**NETWORK IMPLEMENTATION: OPPORTUNITIES AND CHALLENGES**

The development of a statewide health research network like WiNHR is consistent with the NIH Roadmap for Medical Research and holds great potential to enhance integrated and collaborative opportunities. Some of the main recommendations of the NIH Roadmap include greater interdisciplinary research, increased regionalization of research, and better integration of existing single discipline research networks. The potential success of a multi-disciplinary statewide research network in Wisconsin is reinforced by this alignment of WiNHR with the NIH Roadmap. The long history of successful single-discipline research networks in the state (eg, Wisconsin Research and Education Network [WREN], Wisconsin Oncology Network) also suggests the potential for WiNHR success. However, there are both unique and common challenges to overcome as we build an effective and durable statewide health research network including building and fostering communication and relationships, human subject protection, intellectual property, governance, informatics, funding, and expansion. Table 1 lists some of the hurdles encountered to date and solutions that were implemented. Foremost among problems that were resolved were (1) establishing memorandums of understanding that covered transfer of funds to support WiNHR and detailed responsibilities of the founding members, (2) coordinating IRB approval across 4 institutions, and (3) completing material and data-transfer agreements.

**Establishing Partnership**

One of the first and most important steps in uniting a group of institutions toward a common goal is building trust in the mutual benefit for participants and the common purpose of conducting research to improve the health of Wisconsin. Part of the trust developed in the WiNHR mission and governance results from the decision to undertake initial planning and implementation as a group operation, rather than having 1 institution assume all planning and implementation before
asking others to participate. In addition, all participants have an opportunity to comment on proposed research prior to implementation, choose which research projects they participate in, and receive credit/acknowledgment for their participation through authorship on research reports. Mutual benefit is pursued via related paths including performing health research that is pertinent to all Wisconsin residents, broadening opportunities for participation in research through conduct of the research at multiple institutions, and performing research of interest to the majority of the participating health care professionals.

Table 2 shows a list of completed or ongoing WiNHR studies. The study Genetics of Warfarin Dosing was proposed by researchers at Marshfield Clinic Research Foundation. These investigators spent years developing models in white subjects that predict stable warfarin dose based on genetic markers as well as personal factors like age and body surface area. To extend these studies and potentially improve the health of blacks, blacks were recruited from the Milwaukee area by investigators at Aurora Health Care/Center for Urban Population Growth (CUPH). Results from this study have been provided to PharmGKB (www.pharmgkb.org) and will be published as part of a national collaboration.

The study Infectious Disease and Pre-term Labor was proposed by investigators at Gundersen Lutheran Medical Foundation, who had investigated genital mycoplasmas among sexually active young adults in the La Crosse, Wisconsin area. These investigators realized the importance of extending their studies on mycoplasma and pre-term labor to the other sites in WiNHR in order to gather data on distinct regions of the state as well as minority populations that are not prevalent in La Crosse. This study is being performed by UW physicians at Meriter Hospital, where a significant portion of the patients are under-served minorities; at Aurora/CUPH, where a significant portion of the patients are black; and at Marshfield Clinic Research Foundation to cover the northern part of the state.

These 2 projects highlight the potential translational value of WiNHR projects for Wisconsin's residents. The Pre-term Labor study is directly applicable to a pertinent Wisconsin health issue—infant mortality. The Genetics of Warfarin Dosing study is similar to prior studies on the impact of genetics on warfarin dosing that resulted in a change in warfarin labeling by the Food and Drug Administration.

Human Subjects Protection

The protection of human research subjects from unacceptable risk is critical both to performing high-quality clinical research and to maintaining the trust of the community being studied. A hallmark of human subjects' protection is the tension between applying universal protection rules versus local community standards. The application of human subjects protection at a single institution can be complex; the application across multiple, linked groups raises even more issues. Is the community standard from institution to institution similar enough that differences in acceptable risk are rare and easily resolved when they do occur? How much does redundancy in the review process across multiple sites negatively affect research efficiency?

Not unexpectedly, our multisite research group has found the review process for protection of human subjects cumbersome. This has led to expedited discussions between institutions to make the review process across our sites more efficient and less redundant. Some of the measures being discussed include more standardization

<table>
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<tr>
<th>Table 1. Challenges and Solutions to Building a Statewide Research Network</th>
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<tr>
<td>Challenge</td>
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<tr>
<td>Establishment of the network</td>
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<tr>
<td>Funding</td>
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<tr>
<td>Intellectual property protection</td>
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<td>Human subjects protection</td>
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<tr>
<td>Credit for multiple investigators</td>
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<tr>
<td>Biological sample ownership</td>
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<td>Network growth and expansion</td>
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<td>Human subjects protection with additional</td>
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<tr>
<td>community members</td>
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<tr>
<td>Subject enrollment and data management</td>
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54
responsibility allows a research group or network to accommodate varying degrees of experience from site to site and from researcher to researcher. WiNHR governance is accomplished by an executive committee in the form of agreed-upon standard operating policies and procedures. The executive committee is composed of equal representation from the institutions and is the central authority in WiNHR, providing review and final decisions on bylaws, standard operating procedures, funding, and specific health care research performed within the group.

**Medical Informatics**

An increasingly important component of modern health care delivery and research is the secure and efficient transmission of either critical health information or research data. This is especially true for a network of health research sites jointly collecting and reporting research observations. Critical issues are the ability of lead investigators to access ongoing data collection at any site from any location, the ability to monitor data quality, and the ability to efficiently compile data within and across studies. This is currently being pursued by WiNHR via proprietary research database software designed to provide a web-based system to securely provide and maintain all relevant study and subject characteristics plus all data normally collected on a case report form (CRF).

Electronic medical records (EMR) are 1 example of the informatics opportunities provided by networked health research. Marshfield Clinic has been at the forefront of incorporating EMRs and exploring ways to integrate electronic records into health research (eg, Personalized Medicine Research Project). There is a huge potential research value in being able to electronically survey health outcomes/events for up to 3 million Wisconsin residents across health care groups’ EMR systems without requiring hundreds of hours to manually extract or de-indentify data.

**Funding**

Currently, WiNHR is funded by the UW School of Medicine and Public Health from the Wisconsin Partnership Program, with supplemental funds provided by the UW Institute for Clinical and Translational Research and “in-kind” funds from Marshfield Clinic Research Foundation, Aurora Health Care/CUPH, and Gundersen Lutheran Medical Foundation. Other potential sources of support include federal and non-federal reimbursement for research performance. Whether WiNHR can or should try to become entirely funded

### Table 2. Completed and Ongoing WiNHR Studies

<table>
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<tr>
<th>Study</th>
<th>Participating Sites</th>
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<tbody>
<tr>
<td>Chronic Kidney Disease Focus Groups</td>
<td>WREN, UW, GL, CUPH, MCRF</td>
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<tr>
<td>Infectious Disease and Pre-term Labor</td>
<td>UW, GL, CUPH, MCRF</td>
</tr>
<tr>
<td>Genetics of Diabetes</td>
<td>UW, CUPH, MCRF</td>
</tr>
<tr>
<td>Genetics of Scoliosis</td>
<td>UW, GL, MCRF</td>
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<tr>
<td>Vertebral Malformations</td>
<td>UW, GL, MCRF</td>
</tr>
<tr>
<td>Azithromycin Asthma Trial</td>
<td>WREN, UW, CUPH, MCRF</td>
</tr>
<tr>
<td>Genetics of Warfarin Dosing</td>
<td>CUPH, MCRF</td>
</tr>
<tr>
<td>COPD and Heliox</td>
<td>UW, MCRF</td>
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Abbreviations: CUPH, Aurora Health Care/Center for Urban Population Health; GL, Gundersen Lutheran Medical Foundation; MCRF, Marshfield Clinic Research Foundation; UW, University of Wisconsin-Madison; WREN, Wisconsin Research and Education Network.
from research performance is debatable. The advantages of self-sufficiency, like greater administrative autonomy, are apparent. However, self-sufficiency may come at the cost of performing research that is not a priority for the state’s residents or researchers. An effective funding mixture might include both stable infrastructure funds supplemented by research performance reimbursement.

Given the potential benefits of research for improving cost-effective health care delivery in Wisconsin, current health care payers (eg, the health insurance industry or state) might be willing to underwrite core services. At a minimum, infrastructure support should include administrative and regulatory research personnel at numerous sites across the state. Ideal infrastructure costs might include “buying out time” of key researchers around the state as long-term local advocates of health care research. Unfortunately, in the current fiscal climate, such costs may exceed available funding.

Expansion
While the current composition of WiNHR provides greatly enhanced access for the state’s residents to health research participation and benefits, further improvements are slowed by the participation of only 4 health care systems. As a first step in expansion, WiNHR partnered with WREN. This partnership benefits both organizations since WiNHR research projects can now be carried out in participating primary care physician offices statewide, and WREN studies can reach additional patients at WiNHR sites. To ensure continued success in this collaboration, the executive director of WREN holds a voting seat on the WiNHR executive committee. Additional expansion of WiNHR will occur to allow quality health care and health care research to reach beyond the current members of WiNHR. A continued goal of WiNHR is greater access and inclusivity throughout the state. Recruitment of other groups will be balanced against current funding and regulatory constraints.

Completed Study Presentations
Research study outcomes will be disseminated across the state through publication of manuscripts and presentations at state meetings. Examples of relevant forums include WREN convocations, UW Institute for Clinical and Translational Research (ICTR) Research Learning Series, and Grand Rounds at Aurora Health Care, Marshfield Clinic, and Gundersen Lutheran Clinic. Publications may be presented in peer-reviewed journals, including the Wisconsin Medical Journal, Clinical Medicine and Research (Marshfield Clinic Research Foundation), and Gundersen Lutheran Medical Journal (Gundersen Lutheran Medical Foundation).

SUMMARY
The preceding issues are a subset of those this group has encountered and addressed moving toward its stated goals. WiNHR was founded on and will continue to seek the full support of the leadership of current (and future) participating health care groups. One major determinant of success will be the perceived value each clinician and each potential research subject has in health research. Other measures of success will be credit attributed to WiNHR as new drugs, protocols, or technologies enter clinical practice and advancements in health care are made across the state. Thus one of the most important tasks of WiNHR researchers is articulating to busy clinical colleagues the advantages of clinical research participation to their clinical practice and individual patients. Another important task is the ability of WiNHR researchers to translate research knowledge into improved health of our communities at local sites and across the state.

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REFERENCES


Supplement

2011 – Presentation Abstracts
Gundersen Health System


**Background:** Portomesenteric venous thrombosis (PMVT) is uncommon but associated with ischemic bowel and mortality.

**Objective:** The purpose of this study was to determine the occurrence of PMVT in a community setting and evaluate current diagnosis, treatment, and outcomes.

**Methods:** Medical records of consecutive patients admitted to a community-based hospital diagnosed with PMVT were reviewed. Patients were divided into 2 groups: those diagnosed from 1997 to 2003 and those diagnosed from 2004 to 2009.

**Results:** One hundred three patients were included. The proportion of chronic PMVT diagnoses increased in the recent group (14% in contrast to 44%, $P=.001$). Treatment was more common in acute in contrast to chronic PMVTs (70% in contrast to 48%, $P=.035$). The median length of stay decreased over time (6 in contrast to 3 days, $P=.004$). Three patients underwent surgical intervention. Overall, 30-day mortality was 17% and did not change over time.

**Conclusions:** Diagnosis and treatment have changed with increased differentiation between acute and chronic PMVT; outcomes were similar. Surgical intervention was rarely necessary. Mortality is attributed to patient comorbidity rather than PMVT.


**Objectives:**
1. Identify ways to reduce Hospital Acquired Pressure Ulcers in the Surgical Population
2. How to use data and rapid PDSA cycles to create change
3. Identify how to use data with the human side of change to sustain improvement

By focusing pressure ulcer prevention efforts, Gundersen Lutheran made an 18% reduction in hospital acquired pressure ulcers among surgical patients. Data analysis identified at risk surgical patients and through rapid cycles of change we tested and implemented individualized preventative interventions. This change was sustained through the use of data sharing and patient stories at the unit/individual level all the way up to the senior leadership.

**Proposal Description:**
By focusing pressure ulcer prevention efforts through data analysis, Gundersen Lutheran made an 18% reduction in hospital acquired pressure ulcers among surgical patients. Data analysis identified specific surgical patients to apply an individualized preventative intervention on. Through rapid cycle PDSAs, 229 patients received the intervention during a 6 month period. Of these, two patients formed a HAC pressure ulcers. This framework will be used on other patient populations moving forward.


**Case:** A 19 y.o. male presented with a one week history of diffuse myalgias, arthralgias, subjective fevers, and initial sore throat. At the time of admission, pt had also developed chest pain and dyspnea. Exam revealed a pericardial rub and sinus tachycardia. Lab findings included leukocytosis (WBC peak of 43.70, 91.3% granulocytes), anemia, and thrombocytopenia. CXR was significant for a LLL infiltrate. TTE revealed a trivial pericardial effusion without tamponade. Pt was started on NSAIDs for pericarditis and IV ceftriaxone and azithromycin for presumed community acquired pneumonia.

On hospital day #2, pt developed RUQ pain, and a CT abdomen was significant for hepatosplenomegaly and retroperitoneal/mesenteric lymphadenopathy. On hospital day #3, pt developed increased chest pain and dyspnea and repeat TTE was suggestive of impending tamponade. Pt was intubated secondary to acute respiratory failure, and an emergent pericardial window was placed. CXR revealed diffuse infiltrates. Bronchoscopy/BAL were unrevealing. Pt then developed a diffuse maculopapular rash and became febrile to 102.4º F with prior low-grade fevers. Infectious
influenza, enterovirus/coxsackie, adenovirus, parvovirus, Lyme, anaplasma/ehrlichia/rickettsial panel, tularemia, chlamydia, brucella, fungal antibody panel.

Due to a largely negative infectious work-up, lack of clinical improvement, and concern for adult-onset Still’s disease (AOSD), rheumatology was consulted. Ordered labs were all negative with the exception of a significantly elevated ferritin of 11,888 ng/ml, CRP 29.5 mg/dl, and ESR 83 mm/hr. Pt was started on high-dose steroids and began to clinically improve. Pt was discharged on prednisone and started on anti-TNF therapy in outpatient follow-up.

**Discussion:** Adult-onset Still’s disease is a rare inflammatory disorder with yet unclear etiology. Diagnosis may be guided by the Yamaguchi criteria. The major criteria include intermittent fever of at least 39 C for ≥1 wk, arthralgias for ≥2 wks, characteristic skin rash, leukocytosis with ≥80% granulocytes. The minor criteria include sore throat, lymphadenopathy, hepatosplenomegaly, abnormal LFTs, and negative ANA/RF. Significantly elevated ferritin levels are also seen in up to 70% of patients with AOSD.


**Background:** Despite the widespread use of retrievable filters (RF) in trauma patients, actual “retrieval” rates remain low. Implementation of a retrieval protocol has resulted in significant improvements in initial filter retrieval rates. The long-term sustainability of these early results remains unclear.

**Methods:** A retrospective review of a prospectively collected database following implementation of a retrieval protocol in January 2005 was completed. Data from two study periods (Early phase: February 2002–December 2005 and Late phase: January 2006 –December 2010) was compared. Filters were considered non-retrievable if death or transfer out of network occurred prior to meeting retrieval criteria. Statistical analysis included t test and chi-square. \( P<0.05 \) was considered significant.

**Results:** 114 patients underwent RF placement over the study period.

<table>
<thead>
<tr>
<th></th>
<th>Overall</th>
<th>Early Phase</th>
<th>Late Phase</th>
<th>( P ) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>( N )</td>
<td>114</td>
<td>27</td>
<td>87</td>
<td></td>
</tr>
<tr>
<td>Retrievable, n</td>
<td>95</td>
<td>20</td>
<td>75</td>
<td></td>
</tr>
<tr>
<td>Retrieved successfully, n (%)</td>
<td>84 (88%)</td>
<td>18 (90%)</td>
<td>66 (88%)</td>
<td>0.999</td>
</tr>
<tr>
<td>Mean indwelling time (days)</td>
<td>67</td>
<td>50.5</td>
<td>74</td>
<td>0.107</td>
</tr>
<tr>
<td>Retrieval related to complications, n (%)</td>
<td>6 (7%)</td>
<td>2 (10%)</td>
<td>4 (6%)</td>
<td>0.611</td>
</tr>
</tbody>
</table>

**Conclusions:** A structured protocol-driven approach to filter retrieval resulted in sustained retrieval rates and stable associated complication rates and indwelling times.


**Background:** Splenectomy is generally a second-line therapy in patients with immune thrombocytopenic purpura (ITP) and autoimmune hemolytic anemia (AHA) refractory to medical therapy. Our objective was to evaluate outcomes after splenectomy for these disorders.

**Methods:** A retrospective review of the medical records of patients who underwent splenectomy for ITP or AHA from January 1, 1996, to December 31, 2010 was completed.

**Results:** Sixty patients met the study criteria: 45 with ITP and 15 with AHA. The mean age was 49.4 ± 21.7 years; 63% were women. Initially, 91% and 93% of ITP and AHA patients experienced a complete response (\( P=0.999 \)); however, 17% of ITP and 29% of AHA patients relapsed (\( P=0.443 \)). Sixty-four percent of patients responded after relapse for a complete response rate of 85% (82% in ITP and 93% in AHA, \( P=0.427 \)). Thirty-day and long-term complication rates were 10% and 5%, respectively. There were no splenectomy-related 30-day mortalities.
**Conclusions:** Splenectomy for ITP and AHA resulted in favorable response rates with low morbidity and is an effective adjunct in the management course of patients failing to achieve or sustain responses with medical therapy.


7. Cogbill TH. Rural trauma. Presented at Dallas Methodist Hospital, Dallas, Texas, August 15, 2011.


Alcohol and drug abuse account for approximately 100,000 deaths annually, and are the underlying cause of many trauma admissions. Previous literature has reported that 40-60% of trauma patients test positive for alcohol or illicit drugs. It has been reported that alcohol interventions in trauma centers reduce the risk of trauma recidivism, and patients with mild or moderate alcohol problems who underwent brief alcohol interventions decreased their alcohol intake compared to a control group. Intervention also resulted in a 47% reduction in injuries requiring an emergency department visit or trauma admission. Despite evidence that alcohol screening and intervention reduces future injuries, it is still not routinely practiced; less than 15% of trauma centers perform an alcohol screening.

Gundersen Lutheran Medical Center implemented a Screening, Brief Intervention, and Referral to Treatment (SBIRT) program in 2009 to increase the capture rate of “at risk” patients as well as to meet the American College of Surgeons (ACS) current requirements. Due to physician and nursing time constraints, lack of training in behavioral interviewing, and some general discomfort in completing the intervention and treatment plans for patients who screen positive, in 2011 Gundersen Lutheran changed the SBIRT process. Dedicated staff were trained to screen all hospital inpatients; research demonstrates that 34% of patients screened require intervention. Expansion of this process allows Gundersen Lutheran to continue to 1) meet the ACS requirements, 2) meet the projected Joint Commission requirements and 3) prepare for health care model of Accountable Care Association (ACO) organizations.

SBIRT implementation required the establishment of 2 Wellness Coordinator positions, the requirements of which consisted of a bachelor’s degree in Community Health Education with significant additional education and evaluation in behavioral interviewing. Implementation also required the cooperation of nursing and medical staff. The SBIRT process consists of several steps: 1) Initial screening of all patients by nursing staff; 2) consult is placed to Wellness Coordinator on all admitted patients to the facility under the admitting physician; 3) consult is activated for all positive tobacco, alcohol, and illicit drug screens; 4) consult note is completed by Wellness Coordinator and forwarded to attending physician for notification of completion and recommendations for reinforcement of plan developed along with any pharmaceutical interventions that may be desired by the patient to enhance treatment. As part of the process, the Wellness Coordinators also directly submit the billing for this population.

The effectiveness of the SBIRT program for the trauma population was determined by the capture rate, which increased from 34% to 80%. Currently, the capture rate for all assessed hospital inpatients is 95%. All facilities, inclusive of trauma centers, could benefit from implementing SBIRT programs from increased reimbursements, compliance with The Joint Commission and ACS requirements, and the greatest benefit would be for the community as ACO organizations develop organized processes for improving quality and controlling costs of care for a population of beneficiaries.


**Introduction:** Skin rashes are a common and frequently non-specific finding with varying clinical significance. They are often a manifestation of an underlying process such as infection, autoimmunity, malignancy, or medication reaction. For many clinicians, these findings pose a diagnostic challenge and it may be difficult to determine the exact etiology.

**Case:** A 54 year old male with a history of myelodysplastic syndrome was admitted for fever. On admission, his WBC count was 1.25 K/uL with an ANC of 0.490 K/uL. In addition to fever, he complained of right upper quadrant pain. Imaging was negative for acute abdominal pathology. However, he was started on ertapenem for a suspected intra-abdominal infection. Over the course of three days his abdominal pain improved but his low grade fever persisted. On day 4, he spiked a fever of 40°C, and his ANC dropped to 0.08. As a result, he was given Granulocyte Colony Stimulating Factor (G-CSF). Due to continued fever and dropping ANC, on hospital day 6, he was given another dose of G-CSF. That same day, he was found to have developed a non-pruritic, erythematosus, maculopapular rash that involved primarily his chest, abdomen, legs and arms. Skin biopsies were obtained and results were consistent with a diagnosis of neutrophilic eccrine hidradenitis (NEH).
Discussion: NEH is an extremely rare inflammatory skin reaction commonly seen in patients undergoing chemotherapy for hematologic malignancies. It has also been reported in healthy patients, patients with solid malignancies, infections, and in association with certain medications. The eruptions are often seen in neutropenic patients presenting with fever. It is characterized by the sudden onset of erythematous papules and plaques that can affect the trunk, arms, legs and face including the periorbital region. Lesions are typically asymptomatic but can be tender and pruritic. A biopsy is required for diagnosis and histology classically reveals neutrophilic infiltration of the eccrine glands with accompanying necrosis. The pathophysiology is not entirely understood but thought to be due to the direct toxic effect of the offending agent in the sweat glands. Another theory is that NEH is part of the spectrum of neutrophilic dermatoses. NEH is self-limiting and resolves spontaneously within 1-2 weeks without any long term sequelae. Steroids, NSAIDs, and antibiotics have been used for symptom control and to decrease duration. Dapsone has also been suggested for prevention of recurrent NEH.


Purpose: To identify best practices for the management of the pertussis cough.

Method: A PICO question was developed to guide the literature search: “For the patient with pertussis, do inhaled bronchodilators compared to oral steroids improve the cough?” A literature search was conducted using the following sources: PubMed, Cochrane Database, CINAHL, MD Consult, UpToDate, Ovid, MedlinePlus. Key words – Combinations of: pertussis, symptomatic, treatment, steroids, albuterol, bronchodilators, management. Search Results - more than 30 potential research publications were identified. However, only 6 publications were pertinent to the PICO question.

Findings Analyzed: Insufficient evidence exists to draw conclusions about the effects of interventions for the cough in whooping cough. A systematic review concluded that the effectiveness of corticosteroids and inhaled ipratropium was uncertain and not justified.

Implications for Nursing Care: Manage acute pertussis with appropriate antibiotic dosing and timeline. Anticipatory guidance for parents: treat all household contacts prophylactically; provide expectations of the potential for increased cough intensity for an extended period of time; discuss coping mechanisms used successfully in the past; assist parents to identify social supports for up to six weeks.

Educate parents: child to remain out of school and public places for a total of 5 days; research has shown no benefit for the use of oral or inhaled steroids in reducing cough intensity or timeline; advocate the use of honey at bedtime. Research has shown that honey does reduce cough overall and may have some benefit without side effects.


Objective: To evaluate the impact of establishing an inpatient SBIRT program with a dedicated inpatient counselor.

Methods: A retrospective review of trauma patients that met registry inclusion criteria and underwent assessment by the SBIRT counselor from December 2009 to June 2010 was completed. Patients were stratified by alcohol and drug risk: low vs. at risk, harmful or dependent (AR). Public records were reviewed for any citation that occurred before and after SBIRT, not including citations associated with the index hospitalization. Post-discharge clinical follow-up included alcohol and drug-related hospital readmissions or emergency department visits. Statistical analysis included chi-square and Fisher exact test.

Results: Of 192 eligible patients, 154 underwent assessment over the 6 month study period. 56% were male; mean age and ISS were 63.8 and 9.2, respectively. Mechanisms of injury were primarily falls and motor vehicle crashes. One hundred and three (67%) patients were categorized as low risk (LR) and 51 (33%) AR. Alcohol or drug tests were positive in the AR vs LR subgroup in 67% and 11% respectively (P<0.001). Twenty-four (47%) patients in the AR subgroup had a prior citation compared to 11 (11%) in the low risk group (P=0.001), similarly, 7 (14%) in the AR subgroup and 1 (1%) in the low risk group had a citation after SBIRT (P<0.001). Median time to first citation was 134 days. Hospital readmissions and emergency department visits for alcohol or drug-related reasons occurred in 8% in the AR group versus 1% in the low risk group (P<0.042). When legal and clinical follow-up variables were combined, events occurred in 20% in the AR group versus 2% in the low risk group (P<0.001).

Conclusions: SBIRT program captured 80% of eligible patients and accurately substratified patients with respect to risk level. The AR subgroup had a higher incidence of subsequent alcohol or drug related events and may benefit from further in or outpatient therapy.

**Purpose:** To describe the safety for using the LMA (laryngeal mask airway) in a community sample of children and adolescents. To demonstrate the high prevalence of SDB (sleep disordered breathing) in children.

**Method:** Conducted a retrospective chart review of 100 pediatric patients who had undergone a T&A (adenotonsillectomy) at Gundersen Lutheran during a three-year time period. Documentation included: 8-24 hour post-operative complication rate and 30 day complication rate of bleeding and infection.

**Results:** Hypertrophy was the most common implication for surgery. Sleep disordered breathing was the second most common implication for surgery at 84%. Only 1% of the patients in our study were converted from a LMA to endotracheal intubation (ETT) and only 5% of patients required a hospital admission. Reasons for hospital admission included: dehydration, post-operative rebleeding, and significant sleep apnea.

**Summary:** The complication rates of the LMA usage were not significantly different compared to the complication rates of ETT or LMA use reported in the literature.

**Implications for Nursing:** The LMA is a valid method to use with similar event rates to the ETT that correlates to all T&A procedures. Recent data suggest that some diagnostic modalities may underestimate the prevalence of sleep disordered breathing in children. LMA use for surgical airway management is the least invasive method for patients with SDB.


**Background:** Perioperative blood transfusions in patients with colorectal cancer (CRC) is associated with increases in cost, morbidity and mortality, cancer recurrence and decreased long-term survival. In October 2009, a one hour multidisciplinary education session was held with the departments of surgery, anesthesia and hematology on the safety of perioperative anemia and risks to patients due to transfusion. We hypothesized that the education session would lead to less perioperative transfusions without an increase in postoperative complications.

**Methods:** After institutional review board approval, a retrospective review of the records of patients who underwent colon resection for CRC prior to and after the transfusion education was completed. Variables included demographics, transfusions (30 days prior, day of surgery, 30 days after), complications, and survival. Statistical analysis included Wilcoxon rank sum, chi-square, and t-test. Log rank test was used for survival analysis. P<.05 was considered significant.

**Results:** 368 patients were included; 272 in the pre-education (1/2006–10/2009) and 96 in the post-education group (1/2009–3/2011). Patients in the post-education group were younger (69.7 vs. 65.7 years, P=.011), otherwise the groups were similar for body mass index, operative approach, and cancer stage. Patients who received a perioperative transfusion had significantly reduced 3-year survival compared to those who were not transfused. This was true for Stage 1 (68.2 vs 94.1%, P=.034), Stage 2 (68.5 vs. 90.1%, P=.001) and Stage 3 (54.9 vs. 84.3%, P=.001) but not Stage 4 (25.0 vs.23.1%, P=.789).
<table>
<thead>
<tr>
<th>Variable</th>
<th>Pre-education</th>
<th>Post-education</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Postoperative Hgb ≤8 g/dl</td>
<td>37 (14)</td>
<td>19 (21)</td>
<td>.111</td>
</tr>
<tr>
<td>Transfused on day of surgery</td>
<td>33 (12)</td>
<td>3 (3)</td>
<td>.011</td>
</tr>
<tr>
<td>Transfused within 30 days pre-and postoperative</td>
<td>77 (28)</td>
<td>14 (15)</td>
<td>.009</td>
</tr>
<tr>
<td>Median units transfused within 30 days pre- and postoperative, (range)</td>
<td>2 (1 – 6)</td>
<td>1 (1 – 8)</td>
<td>.021</td>
</tr>
<tr>
<td>Median postoperative Hgb (g/dl) among patients transfused, (range)</td>
<td>8.4 (5.1 – 10.9)</td>
<td>7.3 (5.6 – 10.3)</td>
<td>.009</td>
</tr>
</tbody>
</table>

### Complications

<table>
<thead>
<tr>
<th>Complication</th>
<th>Pre-education</th>
<th>Post-education</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anastomotic leak</td>
<td>5 (2)</td>
<td>3 (3)</td>
<td>.457</td>
</tr>
<tr>
<td>Wound infection</td>
<td>23 (8)</td>
<td>9 (9)</td>
<td>.784</td>
</tr>
<tr>
<td>Deep vein thrombosis/pulmonary embolism</td>
<td>2 (1)</td>
<td>3 (3)</td>
<td>.114</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>2 (1)</td>
<td>0</td>
<td>.999</td>
</tr>
<tr>
<td>30-day Mortality</td>
<td>8 (3)</td>
<td>1 (1)</td>
<td>.456</td>
</tr>
<tr>
<td>Any complication (per patient)</td>
<td>54 (20)</td>
<td>16 (17)</td>
<td>.494</td>
</tr>
</tbody>
</table>

### Conclusion:

The rate of perioperative blood transfusions in CRC surgery decreased significantly following multidisciplinary education without an increase in complications. Our hypothesis was supported with patients undergoing less transfusion and receiving less blood when transfusion was required. Additionally, improved survival was observed in patients who did not receive any transfusions. Similar multidisciplinary educational activities at other institutions could potentially lead to less perioperative transfusion without an increase in the complication rate.


**Background:** Temporary abdominal closure (TAC) is an invaluable tool in the armamentarium of surgeons caring for critically ill and injured patients. The objective of this study was to determine the incidence of abdominal wall hernias and intestinal obstructions in patients who underwent TAC.

**Methods:** A retrospective review of the medical records of patients who underwent TAC from September 2000 to December 2007 was completed. Patients were stratified by technique and indication for TAC. Statistical analysis included analysis of variance, $\chi^2$, Fisher’s exact test, Wilcoxon rank sum test, Kruskal-Wallis test, and Kaplan-Meier analysis.

**Results:** One hundred seventeen patients underwent TAC during the study period. Nine patients were excluded from the analysis. For the remaining 108 patients, 30-day mortality was 17%. Definitive fascial closure was accomplished in 91% of patients. Median time to closure was 3 days. Seventy-six (70%) patients survived ≥6 months after definitive fascial or skin-only closure. Median follow-up was 34.5 months. Intestinal obstructions developed in 11% of patients. Abdominal wall hernias developed in 30% of patients with definitive fascial closure. No differences were observed for rates of abdominal wall hernias or intestinal obstructions based on preoperative body mass index, TAC indication, or TAC technique (temporary skin, bridge, or vacuum-assisted device closure).

**Conclusion:** Successful definitive fascial closure was achieved in 91% of patients after TAC. Abdominal wall hernias and intestinal obstructions were associated with longer median time to closure and increased ventilator days. No associations with indications for TAC, temporary closure techniques, or definitive closure methods were demonstrated.


**Objective:** To identify the impact of the Abbreviated Injury Scale (AIS) changes from AIS98 to AIS08 on Injury Severity Score (ISS) and attendant implications for programs.

**Methods:** Injuries for patients within our institution’s trauma registry from July 2008 through July 2010 were coded using both AIS98 and AIS08 scales. Impact of AIS code revisions and severity variations on ISS were determined. Statistical analysis included $t$ test, McNemar’s test, chi-square. A $P<0.05$ was considered significant.

**Results:** 1446 patients were analyzed. Code revisions and severity changes between AIS98 and AIS08 occurred in 361 (25%) and 292 (20%) patients, respectively. Overall, ISS decreased in 19.8% of patients, with code severity changes accounting for greater than two thirds of this decrease.
Conclusions: Revisions from AIS98 to AIS08 resulted in a decrease in overall ISS as well as patients classified as “major trauma” (ISS>15). The decrease in ISS was primarily driven by changes in code severity in three anatomic regions: head/neck, chest and abdomen. The revisions have significant implications for ACS verification criteria and dataset comparisons between AIS versions.


Background: In addition to significant weight loss, laparoscopic Roux-en-Y gastric bypass (LRYGB) has been shown to improve obesity-related comorbidities, including gastroesophageal reflux disease (GERD). Acid pockets near the gastroesophageal junction have been previously proposed to be a factor in the etiology of GERD. Nissen fundoplication failure rates are increased in obese patients. Conversion of a failed Nissen to LRYGB can resolve or improve GERD symptoms. The objective of this study was to compare the outcomes for patients who underwent LRYGB for GERD to those who underwent LRYGB for morbid obesity (MO).

Methods: A retrospective review of our institution’s bariatric database was completed. LRYGB operative technique was the same for the GERD and MO groups. Variables included demographics, body mass index, and postoperative complications over follow-up. Statistical analysis included t-test, Wilcoxon rank sum and $\chi^2$.

Results: 1000 patients underwent LRYGB for MO from 9/2001 to 1/2011 and 12 patients underwent LRYGB for GERD from 2/2009 to 11/2010. Females comprised 82% and 92% and mean age was 43.5 and 49.6 years for the MO and GERD groups, respectively. 83% of patients in the GERD group had a failed Nissen fundoplication.

<table>
<thead>
<tr>
<th></th>
<th>AIS98</th>
<th>AIS08</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISS, mean</td>
<td>10.2</td>
<td>9.2</td>
<td>0.001</td>
</tr>
<tr>
<td>ISS &gt;15, n (%)</td>
<td>326 (22.5)</td>
<td>248 (17.2)</td>
<td>0.001</td>
</tr>
<tr>
<td>AIS ≥3, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Head/Neck</td>
<td>323 (22.3)</td>
<td>256 (17.7)</td>
<td>0.001</td>
</tr>
<tr>
<td>Chest</td>
<td>260 (18)</td>
<td>226 (15.6)</td>
<td>0.001</td>
</tr>
<tr>
<td>Face</td>
<td>5 (0.3)</td>
<td>2 (0.1)</td>
<td>0.083</td>
</tr>
<tr>
<td>Abdomen</td>
<td>75 (5.2)</td>
<td>63 (4.4)</td>
<td>0.001</td>
</tr>
<tr>
<td>Extremities</td>
<td>247 (17.1)</td>
<td>250 (17.3)</td>
<td>0.180</td>
</tr>
<tr>
<td>External</td>
<td>3 (0.2)</td>
<td>6 (0.4)</td>
<td>0.083</td>
</tr>
</tbody>
</table>

Conclusions: Patients undergoing LRYGB for persistent GERD had a shorter interval from initial evaluation to surgery, increased operative times, and an increased rate of marginal ulcers compared to those undergoing LRYGB for MO. The acid pocket theory may explain the increased marginal ulcer rate in the GERD population. Tailoring the operation by making a larger pouch for patients undergoing LRYGB for GERD rather than MO should be discouraged as this may increase the marginal ulcer rate.

**Background:** The AYA, defined as people between ages 15 and 40 years, is projected to increase from approximately 104 million in 2000 to 115 million in 2030. Even though cancer is the leading disease-related cause of death, AYA remains a relatively understudied area in oncology. We assessed the current and projected cancer burden in this population.

**Methods:** We obtained data from the SEER program. We excluded benign tumors, myeloproliferative and myelodysplastic neoplasms, as well as in situ cervical tumors. Incidence was reported per 1,000,000 person-years and age-adjusted to the 2000 US standard population. For current statistics, we used 2003-2007 data, while for trend analyses we used 1973-2007 data unless otherwise stated.

**Results:** Currently, the AYA represent approximately 5.3% of annual new cancer cases diagnosed (86,285) and 2.1% of cancer deaths (9,207) in the US. The 10 leading cancers by incidence (both sexes combined) are breast (115.7), melanoma (103.1), thyroid (81.1), testicular (51.7), non-Hodgkin lymphoma (NHL) (39.7), Hodgkin lymphoma (36.8), central nervous system (CNS) (34.1), colorectal (33.9), cervical (32.0), and leukemia (29.9). The incidences are increasing overall and among the top 10 cancers for thyroid, CNS, testicular, breast, melanoma, and colorectal cancers; decreasing for cervical cancer; and relatively stable for NHL, Hodgkin lymphoma, and leukemia. The 10 leading causes of cancer deaths are breast (12.2%), leukemia (12.1%), CNS (9.1%), colorectal (8.0%), lung (6.3%), NHL (5.7%), cervical (4.8%), sarcoma (4.2%), stomach (4.1%), and melanoma (3.5%). Five-year cancer specific survival rates have been increasing for most cancers except for thyroid and cervical, in which the rates remain stable. If more recent trends continue, the AYA is expected to represent 3.4% of annual new cancer cases diagnosed and 1.2% of cancer deaths by 2030.

**Conclusions:** The AYA have distinct cancer incidences and mortality rates. While the proportions of annual new cancer cases and cancer deaths in AYA are expected to decline relative to the other age groups, the cancer burden is anticipated to increase due to projected growth of the US population and an increasing overall incidence.


**Background:** The NCCCP has engaged in special programs to enhance clinical trial accrual among underserved populations. These include cultural awareness webinars, nurse/lay navigators with translated consent forms and interpreters, expansion of trials in outreach sites, community site pairing, and utilization of a web-based tracking tool to monitor clinical trial screening and accrual barriers.

**Methods:** Screening and accrual data of 19 NCI Cooperative Group trials encompassing 9 disease categories from the geographically diverse NCCCP sites was collected between March 2009 and December 2010. The data included patient demographics, trial eligibility, trial enrollment, and reasons for non-enrollment. We used Fisher’s exact test for determination of P values. This abstract addresses patient demographics.

**Results:** Of the 1,589 patients screened during this period, 359 were enrolled, for an overall accrual rate of 23%. The accrual rates among the various demographic subsets are shown in the table. No disparity based on gender, ethnicity, or race between Whites and African Americans (P value for the latter comparison 0.59) was found and the disparity gap between the young and elderly appears narrowed when compared to historical data (3-fold difference; Murthy VH, et al JAMA 2004).

**Conclusions:** NCCCP has captured clinical trial screening and accrual outcome among several underserved populations coming from diverse geographic locations. Data suggests that through barrier identification and a concerted program of network strategies involving community cancer centers, disparities in clinical trial accrual have been reduced. This project funded in whole or part with federal funds from NCI, NIH under Contract No. HHSN261200800001E.
<table>
<thead>
<tr>
<th></th>
<th># Screened</th>
<th># Enrolled</th>
<th>Accrual rate (%)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>1,589</td>
<td>359</td>
<td>23</td>
<td>--</td>
</tr>
<tr>
<td>Female</td>
<td>1,078</td>
<td>246</td>
<td>23</td>
<td>0.80</td>
</tr>
<tr>
<td>Male</td>
<td>511</td>
<td>113</td>
<td>22</td>
<td></td>
</tr>
<tr>
<td>Age &gt; 65</td>
<td>689</td>
<td>216</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td>&lt; 65</td>
<td>883</td>
<td>2 (10%)</td>
<td>4 (6%)</td>
<td>0.611</td>
</tr>
<tr>
<td>Hispanic</td>
<td>93</td>
<td>20</td>
<td>22</td>
<td>0.80</td>
</tr>
<tr>
<td>Non-Hispanic</td>
<td>1,465</td>
<td>339</td>
<td>23</td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>1,309</td>
<td>306</td>
<td>23</td>
<td>0.59</td>
</tr>
<tr>
<td>African American</td>
<td>205</td>
<td>44</td>
<td>22</td>
<td></td>
</tr>
</tbody>
</table>

20. Harris L, Cole CE. The tick made him nervously sick. WMJ. 2011;110(4)42. http://viewer.zmags.com/publication/a050f6eb#/a050f6eb/42

**Introduction:** Myasthenia gravis is the most common neuromuscular transmission disorder. A myasthenia gravis crisis can be triggered by infections, exertion, excitement, or numerous other stressors. We report a case of myasthenia gravis crisis due to ehrlichiosis.

**Case:** An 86-year-old white man with history of well-controlled myasthenia gravis presented to the ED with weakness and dyspnea that had been worsening progressively over the past several days. Due to impending respiratory failure, the patient required intubation within minutes of presentation. Thus, initial history was limited. Exam revealed a weak, septic patient with a maculopapular rash on the bilateral forearms. Lab work was remarkable for thrombocytopenia and transaminitis. Peripheral blood smear revealed morulae inside several neutrophils. The patient was diagnosed with myasthenia gravis crisis due to sepsis from ehrlichiosis. He was treated with doxycycline, plasmapheresis, and IVIG. Later, the patient was extubated and reported a history of tick exposure. After 1 week, the patient recovered well enough to be discharged from the hospital.

**Discussion:** Many stressors have been associated with causing myasthenia gravis crises but to date there are no other cases of ehrlichiosis-induced myasthenia gravis crisis reported in the literature. This case demonstrates that patients who present with myasthenia gravis crisis can be critically ill, but can quickly recover if their inciting event is identified and treated.


22. Hayter KL Use of systems and task force initiatives in complex adaptive systems to increase pain documentation on the cardiopulmonary unit. Presented at Nursing Research on the Green, Viterbo University, La Crosse, Wisconsin, April 19, 2011.

**Problem:** Documentation of pain assessment and reassessment with administration of medication was not being completed. The first 3 weeks of an audit by QI RN demonstrated a 17%, 12%, and 10% compliance of essential documentation on the Cardiopulmonary Unit.

**Purpose:** Department of Nursing Educators, QI RNs, and unit based managers were given the directive to increase essential documentation of pain.

**Planning Interventions:** Ongoing: QI RN audits occurred throughout the 9 month time frame. (First unit based initiative) Cardiopulmonary Pain Task Force members placed a visual cue on bedside, hallway, and nursing station computers. Unit initiative – QI RN identified charts that were lacking documentation from the audits. Unit managers completed a systems initiative called a care review. This process reviews the RN’s charting for that day. Task force recommended the idea of a Peer Chart Review (unit based), to increase awareness of documentation.

**Summary of Results:** QI RN audits at the unit level with feedback occurred throughout. System wide education and Tracers showed little improvement in documentation. Task force implementations of a visual cue, care review at a staff meeting, and reminder that all staff assist in pain management, increased the median scores of documentation from 27% to 56%. Peer chart review increased the median score from 56% to 72%. Overall pain assessment and reassessment increased 166% over 9 months with system and local initiatives.

**Implications for Practice:** System and unit based initiatives work in partnership to create change. Layered interventions are needed for consistent improvement in complex adaptive systems. Dramatic results can be obtained
in a 9 month period utilizing these techniques. Further data will be collected through a study by the National Database of Nursing Quality Indicators (NDNQI).


Case: A 54-year-old woman with a history of chronic lymphocytic leukemia with progression to prolymphocytic leukemia in remission was admitted with chest pain, exertional shortness of breath, and low back pain. Her vitals were stable and physical examination was unremarkable. An ECG showed electrical alternans and a chest x-ray demonstrated enlargement of the cardiac silhouette with clear lung fields. A transthoracic echocardiogram (TTE) revealed a large infiltrating mass involving the right ventricle, right atrium and atrialventricular groove. The tumor involved the root of the aorta and main pulmonary artery. The patient was noted to have a large circumferential pericardial effusion without evidence of tamponade. Pathology from endomyocardial biopsy of the right ventricle was consistent with a low-grade B-cell lymphoma positive for CD20 and negative for CD3. CT scan showed disease involving the heart, mediastinal and paraspinal regions, bilateral kidneys, distal superior mesenteric artery, mesentery and pericardium. She was initiated on fludarabine, cytoxan, and rituxan (FCR) chemotherapy to which she initially responded well. However, she was readmitted 2 weeks later with recurrence of the effusion and was subsequently initiated on etoposide, doxorubicin, vincristine, cyclophosphamide and prednisone chemotherapy with ribuximab (EPOCH-R). A repeat TTE showed that the effusion as well as the right ventricular outflow area of tumor burden had decreased in size with symptomatic improvement. She is now being followed closely in hematology clinic.

Discussion: This is a very rare and unusual presentation of an aggressive non-Hodgkin lymphoma arising out of prior B-cell prolymphocytic leukemia involving the heart. We initially treated the patient on FCR chemotherapy as her B prolymphocytic leukemia had responded to FCR and was in remission. But she did not respond to FCR chemotherapy. She was later switched over to EPOCH regimen as there is some evidence that EPOCH may produce more cell kill than CHOP-based regimens in untreated B-cell lymphomas (Blood, 2002;99:2685-2693). The prognosis and optimal treatment is uncertain as it has not been reported previously in the literature.


Background: Developed by American Association of Colleges of Nursing and other organizations in response to landmark reports including To Err is Human: Building a Safer Health System and Crossing the Quality Chasm. Due to complex status of current healthcare environment, the need for advanced education, clinical expertise and leadership training at the bedside was recognized. Newest advanced degree in nursing in almost forty years. Little is known about details of CNL role development and implementation within an individual organization.

Purpose: Gain an understanding of key components in CNL role development and implementation on an inpatient unit. Identify staff, unit and organizational needs during CNL role development and implementation.

Planning:
Role Development: Assessment: reviewed role styles; developed, categorized and prioritized role questions; internal dialogue held at various levels. Role Transition: MSN RN to CNL; BSN Bedside RN to CNL Fellow (CNL student). Job Descriptions: PFCC verbiage included. Office Location: placed in central location on unit for access.
Metrics: Increased quality and safety; Increased satisfaction from patients and staff; Reduced costs. Outcomes: Key components in CNL role development and implementation on an inpatient unit were completed. Staff, unit and organizational needs during CNL role development and implementation were recognized. CNL responsibilities continue to evolve. Outcomes of the identified metrics will be determined.
Implications: Utilize phase 1 and 2 lessons learned to refine; implementation of phase 3; continue to identify and collect evaluation data for phase 4; network with academic CNL programs to improve curriculums; network with other macrosystems to share innovative strategies of CNL implementation.
Research Recommendations: Study the implementation journeys of different organizations to identify best practices; identify metrics which most clearly capture


Presentation Objectives: Clinical Nurse Leader (CNL) role overview, Model of care redesign, Evidence Based Practice (EBP) integration, Opportunities created, Improved outcomes, Infrastructure needed, Implementation Timeline, Financial benefits, CNL student experiences, Tools.

Purpose: The purpose of this study was to describe the current workforce supply of nurses in the state of Wisconsin.

Design: Descriptive non-experimental survey. All registered nurses were required to complete the survey as part of the Wisconsin RN licensing process.

Measure: The Wisconsin Registered Nurse Survey was developed by: The Wisconsin Department of Workforce Development in collaboration with: Wisconsin Health Workforce Data Collaborative and the Wisconsin Center for Nursing. It is the result of multiple survey elements of the registered nurse population. It contains all the data elements of the National Nursing Workforce Minimum Dataset: Supply.

Conclusions: 30% of WI nursing workforce is 55 years or older. 11.6% of WI nursing workforce is <30 years old. 36% of the WI nursing workforce plan to leave direct patient care in the next nine years. Nursing academia is the oldest cohort of nurses where 42.8% is age 55 or older. Hospital nurses make up the largest cohort by work area (49.9%) and they work the longest hours. 59.3% report working >40 hours per week. 7.7% of direct care providers report working >49 hours per week. There is a lack of diversity in gender, race, and ethnicity in the WI nursing workforce.

Implications: By 2035 there will not be enough nurses to take care of the Wisconsin community. New nurses are not entering the profession at the rate that current nurses will be leaving. Direct patient care providers plan to leave their positions at very high rate over the next nine years.

Recommendations: More research is needed to: describe employment trends in nursing on an ongoing basis; examine the effect of the economic downturn on the employment prospects of new nurses; describe environmental characteristics that encourage and support older nurse in the workforce; explore ways to recruit and support a diverse workforce. The nursing profession must begin supporting early entry of nurses into academia and seek support of their scholarly efforts from all interested stakeholders. Collaborative efforts among stakeholders are needed to develop public policy that addresses excessive work hours in hospital nursing.


Background: Reinfection with *Borrelia burgdorferi* is recognized increasingly, but long-term outcomes are described incompletely.

Methods: We conducted a retrospective outcome study of patients with Lyme reinfection, characterized by recurrent erythema migrans (EM) lesions, and matched controls with a single episode of early Lyme disease. Long-term outcomes were assessed by chart review, a survey consisting of a 36-item short form health survey (SF-36), and a standardized 10-item symptom questionnaire.

Results: From a population of 404 patients diagnosed with definite Lyme disease during 2000-2004, reinfection was identified in 24 patients (6%). Sixteen patients had complete long-term follow-up data available and were matched to 48 controls. One patient had 2 documented episodes of reinfection. Patients with reinfection were treated with oral doxycycline for a median duration of 14 days (range 5-28). SF-36 scores of patients with reinfection were similar to matched controls. There were no significant differences between patients with reinfection vs controls with regards to pain (78.9 vs 77.1, P=0.747), role limitations due to physical health (84.4 vs 73.6, P=0.248), general health (72.0 vs 65.5, P=0.230), social functioning (93.8 vs 89.1, P=0.403), vitality (60.6 vs 56.4, P=0.515), role limitations due to emotional problems (83.3 vs 85.1, P=0.829), emotional well-being (79.3 vs 81.0, P=0.650), or physical functioning (84.4 vs 74.5, P=0.177). Additionally, there were no significant differences between the 2 groups on the 10-item symptom-based questionnaire.

Conclusion: Lyme reinfection is relatively common in patients from endemic areas. Long-term outcomes were similar to outcomes of patients with a single episode of early Lyme disease. The clinical features and long-term outcomes of patients with recurrent EM lesions are consistent with reinfection etiology and not persistent *B. burgdorferi* infection.

28. Jarman BT. Addressing problems with teaching faculty members or remediation of the difficult teaching faculty member. Presented at Association of Program Directors in Surgery (APDS) - Surgical Education Week 2011, Boston, Massachusetts, March 25, 2011.


Background: The modifier 22 (M22) is utilized to document increased complexity of surgical procedures which is above and beyond what would be typical and expected. The cost recovery of M22 utilization is unknown at our
increase safety. These issues included: safety interventions not individualized to the patient, nursing staff had concern 
about patient falls. To implement a multidisciplinary, multifaceted, evidence-based sustainable falls reduction program. 

**Goals:**

To improve patient safety by decreasing patient falls in inpatient psychiatry by 30%. To reduce the risk of harm from 
patient falls. To implement a multidisciplinary, multifaceted, evidence-based sustainable falls reduction program.

**Assessing the Need for Change:**
The multidisciplinary Falls Advisory Group identified issues within the current system that could be improved to 
increase safety. These issues included: safety interventions not individualized to the patient, nursing staff had concern

Patient had not taken more warfarin than recommended nor was there evidence of him taking super warfarin or 
brodifacoum. Brodifacoum levels were checked and were negative. Warfarin levels checked during his hospital stay 
were adequate and met the international normalized ratio (INR) requirements. He was then started on moxifloxacin for pneumonia, International normalized ratio (INR) on discharge was 1.3. After discharge, INR 
levels remained within normal limits. Patient developed rapid ventricular rate (RVR), bilateral pneumonia and was discharged on warfarin 4 mg per day for atrial fibrillation with rapid ventricular rate (RVR), bilateral pneumonia and was discharged on warfarin 4 mg per day for atrial fibrillation. 

**Conclusion:**
Application of M22 significantly increases reimbursement when it is applied to the procedures reviewed in this study which were all associated with a significant increase in operative time. Utilization of M22 did not significantly increase the time from billing to full payment for any of the procedures. A large percentage of coder 
review and initiation of supporting documentation was noted which suggests a need for more education among our 
general surgeons as to when and how to document accordingly.


**Case:** An 85-year-old man presented to the hospital with shortness of breath and coughing up blood. He had been admitted just 2 weeks prior for non-ST Segment Elevation Myocardial Infarction (NSTEMI), atrial fibrillation with rapid ventricular rate (RVR), bilateral pneumonia and was discharged on warfarin 4 mg per day for atrial fibrillation and moxifloxacin for pneumonia. International normalized ratio (INR) on discharge was 1.3. After discharge, INR 
was monitored closely due to drug interaction between warfarin and moxifloxacin. He did well, but a few days later 
had to stop taking warfarin due to supratherapeutic INR. He then started developing progressive shortness of breath 
followed by nose bleeds and hemoptysis for which he presented to the TEC and was found to be hypoxic with PaO2 
of 49.7 on 3L. INR was noted to be >9 and partial thromboplastin time (PTT) was 67.3. Direct visualization of 
nasopharynx with a rigid scope revealed areas of scabbing and old bleeding sites in the left anterior naris. Vitamin 
K and multiple units of fresh frozen plasma (FFP) were given. INR dropped to 1.6 but climbed up again requiring 
additional doses of vitamin K.

Patient had not taken more warfarin than recommended nor was there evidence of him taking super warfarin or 
brodifacoum. Brodifacoum levels were checked and were negative. Warfarin levels checked during his hospital stay 
were adequate and met the international normalized ratio (INR) requirements. He was then started on moxifloxacin for pneumonia, International normalized ratio (INR) on discharge was 1.3. After discharge, INR 
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nasopharynx with a rigid scope revealed areas of scabbing and old bleeding sites in the left anterior naris. Vitamin 
K and multiple units of fresh frozen plasma (FFP) were given. INR dropped to 1.6 but climbed up again requiring 
additional doses of vitamin K.


**Goals:**

To improve patient safety by decreasing patient falls in inpatient psychiatry by 30%. To reduce the risk of harm from 
patient falls. To implement a multidisciplinary, multifaceted, evidence-based sustainable falls reduction program.

**Assessing the Need for Change:**
The multidisciplinary Falls Advisory Group identified issues within the current system that could be improved to 
increase safety. These issues included: safety interventions not individualized to the patient, nursing staff had concern
regarding the reliability of the fall risk assessment tool, current fall reduction strategies not effective in reducing patient falls, staff were rounding on patients but rounding was not targeted or accountable, patients and families were unaware of the risk of falling during a hospitalization, medication changes and decreased cognition in patients increased their fall risk.

Evidence-Based Interventions:
Initiated an action plan which included a “bundle” that was piloted on the psychiatric unit, developed a standard process for continuous observation, created mobility circles, implemented a new fall risk assessment tool, individualized the patient’s plan of care, instituted safety huddles.

Components of the “Bundle”:
Patient/Family Education: Patients/families are educated on admission with reinforcement every shift, with medication changes and at community meeting about the risk to fall during hospitalization.

Signage in Patient Rooms:
Bright yellow signs are posted underneath the clock in each room and in the bathroom – Call, Don’t Fall.”

Targeted, Accountable Hourly Rounding:
Targeted patient rounding with a focus on bathroom needs, change in position and presence of pain.

Safe Room Order:
A system wide mandatory education component focused on safe patient room environment with reinforcement with tracer questions. As part of safe room audit, staff were directed to insure that the patient’s call light was operational and within their reach. Furniture in patient rooms was decreased and new low psychiatric beds were put in place.

Staff Education:
Falls trending data shared with staff quarterly at staff meetings.

Pharmacist:
To review high risk medications and make recommendations to the psychiatrist.
Key Elements that led to Success:
A multi-layered approach to education was key to staff knowledge and extension of the elements to decrease falls and harm from falls, input from front line staff, designated RN/CNA champions on each unit, support from unit-based quality nurses and educators, advanced practice nurses, patient safety liaisons, clinical managers, the falls coordinator, the Falls Advisory Group and hospital leadership, joint weekly “check-in” meetings hospital-wide, study done by students to measure the effectiveness of patient education.

33. Kobler K, Limbo RK. The art of being in relationship. Presentation at National Hospice and Palliative Care Organization, San Diego, California, October 6, 2011.

Session Description:
This workshop will provide opportunities to explore effective strategies to initiate, maintain and transition relationship in pediatric palliative care settings. The speakers use narratives, visual media, case studies, and small group work to engage participants in exploring the “how-to” of relationship-based care, balancing perspectives of self and those of the patient and family. The interactive format will include opportunities to discuss individualized strategies to develop a reflective practice, share personal experiences within professional relationships, and enhance self-care and self awareness.

Presentation Objectives:
Describe three aspects using “self” in relationship with pediatric palliative care patients and their families
Discuss strategies to develop, maintain and transition relationship
Identify opportunities to effectively use reflective practice
Identify strategies for integrating self-care into professional practice


Purpose: The level of scientific evidence on which the National Comprehensive Cancer Network (NCCN) guidelines are based has not been systematically investigated. We describe the distribution of categories of evidence and consensus (EC) among the 10 most common hematologic malignancies with regard to recommendations for staging, initial and salvage therapy, and surveillance. Methods NCCN uses a system of guideline development distinct from other major professional organizations. The NCCN definitions for EC are as follows: category I, high level of evidence with uniform consensus; category IIA, lower level of evidence with uniform consensus; category IIB, lower level of evidence without a uniform consensus but with no major disagreement; and category III, any level of evidence but with major disagreement. Results Of the 1160 recommendations found in the 10 guidelines, the proportions of category I, IIA, IIB, and III EC were 3%, 93%, 4%, and 0%, respectively. Recommendations with category I were found in acute myeloid leukemia (4%), multiple myeloma (7%), Hodgkin’s lymphoma (1%), diffuse large B-cell lymphoma (4%), follicular lymphoma (11%). Chronic lymphocytic leukemia/small lymphocytic lymphoma, mantle cell lymphoma, marginal zone lymphoma, AIDS-related B-cell lymphoma, and Burkitt lymphoma did not have any category I recommendations. Three percent of all therapeutic recommendations were category I. Therapeutic recommendations were found on staging or surveillance. Conclusion Recommendations issued in the NCCN guidelines are largely developed from lower levels of evidence but with uniform expert opinion. This underscores the urgent need and available opportunities to expand evidence base in oncology.


Introduction: This study's purpose was to evaluate the incidence of aseptic loosening with use of an uncemented tapered femoral component in obese vs nonobese patients at 18 to 27 years (mean 23.5 years).

Methods: Between 1983 and 1987, 285 consecutive uncemented total hip arthroplasties were performed with use of a tapered stem. The patients were divided into 2 groups, obese and nonobese, as determined by their body mass
index (BMI). There were 105 obese patients (119 hips, BMI ≥30) and 156 nonobese patients (166 hips, BMI <30). The outcome of every femoral component with regard to stem fixation, revision, or retention was determined for all 285 hips. Complete follow-up was obtained on the 97 patients (111 hips) surviving a minimum of 18 years (range 18 to 27 years).

**Results:** Of the 119 hips in obese living and deceased patients, 1 stem (1%) had been revised for aseptic loosening and one was loose by radiographic criteria. In the 55 surviving hips, none had been revised for aseptic loosening and one was loose. Of the 166 hips in nonobese living and deceased patients, none had been revised for aseptic loosening and one was loose by radiographic criteria. In the 56 surviving hips, none had been revised for aseptic loosening and one was loose. No significant difference between the 2 groups with regard to clinical outcome or perioperative complications was found.

**Conclusion:** Uncemented tapered stems provide excellent fixation in obese and nonobese patients out to 27 years.


**Objectives:**
1. Describe three current research findings on bereaved fathers.
2. List three perceived social expectations of fathers who are grieving.
3. Discuss responses of others when a child dies.

**Description:** The death of any age child leaves a father questioning the order of life. Parents are supposed to die before children. Yet, the harsh reality that such is not always the case creates the context for fathers’ grief. After a brief overview of current research, a panel of bereaved fathers will share their stories of grief and transformation. They will describe their feelings at the time and over time, the perceived social expectations that influenced them, and how they have adjusted to being a father with a child who is no longer physically present.

**Speakers:**
Rana Limbo, PhD, RN, PMHCNS-BC, Director of Bereavement and Advance Care Planning Services, Gundersen Lutheran Medical Foundation, La Crosse, WI, and a panel of bereaved fathers.


**Background:** Glycemic control in types 1 and 2 diabetes mellitus has become more challenging with the rising obesity epidemic. In patients who require insulin doses exceeding 200 units/day, using U-100 regular insulin may not provide adequate glycemic control because of either poorly absorbed subcutaneous depositions or unreliable absorption patterns.

**Methods:** This study’s purpose was to test the hypothesis that switching from U-100 regular insulin to U-500 regular insulin improves long-term glycemic control in diabetic patients who have not attained glycemic control. A retrospective review was conducted for these patients with U-500 begin dates between January 2005 and December 2010.

The primary measure of long-term glycemic control is a long-term reduction in hemoglobin A1C (Halc). This is defined at a time point greater than 8 months post U-500 initiation and ending either when the patient discontinued the use of U-500 insulin or at the latest available date. Secondary endpoints studied included change in body mass index (BMI) after initiation of U-500 insulin and change in 6-month Halc (collected between 4 and 8 months post U-500 initiation).

**Results:** The mean change in Halc for long-term analysis (n=68) was -1.11 ± 1.95 with *P* value of <0.001 (95% CI: -1.58 to -0.64). The mean long-term follow-up was 35.78 ± 22.62 months with minimum of 9.17 and maximum of 93.99. The mean change in Halc after approximately 6 months (n=44) was -1.32 ± 1.66 with a *P* value of <0.001 (95% CI, -1.82 to -0.81); mean change in BMI at 6 months was 0.67 ± 2.42 (*P*=0.082) and 1.55 ± 5.39 (*P*=0.021) at the latest date.

**Conclusion:** U-500 may improve glycemic control, both in the short term and long term for those patients in whom glycemic control is not achieved with U-100 insulin. There does appear to be a small increase in BMI in the long term. One needs to take this into account when deciding whether or not to use U-500. However, this alone should not deter a clinician from considering the use of U-500.

Introduction: The purpose of this study was to evaluate the incidence of aseptic loosening with use of an uncemented tapered femoral component in obese versus non-obese patients at 18 to 27 years (mean 23.5 years).

Methods: Two hundred eighty-five consecutive uncemented total hip arthroplasties were performed between 1983 and 1987 with use of a tapered stem. The patients were divided into two groups, obese and non-obese, as determined by their body mass index (BMI). There were 105 obese patients (119 hips) (BMI ≥30) and 156 non-obese patients (166 hips) (BMI <30). The outcome of every femoral component with regards to stem fixation, revision, or retention was determined for all 285 hips. Complete follow-up was obtained on the 97 patients (111 hips) surviving a minimum of 18 years (range 18-27 years).

Results: Obese: Of the 119 hips in living and deceased patients, one stem (1%) had been revised for aseptic loosening and one was loose by radiographic criteria. In the 55 surviving hips, none had been revised for aseptic loosening and one was loose. Non-Obese: Of the 166 hips in living and deceased patients, none had been revised for aseptic loosening and one was loose by radiographic criteria. In the 56 surviving hips, none had been revised for aseptic loosening and one was loose. No significant difference between the two groups with regard to clinical outcome, or perioperative complications was found.

Conclusion: Uncemented tapered stems provide excellent fixation in obese and non-obese patients out to 27 years.


Introduction: Wegener's granulomatosis is a necrotizing granulomatous vasculitis associated with antineutrophil cytoplasmic antibodies that typically involves the upper and lower respiratory tracts and the kidneys. It can affect any organ system and many patients will have neurologic involvement at some point in the course of their disease. However, central diabetes insipidus (DI) as the first symptom of Wegener's is extraordinarily rare.

Case: A 66-year-old man presented with a 2- to 3-week history of polyuria and thirst. The symptoms developed gradually with progression to hourly urinary frequency. The patient denied hesitancy, urgency, dysuria, or hematuria. He noted migrating myalgias and arthralgias occurring over the preceding 2.5 years. He also reported a dry cough. Physical exam was unremarkable. Serum osmolality was mildly elevated at 309 with urine osmolality low-normal at 106. A water deprivation test was conducted with findings consistent with partial central diabetes insipidus. The patient was started on nasal DDAVP with appropriate decrease in urine output and increase in urine osmolality. MRI of the brain and sella turcica demonstrated absence of the “normal pituitary bright signal,” which was thought to suggest an infiltrative process in the posterior pituitary gland. A chest CT demonstrated multiple pulmonary nodules bilaterally with necrotic centers. Biopsies of these nodules revealed inflammatory changes with giant cells, microabscesses, and some granulomatous features, with patchy surrounding interstitial fibrosis with centriflobular predilection, favoring a diagnosis of Wegener's granulomatosis. P-ANCA was positive but c-ANCA and myeloperoxidase (MPO) were negative. Renal function was normal. PCR for TB was negative.

Approximately 5% of patients with Wegener’s granulomatosis will be p-ANCA positive, though the majority are c-ANCA positive. As with this patient who had no renal impairment, approximately one-fourth of cases of Wegener’s granulomatosis will occur as a “limited” form with clinical findings isolated to the upper respiratory tract or lungs. Other organ systems that may be involved include the joint, skin, eyes, and nervous system. Central DI associated with Wegener’s granulomatosis is rare, with only approximately 22 cases reported in the literature. Fewer cases exist of central diabetes insipidus as the presenting symptom of Wegener’s granulomatosis.

43. Newberry SM. Conflict engagement: promoting safe and effective communication. Poster presentation at Nursing Research on the Green, Viterbo University, La Crosse, Wisconsin, April 19, 2011.

Background: The Center for American Nurses has developed the Conflict Engagement Profile program in response to a request for programs to address the negative impact of conflict in the workplace.

Purpose: To assess the effectiveness of the Conflict Engagement Portfolio intervention with Gundersen Lutheran nurses at baseline and at one year after the initiative.

Research Questions: What is the prevalence of conflict as perceived by staff RNs at Gundersen Lutheran? What is the perception of Gundersen Lutheran nurses in relation to lateral violence and professional esteem? Are there any differences in the subscales among a) generations or b) formal and informal nurse leaders, and staff nurses?

Methods: Design: Triangulation methodology incorporating both quantitative and qualitative approaches: survey; demographics; rating of conflict; open ended questions.
Implications for Nursing: Need for consistent working definition of conflict. Limited opportunity for structured learning for ongoing skill building (too busy). Belief that all conflict is bad. Perception that conflict doesn't exist in the current work setting. In developing a proactive initiative, research suggests starting with manager training, but little evidence for moving forward with staff nurses.


Background: Joint Commission states that health care organizations must address the problem of destructive behaviors in the workplace. The Center for American Nurses (CAN) offers the Conflict Engagement Profile program to increase the use of constructive conflict engagement behaviors. Following implementation of the CAN’s program for system nurse leaders, participants recommended ongoing coaching and additional practice sessions. The challenge was to deliver this multi-layered program in a manner that is efficient, cost effective and meaningful to staff nurses.

Purpose: To evaluate the effectiveness of a modified program designed to meet the scheduling needs of staff nurses working in a large integrated health system.

Materials/Methods: The CAN’s program was modified to include: online education modules and a half-day workshop followed by one-hour Learning Circle meetings held monthly for four months. A convenience sample of nurse Expert Leaders (unit level staff nurse leaders) agreed to participate. IRB approval was obtained. Data was collected at baseline and will be collected at six months (April 2011) using a demographic survey, the Conflict Dynamic Profile instrument and focus groups.

Results: A cohort of 45 (22%) Expert Leader nurses participated with >90% attendance at monthly meetings. Characteristics of this sample include: median age of 50 years, 58% working in the hospital setting, 56% bachelor degree prepared and 58% active in the system's shared governance structure. While only one participant indicated previous training in conflict management, 62% indicated they were moderately to very confident in dealing with conflict. In the pre-workshop focus groups, nurses provided numerous examples of overt and subtle negative conflict behaviors but no clear definition of conflict. Although participants stated that good conflict existed, very few examples were presented.

Conclusions: High participation at monthly Learning Circle meetings reflect staff nurses’ active interest in practice exercises, mutual support for engaging in conflict situations and problem solving system issues. Six-month data will be presented with lessons learned and recommendations for future implementation of the CAN’s program.

45. Newberry SM, Schaper AM, Inglis RL. Conflict is not common in our workplace. Poster presented at Sigma Theta Tau International 41st Biennial Convention, Grapevine, Texas, October 30, 2011.

Purpose: To describe results of a baseline assessment of conflict in the workplace and present implications for initiating an intervention program. A national survey (Dewitty et al, 2009) indicated that 53% of nurses reported conflict as “common” or “very common” in the workplace. Conflict situations can lead to poor patient outcomes. To improve patient care quality and safety; a conflict engagement program, developed by the Center for American Nurses (centerforamericaninnurses.org), was implemented. A first step was to assess staff nurses’ perceptions of conflict prevalence and type, and to gain insights into their interpretation of the baseline data.

Methods: Survey Monkey was utilized to distribute the survey to 1,174 staff nurses (52% return rate). In focus groups nurses discussed survey results compared with national data.

Results: Survey results demonstrated that 36% of staff nurses reported conflict as “common” or “very common” with an additional 49% rating conflict as “somewhat common”. Hospital nurses reported more conflict than clinic nurses, but there were no generational differences. Conflict occurred most commonly nurse to nurse and between nurse and physician. Focus group data suggested that conflict was narrowly defined as overt confrontation based on past negative experiences, and was more prevalent than reported. The majority of write-in comments (44%) indicated that nurses believed all conflict was negative and should be avoided.

Conclusion: Providing nurses with a clear definition of conflict and examples of positive outcomes when conflict exists are key to preparing for a conflict engagement intervention program. While a low level of conflict appears ideal, conflict can lead to innovation. A clear definition of conflict and understanding of its value may result in higher reports of conflict in the workplace.

**Case:** A 74-year-old woman with rheumatoid arthritis treated with hydroxychloroquine developed 1 episode of mild gastroenteritis of 1 to 2 days duration while on a week-long vacation in the Caribbean. Six weeks later, the patient was admitted to a local hospital with gradual worsening of her chronic back pain, generalized weakness, frequent falls, and episodes of confusion. She was afebrile with stable vitals and had marked back pain with movement. Palpation tenderness was present in the paraspinal region of her lower back. Head CT and x-ray of lumbar spine was unrevealing. Blood cultures grew *Salmonella* serotype Enteritidis. The patient received IV levofloxacin for 5 days, and with clinical improvement, she was discharged with an additional 5 days of oral levofloxacin.

Three weeks later, the patient was readmitted to the same hospital with complaints of persisting back pain, weakness, and confusion. She had a fever of 104.2ºF with midline lumbar tenderness. After transfer to our hospital for further care, we performed an MRI of the spine that showed L4-L5 diskitis. Blood cultures and disc space aspirate cultures grew *S. enteritidis*. Abdominal CT showed a 2-cm saccular mycotic aneurysm of the distal abdominal aorta. While on ceftriaxone, patient underwent aneurysmectomy with aortic reconstruction using autologous spinal saphenous vein graft. Tissue culture from the resected aneurysm also grew *S. enteritidis*. She was continued on ceftriaxone for a total of 6 weeks. Her pain improved and she was doing well when seen 2 months later at follow-up in clinic.

**Discussion:** Mycotic aneurysm is a rare but serious complication of nontyphoidal *salmonella* bacteremia, occurring most commonly in the abdominal aorta. This case demonstrates the importance of clinicians’ awareness that adults with a relapse of *salmonella* sepsis often have a serious endovascular infection. This risk is increased in patients above 50 years of age with atherosclerosis. Anti-*salmonella* antimicrobial therapy should be started and a CT or MRI with contrast should be performed on an emergency basis. Following diagnosis, surgical resection of the aneurysm with in situ graft revascularization, the procedure of choice, should be done as soon as possible. Postoperative antimicrobial therapy for 6 to 8 weeks based on ESR and clinical response is recommended.


**Objective:** To identify the impact of the Abbreviated Injury Scale (AIS) changes from AIS98 to AIS08 on Injury Severity Score (ISS) and attendant implications for programs.

**Methods:** Injuries for patients within our institution's trauma registry from July 2008 through July 2010 were coded using both AIS98 and AIS08 scales. Impact of AIS code revisions and severity variations on ISS were determined. Statistical analysis included t test, McNemar's test, chi-square. A *p*<0.05 was considered significant.

**Results:** 1446 patients were analyzed. Code revisions and severity changes between AIS98 and AIS08 occurred in 361 (25%) and 292 (20%) patients, respectively. Overall, ISS decreased in 19.8% of patients, with code severity changes accounting for greater than two thirds of this decrease.

<table>
<thead>
<tr>
<th></th>
<th>AIS98</th>
<th>AIS08</th>
<th><em>P</em> value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISS, mean</td>
<td>10.2</td>
<td>9.2</td>
<td>0.001</td>
</tr>
<tr>
<td>ISS &gt;15, n (%)</td>
<td>326 (22.5)</td>
<td>248 (17.2)</td>
<td>0.001</td>
</tr>
<tr>
<td>AIS ≥3, n (%)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Head/Neck</td>
<td>323 (22.3)</td>
<td>256 (17.7)</td>
<td>0.001</td>
</tr>
<tr>
<td>Chest</td>
<td>260 (18)</td>
<td>226 (15.6)</td>
<td>0.001</td>
</tr>
<tr>
<td>Face</td>
<td>5 (0.3)</td>
<td>2 (0.1)</td>
<td>0.083</td>
</tr>
<tr>
<td>Abdomen</td>
<td>75 (5.2)</td>
<td>63 (4.4)</td>
<td>0.001</td>
</tr>
<tr>
<td>Extremities</td>
<td>247 (17.1)</td>
<td>250 (17.3)</td>
<td>0.180</td>
</tr>
<tr>
<td>External</td>
<td>3 (0.2)</td>
<td>6 (0.4)</td>
<td>0.083</td>
</tr>
</tbody>
</table>

**Conclusions:** Revisions from AIS98 to AIS08 resulted in a decrease in overall ISS as well as patients classified as “major trauma” (ISS>15). The decrease in ISS was primarily driven by changes in code severity in three anatomic regions: head/neck, chest and abdomen. The revisions have significant implications for ACS verification criteria and dataset comparisons between AIS version.

Issue:
Education and compliance with hand hygiene recommendations remains a challenge for Infection Control Practitioners (ICPs). Since the days of Semmelweis, identifying effective methods for education has been a challenge.

Project:
Hand hygiene data is evaluated on a monthly basis in the hospital, and annually system-wide. With rates not reaching the organizational goal of 95%, in June 2010 a challenge was issued to nursing partners to develop innovative educational tools to promote hand hygiene. In addition to signage encouraging hand hygiene, a collaborative effort was undertaken to develop a short video to serve as social marketing for hand hygiene.

Results:
Hand hygiene rates have been positively impacted by ongoing and multi-modal educational campaigns. Involvement of staff from the front-line is essential to developing educational strategies that stick. Staff buy-in came in the form of participation in the process and a personalized song for our organization entitled “We’ve Got the Whole Place In Our Hands.”

Lessons Learned:
In the fast-paced society we live in, ICPs must evolve and embrace new modalities to deliver education. Front-line staff and key leaders were in the video to accomplish a goal of inclusiveness and support from all levels of the organization. The process for development of an effective video is arduous. ICPs must take on the challenge to continually develop innovative educational techniques to meet the educational needs of the busy healthcare worker.


Issue:
Cleaning high-touch objects is critical to prevent the transmission of germs from the environment. Two cases of vancomycin resistant enterococcus (VRE) were identified in a short period of time in a 16-bed intensive care unit.

Project:
A luminometer was used to evaluate unoccupied terminally cleaned patient rooms. The device measures adenosine triphosphate (ATP). The parameters set for acceptable ATP readings were color-coded and set at: <100 passing [green]; 101-300 acceptable [yellow]; >301 unacceptable [red]. Expectations for daily high touch surface cleaning were explained and included a hands-on experience with the IV pumps. Environmental Assistants, supervisors, manager and director for all three shifts reviewed the data and took the challenge to “Go Green” in 2011, by cleaning so well that all ATP readings are in the <100 RLU [GREEN] range.

Results:
Observational data indicated staff cleaned high touch surfaces only 60% of the time. ATP results showed that only 21-25% of the bedrails and keyboards had ATP results <300. Door knobs, drawer handles, call lights all failed.

Lessons Learned:
Multiple surfaces in clean patient rooms have high readings for ATP. Benchmarking with other facilities is providing strategies to bring surfaces to a ‘green’ level of clean. Different groups engage more readily in the shared task of keeping the patient environment clean; the team continues to evaluate engagement with nursing and ancillary services. ATP provides an objective, non-discriminatory measure of performance. The challenge to “Go Green” was positively received.


Issue:
Conducting Infection Control Risk Assessments (ICRA) during all phases of construction and maintenance activities is necessary in the ever-evolving hospital environment. In February of 2011, Gundersen Lutheran broke ground for a new hospital building that will serve the needs of the community for generations to come. The ICRA for this large scale project is fluid and relies on establishing key relationships.

Project:
The ICRA for the project began over a year before the groundbreaking event. Infection Control provided input on design and engineering for the new facility, and for the many phases that modify current building infrastructure. Baseline particle counts were conducted in high-risk areas of the existing structure to evaluate and monitor containment efforts.
Results:
Infection control needs were addressed for all phases of the project. The project required insight for design specifications and for the impact it would have on the existing hospital structure. Key communication between clinical partners, facility operations staff, and the construction contractors was facilitated by infection control. Particle counts led to halting the project to refine containment on at least one occasion.

Lessons Learned:
Infection control practitioners need to collaborate with architects, project managers and engineers in design efforts for new facilities. Infection control expertise reassures front-line staff that plans protect patient safety. Particle counting is an objective measure to facilitate communication among clinical and construction operations. Infection Control maintains involvement through all phases of construction from design to occupancy and beyond.


Introduction: The syndrome of diffuse pulmonary hemorrhage (DPH), which includes hemoptysis, anemia, and bilateral pulmonary infiltrates, has a broad differential diagnosis. Establishing the specific cause of DPH can be challenging. Hemoptysis can be a feature of metastatic angiosarcoma, but these patients often have an established diagnosis of angiosarcoma from their primary tumor. We report a case of metastatic angiosarcoma presenting as diffuse pulmonary hemorrhage, a rare presentation for this uncommon disease.

Case: A 32-year-old white man with no significant past medical history presented with hemoptysis for 6 weeks. He reported dyspnea and palpitations for 3 weeks. He had a 10-pack/year history of tobacco abuse and also reported binge alcohol use and smoking marijuana. He denied intravenous drug use. His physical exam was normal except for pallor. Laboratory studies revealed hemoglobin of 6g/dL. His ESR and C-reactive protein were elevated. Tests for HIV, fungal infection, autoimmune disease, and TB were negative. Chest radiograph revealed diffuse ground glass appearance. Chest CT revealed innumerable clusters of micronodules in the peripheral distribution in upper and lower lobes bilaterally. Nodular lesions also were noted in the liver and spleen. Percutaneous liver biopsy showed malignant cells with extensive necrosis, but a definitive...


Background: Despite the lack of evidence to support its utility, routine CEF measurement prior to ABC is a common practice in the community, required in most US clinical trials, endorsed by the American Heart Association and American College of Cardiology, and appears on Food Drug Administration-approved labeling guidelines.

Objectives: We determined the frequency of the following events in newly diagnosed invasive breast cancer patients: a) CEF measurement prior to ABC; b) asymptomatic left ventricular dysfunction; c) modification in initial treatment strategy as a result of CEF measurement; d) development of congestive heart failure (CHF) after ABC.

Methods: From our cancer registry, we obtained a list of all female patients with newly diagnosed stage I-III breast cancer who were treated with chemotherapy as part of initial therapy at our institution in 2000-2010 (N=562). We excluded those with prior CHF, ABC, and those who had Her2-positive disease (n=66). CEF <50% was considered low. CHF risk factors including coronary heart disease, cigarette smoking, hypertension, obesity, and diabetes mellitus were collected.

Results: We included 496 patients with the following stage distribution: I (22%), II (54%), and III (24%). The mean age was 53 years (SD ± 11; range 25-88). In 30 (7%) patients, ABC was considered inappropriate by the physician provider due to poor performance status, co-morbidities, and physician or patient preference. Of the 466 patients considered for ABC, CEF was measured in 241 (52%) patients before chemotherapy. In the latter group, only 1 (0.4%) patient was found to have asymptomatic left ventricular dysfunction with CEF of 48%. Among patients considered for ABC, 10 (2%) did not receive ABC for the following reasons: low or borderline CEF (2), patient preference (3), co-morbidities (2), and randomization to non-ABC in clinical trials (3). After a mean follow up of 57 months (SD ± 34), only 3 of 456 (0.7%) patients who received ABC developed CHF. Two had normal CEF prior to treatment while the other did not have CEF measured. The practice of CEF measurement prior to ABC varied among physician providers, ranging from 23% to 67% (mean/SD 47% ± 15%). Those who had CEF measured before chemotherapy were older (55 vs. 50 years; P<0.001) and had more CHF risk factors (1.3 vs. 0.9; P<0.001).

Conclusions: At our institution, routine CEF measurement prior to ABC as initial therapy for early-stage Her2-negative invasive breast cancer patients is a common though not uniform practice. Asymptomatic left ventricular dysfunction is rarely detected and generally mild. Our findings do not support the utility of routine CEF measurement...
in this population and challenge current practice and guidelines. Potential cost implications to our health care system can be substantial.

54. Poonacha TK, Go RS. Level of scientific evidence underlying recommendations arising from National Comprehensive Cancer Network Clinic Practice Guidelines. WMJ. 2011;110(4)190.

Purpose: The level of scientific evidence on which the National Comprehensive Cancer Network (NCCN) guidelines are based has not been investigated systematically. We describe the distribution of categories of evidence and consensus (EC) among the 10 most common cancers with regard to recommendations for staging, initial and salvage therapy, and surveillance.

Methods: We obtained the latest versions (as of July 6, 2010) of relevant guidelines. The NCCN definitions for EC were Category 1 (high level evidence with uniform consensus), Category II A (lower level of evidence with uniform consensus), Category II B (lower level of evidence without a uniform consensus but with no major disagreement), and Category III (any level of evidence but with major disagreement).

Results: Of the 1023 recommendations found in the 10 guidelines, the proportions of Category I, II A, II B, and III EC were 6%, 83%, 10%, and 1%, respectively. Recommendations with Category I EC were found in kidney (20%), breast (19%), lung (6%), non–Hodgkin lymphoma (6%), melanoma (6%), prostate (4%), and colorectal (1%) guidelines. Urinary bladder and uterine guidelines did not have any Category I recommendation. Eight percent of all therapeutic recommendations were Category I. Guidelines with the highest proportions of Category I therapeutic recommendations were breast and kidney cancers (30% and 28%, respectively). No Category I recommendation was found on screening or surveillance.

Conclusion: Recommendations issued in the NCCN guidelines are developed largely from lower levels of evidence but with uniform expert opinion. This underscores the urgent need and available opportunities to expand evidence base in oncology.


Introduction: Recent data have drawn interest in the potential association of lenalidomide and the risk of developing of second cancers in patients with MM. However, available data are limited. Though there is lack of chemotherapy specification, SEER data segregated into diagnosis periods may be useful as a surrogate to detect changes in the incidence of second cancers corresponding to the introduction of novel agents.

Methods: Patients who had MM diagnosed as a first cancer from 1973–2008 were identified in the SEER 17 database. We included only patients who survived at least 2 years after diagnosis. Time segments were created based on the era of novel agents approved for MM: before January 2000 (Period 1; control), January 2000-April 2003 (Period 2; off-label thalidomide), May 2003-April 2006 (Period 3; bortezomib approval), May 2006-September 2006 (Period 4; thalidomide approval) and October 2006-December 2008 (Period 5; lenalidomide approval). The primary outcome measure was incidence of second cancer within 2 years of MM diagnosis. All second cancers were included except for myelodysplastic syndrome and in situ cancers that were not of breast and bladder. Odds ratios (ORs) were adjusted and P values < 0.05 were considered statistically significant.

Results: There were 29,259 eligible patients. Majority were males (53%) and the mean age at MM diagnosis was 65 years (std. +/- 12). The incidence of second cancers was associated with period of diagnosis (P=0.048), sex (P<0.001), treatment (P<0.001), and age (P<0.001), but not with race (P=0.108). Multivariate analyses showed that higher risk of second cancers was associated with older age (OR=1.03; P<0.001), male sex (OR=1.41; P<0.001), radiation and/or surgery as compared to neither treatment (radiation and surgery OR=1.77, radiation only OR=0.82, surgery only OR=2.31; P values: 0.002, 0.040, and <0.001, respectively), and Periods 3 and 4 as compared to Period 1 (Periods 2–5 ORs: 1.11, 1.22, 1.63, and 1.53, respectively; P values: 0.260, 0.033, 0.011, and 0.096, respectively).

Conclusions: Our population-based study suggests that the risk of developing second cancers in patients with MM may be increased in the recent decade wherein novel agents were introduced. A more specific study linking SEER to Medicare database is recommended in order to further define the risk specific to novel agents.

**Goal:** Registered Nurses providing direct care to patients in the hospital and clinic setting at Gundersen Lutheran will be distinguishable from other staff and disciplines to make them easily identifiable “as nurses” by colleagues, patients, families and others.

**Why is this important?** To improve identification of the nurse across the health care system; regional locations, main campus and hospital to provide for fast identification and communication with a RN in an urgent or emergent situation to enhance the comfort of the patient and family with a known presence to decrease confusion in a complex environment.

**What will success look like?**
Patients, families and colleagues will easily identify nursing staff at Gundersen Lutheran through visual cues. This ease in identification will be measured in patient comments and satisfaction scores as well as staff satisfaction.

**Outcomes:** Uniform Color Selection: RN: white scrub top and navy blue pants; LPN: caribbean blue scrub top and pants; MA and Technician: charcoal grey scrub top and pants; CNA: khaki scrub top and black pants.

**Lessons Learned:** Change in leadership of the Council challenging during a major initiative. Timeline too fast - Timeline too slow. Additional communication and interactions with other Nursing Councils: enhance transparency of the process; allow additional option for nurses to share their voices. Opinion poll perceived as a vote in the decision making process. Process effectively set the stage for move to standardized uniforms for LPNs, CNAs, MAs and Technicians using appropriate decision making strategies for each group to determine uniform color.

**Positive Outcomes:** Consistent approach of using the principles of patient safety and patient-and family-centered care to guide decision making was key to uniting the Council. Committee moved to Council status to have the power to make decision for nurses by nurses: solidarity of members followed open debate; administrative support. Positive stories from employees and patients.

57. Schulz R, Archer S. *Incorporating American Association of Colleges of Nursing Essentials of Baccalaureate Education for Professional Nursing Practice into the nursing curriculum at Balakovo Medical College.* Presented at Bridging Cancer Care, Balakovo, Russia, December 10, 2011.

58. Schulz R, Archer S. *Integrating nursing students project into agency work.* Presented at Bridging Cancer Care, Balakovo, Russia, December 12, 2011.

59. Schulz R, Archer S. *The role of the care coordinator.* Presented at Bridging Cancer Care, Balakovo, Russia, December 12, 2011.


**Workshop Description:** Appropriately using “self” in work with bereaved parents is a fundamental component of relationship-based care. Engaging with bereaved families as a health care professional requires preparation and reflective work before the relationship begins. Effective use of self can be optimized in a relationship through continued reflective practice.

This workshop will use narratives, visual media, and case studies to engage the audience in exploring the “how-to” of relationship-based care, balancing perspectives of “self” and those of the family. Topics will include self awareness, self-care, compassionate silence, and using relationship to co-create ritual. The workshop format provides opportunities to discuss individualized strategies to develop a reflective practice, share personal experiences within professional relationships, and increase sensitivity to a family’s perspective. Two brief films (described below) will be shown as part of the workshop to provide real life stories about a bereaved family, healthcare professionals, and their relationships. From the award-winning educational film, *When a Child is Dying*, you will view the story about bereaved parents Mary Jannelli and Bob Strauss and their premature twin daughter who was 2 months old when she died from RSV contracted in the hospital. Mary and Bob are both Obstetricians and they discuss the difficulties they faced straddling the roles of being physicians and parents, relying on the #s, maintaining hope, and how they have changed as a result of Gabriella’s death. The film offers the healthcare team insights into a family’s grief and ideas how to improve the care and support they provide to families.

**Nurses Grieve Too:** Insights into Experiences with Perinatal Loss is a ground-breaking documentary that shares what grief is for nurses who care for bereaved families with perinatal loss. Nurses describe the professional and personal impact of grieving, what helps them and how the experience has changed them and help them to grow. This research-based documentary makes the invisible grief of nurses visible. It aspires to support healthcare professionals so they no longer feel alone or isolated in their experiences of grieving, as many can carry the pain and memories of the families’ loss and experiences with them for years.
Methods: We present the case of a 50-year-old obese woman (body mass index (BMI) = 35 kg/m²), with a history of failed fundoplication than normal weight patients. 93% effective in controlling symptoms. In contrast, morbidly obese patients are four times more likely to experience GERD symptoms. Standard surgical treatment of GERD is fundoplication, which, in normal weight individuals is 55-62% of patients presenting for gastric bypass (GB) complain of stricture appreciated on barium esophagram. The benefits and risks of re-do fundoplication versus conversion to GB were discussed with the patient, who decided to proceed with GB.

Results: Copious adhesions were noted along the stomach where the wrap was formed as well as the liver and diaphragmatic hiatus. An incarcerated gastric fat pad was found in the wrap, and believed to be the cause of the previous failure. The fundoplication was taken down using laparoscopic staplers. A 30 cc gastric pouch was created, and the tip of the fundus became ischemic due to the division of the lesser curvature mesentery. The fundus was resected and a standard retrogastric, retrocolic GB was performed. The patient is currently one year out from surgery, and the tip of the fundus became ischemic due to the division of the lesser curvature mesentery. The fundus was resected and a standard retrogastric, retrocolic GB was performed. The patient is currently one year out from surgery, with a BMI of 26 kg/m², and reports satisfaction with the procedure.

Conclusion: Conversion of laparoscopic Nissen fundoplication to GB remains a viable option for morbidly obese patients who present with recurrent GERD symptoms following Nissen fundoplication.
Background: Percutaneous cholecystostomy tubes (PCT) are useful for the treatment of acute cholecystitis in elderly and high-risk patients. The objective of this study was to compare PCT to operative management of acute cholecystitis and to examine changing trends in the utilization of PCT over two time periods at a community-based teaching hospital.

Methods: A retrospective review of medical records of consecutive hospitalized patients who underwent PCT placement for acute cholecystitis from April 1998 through December 2009 (time period 2) was completed. Each PCT patient was matched with 2 hospitalized patients who underwent cholecystectomy for acute cholecystitis. Previously published institutional data from a cohort of PCT patients from March 1989 to March 1998 (time period 1) were reviewed to compare trends in utilization. Statistical analysis included t-test, chi-square, and Kaplan Meier analysis. A P value <.05 was considered significant.

Results: One hundred fifty-one hospitalized patients successfully underwent PCT in time period 2 for acute cholecystitis. Median time to clinical improvement was 24 hours. PCT-related complications (dislodgement, bile leak, pain, occlusion, infection, hemorrhage) occurred in 21 (14%) of 151 patients, none of which required operative intervention. Seventy (46%) PCT patients subsequently underwent cholecystectomy. Use of PCT increased from a total of 22 (0.8%) to 151 (3%) patients among those that underwent cholecystectomy in time periods 1 and 2, respectively.

Conclusions: This study demonstrates the efficacy of PCT to manage acute cholecystitis in older patients with comorbidities when compared to matched controls. Over time, PCT is being used more frequently and in patients with fewer comorbidities, resulting in a reduction in 30-day mortality. Potential reasons for this change in utilization are multifactorial, including changes in work flow, mandatory reporting, increased transparency, and pay for performance which was not as prevalent in time period 1. These factors may be influencing surgical decisions towards nonoperative management in the acute setting.

References:


Background: Yttrium90 ibritumomab tiuxetan (Y90IT) radio-immunotherapy has proved to be an effective therapy in relapsed follicular lymphoma (FL). The Wisconsin Oncology Network conducted a clinical trial in which Y90IT followed by maintenance rituximab (MR) was evaluated as initial therapy for high tumor burden FL.

Methods: Eligible patients had histologically confirmed follicular lymphoma and met GELF criteria for high tumor burden. All patients received a single dose of Y90IT. At 6 months, patients without PD received 4 weekly doses of rituximab 375 mg/m² followed by MR consisting of a single dose every 3 months for a planned duration of 5 years.

Results: Sixteen eligible patients were enrolled from 1/05-11/07. The protocol was closed in 5/08 secondary to slow accrual (planned N = 36). Baseline characteristics include median age of 55 years (37-75) and FLIPI distribution of 19% low, 44% int, and 37% high. The major toxicities from Y90IT were expected myelosuppression with 88% and 31% experiencing grade 3 and 4 heme toxicity, respectively. Median nadir was 752/mm³ for ANC, 46k/ mm³ for platelets, and 11.5 g/dL for hemoglobin. Median duration of grade 3 and grade 4 toxicities was 2.5 weeks (1-7) and 1 week (1-2), respectively. One patient developed MDS/AML and has since expired. Response to Y90IT induction therapy included 7 CR/C Ru, 4 PR, 3 SD, and 2 PD. All 4 PR patients converted to CR/C Ru during MR therapy. We identified 6 patients with early PD (range 4-7 months) and 10 patients with prolonged remissions (range 37-71+ months). All patients with baseline masses over 9 cm experienced early PD, while 7/9 patients with masses less than 9 cm are experiencing prolonged remissions ranging from 39+ to 71+ months. With a median follow up of 48 months, the 3 year PFS and OS were 63% and 94% respectively.

Conclusions: The ORR to Y90IT was 69% in previously untreated, high tumor burden FL patients, which is lower than what is observed with contemporary rituximab-chemotherapy combinations. FL patients with large nodal masses (> 9cm) should be considered for alternative therapies while patients with intermediate size masses (3-9 cm) have the potential for durable responses.


Background: The need for routine surgical excisional biopsy of borderline breast lesions discovered on percutaneous core needle biopsy (CNB) is controversial.
Objective: This study was designed to determine our institutions upgrade percentage of borderline breast lesions and fibroepithelial lesions (FEL) on CNB to malignancy or phyllodes tumor, respectively, on open biopsy. Furthermore, we wish to classify any specific lesions or risk factors that predict a higher rate of malignancy.

Methods: We performed a retrospective chart review of prospectively collected data on patients from 2005-2006. The following pathology reports on CNB were reviewed: atypical ductal hyperplasia, atypical lobular hyperplasia, lobular carcinoma in situ, flat epithelial atypia, any lesion with atypia, papillary lesion, radial scar, mucocle like lesion, spindle cells, FEL and fibroadenoma (FA). FEL and FA were separated from the other borderline lesions for analysis, and then reviewed for upgrade to phyllodes tumor or malignancy respectively on surgical biopsy or in follow-up. The patient charts were then analyzed for multiple clinical and pathological factors, such as method of detection, palpability of the lesion, lesion type, and BI-RADS category, for a significant predictor of upgrade to malignancy. Only breast subspecialty pathologist opinion aids in surgical decision making for open biopsy significantly predicted upgrade.

Results: A total of 177 patients were reviewed with 54 having borderline lesions on CNB. Thirteen (24%) of the 54 underwent observation only with no reported cancer at last follow-up (5 years). The remaining 41 (76%) patients underwent surgical biopsy with 9 (22%) upgraded to malignancy (5 DCIS, 4 invasive). Recommendation of surgical biopsy by a breast subspecialty pathologist was found to be statistically associated with being upgraded to malignancy (p-value 0.003); 6/10 pathology recommend open biopsies were upgraded to malignancy; 3/31 not recommended were upgraded. A total of 84 patients had FEL on CNB and 65 (77%) underwent observation only. One of these had malignancy at the previous biopsy site on 3 month follow-up. Of the patients with FEL, 19 (22%) underwent open biopsy with 6 (32%) upgraded to phyllodes tumor (5 benign, 1 malignant) and 1 upgraded to DCIS.

Conclusions: Our institutional upgrade of borderline breast lesions to malignancy and FEL to phyllodes tumor when CNB is followed by open biopsy is 22% and 32% respectively. We identified no “interval” cancers in patients who did not undergo surgical biopsy which validates the idea that not all patients with borderline lesions require surgical biopsy. Furthermore, breast subspecialty pathologist opinion aids in surgical decision making.


Introduction: Diffuse large B cell lymphoma (DLBCL) has a highly variable outcome, and individual risk assessment is largely based on clinical features. Gene expression profiling (GEP) stratifies patients into those with germinal center B-cell (GCB) and activated B-cell subtype (ABC) subtype with different prognoses. These groups have been shown to predict prognosis in patients treated with CHOP or R-CHOP. Conversely, the role of other recognized prognostic markers, such as BCL2 gene abnormalities or Bcl2 expression has been questioned in the new therapeutic era. Materials and Methods: In 438 patients treated with R-CHOP for de novo DLBCL, we analyzed the tumors by immunohistochemistry for Bcl2 protein expression and by interphase fluorescence in situ hybridization (FISH) for BCL2 translocation and other abnormalities. All cases were successfully studied by GEP. The cutoff for Bcl2 protein expression, 60%, used as prognostic factor was determined using receiver operating characteristic curves. Progression-free survival (PFS) and overall survival (OS) were assessed.

Results: The t(14;18)(q32;q21) was detected in 82 cases (18.7%) and BCL2 gains occurred in 63 cases (14.3%). Both t(14;18) and BCL2 gains strongly correlated with higher levels of Bcl2 protein expression (P<0.0001 for both). Presence of t(14;18) was associated with the GCB subtype (P<0.0001), whereas BCL2 gains were associated with the ABC subtype (P=0.004). BCL2 gains were not predictive of PFS in any patients’ subgroups. Conversely, within the GCB subtype, patients with the t(14;18) displayed a significantly worse outcome compared to GCB patients without t(14;18) with a 5-year PFS of 45% vs 68%, respectively (P<0.0001). Outcome of patients with DLBCL associated with t(14;18) was similar to patients with the ABC subtype (45% vs 48%, P=0.30, Figure 1). No impact of the t(14;18) and BCL2 gains was observed on patients with ABC-DLBCL. Using immunohistochemistry, patients with Bcl2 positive (>60%) tumors had significantly inferior PFS in the GCB subgroup (P=0.03), but not in the ABC subgroup (P=0.54). Multivariate analysis revealed that the presence of the t(14;18), but not Bcl2 protein expression, was independent of the International Prognostic Index in predicting outcome of our patients.

Conclusions: Patients with the GCB subtype and t(14;18) exhibit a significantly worse prognosis than patients without t(14;18) when treated with R-CHOP. The assessment of t(14;18) by FISH approach not only functions as a valuable prognosticator for individual risk estimation in GCB-DLBCL patients in addition to the established parameters, but also provides valuable result for therapeutic intervention.
68. Walter MA. **Bereavement training: applying and practicing the skills of a compassionate caregiver.** Presented at Caring for the Sorrow of Pregnancy & Infant Loss: A Conference for the Caregiver, Minneapolis, Minnesota, April 13, 2011.


70. Walter MA. **The medical and emotional aspects of loss in a pregnancy with multiples.** Presented at Resolve Through Sharing National Webinar, La Crosse, Wisconsin, October 1, 2011.


**Background:** Complicated diverticulitis is a common surgical diagnosis with significant morbidity and the possibility of mortality if not managed sufficiently and in a timely manner. The optimal treatment for patients with Hinchey stage III disease is debatable. Three main approaches have been utilized: 1) Two or three stage resection (diversion, resection and re-anastomosis), 2) One stage resection and anastomosis and 3) Laparoscopic peritoneal lavage (LPL) and drainage with or without interval resection and primary anastomosis. The latter option has been reported in recent literature as an option for these patients but it is unclear what factors guide this treatment decision and whether or not definitive resection is mandated.

**Objective:** To review the clinical management of patients who presented with complicated diverticulitis (Hinchey stage III) and underwent LPL and drainage.

**Methods:** After obtaining institutional review board approval, we performed a retrospective case review of the medical records of patients who underwent treatment of complicated (Hinchey II-IV) diverticulitis with a focus on those who underwent LPL and drainage. Patient demographics, comorbidities, treatment plans, length of hospital stay, recurrence, resection, time until interval resection and short and long-term outcomes were assessed. Treatment algorithms were directed by the admitting surgeon.

**Results:** We identified 5 patients who underwent LPL from 3/2010 through 5/1/2011. All of the patients presented acutely with complicated diverticulitis not amendable to non-operative treatment. Mean age was 70.2 years (range 45-83) and all were male. Mean hospital length of stay was 8 days (range 6-13 days). All patients were either ASA class I (n=2) or III (n=3). One patient underwent an elective resection (ASA I) and had a superficial surgical site infection. Another patient was recommended for resection (ASA III) but declined and has had no recurrence over a 9 month follow-up. Three patients were not recommended for resection and have not had recurrence of symptomatology (follow-up 5-18 months).

**Conclusion:** Patients who have undergone LPL and drainage at our institution have been successfully managed without significant morbidity/mortality. The decision to proceed with definitive resection is based on an informed discussion between surgeon and patient based on the evidence-based guidelines available. Continued research is needed in order to compare LPL to resection with Hartman’s procedure.
Supplement
2012 – Presentation Abstracts
Gundersen Health System


   **Background:** Endovenous laser therapy (EVLT) has become the standard of care for the treatment of varicose veins and venous disease due to faster recovery, improved cosmesis, and equivalent outcomes to the gold standard of open vein ligation. The current literature reports results of EVLT performed on one leg at a time; therefore, the safety and efficacy of concurrent bilateral EVLT is largely unknown. Specific concerns include local anesthetic toxicity, increased DVT risk and pain. The objective of this study was to evaluate the safety and efficacy of bilateral EVLT performed concurrently.

   **Methods:** A retrospective review of the medical records of all patients who underwent EVLT between January 2005 and March 2012 at our institution was completed. The incidence of postoperative DVT, endovenous heat-induced thrombosis (EHIT), recanalization, and tumescent volume was assessed.

   **Results:** During the study period, 958 legs were treated by unilateral EVLT and 220 legs were treated with concurrent bilateral EVLT. Mean age was 49.9 vs. 53.4 years in the bilateral vs. unilateral group, respectively ($P=0.001$). EVLTs were performed in the clinic in 23% and 21% of the bilateral group and unilateral group, respectively ($P=0.617$). There was no difference in the composite endpoint of EHIT, DVT, or recanalization in the bilateral vs. unilateral group (3% vs. 4%, $P=0.497$). A larger amount of tumescent anesthesia was administered in the bilateral vs. unilateral group (502.3 vs. 291.1 mL, $P=0.001$). No complications related to anesthesia or sedation occurred. A trend towards a higher percentage of concurrent bilateral EVLTs was observed in recent years ($P=0.001$).

   **Conclusions:** Concurrent bilateral EVLTs, performed in both the clinic and operating room, are as safe and effective as unilateral EVLT. Despite increased amounts of local anesthetic, there were no related complications. Use of bilateral EVLT may decrease costs and increase convenience for patients by avoiding multiple appointments. Keys to success are experience with the procedure, continuous ultrasound guidance and appropriate patient selection including patient choice.


   **Background:** Gundersen Lutheran Health System started the Global Partners program in 2008 and initiated a long-term, sustainable partnership Pine Ridge Indian Reservation in South Dakota. Since 2009, volunteer medical teams have provided primary care and chronic disease management services on Pine Ridge.

   **Significance:** An assessment of a volunteer’s experience provides insights into how nursing, medical and support staff may be impacted professionally or personally through participation in a volunteer trip.

   **Methods:** The literature identifies a number of potential benefits to professional practice and personal development related to volunteerism. Participants were volunteers to Pine Ridge Reservation from October 2009 to November 2011. An anonymous evaluation survey was sent via survey monkey. Self-selected volunteers wrote entries in a team journal describing insights and stories of their experiences.

   **Results:** Survey response rate was 40% with data from 12 physicians, 26 nurses and 8 support staff. Program strengths included: an effective orientation, well organized travel, and good teamwork. Most satisfying experiences centered around helping others and building new relationships. Least satisfying aspects of the experience related to system barriers limiting health service delivery, and the overwhelming health needs of people living on Pine Ridge reservation. Survey data and journal entries documented personal and professional development through the volunteer experience.

   **Implications:** Numerous programmatic changes have been implemented following the feedback received from the survey, journal, as well as debriefing meetings held by each team. Recent changes aim to increase employee engagement, expand partnerships to create more sustainable development, and address system barriers. Continued evaluation of the volunteer’s experience is needed to understand how site, role, prior experience or satisfaction specifically impact professional and personal development.


Objective: To evaluate the incidence, injury mechanisms, management, and outcomes of patients with logging-related injuries who were treated at a rural, ACS-verified level II trauma center to develop possible prevention strategies.

Methods: A retrospective review of all patients with a logging-related injury treated at Gundersen Lutheran Medical Center from 1/1/2001-1/31/2012 was completed. Patients were identified by querying our institution's trauma registry for E-codes 916-920.1. Hospital and outpatient clinic records were reviewed. Statistical analysis included t test, Wilcoxon rank sum test, and Fischer exact test.

Results: Fifty eight patients were identified and divided into two groups; those sustaining penetrating chainsaw injuries (n=9) and those sustaining blunt trauma from falling trees/limbs/branches (n=48). One patient experienced a logging-related tractor injury. Overall, 98% of patients were male, mean age and length of stay was 49.1 years and 4.8 days, respectively. Mean injury severity score (ISS) was 13.8 with a maximum ISS of 75. Mean functional independence measure (FIM) was 11.1. Median ISS was higher for the blunt compared to the penetrating trauma group (13.5 vs. 2, P=0.001). The most common injuries involved the head, spine and extremities. One-third of patients had an ISS >15. Five deaths occurred within 30 days of injury, all in the blunt trauma group. Most patients (80%) were discharged to home.

Conclusions: Logging-related activities result in significant morbidity and mortality. Neurosurgical and orthopaedic injuries were most common. Blunt trauma from falling trees/limbs/branches was more severe compared to chainsaw injuries, as evidenced by a higher ISS and mortality rate. Chainsaw safety mechanisms have been developed, but additional education and training are crucial to injury prevention for logging activities.


Background: One way to enhance an environment that supports healing for patients, families and staff is through the use of complementary therapies. Based on expressed interest from patients, staff and physicians that timing was right, discussion occurred regarding the use of essential oils for patient care.

Significance: Creating a well-organized plan for implementing a low-risk and beneficial complementary therapy and showing tangible enhanced patient and staff experiences would be instrumental in setting precedence for Gundersen Lutheran to adopt additional healing modalities.

Purpose/Objective: To design and implement a pilot process that potentiates a healing environment through the use of essential oils with a specific patient population and can be expanded as appropriate for the organization.

Methods/Project Design: In June of 2010, Gundersen Lutheran nursing leaders met with Val Lincoln, PhD, RN, AHN-BC, Clinical Lead - Integrative Services, Woodwinds Health Campus. In July of 2010 and August of 2011, Dr. Lincoln presents healing environment information to Gundersen Lutheran nurses. Work continued October 2011 through January 2012 with interprofessional team meetings for project planning and development. A standard operating procedure was created. Education to staff occurred in January. January 31, 2012 was our Go-Live date for use of essential oils in our pilot peri-operative units and Ortho/Neuro unit with patients having surgery with Edward Riley, MD.

Results/Outcomes/Findings: Evaluation measures will include: quality of essential oil administration; surgery outcomes; patient perceptions of nausea, anxiety and pain; and patients’ and nurses’ perception of the experience using essential oils.

Clinical Implications: Patients will experience decreased anxiety, nausea and pain with the use of essential oils. While the goal is not to substitute essential oils for medication, we anticipate that patient use of essential oils will decrease the amount of medications used. Staff will understand the benefits of potentiating an optimal healing environment for our patients. The use of essential oils will serve as a reminder that there are multiple ways to create this environment.


Introduction: Angiogenesis as an important feature of malignant propagation in MM and other malignancies. This had led to the development of treatment strategies focused on inhibition of vascular growth. Bevacizumab (B) has previously been reported to increase response rate as well as time to progression when combined with standard therapies in several tumor types. Bone marrow biopsy samples from pts with MM consistently demonstrate increased blood vessel, therefore investigated the combination of the VEGF inhibitor bevacizumab with L and D in patients with relapsed or refractory MM.
Eligibility: relapsed or refractory MM patients (pts), failing > 1 therapy, with no previous exposure to lenalidomide, with measurable M protein in serum and/or urine, no current history of unstable cardiovascular disease or uncontrolled thrombosis, without therapy for ≥28 days, and no contraindication to aspirin.

Methods: Each 4 week cycle consisted of lenalidomide (L) 25 mg PO d1–21, bevacizumab (B) 10 mg/kg IV over 2 hours every two weeks, and dexamethasone (D) 40 mg PO q week. All pts received aspirin 325 mg PO daily. Plasma levels of VEGF, VEGFR1, VEGFR2, MIP-1α were measured by ELISA prior to, after 1 and 4 cycles of therapy. Clinical responses were assessed using IBMTR criteria.

Results: 39 subjects were enrolled; 36 evaluable for response. Median age of pts was 69; 62% of pts were male, median time from diagnosis to study treatment was 29 months. The combined complete and partial remission rate (CR+PR) were 64.1 %. For the entire group, the median PFS and median OS were 9 and 36 months, respectively. Grade 3 AEs occurred in 72% of patients. Common adverse events (AE) included DVT/PE in 5 pts, neutropenia 6 pts, infection (5 pts). Specific Gr3-4 AE likely attributable to inclusion of B were GI perforation (3), cardiac events (4) and mucositis (4pts) Fifteen pts (39%) discontinued therapy early due to toxicity or withdrawal of consent. Response was correlated with lower baseline MIP-1 and VEGFR1 levels (.007 and .04 respectively). No correlation was seen with previous thalidomide exposure, previous transplant, lytic bone disease or standard vs high risk myeloma.

Conclusions: The addition of bevacizumab did not translate to either increased response rate or prolongation of PFS. While the incidence of AE was lower than previously reported with L and high dose D, the increased GI and cardiac toxicity and the expected increase cost would not justify further exploration of this combination. Bevacizumab and lenalidomide were generously supplied by Genentech, Celgene and by the NCI.

Introduction: BR chemoimmunotherapy was shown to have an overall response rate of 59%, a median progression free survival of 14.7 months, and an acceptable toxicity profile in R/R CLL (Fischer K, et al. J Clin Oncol 2011). Given the single-agent activity of lenalidomide in R/R CLL/SLL, we hypothesized that maintenance lenalidomide after BR induction could improve PFS.

Methods: 34 patients requiring therapy for R/R CLL/SLL were treated with bendamustine 90 mg/m² IV on days 1 & 2 and rituximab 375 mg/m² IV on day 1 every 28 days for a maximum of 6 cycles. Growth factor support was permitted. Patients achieving at least a minor response (objective improvement even if not meeting criteria for partial response) were eligible to proceed with 12 cycles of maintenance therapy with lenalidomide 5-10 mg/day orally given continuously in each 28-day cycle. Patients were eligible if they had histologically proven CLL/SLL and had received >1 but ≤5 prior cytotoxic chemotherapy regimens (retreatment with an identical regimen was not counted as a separate treatment). The primary endpoint was PFS.

Results: Baseline characteristics include median age 67 (range 38-86), 25 men, 9 women, 26 CLL, 8 SLL, median 2 prior therapies (range 1-4). Cytogenetic profiling by FISH analysis was available in 22 patients (65%), with 10/22 demonstrating presence of 17p and/or 11q deletion. Twenty-five patients (74%) completed 6 cycles of induction BR. Two patients died of toxicities of pneumonia and heart failure during cycle 1; 7 patients received < 6 cycles due to toxicities (n=4), progressive disease (n=2), and stable disease (n=1). Dose modifications were required in 14 (41%) patients, most commonly for neutropenia (12/14), thrombocytopenia (3/14), and weight loss/failure to thrive (3/14). Grade 3/4 toxicities were primarily hematologic, with neutropenia in 20 patients, anemia in 1, and thrombocytopenia in 7. Febrile neutropenia occurred in 4 patients. Infections with or without neutropenia were common; grade 2 infections in 16 patients, grade 3 in 7 patients. Grade 2 rash occurred in 4 patients. Eleven deaths have been observed, 7 events due to progressive disease (including 2 events of transformed lymphoma). Responses were evaluable in 31/34 patients. The ORR was 65%, with 16 PR (47%) and 6 CR (18%). An additional 7 patients achieving stable disease were eligible to proceed to maintenance therapy. With a median follow up of 20.1 months, the median PFS and OS are 24.3 and 27.9 months.

Conclusions: In our multicenter trial for patients with R/R CLL/SLL, the BR induction produced an ORR is comparable to historical observations (65% vs 59%). However, the median PFS is longer (24.3 vs 14.7 months), suggesting maintenance lenalidomide may be contributing to an improved response duration. Based upon these promising results, we have initiated a successor study in which patients will receive lenalidomide plus rituximab maintenance after a BR induction.

The Electronic trauma record was identified as a weakness post reverification in October 2010 due to incomplete records and difficulty of data abstraction. A collaborative meeting inclusive of Trauma administrative team and providers, Emergency Department administrative and frontline staff, Intensive Care (Adult and Pediatrics) administrative and front line staff, Information System programmer and report writer, was convened to define current state, future state and complete problem analysis.

**Problem analysis** identified the following issues:
1. Inconsistent documentation practices and location of documentation in the EMR making abstracting and report building difficult.
2. Time constraints for completing documentation
3. Lack of defined roles of nurses responding to trauma activations
4. Lack of staff accountability and defined compliance requirements
5. Lack of reports.

**Resolution of identified issues:**
1. Trauma navigator:
   a. Reviewed and eliminated fields not critical for evaluation and patient treatment or mandatory for trauma registry, facility, and regulatory compliance.
   b. Data dictionary developed for all documentation fields
   c. All narrative assessments entered under observations
2. ED RN identified as responsible for documentation requirements
   a. Weighted documentation grid developed. All trauma records reviewed by PI RN, feedback provided to individual RN and clinical manager.
   b. GOAL: 90% completion, all records not meeting goal are reviewed with unit educator and documenter; loop closure to Trauma Division of completion
3. Accountability of documentation completion attached to Annual Performance
   a. Greater than 5 records per year basis not meeting requirements result in ‘Inconsistently Met’ for performance review
4. Reports built to abstract the ‘trauma story’ in a collection of reports enabling abstraction
   a. Trauma Overview, Trauma History and Prehospital Information, Trauma Vitals, Observations & primary Survey, Lines, Drains, Airways, and Wounds, Meds & Pain Report, Flow sheets, I&O, Trauma GCS & Pupils, LMR Trauma Record, Patient ADT events, Trauma Results, PI Timeline, and Trauma Temp.
5. Education provided to all staff members
Outcomes: Average monthly completion improved from 84% in 2010 to 95% in 2011, and current average of 94% completion. One ED RN had a completion of less than 90% on five records. The consolidation of the data into reports has decreased PI review time by 50%.

Background: The NCCCP is a network of 30 community cancer center (CCC) sites that strive to expand cancer research capacity and deliver advanced care in the community. The EPWG was formed to facilitate NCCCP site participation in EP (phase I-II) CTs, thus allowing patients (pts) to be treated within their communities. This study describes the CT infrastructure at NCCCP sites and its association with EP accrual.

Methods: A BAS was conducted to obtain data on NCCCP site CT infrastructure, funding, sponsor affiliations, and barriers to EP CTs. To evaluate EP performance, EP accruals during July 2010-June 2011 were obtained. High accruing sites were those with EP accrual above the median EP accrual per 1,000 new analytical cases seen in 2009 or 2010.

Results: 27 sites, caring for ~56,000 new cancer pts annually, participated in the study. Median number of accruing EP trials/site was 6 (mean 7.4). Median EP accrual/site was 14 (mean 16). Median EP accrual rate was 7/1,000. Trials with a phase I component were open at 21 sites. Most sites (24) are members of multiple CGs (median 4) and enroll pts via the CTSU (70%). The more common barriers to EP trial implementation were related to infrastructure (59%), cost (52%), and access to trials (41%). When accrual rates to NCCCP CTEP EP trials only were analyzed, we found that between high vs low accruing sites, respectively, higher accrual rates were associated with higher number of CRAs devoted to EP trials (median 3.25 vs 1; \( P = .05 \)) and lower proportion of funding from industry (median 18% vs 40%; \( P = .02 \)). We did not, however, find significant associations when EP trials were examined across all sponsors.

Conclusions: CCCs are capable of conducting, and actively participating in, EP trials. Infrastructure and collaborations are critical components of success. Our study provides useful information for those planning to begin EP trials in the community setting.

Background: We performed a population-based study to determine the rates of major complications related to multiple myeloma, lymphoplasmacytic lymphoma, and Waldenstrom's macroglobulinemia (hence abbreviated as MM) at the time of cancer diagnosis in the US, their trends over time, disparities among demographic subsets, and the impact of preceding follow-up for MGUS.

Methods: Data were obtained from the Surveillance Epidemiology and End Results (SEER) database linked to Medicare claims. We considered patients age ≥67 years with MM diagnosed from 1994-2007 (N=28,879). We excluded those who were diagnosed by autopsy or death certificate only, had invasive cancers within 5 years prior to
MM diagnosis, lacked date of either diagnosis or death, lacked complete Medicare parts A/B coverage 15 months prior to or 3 months after MM diagnosis date (or to date of death, if death was within 3 months), and receiving dialysis for other conditions (n=11,450). Major complications including acute kidney injury (AKI), dialysis requirement, cord compression, fracture, and hypercalcemia presenting within 3 months before or after MM diagnosis were obtained from diagnosis and procedure claims. MGUS follow-up was defined as having a diagnosis claim 3-15 months prior to MM diagnosis.

Results: Of the 17,429 MM patients included in our study, 50.6% were males and the median age was 77 years. Major complications were present at diagnosis in 31.9% of the patients in the following order of frequency: fracture (16.6%), acute kidney injury (13.5%), hypercalcemia (5.5%), dialysis (5.3%), and cord compression (2.4%). There was a significant increase in most complication rates (unadjusted) over time (P<.001) except for hypercalcemia and cord compression. Females were more likely to have hypercalcemia (6.0% vs 5.1%; P=.005) or fracture (19.4% vs 13.9%; P<.001), but men were more likely to have AKI (14.6% vs 12.3%; P<.001) and to require dialysis (5.8% vs 4.8%; P=.002). Blacks were more likely to have hypercalcemia (7.1%; P<.001), AKI (18.3%; P<.001), cord compression (3.1%; P=.009), or require dialysis (7.8%; P<.001), but were less likely to have fracture (14.6%; P<.001) compared to whites (5.4%, 12.9%, 2.3%, 5.0%, and 17.1%, respectively) or other races (4.6%, 12.5%, 1.0%, 4.8%, and 16.0%, respectively). Overall, 6% of the patients had MGUS follow-up (n=1,037) preceding MM diagnosis with an increasing trend from 2.6% in 1994 to 6.9% in 2007 (P<.001). Complication rates were lower in the group with MGUS follow-up compared to those without follow-up: any complication (20.8% vs 32.6%; P<.001), AKI (10.1% vs 13.7%; P<.001), cord compression (1.4% vs 2.4%; P<.001), dialysis (3.4% vs 5.4%; P=.004), fracture (11.0% vs 17.0%; P<.001), and hypercalcemia (2.4% vs 5.7%; P<.001).

Conclusions: At the time of MM diagnosis, major cancer-related complications were present in a third of patients with increasing trends from 1994-2007 for fracture, AKI, and requirement for dialysis. Complication rates varied among gender and race. Patients being followed for MGUS had significantly lower complications rates compared to those who were not.


Background: The CNLs with support from Information Systems, designed electronic tools to provide point in time reports allowing interdisciplinary staff to efficaciously coordinate and manage the needs of patients.

Significance: Multiple demands during acute care hospitalization, fragmentation across the continuum of care, lack of efficacious methods to identify, prioritize, respond to, communicate and track the ever-changing needs of patients and families, national initiative to operationalize Patient and Family Centered Care, nation initiative to leverage electronic medical record (EMR).

Purpose: Understand how the electronic medical record is leveraged to efficaciously coordinate and manage care throughout hospitalization, including discharge.

Methods: Workflow processes were determined through interdisciplinary collaboration, electronic tools were designed, staff were educated, application of tools was hardwired into interdisciplinary staff practices.

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Medical Oncology</th>
<th>Cardio-Pulmonary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct Expense/Discharge</td>
<td>8%</td>
<td>22%</td>
</tr>
<tr>
<td>HPPD</td>
<td>15.5%</td>
<td>1%</td>
</tr>
<tr>
<td>Delays to Skilled Nursing</td>
<td>26%</td>
<td>Continuous Observation 54%</td>
</tr>
<tr>
<td>Facilities</td>
<td></td>
<td>Hours</td>
</tr>
<tr>
<td>Continuous Observation</td>
<td></td>
<td>Injury from Falls 22%</td>
</tr>
<tr>
<td>Hours</td>
<td>52%</td>
<td>RN Overtime      37%</td>
</tr>
<tr>
<td>Continuous Observation</td>
<td></td>
<td>General Event Reporting 67%</td>
</tr>
<tr>
<td>Hours</td>
<td>66%</td>
<td></td>
</tr>
<tr>
<td>Injury from Falls</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RN Overtime</td>
<td>32%</td>
<td></td>
</tr>
<tr>
<td>Patient Satisfaction</td>
<td>6%</td>
<td></td>
</tr>
<tr>
<td>General Event Reporting</td>
<td>94%</td>
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</tr>
</tbody>
</table>
Conclusions: The electronic medical record is a valuable health care resource that can be used to efficaciously coordinate and manage care of multiple patients in demanding acute care settings. Electronic tools extend our eyes and ears and give us direction as we collaborate with interdisciplinary staff.

Clinical Implications: Enhances communication of nurses and interdisciplinary staff and other facilities, increases efficiency, promotes staff engagement and patient satisfaction, results in cost savings, decreased delays, smooth transitions of care and increased safety.

Research Recommendations: Study the implementation and outcomes within other microsystems, identify how to link these tools to the outpatient settings, study how use of the electronic medical record affects Patient and Family Centered Care, identify those metrics which most clearly capture the efficacy of leveraging the electronic medical record.


Background: Metaphase cytogenetics and FISH panel testing are commonly performed on bone marrow aspirate samples from patients suspected of having MDS. We performed this study to determine the frequency of simultaneous testing in academic versus community practices and whether routine FISH panel provides additional information to metaphase cytogenetics.

Methods: After approval from our institutional review boards, a list of patients who had bone marrow aspirate samples submitted to the Wisconsin State Laboratory of Hygiene between January 2000 to June 2011, with a diagnosis of anemia, thrombocytopenia, neutropenia, or pancytopenia, and suspected MDS was obtained from Wisconsin State Laboratory of Hygiene. If multiple samples were submitted for the same patient, we included only the first sample. We collected data pertaining to demographics, indication/diagnosis, requesting institution, date of request, and cytogenetics/FISH results. The FISH panel included probes for chromosomes 5q31, 7q31, 8, and 20q (Abbott Molecular, Abbott Park, IL).

Results: We included 3,418 patients who met our study criteria. The median age was 57.5 years (18-97 years) and 55.2% were males. The samples came from 1 academic center (36.9%), 4 community practices (44.7%), and 3 referral laboratories (18.4%). The top clinical indications for bone marrow aspiration were anemia (48.5%), pancytopenia (26.8%), thrombocytopenia (15.2%), neutropenia (5.2%) and possible MDS (2.3%). Karyotype was normal in 2,527 (73.9%), abnormal in 617 (18.1%), and could not be determined in 274 (8.0%) due to culture failure or inadequate karyotypes. Simultaneous testing for cytogenetics and FISH was performed in 379 patients (11.1%). In this subgroup, abnormal karyotypes were identified in 64 (16.8%) and abnormal FISH results in 55 (14.5%). Among the 299 samples which had adequate metaphases for cytogenetic analysis, FISH panel detected additional cytogenetic abnormalities in 11 (3.6%) patients. The cytogenetic abnormalities detected by FISH but not by karyotyping were -20q (5 patients), -7q (4 patients), -5q (1 patient), and -5q/-20q (1 patient). However, this would have changed the MDS International Prognostic Scoring System karyotype score in only 5 out of 11 (45.4%) patients. In cases with inadequate karyotypes or no growth (n=80), abnormal FISH result was found in 13 (16.2%). The cytogenetic abnormalities detected were -20q (4 patients), -7q (4 patients), -5q (3 patients), and -5q/-20q (1 patient). The karyotype inadequacy/failure rates were similar regardless of whether samples came from academic center or the community (8.0% vs 8.7%; P=0.979). However, community physicians were more likely to perform simultaneous cytogenetic and FISH testing compared to academic physicians (13.3% vs 7.3%; P<0.0001). FISH testing detected additional abnormalities at a similar rate among samples coming from the academic and community practices (3.3% vs 6.9%; P=0.396). There was a significant variability in the rates of simultaneous cytogenetic and FISH testing among community practices ranging from 0% to 23.4% (P<0.0001).

Conclusion: In our study of a large sample of patients being evaluated for cytopenias and suspected of MDS, routine bone marrow FISH panel testing added little to cytogenetic study except when karyotype failed or was inadequate. Community physicians requested simultaneous testing for cytogenetics and FISH significantly more often than their academic counterparts even though karyotype inadequacy or failure rate was similar. There was a large variation in simultaneous testing rates among community practices.


Background: The reported morbidity and mortality rates after esophagectomy are approximately 49.6%–50.6% and 8.4%–10.6%, respectively. Minimally invasive surgical (MIS) techniques may reduce the morbidity, mortality and length of stay (LOS) for patients undergoing esophagectomy. The objective of this study was to compare the outcomes of minimally invasive esophagectomy to open esophagectomy.

Methods: After receiving IRB approval, the medical records of all patients who underwent esophagectomy for cancer from January 2000-February 2012 were reviewed. Esophagectomies were performed via an open approach from January 2000-August 2005. In September 2005, a MIS approach was implemented. Variables included demographic data, LOS, lymph node retrieval, morbidity (anastomotic leak, surgical site infection, urinary tract infection, DVT/PE, chylothorax, and transfusion) and mortality. Statistical analysis included Fisher’s exact test, t-test, and Wilcoxon Rank Sum.

Results: Forty-nine patients underwent esophagectomy; 22 in the open era, and 27 in the MIS era. Overall, 80% were male. There was no difference between the open and MIS groups with respect to sex, or ASA class. Mean age was 71.5 vs. 64.5 years in the open and MIS groups, respectively ($P=0.027$).

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<tbody>
<tr>
<td>N</td>
<td>22</td>
<td>27</td>
<td></td>
</tr>
<tr>
<td>Median operative time, min. (range)</td>
<td>261 (167-509)</td>
<td>380 (189-604)</td>
<td>0.001</td>
</tr>
<tr>
<td>Median LOS, days (range)</td>
<td>13.5 (9-26)</td>
<td>8.0 (6-40)</td>
<td>0.001</td>
</tr>
<tr>
<td>Mean Lymph node retrieval, no.</td>
<td>7.1 ± 5.5</td>
<td>10.7 ± 7.1</td>
<td>0.063</td>
</tr>
<tr>
<td>Any 30-day complication, n (%)</td>
<td>7 (32)</td>
<td>12 (44)</td>
<td>0.367</td>
</tr>
<tr>
<td>30-day Mortality, n (%)</td>
<td>3 (14)</td>
<td>1 (4)</td>
<td>0.314</td>
</tr>
<tr>
<td>1 year Mortality, n (%)</td>
<td>5/22 (23)</td>
<td>7/23 (30)</td>
<td>0.738</td>
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</table>

Conclusions: A minimally invasive approach to esophagectomy resulted in a longer operative time, but significantly shorter hospital LOS compared to an open approach. Lymph node retrieval, morbidity and mortality were similar between an open and minimally invasive approach.


Motor vehicle crashes (MVC) are the leading cause of death for U.S. teens, accounting for more than one in three deaths in this age group. The highest probability of a MVC involving a teen driver occurs within 6 months of licensure. Most crashes are attributable to inattentive driving and loss of control versus environmental conditions, aggressive or impaired driving. Traffic crashes are disproportionately more severe when they occur on rural roads. While only 25% of our national population live in rural areas, deadly crashes on rural roadways account for more than half of all traffic fatalities. Among the population Gundersen Lutheran served from 2001-2011, 67% of crashes were due to loss of control, 90% occurred in a rural setting, an average seat belt use of 37%, and 52% male. Mortality rate of 4% and 10% was admitted to or transferred for rehabilitation with an average FIM score of seven. Current driver education programs focus primarily on rules of the road and basic vehicle operation with little emphasis on driving techniques. Our objective was to examine the effect of implementing a Teen Car Control Clinic (TCCC), as a MVC prevention initiative at an American College of Surgeons verified Level II Trauma Center.

Participants were required to have a driver’s license or permit, a roadworthy vehicle (preferably the one they usually drove), and be accompanied by a parent or guardian. The program consists of rotating classroom lecture and “hands on” driving exercises reinforcing the classroom content. Classroom concepts include: Basic knowledge of vehicle operation and handling physics. Vehicle exercises include: Emergency braking, weight transfer with the use of a slalom course, wet road conditions using a wet circular skid pad, and accident avoidance with sudden lane changes.

A retrospective review of data from ten consecutive TCCCs (May 2009 through May 2012) was completed. Written surveys were completed pre and post TCCC and 6 months post phone survey to assess driving confidence, changes in driving patterns, application of techniques learned, MVC, and injury rates.

Two hundred eighty one teenagers have participated in TCCCs. Fifty one percent were male with an age range of 15 to 22. Perceived confidence in driving was measured at pre course, post course, and at a six month post interval.
Complete data for the first ‘Perceived Confidence’ interval was available for 261 (93%) of the participants. Chi Square statistical analysis revealed a significant improvement in ‘Perceived Confidence’, $P=0.000$. The 6 month interval was compared to the post course results, 149 (57%) and showed continued improvement in ‘Perceived Confidence’, $P=0.005$. Of the 149 participants with 6 month follow-up, 138 (89%) reported changes in driving patterns based on topics covered at the clinic and 86 (58%) encountered situations that required application of a technique taught. Overall MVC rate was 8%, only minor injuries reported.

TCCC participation resulted in an overall improvement in driving confidence, application of practiced techniques and a low incidence of MVC. Given the magnitude of death and disability rates associated with MVC involving teenagers, it is imperative that trauma centers play a lead role in crash prevention initiatives such as TCccCs. The implementation of TCccCs requires planning among trauma center staff to coordinate a driving area, classroom space, volunteer driving instructors, food sponsors, and program promotion to conduct the day long clinics. Funding for this free program is made possible through grants and donations. Lessons learned: Without financial accountability, individuals didn’t see the value of the program. This led to the implementation of a refundable registration deposit. Community, parent, and school involvement is key in the promotion of TCCC’s.


With healthcare reform changing the focus of payment and delivery, marketers are called on to develop focused marketing strategies that engage consumers in getting and staying healthy and building a relationship with their primary care team through medical homes. Explore population health marketing strategies executed in collaboration with some non-traditional partners.


**Background:** NCCN Clinical Practice Guidelines are the most widely recognized and comprehensive clinical policies used in oncology written by multidisciplinary panels of expert physicians from NCCN member institutions. However, the recommendations are largely developed from lower levels of evidence or expert opinions, and therefore, potentially vulnerable to influence by financial conflicts of interest (FCOIs) (Poonacha T, et al. *J Clin Oncol* 2011;29:186-191).

**Objective:** We performed this study to describe the nature and extent of self-reported FCOIs of NCCN panel members among the 10 most common cancers in the US.

**Methods:** We obtained the disclosures from the NCCN website (accessed December 1, 2011). FCOIs are reported under 4 categories: clinical research support (research), advisory board/speaker bureau/expert witness/consultant (honoraria), patent/equity/royalty (equity), and other remunerations.

**Results:** There are 330 panel members with a mean of 33 per panel. Most (94%), but not all, disclosures are up to date as of 2011. 141 (43%) panel members reported FCOIs. The extent of FCOIs among panel members according to disease sites are as follows: non-Hodgkin lymphoma (60%), breast (52%), kidney (49%), colorectal (48%), lung (47%), prostate (41%), bladder (40%), melanoma (29%), thyroid (28%), and uterine (25%) cancers. 74% (n=23) of writing committee members and 83% of panel chairs have FCOIs. Among the panel members with FCOIs, 51%, 48%, 1%, and 1% of the FCOIs are related to research, honoraria, equity, and other remunerations, respectively. Of those with non-research FCOIs (n=109), 38%, 29%, and 33%, reported 1, 2-3, and > 4 disclosures, respectively.

**Conclusions:** A substantial proportions of NCCN panel members as well as the majority of panel chairs and writing committee members have FCOIs. Nearly half of the FCOIs are unrelated to research support. While the actual impact of FCOIs on the NCCN recommendations cannot be determined from our study, the potential for such influence can be considerable.

http://meeting.ascopubs.org/cgi/content/abstract/30/15_suppl/e16555;sid=004fd8cc-0534-4409-b7ce-fd132f87901


**Background:** In DLBCL, multiple extranodal sites of involvement and MYC/BCL2 translocations (double hit lymphoma) are associated with a poor clinical outcome. The associations between the pattern of extranodal involvement and MYC and BCL2 protein expression, as well as the prognostic significance of expression, are unknown.
Methods: We analyzed the clinical data of 487 DLBCL patients treated with R-CHOP. Immunohistochemical (IHC) studies were performed on paraffin-embedded tissue samples for MYC and BCL2. A double-hit score (DHS) of 0, 1, or 2 was assigned to all patients based on protein expression of MYC and BCL2. Those with both MYC and BCL2 expression were DHS 2, with MYC or BCL2 was DHS 1, and neither was DHS 0. Cell-of-origin classification was achieved by combining gene expression profiling (GEP) and IHC data with GEP as the gold standard. Patient characteristics were compared using Fisher’s exact test. Survival analyses were performed using Kaplan-Meier curves and compared using log-rank test. The Cox proportional regression model was used for multivariate analysis.

Results: Approximately half of the patients (n = 251; 51.5%) had at least 1 extranodal site of involvement. In this group, the clinical features were: median age of 63 years (range, 12-88), male (58.6%), stage III/IV (63.2%), elevated serum LDH (66.8%), and International Prognostic Index (IPI) of 3-5 (48.5%). IHC features were: non-germinal center B-cell like (non-GCB) (53%), MYC+ (64.9%), BCL2+ (49.8%), MYC-/BCL2- (DHS 0; 20.3%), MYC+/BCL2- or MYC-/BCL2+ (DHS 1; 44.6%) and MYC+/BCL2+ (DHS 2; 35.1%).

The common extranodal sites of involvement were genitourinary tract (18.3%), gastrointestinal tract (15.1%), sinonasal (14.3%), bones (13.9 %), lung (11.6 %), skin/soft tissues (9.9%), liver (9.1%), and bone marrow (8.4%). MYC+ was associated with bone marrow (odds ratio [OR]: 5.67; P=0.009) and skin (OR: 3.11; P=0.045) involvement, BCL2+ with sinonasal (OR: 2.26; P=0.032) involvement, and MYC+/BCL2+ with skin/soft tissue (OR: 2.38; P=0.049) and lung (OR: 2.37; P=0.04) involvement. Non-GCB subtype was associated with genitourinary tract (OR: 1.47; P=0.005) and bone marrow involvement (OR: 1.5; P=0.038).

The DHS 2 subgroup was significantly associated with lower complete response rate (62.5% vs 76.1%; P=0.023), shorter progression-free-survival (PFS) (median 23.1 months vs 80.7 months; P<0.001), and shorter overall survival (OS) (median 25.0 months vs 94.5 months; P<0.001) compared with the DHS 0-1 subgroups. Using multivariate analysis, DHS 2 remained significantly associated with a worse outcome.

<table>
<thead>
<tr>
<th>Variable</th>
<th>OS</th>
<th>PFS</th>
</tr>
</thead>
<tbody>
<tr>
<td>IPI (3-5 vs 0-2)</td>
<td>1.5</td>
<td>1.07-1.88</td>
</tr>
<tr>
<td>COO (non-GCB vs GCB)</td>
<td>1.05</td>
<td>0.71-1.52</td>
</tr>
<tr>
<td>DHS (2 vs 0-1)</td>
<td>2.97</td>
<td>2.00-4.39</td>
</tr>
</tbody>
</table>

Conclusions: In DLBCL with extranodal disease, MYC and BCL2 protein expressions and cell-of-origin are associated with distinct patterns of organ involvement. Patients with DLBCL expressing both MYC and BCL2 (score DHS 2; double hit biology) have a poor outcome independent of IPI and cell-of-origin.


Background: Lenalidomide has proven to be a highly effective treatment agent in relapsed myeloma, particularly when used in combination with dexamethasone. However, over 30% of patients with myeloma have renal insufficiency and as lenalidomide is renally excreted, little information is available about its use in myeloma patients with impaired kidney function. Defining a safe and effective dose of lenalidomide in this context is critical.

Objective: We undertook this study to establish the maximum tolerated dose of lenalidomide in three cohorts of patients with different levels of impaired renal function: Group A - patients with creatinine clearance between 30 and 60 mL/min, Group B - patients with creatinine clearance <30 mL/min not on dialysis, and Group C - patients with creatinine clearance <30mL/min who are on dialysis.

Methods: Eligible patients had previously treated multiple myeloma with renal impairment defined as creatinine clearance <60 mL/min measured within 21 days prior to registration. Patients previously treated with lenalidomide were required to demonstrate clinical response (any duration) or stable disease with progression-free interval of >6 months from start of that therapy. All patients received dexamethasone 40 mg orally on days 1, 8, 15 and 22 of a 28-day cycle. Prophylactic anticoagulation consisted of either 81 mg or 325 mg per day of aspirin. Patients also received lenalidomide orally every 1 or 2 days on days 1 through 21 of a 28-day cycle, as described below (Table 1). Dose escalation follows a standard 3+3 design.

Results: There have been 23 patients enrolled into groups and cohorts as shown in Table 1. Median age was 73 (range 49-89) and 13 (57%) were women. ISS stage was advanced in all patients, 0 in stage 1, 4 (18%) in stage 2 and 19 (82%) in stage 3. The regimen was well tolerated. The most commonly reported clinical adverse events (all
grades, independent of attribution) across all patients included infections, hyperglycemia, constipation, dizziness, hyponatremia, hypocalcemia and tremor. Hematological toxicities (grade 3-4) occurred in 11 out of 16 pts (69%), mostly neutropenia and thrombocytopenia. Grade 3-4 events at least possibly related to the regimen occurred in 60% and included pneumonia (26%) and otitis media (9%). However, no DLT’s have occurred to date. Response was seen in 14 patients, resulting in an overall response rate of 61%. Best confirmed response is CR in 1 patient (4%), VGPR in 2 patients (9%), PR in 11 patients (43%), and SD for 9 patients. With median follow-up of 15.5 months, median progression-free survival is 9.8 months and median overall survival is 22 months. One patient has developed a second primary cancer.

**Conclusion:** Lenalidomide and dexamethasone is a safe and effective regimen in patients with myeloma and renal insufficiency. It is also very well tolerated, although cytopenias are common but manageable. MTD has yet to be reached in each group, allowing for higher doses to be given than previously thought, including 25mg daily (for 21/28 days) in patients with CrCl 30-60 mL/min, 25 mg every other day (for 21/28 days) in patients with CrCl <30 mL/min not on dialysis, and 10mg daily (for 21/28 days) in patients on dialysis. These results will provide needed, clinically relevant dosing for lenalidomide in patients with renal insufficiency.

**Table 1: Dosing Schedule and Patients Enrolled**

<table>
<thead>
<tr>
<th>Dose level</th>
<th>Patients Enrolled</th>
<th>DLT’s</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Group A: patients with creatinine clearance 30 - 60 mL/min</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dose level 1 (10mg qd)*</td>
<td>6 of 6</td>
<td>0</td>
</tr>
<tr>
<td>Dose level 2 (15mg qd)</td>
<td>3 of 3</td>
<td>0</td>
</tr>
<tr>
<td>Dose level 3 (25mg qd)</td>
<td>2 of 6</td>
<td>0 (to date)</td>
</tr>
<tr>
<td><strong>Group B: patients with creatinine clearance &lt; 30 mL/min not on dialysis</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dose level 1 (15mg q2d)*</td>
<td>3 of 3</td>
<td>0</td>
</tr>
<tr>
<td>Dose level 2 (25mg q2d)</td>
<td>3 of 3</td>
<td>0</td>
</tr>
<tr>
<td>Dose level 3 (15mg qd)</td>
<td>Opened 5/17/12 (0 pts)</td>
<td></td>
</tr>
<tr>
<td>Dose level 4 (25mg qd)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Group C: patients with creatinine clearance &lt; 30 mL/min on dialysis</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dose level 1 (5mg qd)*</td>
<td>3 of 3</td>
<td>0</td>
</tr>
<tr>
<td>Dose level 2 (10mg qd)</td>
<td>3 of 3</td>
<td>0</td>
</tr>
<tr>
<td>Dose level 3 (15mg qd)</td>
<td>Opened 5/17/12 (0 pts)</td>
<td></td>
</tr>
<tr>
<td>Dose level 4 (25mg qd)</td>
<td></td>
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</table>

* Starting dose


**Background:** Pain is a major concern for hospitalized patients. Despite multiple quality initiatives to improve pain management, national studies continue to demonstrate that pain is inadequately managed. To date, no national study directly asked patients for their perception of their pain management.

**Significance:** This is a national study involving 400 hospitals, conducted by the National Database for Nurse Quality Indicators (NDNQI), and funded by the Robert Wood Johnson Foundation. The goal of this study is to “implement and evaluate an innovative research program to measure and improve pain care processes and outcomes in a sample of hospitals across the U.S.”.

**Purpose/objective:** The purpose of this presentation is to compare data from patient responses at Gundersen Lutheran (GL) hospital with responses from comparable hospitals participating in this research.

**Methods:** Nursing students, trained in research ethics and data collections, interviewed patients on one day in April and November, 2011. Data were collected from patients on the following units: Medical-Surgical, Rehabilitation and Postpartum.

**Results:** National data indicated that patients’ mean pain score in the past 24 hours of their hospitalization was 5.7 + .6. Patients believed their reports of pain and they received pain medication in a timely manner. Patients were less likely to
report that nurses offered them additional approaches to manage pain and that side effects of pain medications were discussed. Ratings from GL patients were the same or higher than those of national participants.

**Clinical Implications:** Research supports the effectiveness of a growing number of nursing interventions that help manage patients’ pain. The challenge is to deliver nursing interventions, particularly complimentary, holistic care practices given the daily demands of the work setting.


**Abstract**

**Background:** During the last decade, the literature suggests there has been an increase of both student and faculty incivility in higher academic education across the country. Incivility in higher education occurs on a continuum with a range from low risk behaviors to high risk, threatening behaviors. Low risk behaviors often trend toward more aggressive behaviors such as verbal taunting, spreading rumors, and racial or ethnic slurs. The natural progression of escalating behaviors can result in the participant performing aggressive, potentially violent behaviors such as intimidation and physical violence. Incivility in nursing education is documented as a moderate problem intensified by situational stressors. While recent attention has been focused on developing appropriate policy to address the problem, less attention has focused on systematic documentation of uncivil behaviors by both students and faculty as the basis for developing interventions to promote civility in the classroom. This project is an initial effort to support positive student experiences in working through conflicts in the educational setting. The long-term goal is for nursing students to carry civil behaviors forward into the future workplace when dealing with stress and conflict.

**Purpose Statement:** The purposes of this study are; 1) to document students’ perceptions of uncivil behaviors in higher education entering and enrolled in the Winona State Nursing program; 2) to track uncivil behaviors as perceived by students and faculty of the Winona State Nursing program over the next year and 3) to generate creative strategies to promote civility and address stress in higher education.

**Method:** This project will use a descriptive research design to document incivility in nursing education at two points in time. The sample will be drawn from faculty members who teach and nursing students who attend the Winona State University Nursing program. The faculty sample is expected to be approximately 38 faculty members. The nursing student sample is expected to be approximately 150 Junior-level students and 150 Senior-level students. The student sample will be comprised of Junior-level students entering the school of nursing and Junior- and Senior-level students at different points in the school of nursing curriculum. During the Spring Semester of 2012 and 2013, all faculty and students will be invited to complete a demographic survey along with the Incivility in Higher Education Scale (IHE). This year during the spring (2012) semester a summary of survey results will be shared with students and faculty. Faculty and Junior-level students will be invited to attend one of two focus groups of their peers. Focus groups will be led by a member of the research team. The purpose of the focus group is to gain insight into the survey results and generate ideas to create a culture of civility within the Winona State University Nursing program. The results of the faculty focus group and Junior-level focus groups will be shared in a summary format of major points and themes via email.

**Data Analysis:** Descriptive statistics will be used to describe the cohorts of students and faculty participating in the survey each year. Chi-square and regression analysis will be used to test for association between faculty and student responses. Qualitative data analysis of focus group data will be analyzed for themes. NVivo software will be used to support data management and to document an audit trail of decision making in the identification of themes.


For centuries, essential oils have been used to treat nausea and vomiting. Research supports this practice and has demonstrated that essential oil use is effective as an adjunct therapy in the management of post-operative nausea and vomiting.

As bedside nurses, focusing more on the tasks related to patient care creates a barrier to making an authentic caring connection with our patients. Introducing staff to the use of essential oils with our orthopedic surgical patients, as a complimentary therapy is one way to begin creating a healing environment.

The purpose of this pilot project was to design and implement a process that educates staff on: the use of essential oils, individualization of the patients’ plan of care, documentation, and creating a healing environment for our patients on all levels (mind, body and spirit). Dr. Val Lincoln Ph.D., RN of the Woodwinds Health Campus was instrumental in inspiring nurses on the orthopedic unit to engage in this initiative. Dr. Ed Riley II serves as the Physician champion and Jill Blackbourn RN, Nursing Systems Specialist, is the project chair. Education for staff was provided and a
Background: Laparoscopic Roux-en-Y gastric bypass (LRYGB) is the most commonly performed bariatric procedure. LRYGB can lead to iron malabsorption through exclusion of the duodenum and proximal jejunum, decreased gastric acidity, and modified diet. Intravenous (IV) iron is a treatment for severe iron deficiency after LRYGB, but the incidence is largely unknown. The objective of this study was to evaluate the incidence and treatment of iron deficiency after LRYGB.

Methods: After obtaining IRB approval, the medical records of all patients who underwent LRYGB from September 2001 to December 2011 were retrospectively reviewed. Patients were grouped into those who received IV iron treatment and those who did not. Inclusion criteria consisted of at least one ferritin value measured. Variables reviewed included co-morbidities, oral and IV iron supplementation, and laboratory values including hemoglobin, ferritin, and iron binding capacity. Patients with at least one ferritin <50 ng/mL were considered iron deficient. Statistical analysis included ANOVA.

Results: There were 959 patients included in our series, of which 84.9% were female. The mean age was 43.8 years, and mean preoperative body mass index was 47.4 kg/m². 51.3% of patients were iron deficient. The iron deficient group had lower mean Hgb and MCV values preoperatively and at 1, 2, and 3-5 years postoperative ($P=0.001$). Mean ferritin was 45.8, 36.8, and 22.1 ng/mL versus 159.4, 155.9, and 129.0 ng/mL in the iron deficient versus normal group at 1, 2, and 3-5 years postoperatively, respectively ($P=0.001$). Treatment with IV iron was required by 6.67%, and all had ferritin >50 ng/mL after treatment.

Conclusion: Given the incidence of iron deficiency after LRYGB observed in our series, patients should have iron status monitored carefully by all providers and be appropriately referred for treatment.


shorter PFS compared to those without cold brain, although this was not statistically significant (hazard ratio: 3.13; 95% CI: 8.20–1.22; P=0.096).

**Conclusion:** In our study, cold brain was a phenomenon frequently observed among patients with newly diagnosed DLBCL. It was associated with higher risk disease, lower complete response rate to R-CHOP chemotherapy, and potentially shorter PFS. Further studies in larger patient population are needed to determine its true prognostic significance.


**Presentation Summary:** Binge drinking and the harms that result from it are a significant health issue in most communities in Wisconsin. This presentation will share our efforts to reduce these harms by forming a county-wide citizen-led coalition, gathering data to identify the problem, and creating and adopting a five-year strategic plan focused on evidence-based, environmental strategies. With the goal of reducing overall harm through a sustainable change in policies and practices in our community, we focused our data collection and strategies on binge drinking at community festivals, at taverns, and on our campuses. By presenting binge drinking as a public health issue rather than a behavioral problem, we were able to engage our target audience, including festival organizers, tavern owners, and educational leaders. This “soft approach” of creating awareness and ownership of the issue is allowing us to move toward the introduction of policy changes as partners rather than opponents.

**Presentation Learning Objectives:**
1. To understand how one community coalition can use data to create a strategic plan that empowers a community to address a significant health issue through sustainable policy changes.
2. To learn how one coalition worked with festival organizers to create an assessment tool of best-practices that can be used in a variety of communities, and provides objective and actionable data.
3. To learn how we engaged tavern owners to voluntarily adopt best practices as a first step to control binge drinking behaviors.

**Implications for Public Health:** Binge drinking is common at community festivals, taverns and house parties on and near college campuses, in part because the culture created by our state’s history with brewing and traditions surrounding alcohol. As a result, practices related to alcohol use and availability threaten public health through intentional and unintentional injury and death. Passing and implementing alcohol-related policies is generally fought by alcohol sellers and those tolerant of its misuse. We will discuss how we framed binge drinking as a public health and safety concern and engaged potential antagonists in our strategies such that policy change would be seen as a positive next step, rather than a prohibitive approach. We are beginning to show how providing tools that help our would-be adversaries grow their businesses and their communities can lead to broad-based support for policy changes that protect and sustain public health.

Brenda Rooney is the Medical Director of the Department of Community and Preventive Care Services at Gundersen Lutheran Medical Center, La Crosse, Wisconsin. She directs the health promotion and disease prevention activities for the health system that covers a services area of about 600,000 people in western Wisconsin, southeastern Minnesota and northeastern Iowa. Dr. Rooney received her MPH and PhD degrees from the University of Minnesota, School of Public Health. She received a Behavioral Aspects of Cardiovascular Disease pre-doctoral fellowship from the National Cancer Institute during her training. A strong focus of her training was on evaluation of community-based health promotion activities. Dr. Rooney has conducted extensive research in smoking prevention and treatment, obesity prevention and treatment. She has authored or co-authored more than 90 scientific publications, abstracts and national presentations.

Catherine Kolkmeier is the Director of the La Crosse Medical Health Science Consortium, a collaboration of healthcare and education partners in La Crosse, Wisconsin, dedicated to strengthening the healthcare workforce and improving population health in its region. The Consortium’s partners are Western Technical College, Viterbo University, the University of Wisconsin-La Crosse, Gundersen Lutheran, Mayo Clinic Health System Franciscan Healthcare, the La Crosse School District and La Crosse County Health Department. Catherine began her career in the field of biology and obtained her master’s degree in Animal Behavior from the University of Tennessee. After several years working as an environmental biologist, she delved into nonprofit fundraising and grant writing, which brought her to La Crosse in 2000. She worked as a freelance technical and scientific writer for five years and joined the Consortium staff in 2007, where she specializes in creating and maintaining cross-discipline collaborations.

Pat Ruda is the Agency Director for Coulee Council on Addictions. Coulee Council is a non-profit community based agency that provides confidential assistance information, education and services to people of all ages dealing with substance abuse and other addictions. Pat has a BS in Social Work from the University of Wisconsin-La Crosse.
and has worked in the La Crosse community for 30 years in business, marketing, human resources, public relations and governmental affairs. She has been active on numerous boards and community activities like the Downtown Rotary Club Board of Directors, Communications Committee of University of Wisconsin-La Crosse, Chamber of Commerce and Business Associations.

Al Bliss is a Community Health Educator who has been employed with La Crosse County Health Department for 16 years. Currently, Mr. Bliss is the Project Manager for the local Community Coalition Changing the Culture of Risky Drinking Behavior: to reduce alcohol-related injuries among 12-24 year olds in La Crosse County.


Binge drinking is a major public health threat in the United States. Community festivals provide an opportunity for binge drinking to occur nearly every summer weekend in our community, where there have been over 10 alcohol-related drownings and numerous serious injuries in the past decade. In 2010 and 2011, we conducted evaluations of 19 festivals in our community, using volunteers to evaluate the use of 12 specific strategies related to preventing underage or binge alcohol consumption. Each strategy was given a score from 1 to 3 (1-not met, 2 -inconsistently met, 3-fully met). Scores were summed and standardized on a scale from 33.3 to 100. Total number of strategies “fully met” was also determined. After the first year's evaluation, we reviewed the results with festival organizers. After discussing each strategy and our findings, we discussed ways the festival could adopt safer practices and share ideas among festival organizers. The average score increased from 68.4 to 74.3. In 2010 an average of 4.2 strategies were fully met. In 2011, this had increased to 5.2 strategies. There were improvements in offerings of food and non-alcoholic beverages in the beer tents, fewer servers drinking, and more consistent use of wrist bands and ID checking. Limiting serving size and restricting alcohol sales to a designated location were strategies less frequently adopted. Continued efforts in future years are necessary. We've initially pursued a voluntary adoption of strategies to build support for the acceptance of future policies that will be pursued as conditions on alcohol licenses.


**Background:** There is a perception that patient accrual may be slower in the US than it is in Europe (Wang-Gillam A et al, J Clin Oncol 2010;28:3803-3807). However, a systematic study has not been performed. We seek to determine the speed at which patients are accrued into published phase III oncology trials across geographic locations and to identify factors that may influence this process.

**Methods:** We searched MEDLINE and identified all original phase III oncology therapeutic trials published in 2006-2010 (N = 567). Trials with no reported activation and completion dates were excluded (n = 20). Accrual speed per trial was expressed as patients per month and was calculated by dividing the number of patients enrolled by number of months a trial was open.

**Results:** The 547 trials included in our study enrolled 281,340 patients. Most trials were for adults only (95.6%), late stage cancers (77.5%), and involved multinational participation (44.1%). Funding sources were cooperative groups (45.5%), industry (33.8%) and academic centers (20.5%). The top 5 cancers studied were hematologic (19.2%), gastrointestinal (16.5%), lung (16.3%), breast (15.4%), and gynecologic (8.4%). Trial results were negative (57.4%), positive (38.2%), or equivalent (4.4%). The mean (±SD) accrual speeds varied according to trial location (multinational [25.0±25.4], US [13.3±16.5], other countries [11.4±15.7], Europe [8.7±11.8]; [P=.001]), funding source (industry [28.3±24.7], cooperative groups [13.3±19.0], academic [6.8±6.5]; [P=.001]), and cancer type (breast [24.0±29.4], gastrointestinal [20.2±24.2], lung [19.3±22.7], gynecologic [15.3±19.2], hematologic [11.2±10.7]; [P=.001]). After adjusting for funding source, accrual speeds were significantly different across trial locations only in 2 cancers: gastrointestinal (multinational [25.2±3.7], US [24.1±8.2], Europe [11.5±3.7], other [7.5±8.5]; P=.046) and gynecologic (multinational [28.9±5.4], other [10.5±7.8], US [6.6±5.3], Europe [4.2±5.9]; P=.004) studies.

**Conclusions:** Among published phase III oncology trials, multinational studies accrued patients faster in gastrointestinal and gynecologic cancers and at a similar speed in other cancers.

Background
Joint Commission states that health care organizations must address the problem of destructive behaviors in the workplace. The Center for American Nurses (CAN) offers the Conflict Engagement Profile program to increase the use of constructive conflict engagement behaviors. Following implementation of the CAN’s program for system nurse leaders, participants recommended ongoing coaching and additional practice sessions.

Significance
The challenge was to deliver this multi-layered program in a manner that is efficient, cost effective and meaningful to staff nurses.

Purpose/objective
To assess the effectiveness of a modified Conflict Engagement Portfolio intervention with Gundersen Lutheran staff nurses at baseline and at six months.

Methods
The CAN’s program was modified to include: online education modules and a half-day workshop followed by one-hour Learning Circle (LC) meetings held monthly for four months. A convenience sample of nurse Expert Leaders (unit level staff nurse leaders) agreed to participate. Data was collected at baseline at six months using a demographic survey and the Conflict Dynamic Profile (CDP) instrument.

Results
A cohort of 45 (22%) Expert Leader nurses participated with > 90% attendance at Learning Circles. Characteristics of this sample include: median age of 50 years, 58% working in the hospital setting, 56% bachelor degree prepared and 58% active in the system’s shared governance structure. CDP pre-test results raised awareness of one’s own behaviors. The CDP at six-months demonstrated that the use of constructive strategies remained the same or improved. With the exception of “demeaning others”, destructive strategies remained the same or deceased.

Clinical Implications
High participation at monthly Learning Circle meetings reflected staff nurses’ active interest in practice exercises, and mutual support for engaging in conflict situations. Skill building occurred over time. At the fourth LC, participants were able to identify how their own behaviors contributed to conflict and the challenges in changing behaviors.


Background: Incivility in higher education is a growing problem in the U.S. Faculty and students’ past experiences influence their interactions within the Nursing classroom.

Significance: The goal is to develop a culture of civility.

Purpose/objective: In order to understand the perceptions that contribute to incivility within Nursing education, the present study aims to: 1) to document students’ perceptions of uncivil behaviors in higher education prior to entering the Western Campus program; 2) to track uncivil behaviors as perceived by students and faculty of the Western Campus program over the next five years and 3) to generate creative strategies to promote civility and address stress in higher education.

Methods/Project: Nursing faculty (n=9) from the Western Campus of the University of Wisconsin, Madison completed the Incivility in Higher Education (IHE) scale prior to beginning the 2011-2012 school year. Students (n=24) completed the IHE scale during orientation to the School of Nursing. Focus groups of faculty and students were held to discuss the data.

Results: Respondents indicated that incivility was a mild to moderate problem. Students’ behavior consistently reported as uncivil by students included: holding distracting conversations, cheating, being unprepared, using a computer unrelated to class and creating tension by dominating discussion. Students’ behavior consistently reported as uncivil by faculty included: demanding make up examinations/extensions, cheating, using cell phones during class and not paying attention. Faculty behaviors perceived as uncivil by both students and faculty included: making rude gestures, being distant and cold, and refusing to answer questions. Both cohorts reported that faculty’s failure to address disruptive behaviors as they occur contributes to the problem.

Clinical Implications: Faculty and students need foundational skills to address uncivil behaviors and to work together to develop a culture of civility in nursing education. In a culture of civility, faculty strives to empower students and students actively contribute to a civil learning environment.

The purpose of the WELEAP Linking Education and Practice for Excellence in Public Health Nursing (LEAP) Regional Learning Collaborative is to strengthen the public health nursing workforce and improve the quality of public health nursing practice in a changing public health system. The WELEAP RLC met the learning and development needs of collaborative academic and practice members by facilitating presentations for professional development, stimulating student interest in public health nursing, identifying specific projects to benefit the region and state wide needs, and targeting educational events to improve networking and relationship building, addressing critical issues for strengthening the public health workforce and improving the quality of public health nursing practice. This poster demonstrates the collaborative strategies that were used to generate innovation of local academic, practice, and community partner linkages.


**Background**
Incivility in higher education is a growing problem in the U.S. Faculty and students’ past experiences influence their interactions within the Nursing classroom.

**Significance**
The goal is to develop a culture of civility.

**Purpose/objective**
In order to understand the perceptions that contribute to incivility within Nursing education, the present study aims to: 1) to document students’ perceptions of uncivil behaviors in higher education prior to entering two nursing programs in the Midwest; 2) to track uncivil behaviors as perceived by students and faculty of the two nursing programs and 3) to generate creative strategies to promote civility and address stress in higher education.

**Methods/project**
Nursing faculty (n=9) from the Western Campus of the University of Wisconsin, Madison and Nursing faculty and Staff (n=29) from Winona State University completed the Incivility in Higher Education (IHE) scale prior to beginning the 2011-2012 school year. Students (n=24) from Western Campus of the University of Wisconsin and (n=32) from Winona State University completed the IHE scale during orientation to the School of Nursing. Focus groups of faculty and students were held to discuss the data.

**Results**
Student respondents indicated that incivility was a mild to moderate problem. Students’ behavior consistently reported as uncivil by students included: holding distracting conversations, cheating, being unprepared, using a computer unrelated to class and creating tension by dominating discussion. Students’ behavior consistently reported as uncivil by faculty included: demanding make up examinations/extensions, cheating, using cell phones during class and not paying attention. Faculty behaviors perceived as uncivil by both students and faculty included: making rude gestures, being distant and cold, and refusing to answer questions. Both cohorts reported that faculty’s failure to address disruptive behaviors as they occur contributes to the problem.

**Clinical implications**
Faculty and students need foundational skills to address uncivil behaviors and to work together to develop a culture of civility in nursing education. In a culture of civility, faculty strives to empower students and students actively contribute to a civil learning environment.


**Background:**
The World Health Organization (2010) states that education is a necessary step in preparing a “collaborative practice-ready” health workforce that is better prepared to respond to local health needs. Education must include opportunities for “students from two or more professions learn about, from and with each other to enable effective collaboration and improve health outcomes.”

**Purpose:**
This presentation describes the development of an interprofessional education program using video simulation and a facilitator guide that: provides knowledge and education to assist with improved communication between patients and families and health care professionals, and encourages continuous collaborative care from participants.
Methods:
Key steps in the process included: writing a script to depict not ideal and ideal care of a patient seen in a regional clinic requiring transfer to a major medical center, selection of PFCC components to be showcased, production of video simulations, development of a facilitator guide and scheduling time for delivery of an interprofessional learning experience. A partnership was created with the La Crosse Community Theatre for assistance in direction and production of the video simulations.

Results:
Participation in developing and creating the education program provided opportunities for each person to bring their own stories and histories to creating the videos. Individual creativity added to the realistic depiction of challenges to delivering PFCC. Stories of personal and professional growth were provided by team members, the cast and crew working on the education program. The completed program is comprised of short didactic instruction, viewing of the video simulations followed by group debriefing on non-ideal and ideal practices, and a personal commitment to improve patient-centered care delivery.

Clinical Implications:
Collaboration between Gundersen Lutheran Health System and the community assisted in the further understanding of interprofessional work as well as professional growth.


Introduction: Safety in the operating room (OR) is a priority for both patients and hospital staff. Our hospital administration promoted education regarding a culture of safety in June 2010 when all OR staff were required to attend a 4 hour seminar presented by an outside consultant highlighting safety culture. Data reflecting employee perspectives of perioperative safety were collected before and after this intervention. Despite a decrease in the perception of safety in the OR based on the employee surveys, we hypothesized that, in fact, safety had improved.

Methods: After obtaining IRB approval, OR incident reports, antibiotic timing/selection/discontinuation, and OR time out frequency for 2 years before and after our intervention were evaluated. Statistical analysis included chi square and a P value <0.05 was considered significant.

Results: There were fewer OR incident reports per month (12.5 vs 15.5) in the pre-intervention period compared to the post-intervention period. Fewer “near misses” (18 vs. 113) and decreased severity of incidents (those requiring intervention or resulting in harm; 20 vs. 56) were observed in the pre vs. post-intervention period. Preoperative time out was completed less often in the pre vs. post-intervention period (98.1% vs. 99.1%, P=0.001). Significant improvements in antibiotic timing (92% vs. 96.5%, P=0.001), selection (95.3% vs. 97.9, P=0.001) and appropriate discontinuation times (96.8% vs. 98.2%, P=0.038) were observed in the post-intervention period.

Conclusion: Based on the evaluation of preoperative time out frequency and appropriate antibiotic administration, it appears our patients are not less safe in the OR after a safety culture intervention. Perioperative incident reports show both increase in “near miss” incidents as well as higher acuity events. This warrants further investigation. The reason for the declining employee perception of patient safety is unclear. In addition, these data suggest that simple interventions can produce significant improvement in aspects of perioperative safety. This study illustrates the complexity of studying a multifaceted subject such as perioperative safety.

44. Van Osdol A, Andersen JJ, Ellis RL, Gensch E, Gundrum JD, Johnson JM, De Maiffe BM, Marcou KA, Landercasper J. Fibroadenoma or phyllodes tumor: should fibroepithelial lesions found on breast needle biopsy be excised or observed? Presented at Wisconsin Surgical Society Fall Meeting (2012), Kohler, Wisconsin, November 2-3, 2012.

Background: There is no consensus for which fibroepithelial lesions (FEL) of the breast discovered on core needle biopsy (CNB) require surgical excision.

Objectives: This study was designed to determine the institutional upgrade of FEL on CNB to benign or malignant phyllodes tumor on surgical biopsy. We sought to identify any pre-operative factors that correlated with upgrade of FEL to benign or malignant phyllodes tumor. If identified, this information could aid future patient informed consent regarding observation or excision of FEL.

Methods: A retrospective chart review of a prospective breast center database for 2001-2006 was performed. These years were chosen to provide adequate time to identify missed lesions in patients undergoing observation. Inclusion criteria for the study included all patients with FEL or Fibroadenoma (FA) on CNB. A policy of selective surgical excision of FEL identified on CNB was utilized. CNB was performed by breast specialty radiologists and all patients had BIRADSTM assessment and concordance testing for imaging and histology, followed by an informed consent discussion regarding observation or surgical excision. Multiple clinical and pathological factors, such as method of detection, lesion palpability, lesion type, size of CNB, type of CNB and BI-RADSTM Assessment, were analyzed
for upgrade to phyllodes tumor. Statistical methods utilized were chi-square test (Fisher exact tests) for categorical evaluation and Wilcoxon rank-sum for follow up times.

Results: A total of 322 patients met inclusion criteria. 269 (84%) of the 322 underwent observation only with a mean follow up of 6.1 years. There were no missed malignant phyllodes tumors in the 269 observed patients. One observed patient had a benign phyllodes tumor in follow up and another patient had an adenocarcinoma at the CNB site discovered 3 months after biopsy. Fifty-three (16%) patients underwent surgical biopsy with 1 (1.8%) upgraded to malignant phyllodes and 18 (34%) upgraded to benign phyllodes. Of 11 pre-operative factors tested for correlation with upgrade, only the recommendation for surgical biopsy by a breast subspecialty pathologist was found to be associated with upgrade to benign or malignant phyllodes tumor on excision (p-value 0.003); 18/33 (55%) pathology recommended open biopsies were upgraded to benign or malignant phyllodes tumor; 1/20 (5%) not recommended were upgraded. Lesion BIRADSTM assessment category approached statistical significance for upgrade (p-value of 0.06).

Conclusions: Sixteen percent of 322 patients with FEL underwent surgical excision with only 0.7% of observed patients subsequently discovered to have a missed lesion. For patients undergoing excision, FEL on CNB was upgraded to phyllodes tumor in 35%. Breast subspecialty pathologist opinion and BIRADS assessment aid the decision making process of observation versus excision. The majority of patients undergoing CNB of a BIRADS 3 breast lesion identifying FEL, free of phyllodes features as determined by a breast pathologist, may safely avoid surgery. This study validates our institutional policy of selective excision for FELs.


Background: The National Kidney Foundation Disease Outcomes Quality Initiative (K/DOQI) guidelines recommend autologous arteriovenous access treatment options in the following order: 1) radiocephalic or brachiocephalic 2) arteriovenous graft or brachiobasilic. Our objective was to evaluate the outcomes of transposed brachiobasilic arteriovenous fistula (AVF) at our community-based teaching hospital.

Methods: After receiving IRB approval, the medical records of all patients who underwent transposed brachiobasilic AVF creation from 2005-2010 were reviewed. AVF failure was defined as a fistula that was inadequate for hemodialysis or no thrill on clinical exam in patients not requiring dialysis. AVFs were considered patent if they were accessed for dialysis or had a palpable thrill in patients not yet requiring dialysis. Patients with AVF failure were compared to those with a patent transposed brachiobasilic AVF. Variables included demographics, operative time, comorbidities, long-term AVF patency rates, morbidity and mortality. Statistical analysis included Fisher's exact test, t-test and Kaplan-Meier survival.

Results: Forty-nine patients underwent transposed brachiobasilic AVF creation; 53% were female. Mean age was 66.9 years and preoperative hemoglobin was 11.6 g/dL. Median operative time was 95.3 minutes. There were no differences with respect to sex, age, preoperative hemoglobin, coronary artery disease, peripheral vascular disease, hypertension, diabetes, congestive heart failure, or tobacco use between the failed AVF vs. patent AVF groups. Complications included hematomas in 3 (6%) patients, thrombosis in 3 (6%) patients, infections in 3 (6%) patients and steal syndrome in 2 (4%) patients. Clinical patency rates at 3, 6, 12, and 24 months postoperative were 85.7%, 79.6%, 75.2%, and 72.4%, respectively. There were no 30-day mortalities; however, 15.6% died within 1 year.

Conclusions: K/DOQI guidelines suggest that a primary AVF patency rate of greater than 70% should be achieved. The literature reports transposed brachiobasilic patency rates at 1 year ranging from 50-92% and each surgeon/ institution must verify that they are achieving the recommended goal of 70%. Regardless of patient comorbidities, brachiobasilic AVFs with transposition at the time of initial operation can achieve this goal.


Gundersen Lutheran, a regional healthcare system, has launched a campaign to promote wellness with an innovative tool designed to engage staff, patients and the community. Balance Your 7 provides information, ideas, inspiration and activities focusing on the seven dimensions of wellness—body, community, feelings, learning, relationships, spirit and work. Attendees will learn how the development, involving a multi-disciplinary healthcare team, lead to the implementation of an on-line resource that complements and supports existing employee and community programming and encourages taking charge - being proactive towards health rather than only reactive to illness.


**Background:** Laparoscopic Roux-en-Y gastric bypass (LRYGB) is the current “gold standard” bariatric procedure in the United States. Laparoscopic sleeve gastrectomy (LSG) has recently become a more commonly performed procedure for a variety of reasons including patients’ perceived notion that LSG is associated with less complexity, lower risk, and less invasiveness.

**Objective:** To review the current surgical literature over the last decade to compare the leak rates as well as morbidity and mortality and weight loss for LRYGB versus LSG.

**Methods:** A MEDLINE search was performed to identify reports of LRYGB and LSG published from 2002-2012. Publications were included if they reported an n >25 and a postoperative leak rate. Only the most recent publication was included from institutions with multiple publications identified. Statistical analysis included chi square according to patient number.

**Results:** 28 (10,906 patients) LRYGB and 34 (4,836 patients) LSG articles met inclusion criteria and were reviewed. The leak rates after LRYGB versus LSG were 1.9% (n=206) versus 2.3% (n=112), respectively (P=0.079). In articles reporting mortality, the mortality rates were 0.4% (27/7117) for LRYGB and 0.2% (7/3594) for LSG (P=0.110). Timing from surgery to leak ranged from 1 to 12 days for LRYGB versus 1 to 35 days for LSG. Mean excess weight loss at 1 year postoperative ranged from 50 - 79% for LRYGB (n=5) and 38 - 81% for LSG (n=16).

**Conclusion:** Both LRYGB and LSG are effective surgical options for weight loss. The leak rates, mortality rates and excess weight loss after LRYGB and LSG were comparable. Patients should be advised of these similarities when considering LRYGB versus LSG. The most appropriate procedure should be tailored based on a comprehensive multidisciplinary discussion between the patient and bariatric team weighing patient factors, comorbidities, patient and surgeon comfort level, surgeon experience, and the institution’s outcomes.

CALL FOR PAPERS

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