



SURGERY NEWS



BOB GARYPIE/UNIVERSITY OF MICHIGAN TRANSPLANT CENTER

Five crashes related to organ procurement have occurred since 1990, said Dr. Michael Englesbe (R) of the University of Michigan.

Organ Procurement Risks Raise Concerns

BY MICHELE G. SULLIVAN

Elsevier Global Medical News

Most transplant team members feel unsafe on organ procurement missions, and their fears are not unfounded: 15% of U.S. transplant surgeons have been involved in at least one accident while traveling to procure organs, according to Dr. Michael Englesbe.

Since 1990, five plane crashes related to organ procurement have occurred, four of which resulted in 10 deaths. A crash in 2007 cost the lives of two surgeons and two technicians who were part of the University of

Michigan's transplant team. Both pilots also died when the plane crashed into Lake Michigan shortly after taking off from Milwaukee. The cause of the accident remains under investigation.

The crash shocked Dr. Englesbe and his colleagues in the university's transplant department, prompting them to examine the problem in a broader sense, and to seek solutions.

A survey they sent last year to all members of the American Society of Transplant Surgeons is the only source of systematically collected data on the dangers of organ procurement trav-

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Early Data Show Percent Body Fat As SSI Predictor

Ongoing study of over 400 patients.

BY DAMIAN McNAMARA
Elsevier Global Medical News

MIAMI BEACH — Preoperative percent body fat is an independent predictor of surgical site infection risk and is a more accurate way to define obesity than is body mass index, according to preliminary results of a prospective, ongoing trial.

Surgical site infections (SSIs) develop in an estimated 290,000 of the 27 million procedures performed annually in the United States, data from the Centers for Disease Control and Prevention indicate. Previous research has linked obesity—as well as type of procedure, patient comorbidity, immunosuppression, and cigarette smoking—to an increased risk of such infections (Dis. Colon Rectum. 2007;50:2223-37; J. Cardiovasc. Surg. 2007;48:641-6).

In the initial cohort of 194

patients in this study, Harvard medical student Emily Waisbren and her associates in the departments of anesthesiology and surgery at Brigham and Women's Hospital in Boston measured percent body fat using bioelectrical impedance analysis and body mass index (BMI) using the standard height and weight formula. Patients ranged in age from 18 years to 64 years (mean age, 49), and 66% were women. The mean BMI was 29.5 kg/m², while overall mean body fat was 34%. Patients were considered obese if their BMI exceeded 30 kg/m² and if body fat exceeded 25% (in men) or 31% (in women), based on the definition from the American Council on Exercise. "This has an accuracy of 2% plus or minus compared to water immersion studies, which are the gold standard,"

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Stimulus Bill Pushes EHR Adoption

BY MARY ELLEN SCHNEIDER

Elsevier Global Medical News

The newly enacted economic stimulus law will infuse tens of billions of dollars into the health care sector, providing incentives for using health information technology and launching initiatives in comparative effectiveness research.

The \$787 billion American Recovery and Reinvestment Act of 2009 (H.R. 1), signed into law by President Obama on Feb. 17, includes about \$17 billion in financial incentives through the Medicare and Medicaid programs to physicians and other health care providers to adopt and use electronic health records (EHRs). Another \$2 billion in funding is designated for the

Office of the National Coordinator for Health Information Technology to encourage health IT adoption, aid in standard setting, and support regional efforts at health information exchange.

Under Medicare, providers could receive incentives for EHR use over 5 years starting at a maximum of \$18,000 in the first year and dropping to a maximum of \$2,000 in year 5.

However, physicians who do not engage in "meaningful" EHR use by 2015 could see cuts to their Medicare payments starting at 1% in 2015 and rising to 3% in 2017 and subsequent years.

Physicians who have a Medicaid patient volume of at least 30% will be eligible to receive incentive payments for EHR

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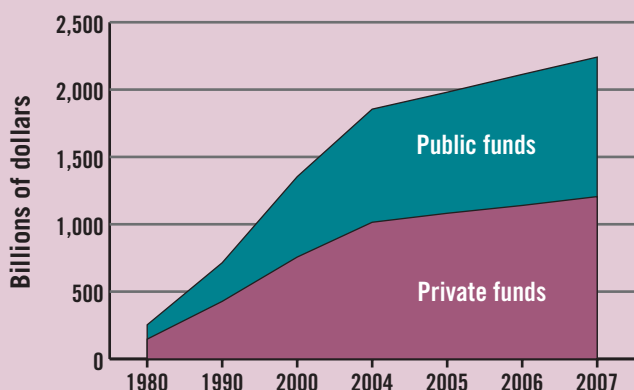
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VITAL SIGNS

Annual National Health Expenditure Has Risen Ninefold Since 1980



Note: Based on data from the Centers for Medicare and Medicaid Services' Office of the Actuary.
Source: Health Affairs 2009;28:246-61

How can you accelerate upper and lower GI recovery?



Important Safety Information

WARNING: FOR SHORT-TERM HOSPITAL USE ONLY

ENTEREG is available only for short-term (15 doses) use in hospitalized patients. Only hospitals that have registered in and met all of the requirements for the ENTEREG Access Support & Education (E.A.S.E.[™]) Program may use ENTEREG.

- ENTEREG is contraindicated in patients who have taken therapeutic doses of opioids for more than 7 consecutive days immediately prior to taking ENTEREG
- There were more reports of myocardial infarctions in patients treated with alvimopan 0.5 mg twice daily compared with placebo-treated patients in a 12-month study of patients treated with opioids for chronic pain. In this study, the majority of myocardial infarctions occurred between 1 and 4 months after initiation of treatment. This imbalance has not been observed in other studies of alvimopan, including studies of patients undergoing bowel resection surgery who received alvimopan 12 mg twice daily for up to 7 days. A causal relationship with alvimopan has not been established

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(alvimopan)

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- ENTEREG is not recommended for use in patients with severe hepatic impairment, end-stage renal disease, or in patients undergoing surgery for correction of complete bowel obstruction
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 - Hospital staff who prescribe, dispense, or administer ENTEREG have been provided the educational materials on the need to limit use of ENTEREG to short-term, inpatient use
 - Patients will not receive more than 15 doses of ENTEREG
 - ENTEREG will not be dispensed to patients after they have been discharged from the hospital

For more information on the E.A.S.E. Program, contact Adolor Corporation at 1-866-4ADOLOR (1-866-423-6567) or visit www.entereg.com.

Please see Brief Summary of Prescribing Information on next page.

Survey Flags Travel Hazards

Procurement • from page 1

el, according to Dr. Englesbe, who is the lead author of two unpublished papers on the topic. The survey confirmed the impression of the generally unsafe conditions inherent in organ procurement: bad weather, night travel, and the sense of urgency.

"There was a general belief that we are doing this under circumstances that no one else would accept. The thinking is, when there's an organ available, you

go. You never refuse," Dr. Englesbe said.

"Most of the respondents (87%) said they simply do not feel very safe, especially when flying. And there was a broad consensus that there must be a better way to do it."

The lack of national data hampers efforts to solve the problem, however. "We've been trying to figure out how many organ procurement flights happen yearly in the U.S., and no one even

knows this. It's a totally unregulated system," Dr. Englesbe said.

Typically, a hospital lacking its own aircraft uses air charter services. "These are usually small planes or helicopters, and they're not always maintained at the level of a commercial airline," he explained.

Nor are they always captained by accomplished pilots, according to a search of the National Transportation Safety Board (NTSB) database. For instance, in 1992, a heart transplant surgeon who flew from Albuquerque to Las Cruces at night to retrieve a heart crashed; he and a physician assistant were both killed.

The surgeon had been working for 22 hours without a break before he took off, and he was not rated for night flight.

Dr. Englesbe contends that alternatives to risky travel would be to have the "home" team retrieve the organ and ship it to the recipient site, or to ship the patient. Once a donor is declared brain-dead, he or she can be transported to either the recipient's hospital or a central location where organs can be removed and shipped.

Mid-American Transplant Services (MTS), an organ procurement agency that serves parts of Missouri, Arkansas, and Illinois, is exploring both alternatives. In 2001, MTS built an operating suite for tissue recovery at its St. Louis headquarters. Since then, 90% of the agency's 1,000 annual tissue recoveries have been performed there, according to Dean F. Kappel, the agency's president and chief executive officer.

The suite cost \$250,000 to create, but the investment was recovered within about 15 months, Mr. Kappel said. Most of the savings resulted from eliminating operating room (OR) time in the donor hospital.

While the suite accommodated most of the tissue recoveries, some organ recoveries still had to be performed in the donor hospitals. "At that time, it wasn't uncommon for us to be in the hospital for 18-24 hours for a single donor, from the time of referral to the end of our OR time. We often ended up bumping private cases."

Adding a second OR at MTS headquarters has provided a cardiac catheterization lab, so that surgeons can check the vessels on any hearts they recover.

Donors arrive either by ambulance from nearby hospitals or by air. Organs not used locally are routinely shipped to the recipient site, unless they are hearts. "Surgeons who transplant hearts still want to be the ones to take them and make sure they're OK" before giving the final go-ahead for the transplant, Mr. Kappel said.

On-site recovery has slashed in-hospital time from 24 hours or more to about 8 hours, and overall costs from an average of \$30,000 for processing in the hospital to about \$15,000 for processing done at the agency, he said.

The change has been overwhelmingly popular among surgeons and families alike. "We don't have to worry about our hospital OR time getting bumped for big emergency cases, so we don't keep the families waiting. They know when their loved one is going into surgery, and they know when that person will be coming to the funeral home," Mr. Kappel said.

Dr. Englesbe has secured a \$50,000 grant for a 1-day seminar to be held in spring 2009 with surgeons, reimbursement experts, and air medical transport representatives. "We hope to produce a white paper that may help guide national policy on the issue," he said.

He believes that the potential cost savings of the alternative approaches might attract national attention. "If Medicare got wind of the possibility of saving a billion dollars, that could end up being pretty powerful." ■

BRIEF SUMMARY

ENTEREG® (alvimopan) Capsules

The following is a brief summary only; see full prescribing information for complete product information.

WARNING: FOR SHORT-TERM HOSPITAL USE ONLY

ENTEREG is available only for short-term (15 doses) use in hospitalized patients. Only hospitals that have registered in and met all of the requirements for the ENTEREG Access Support and Education (E.A.S.E.) program may use ENTEREG. [See Warnings and Precautions (5.1 and 5.2)]

4 CONTRAINDICATIONS

ENTEREG is contraindicated in patients who have taken therapeutic doses of opioids for more than 7 consecutive days immediately prior to taking ENTEREG.

5 WARNINGS AND PRECAUTIONS

5.1 Myocardial Infarction in a 12-Month Study in Patients treated with Opioids for Chronic Pain

There were more reports of myocardial infarctions in patients treated with alvimopan 0.5 mg twice daily compared with placebo-treated patients in a 12-month study of patients treated with opioids for chronic pain. In this study, the majority of myocardial infarctions occurred between 1 and 4 months after initiation of treatment. This imbalance has not been observed in other studies of alvimopan, including studies in patients undergoing bowel resection surgery who received alvimopan 12 mg twice daily for up to 7 days. A causal relationship with alvimopan has not been established.

5.2 Distribution Program for ENTEREG

ENTEREG is available only to hospitals that enroll in the E.A.S.E. program. To enroll in the E.A.S.E. program, the hospital must acknowledge that: hospital staff who prescribe, dispense, or administer ENTEREG have been provided the educational materials on the need to limit use of ENTEREG to short-term, inpatient use; patients will not receive more than 15 doses of alvimopan; and ENTEREG will not be dispensed to patients after they have been discharged from the hospital. Contact the E.A.S.E. program at 1-866-4ADOLOR (1-866-423-6567).

5.3 Opioid Tolerance and Gastrointestinal-Related Adverse Effects

Patients exposed to opioids are expected to be more sensitive to the effects of μ -opioid receptor antagonists. Since ENTEREG acts peripherally, clinical signs and symptoms of increased sensitivity would likely be limited to the gastrointestinal tract (e.g., abdominal pain, nausea and vomiting, diarrhea). Patients receiving more than 3 doses of an opioid within the week prior to surgery were not studied in the postoperative ileus clinical trials; therefore, ENTEREG 12 mg capsules should be administered with caution to these patients.

5.4 Severe Hepatic Impairment

In patients with severe hepatic impairment, there is a potential for 10-fold higher plasma levels of drug [see Clinical Pharmacology (12.3) of full prescribing information]. There are no studies of ENTEREG in patients with severe hepatic impairment undergoing bowel resection. Because of the limited data available, ENTEREG is not recommended for use in patients with severe hepatic impairment.

5.5 End-Stage Renal Disease

No studies have been conducted with end-stage renal disease. ENTEREG is not recommended for use in these patients.

5.6 Bowel Obstruction

Use of ENTEREG in patients undergoing surgery for correction of complete bowel obstruction is not recommended.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice. The adverse event information from clinical trials does, however, provide a basis for identifying the adverse events that appear to be related to drug use and for approximating rates.

The data described below reflect exposure to ENTEREG in 1,650 patients in 9 placebo-controlled studies worldwide. The population was 19 to 97 years old, 68% were female, and 83% were Caucasian; 61% were undergoing bowel resection surgery. The first dose of ENTEREG was administered 30 minutes to 5 hours before the scheduled start of surgery and then twice daily until hospital discharge (or for a maximum of 7 days of postoperative treatment).

Table 1 presents treatment-emergent adverse reactions reported in $\geq 3\%$ of patients treated with ENTEREG and for which the rate for ENTEREG was $\geq 1\%$ than placebo. Treatment-emergent adverse reactions are those events occurring after the first dose of study medication treatment and within 7 days of the last dose of study medication or those events present at baseline that increased in severity after the start of study medication treatment.

Table 1. Treatment-Emergent Adverse Reactions That Were Reported in $\geq 3\%$ of Either Bowel Resection Patients Treated With ENTEREG or All Surgical Patients Treated With ENTEREG and for Which the Rate for ENTEREG Was $\geq 1\%$ Than Placebo

System Organ Class	Bowel Resection Patients		All Surgical Patients	
	Placebo (n = 986) %	ENTEREG (n = 999) %	Placebo (n = 1,365) %	ENTEREG (n = 1,650) %
Blood and lymphatic system disorders				
Anemia	4.2	5.2	5.4	5.4
Gastrointestinal disorders				
Constipation	3.9	4.0	7.6	9.7
Dyspepsia	4.6	7.0	4.8	5.9
Flatulence	4.5	3.1	7.7	8.7
Metabolism and nutrition disorders				
Hypokalemia	8.5	9.5	7.5	6.9
Musculoskeletal and connective tissue disorders				
Back pain	1.7	3.3	2.6	3.4
Renal and urinary disorders				
Urinary retention	2.1	3.2	2.3	3.5

7 DRUG INTERACTIONS

7.1 Potential for Drugs to Affect Alvimopan Pharmacokinetics

Based on *in vitro* data, alvimopan is not a substrate of CYP enzymes. Therefore, concomitant administration of ENTEREG with inducers or inhibitors of CYP enzymes is unlikely to alter the metabolism of alvimopan. No clinical studies have been performed to assess the effect of concomitant administration of inducers or inhibitors of cytochrome P450 enzymes on alvimopan pharmacokinetics.

In vitro studies suggest that alvimopan and its 'metabolite' are substrates for p-glycoprotein. A population PK analysis did not reveal any evidence that alvimopan or 'metabolite' pharmacokinetics were influenced by concomitant medications that are mild-to-moderate p-glycoprotein inhibitors. No clinical studies of concomitant administration of alvimopan and strong inhibitors of p-glycoprotein (e.g., verapamil, cyclosporine, amiodarone, itraconazole, quinidine, spirinolactone, quinidine, diltiazem, bepridil) have been conducted.

A population PK analysis suggests that the pharmacokinetics of alvimopan were not affected by concomitant administration of acid blockers or antibiotics. However, plasma concentrations of the 'metabolite' were lower in patients receiving acid blockers or preoperative oral antibiotics (49% and 81%, respectively). Because the 'metabolite' is not required for efficacy, no dosage adjustments are necessary in these patients.

7.2 Potential for Alvimopan to Affect the Pharmacokinetics of Other Drugs

Alvimopan and its 'metabolite' are not inhibitors of CYP 1A2, 2C9, 2C19, 3A4, 2D6, and 2E1 *in vitro* at concentrations far in excess of those observed clinically. Alvimopan and its 'metabolite' are not inducers of CYP 1A2, 2B6, 2C9, 2C19 and 3A4. *In vitro* studies also suggest that alvimopan and its 'metabolite' are not inhibitors of p-glycoprotein. These *in vitro* findings suggest that ENTEREG is unlikely to alter the pharmacokinetics of coadministered drugs through inhibition or induction of CYP enzymes or inhibition of p-glycoprotein.

Coadministration of alvimopan does not appear to alter the pharmacokinetics of morphine and its metabolite, morphine-6-glucuronide, to a clinically significant degree when morphine is administered intravenously. Dosage adjustment for intravenously administered morphine is not necessary when it is coadministered with alvimopan.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Teratogenic Effects: Pregnancy Category B: Reproduction studies have been performed in pregnant rats at about 68 to 136 times the recommended human oral dose based on the body surface area and intravenous doses of about 3.4 to 6.8 times the recommended human oral dose based on the body surface area and in pregnant rabbits at intravenous doses at about 5 to 10 times the recommended human oral dose based on the body surface area and have revealed no evidence of impaired fertility or harm to the fetus due to alvimopan. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

8.2 Nursing Mothers

Alvimopan and its 'metabolite' are detected in the milk of lactating rats. It is not known whether alvimopan is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when ENTEREG is administered to a nursing woman.

8.3 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

8.4 Geriatric Use

Of the total number of patients in 5 clinical efficacy studies treated with ENTEREG or placebo, 45% were 65 years of age and over, while 18% were 75 years of age and over. No overall differences in safety or effectiveness were observed between these patients and younger patients, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out. No dosage adjustment based on increased age is required [see Clinical Pharmacology (12.3) of full prescribing information].

8.5 Hepatic Impairment

Although there is a potential for higher plasma levels of drug in patients with mild-to-moderate hepatic impairment [see Clinical Pharmacology (12.3)], dosage adjustment in these patients is not required. Patients with mild-to-moderate hepatic impairment should be closely monitored for possible adverse effects (e.g., diarrhea, gastrointestinal pain, cramping) that could indicate high drug or 'metabolite' levels, and ENTEREG should be discontinued if adverse events occur. ENTEREG is not recommended for use in patients with severe hepatic impairment. [See Warnings and Precautions (5.4) and Dosage and Administration (2.2) and Clinical Pharmacology (12.3) of full prescribing information].

8.6 Renal Impairment

Alvimopan has not been studied in patients with end-stage renal disease and ENTEREG is not recommended for use in these patients. Patients with mild-to-severe renal impairment do not require dosage adjustment, but they should be monitored for adverse effects. [See Dosage and Administration (2.2) and Clinical Pharmacology (12.3) of full prescribing information]. Patients with severe impairment should be closely monitored for possible adverse effects (e.g., diarrhea, gastrointestinal pain, cramping) that could indicate high drug or 'metabolite' levels, and ENTEREG should be discontinued if adverse events occur.

9 DRUG ABUSE AND DEPENDENCE

ENTEREG has no known potential for abuse or dependence.

10 OVERDOSAGE

There is no specific antidote for overdose with ENTEREG. Patients should be managed with appropriate supportive therapy. Single doses up to 120 mg and multiple doses up to 48 mg for 7 days have been administered to normal, healthy subjects in clinical studies and were well tolerated.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Two year carcinogenicity studies have been conducted with alvimopan in CD-1 mice at oral doses up to 4000 mg/kg/day and in Sprague Dawley rats at oral doses up to 500 mg/kg/day. Oral administration of alvimopan for 104 weeks produced significant increases in the incidences of fibroma, fibrosarcoma and sarcoma in the skin/subcutis, and osteosarcoma/osteosarcoma in bones of female mice at 4000 mg/kg/day (about 674 times the recommended human dose based on body surface area). In rats, oral administration of alvimopan for 104 weeks did not produce any tumor up to 500 mg/kg/day (about 166 times the recommended human dose based on body surface area).

Alvimopan was not genotoxic in the Ames test, the mouse lymphoma cell (L5178Y/TK⁺) forward mutation test, the Chinese Hamster Ovary (CHO) cell chromosome aberration test or the mouse micronucleus test. The pharmacologically active 'metabolite' ADL 08-0011 was negative in the Ames test, chromosome aberration test in CHO cells and mouse micronucleus test.

Alvimopan at intravenous doses up to 10 mg/kg/day (about 3.4 to 6.8 times the recommended human oral dose based on the body surface area) was found to have no adverse effect on fertility and reproductive performance of male and female rats.

13.2 Animal Toxicology and/or Pharmacology

A single oral dose of 500 mg/kg of alvimopan was not lethal to mice and rats. Reproduction studies have been performed in pregnant rats at oral doses up to 200 mg/kg/day (about 68 to 136 times the recommended human oral dose based on the body surface area) and intravenous doses up to 10 mg/kg/day (about 3.4 to 6.8 times the recommended human oral dose based on the body surface area) and in pregnant rabbits at intravenous doses up to 15 mg/kg/day (about 5 to 10 times the recommended human oral dose based on the body surface area) and have revealed no evidence of impaired fertility or harm to the fetus due to alvimopan.

17 PATIENT COUNSELING INFORMATION

17.1 Recent Use of Opioids

Patients should be informed that they must disclose long-term or intermittent opioid pain therapy, including any use of opioids in the week prior to receiving ENTEREG. They should understand that recent use of opioids may make them more susceptible to adverse reactions to ENTEREG, primarily those limited to the gastrointestinal tract (e.g., abdominal pain, nausea and vomiting, diarrhea).

17.2 Hospital Use Only

Patients should be informed that ENTEREG is for hospital use only for no more than 7 days after their bowel resection surgery.

17.3 Most Common Side Effects

Patients should be informed that the most common side effects with ENTEREG in patients undergoing bowel resection are constipation, dyspepsia, and flatulence.

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Body Fat Best Defines Obesity

SSI • from page 1

Ms. Waisbren said at the meeting on perioperative medicine at the University of Miami.

A total of 130 patients (67%) were obese according to the body fat criterion, compared with 74 (38%) using the BMI definition.

Participants were assessed before, during, and 30 days after elective surgery (primarily general, orthopedic, and obstetric procedures) on the basis of medical records, questionnaires, and follow-up telephone interviews. A total of 31% of the patients were taking antihypertensive medication, and 18% were current smokers. Most patients had an American Society of Anesthesiologists (ASA) Score of II, "so they were relatively healthy," Ms. Waisbren said.

Surgical site infections (SSIs) developed in 27 patients (14%). According to the percent body fat cutoffs, infections occurred in 4.7% of nonobese patients and in 18.5% of obese patients. In contrast, when the BMI cutoff was used, 14.2% of the nonobese and 13.5% of obese patients developed SSIs.

As percent body fat increased, there was a statistically significant increase in SSIs. For example, patients with percent body fat greater than 37% were two times more likely to develop an SSI, Ms. Waisbren said. "An association with increased SSI risk was seen with BMI also, but it was not statistically significant."

Although there were no deaths related to these infections, Ms. Waisbren said that patients with an SSI experienced more adverse outcomes, includ-

ing wound dehiscence, seroma, and hematoma, than did those without infections.

A meeting attendee asked if patients were possibly overlabeled as obese because two-thirds met the percent body fat definition.

"There have been very little data to define the cutoff point," Ms. Waisbren said. "But you raise the point of how appropriate the American Council on Exercise definition is."

When a meeting attendee asked why the hip-to-waist ratio was not assessed, Ms. Waisbren said the investigators believed BMI was more accurate than hip-to-waist ratio. However, she said, "BMI misses an important difference in body composition." For example, a male body builder and an overweight woman with the same height and weight would have the same BMI, but very different body fat percentages.

Percent body fat was an independent predictor of SSI, according to a univariate analysis. Pedal edema, recent surgery, higher National Nosocomial Infection Surveillance score, and class 2 (clean-contaminated) or higher wound ratings were other predictors. A multivariate assessment is planned as part of the ongoing study, Ms. Waisbren said.

This study was awarded the best research abstract at the meeting. Data collected for a total of 436 patients in this ongoing study concur with the initial cohort findings, Ms. Waisbren said. She added the plan is to enroll 600 elective surgery patients in the final assessment. ■

Health Research Also Supported

Stimulus • from page 1

adoption and use. Eligible Medicaid providers could receive incentives of up to \$75,000 over 5 years. Under the law, Medicaid providers could receive up to \$25,000 for the purchase and initial implementation of a certified EHR system and up to \$10,000 a year for the maintenance and use of the system.

The funding in the law is likely to fuel significant activity in the health information technology area, said Dr. Don Detmer, president and CEO of the American Medical Informatics Association (AMIA), although the federal government will need to clarify some of the provisions in the law through regulation, particularly how the new privacy protections will be implemented.

Recent surveys show that most physicians would be motivated to adopt EHRs if given this level of incentives, said Douglas Peddicord, Ph.D., president of Washington Health Strategies Group, which represents AMIA in the District of Columbia.

Also under the new law, the Health and Human Services department will provide competitive grants to states to help them develop loan programs. The loans will enable health care providers to purchase, upgrade, or improve the security of EHR systems or to train staff on the technology.

The law also includes \$87 billion to help states pay for their Medicaid programs. With a higher percentage of funds for their Medicaid programs coming from federal dollars, "a state with a budget shortfall won't feel as much pressure to cut Medicaid back," said Kathleen Stoll, deputy executive director of

Families USA, noting that at least 40 states have proposed cuts to their Medicaid programs.

About \$10 billion in funding under the new law has been slated for the National Institutes of Health to use toward research grants, construction, and the purchase of research equipment. A little over \$1 billion has been aimed at comparative effectiveness research, with \$300 million going to the Agency for Healthcare Research and Quality, \$400 million to the NIH, and \$400 million to be used at the HHS secretary's discretion.

The research will be overseen by a new national council that will advise Congress and federal agencies on priorities. Many in the pharmaceutical and medical device industry supported the notion of comparative effectiveness studies, but did not want to see the money used to support coverage decisions. The House and Senate conference report specifically stated that the research could not be used to "mandate coverage, reimbursement, or other policies for any public or private payer."

That brought applause from AdvaMed, the medical device industry trade group. "The purpose of the research is to assist patients and health professionals in making better treatment decisions, not to mandate one-size-fits-all coverage decisions that would deny patients access to safe and effective treatments," Stephen J. Ubl, president and CEO of AdvaMed, said in a statement. ■

Alicia Ault and Joyce Frieden contributed to this story.



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THE 20/20 VISION

BY DENISE NAPOLI
Elsevier Global Medical News

A one-day, hands-on surgery training course focusing on penetrating trauma to the chest and abdomen not only boosts residents' skills but also serves more experienced surgeons who may encounter these types of injuries in-

frequently in their practice, according to Dr. Lenworth Jacobs, creator of the course.

The Acute Trauma Operative Management (ATOM) course, which is certified and operated by the American College of Surgeons, aims to build competence and confidence in surgeons who don't see many of these types of injuries. Students encounter 12 different real-life operating experiences on a 50-kg swine, ranging from a stab wound (created by

the course instructor) to heart surgery. They also attend six 30-minute lectures and complete pre- and postcourse exams online.

"It's a full operative experience. [The animal is] fully anesthetized in an operating room, you're in a full gown, with scrubbing, and with full operating instruments—exactly the same as you would find in a human environment," said Dr. Jacobs, an ACS Fellow, in an interview. "There are auditory cues, the

beepers from the cardiac monitor, the visuals from the EKG.

"You have to be totally prepared or you won't be able to achieve it. But having done appropriate preparation, at the end of the day you are really boned up on your skills," he added.

Although the course was originally designed for fifth- or sometimes fourth-year surgical residents (for whom the modern mandatory 80-hour work week has meant less exposure to these types of injuries), ATOM has been enjoying an "exponential ride" since its inception in 1999. There are now a total of 26 sites in the United States, Canada, Africa, Japan, and the Middle East, and about 1,100 graduates.

In addition, the course is not targeted exclusively at residents. Course participants have also included students "and other surgeons who may be out [of residency] 10 or 15 years, but who are taking call in a hospital. They may have restricted their practice to breasts, or only parathyroid, or something, but they are expected to take care of these [traumatic penetrating] injuries, because that's what going to come in tonight," said Dr. Jacobs, a professor of surgery at the University of Connecticut, Hartford, and director of the trauma program at Hartford Hospital. "That's a huge group of people who require being comfortable" with this type of surgery.

Dr. Brock Bordelon, a surgeon and ACS Fellow in Colorado Springs, said in an interview that although he hasn't taken the course, he sees its utility, and not only for residents.

"It is probably also helpful to the folks who practice emergency general and trauma surgery only, who, as a result, have less operative experience than those who perform a large volume of abdominal surgery in the elective setting." At least one of his colleagues has taken the course, Dr. Bordelon said, and has gone on to become an instructor.

The course, which costs about \$1,750, gives 7.5 AMA PRA Category 1 Credits. Although it is completed in 1 day, Dr. Jacobs said that without extensive preparation, students will be overwhelmed. Preparation takes the form of studying a CD-ROM and other materials provided in advance of the course.

According to Dr. Jacobs, there is another European hands-on surgery course, but ATOM is unique in its rigor and authenticity.

"It's a very tightly evaluated course," he said. "We measure [students'] perception of whether this was helpful. Did it help them increase their confidence in dealing with these injuries? Do they feel they are more competent, and if they [saw] such an injury [in practice], did the course help? And the scores on all of these measures are very high, which really leads us to believe that this is a very successful and helpful educational tool." ■

For more information about the ATOM course, visit www.atomcourse.com.

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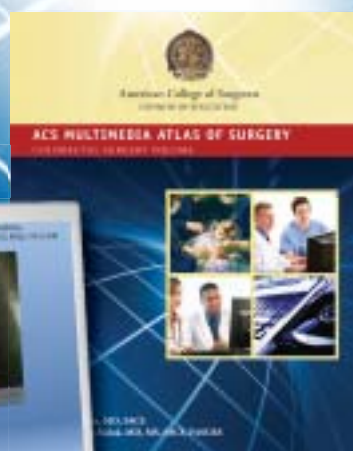
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COMMENTARY

Lower Your Liability Risk



BY RICHARD C. BOOTHMAN

Many physicians fail to understand that their behavior influences the odds of being sued. They frequently blame lawyers and the legal system, but in a study of nearly 1,500 closed cases, lawyers actually got it right about 75% of the time (N. Engl. J. Med. 2006;354:2024-33).

When patients sue, it's most often because the physician failed to provide an explanation or to be accountable, and because they want to ensure that others won't experience the same problem they did (Lancet 1994;343:1609-13).

A strong commitment to patient safety is the best prophylaxis against professional liability claims. But even being error-free may not insulate you from claims when things go wrong. How you communicate with your patients before, at the time of, and after a complication may make all the difference.

Too often, surgeons create unreasonable expectations at the outset of the patient-physician relationship. It is the surprise, not the complication, that creates the impression that mistakes were made.

"I've done more of these procedures than anyone. We'll have you up and running in no time," and similar comments create a sense of false security in patients. Seeing patients as people—not diseases, injuries, or disorders—is crucial. Prepare the patient for the possibility of complications, their impact on daily life, and the demands of rehabilitation. If the patient permits it, include family members in your conversations. The stress of anticipating surgery often causes patients to hear only what they want to hear.

"The percentage chance you'll have a serious problem is low, Mrs. Jones, but if it happens to you, it's 100%. Some of these complications could seriously alter your life. You should carefully consider these risks and options, including the risk of doing nothing. I can't even guarantee I won't make a mistake. All I can promise you is that I'll do my best, and I'll be there when you come out. Do you have any questions?" Messages like this prepare patients much better than meaningless reassurances.

At the University of Michigan Health System, patients in the trauma service are most likely to have a lawyer in their future pursuing automobile negligence claims, workers' compensation, and social security disability claims, among others. Yet, the level 1 trauma service paid on only 16 claims over a 10-year period. Why? Because trauma patients are much better prepared than other patients are for less-than-optimal outcomes.

Once a complication occurs, you must honestly and forthrightly explain to the patient what is known. Avoid speculating about what is not yet known. This strategy makes you credible and offers an opportunity to answer questions and clarify misconceptions. In one study, 24% of

patients sued their doctors because they felt that their doctors were not being honest (JAMA 1992;267:1359-63).

Never make excuses, but be careful not to assume more responsibility than you actually have. Defer to another team member who can explain the complication; don't criticize a physician who is not present or to try to explain something in which you weren't involved.

We all know that five people can experience the same event and have five dramatically different recollections of it. Keep charts up to date, and never alter records later; modifications can be detected. Shorthand is better than nothing—even notes that say things like "all questions answered, risks explained, patient wants to proceed" are powerful evidence for the future.

Finally, beware of distractions. Financial problems, divorces, deadlines, and other concerns can cause you to cut corners, take risks, or push yourself beyond what is prudent. ■

MR. BOOTHMAN is chief risk officer for the University of Michigan Health System.

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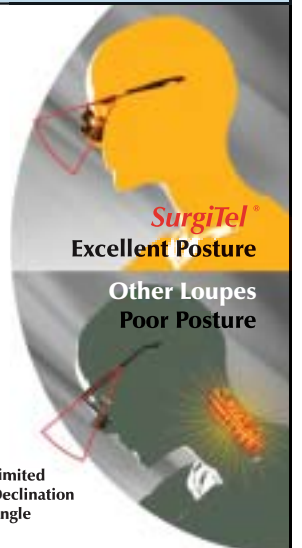
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Raymond L. Singer, MD

Hybrid Aortic Arch Procedures Appear Promising

BY MARK S. LESNEY
Elsevier Global Medical News

SAN FRANCISCO — Disease of the aortic arch can now be treated by combining open surgical procedures with endovascular repair—a hybrid technique that offers a less invasive option for the patient. But the novelty of such techniques raises questions about procedural indications and outcomes.

In an attempt to come up with benchmarks for this evolving approach, Dr. George J. Koullias and Dr. G.H. Wheatley performed a meta-analysis of the published literature to date regarding hybrid repair of aortic arch. They reviewed a total of 718 retrospective studies and case reports of hybrid arch procedures that were listed in PubMed through May 2008.

Excluded from their analysis were reports involving only left common carotid to left subclavian artery bypass; landing of the covered portion of the stent-graft in zones 2-4; and arch



Outcomes of hybrid procedures compare favorably with those of standard operative repair.

DR. KOULLIAS

repairs using extrathoracic approaches, said Dr. Koullias at the annual meeting of the Society of Thoracic Surgeons.

A total of 55 studies, comprising 28 retrospective studies and 27 case reports, was identified. These included 582 patients (412 men and 170 women). Based on sample size criteria, a final total of 15 studies with 463 patients (320 men and 143 women) was included in the meta-analysis. The 40 remaining studies included up to 119 patients (92 men and 27 women) and comprised case reports and small retrospective studies (fewer than 11 patients per study). These were analyzed descriptively, according to Dr. Koullias, who is with a cardiac surgery practice in Peoria, Ill., and Dr. Wheatley, of a cardiac group practice in Phoenix.

Meta-analysis end points were perioperative mortality, 30-day mortality, permanent and temporary stroke rate, permanent and temporary paraplegia rate, and endoleak rate.

On the meta-analysis of the 463 patients undergoing hybrid arch procedures,



The hybrid approach was used to repair an ascending arch and descending aneurysm (L), and a type A aortic dissection.



IMAGES COURTESY DR. GEORGE J. KOULLIAS/DR. G.H. WHEATLEY

the overall perioperative mortality was 6.4% and the 30-day mortality was 8.3%. The overall endoleak rate was 9.2%, the permanent and temporary stroke rate was 4.4%, and the permanent and temporary paraplegia rate was 3.9%, with an average follow-up of about 19 months.

The 463 patients were divided into two groups: one consisting of 324 patients who had their procedure done on cardiopulmonary bypass (CPB), and a second group of 139 patients who had

their procedure off CPB. Secondary meta-analysis between those two patient groups showed no statistically significant differences in any of the end points.

These operative results for the hybrid procedures compare favorably with standard operative repair, according to the investigators. However, they indicated that there was a need for long-term follow-up and additional study.

The investigators had nothing to disclose with regard to this study. ■

Routine Mediastinoscopy For Early NSCLC Questioned

BY SHERRY BOSCHERT
Elsevier Global Medical News

SAN FRANCISCO — Only 4% of 968 patients with early-stage non-small cell lung cancer had occult lymph node metastases, and invasive mediastinoscopy was unlikely to detect the metastases, a retrospective study found.

The results challenge the utility of routine mediastinoscopy in patients with clinical stage T1 non-small cell lung cancer (NSCLC), Dr. Sebastian DeFranchi and his associates reported in a prize-winning poster at the annual meeting of the Society of Thoracic Surgeons.

Postoperative pathology reports showed positive mediastinal lymph nodes (N2 disease) in 59 (6%) of the 968 consecutive patients who underwent lung resection for T1 lesions in 1998-2005. The patients' records showed that noninvasive staging using CT or PET scans identified 23 patients with positive nodes, leaving 36 patients (4% of all patients) with occult disease in lymph nodes.

Mediastinoscopy performed in 16 patients with negative results on noninvasive imaging found lymph node metastases in 3 patients (19% of those who underwent mediastinoscopy), said Dr. DeFranchi of the Mayo Clinic, Rochester, Minn.

Among 66 lymph node stations with metastases identified on pathology, 24 (36%) were in locations not accessible by routine mediastinoscopy.

The rates of occult N2 disease in various stages of NSCLC have been unknown,

and the optimal strategy for mediastinal staging is unclear. "Routine mediastinoscopy in clinical T1N0 NSCLC results in a low yield of occult N2 disease in patients with negative noninvasive staging," Dr. DeFranchi concluded.

Of the 23 patients with positive nodes on noninvasive imaging, CT scans showed adenopathy in 17 patients, and PET scans identified positive lymph nodes in 9 patients. Overall, 17 patients had CT scans, and 29 patients had PET scans.

Among 66 diseased lymph node stations found on pathology in 59 patients, the most frequent site of metastases was station 7, in 22 (37%) of the 59 patients. Stations 5 or 6 each were positive in 18 patients (31%), and station 4R was positive in 15 patients (25%). Right-sided tumors were seen in 29 lymph node stations in 25 patients, and left-sided tumors were found in 38 lymph node stations in 25 patients.

Survival rates in patients with stage T1 NSCLC and positive lymph nodes undetected by noninvasive techniques were 87% at 1 year, 71% at 2 years, 56% at 3 years, 46% at 4 years, and 41% at 5 years. That's better than mean survival rates for patients with stage IIIA NSCLC, Dr. DeFranchi noted.

Patients in the study had a mean age of 69 years, and 83% had a history of smoking. The 59 patients with T1N0 disease had adenocarcinoma in 46 cases (78%), squamous cell carcinoma in 8 (14%), large cell carcinoma in 2 (3%), and mucinous adenocarcinoma in 1 (2%).

The investigators had no potential conflicts of interest related to this study. ■

Specialty Training Tied to Lung Cancer Outcomes

BY MARK S. LESNEY
Elsevier Global Medical News

SAN FRANCISCO — Patients with operable lung cancer appear to experience better long-term outcomes when treated by a specialist in general thoracic surgery, according to large database study.

This study is the first description of an association between surgeon specialty and long-term survival in operable lung cancer, according to Dr. Feroz Farjah, who presented his study as the J. Maxwell Chamberlain Memorial Paper for General Thoracic Surgery at the annual meeting of the Society of Thoracic Surgeons.

"There have long been studies [that] show that specialists have better outcomes than generalists," said Dr. Douglas Wood, an ACS Fellow and one of the paper's coauthors, in an interview. "But this is the first study of outcomes that shows a significant impact on lung cancer survival."

A cohort study of 19,754 patients from 1992 to 2002, with a follow-up through 2005 was conducted using the National Cancer Institute's Surveillance, Epidemiology, and End Results data, which were linked to the American Board of Thoracic Surgery Diplomates List. Board-certified thoracic surgeons were designated as cardiothoracic surgeons (CTS) if they performed cardiac procedures and as general thoracic surgeons (GTS) if

they did not, according to the researchers and from the University of Washington, Seattle.

Results showed that surgeons not board certified in thoracic surgery (NBTS) cared for 4,677 (24%) of the patients, and a total of 8,807 (45%) patients were cared for by CTS, and 6,261 (32%) were cared for by GTS. Of the 1,848 surgeons who cared for the cohort, 770 (42%) were NBTS, 687 (37%) were CTS, and 391 (21%) were GTS. Patient age, comorbidity index, and resection type did not significantly vary by surgeon specialty.

After adjustment for patient, disease, and management characteristics, hospital teaching status, and surgeon and hospital volume, patients who were treated by GTS had an 11% lower hazard ratio of death, compared with those who underwent resection by NBTS, for an HR of 0.89 (with a 99% confidence interval of 0.82-0.97). However, the risk of death did not vary significantly between CTS and NBTS or between CTS and GTS.

"Lung cancer patients treated by general thoracic surgeons had better long-term outcomes than [did] those treated by surgeons without board certification in thoracic surgery," according to Dr. Farjah. These findings have important implications for regionalization of care and pay for performance in lung cancer care, he said.

The investigators reported no conflicts with regard to this study. ■

New Plan Aims to Widen Health Coverage, Cut Costs

BY MARY ELLEN SCHNEIDER
Elsevier Global Medical News

A national health insurance exchange that would allow individuals to choose among private plans or a new nationwide public plan is the cornerstone of an expert panel's proposal to cover nearly all Americans within 2 years and slow the growth of health care spending by nearly \$3 trillion over the next decade.

The health reform proposal, unveiled by the Commonwealth Fund on Feb. 19, is similar to plans outlined by President Barack Obama and Senate Finance Chairman Max Baucus (D-Mont.). It was developed by the Commonwealth Fund's Commission on a High Performance Health System, a 19-member panel formed in April 2005 to study possible changes to the delivery and financing of health care.

The difference between the Commonwealth Fund's plan and other policy proposals is that it provides details on implementation of these broad policies, as well as their financial and clinical consequences, said Karen Davis, president of the Commonwealth Fund. Modeling and estimates outlined in the report were performed by the Lewin Group.

Under the proposal, individuals could choose to keep their own coverage or obtain new coverage through the insurance exchange. The public plan would initially be available to those seeking insurance on the individual market and those working for small employers, but by 2014 it would be available to the entire under-65 population, including individuals working for large employers. The public plan would offer benefits similar to the standard option available to federal employees and members of Congress, but at premiums at least 20% lower than those of private plans offered in small group markets.

Private plans would be required to guarantee the issue and renewal of policies regardless of health status, and to provide community-rate premiums. But they would be able to stay competitive with the public plan, according to Cathy Schoen, lead author of the report and senior vice president of the Commonwealth Fund, because they would be able to reduce costs such as underwriting and marketing.

"The report's central message is that we all stand to gain by taking bold action," Ms. Schoen said at a press briefing to release the report.

The Commonwealth Fund proposal would impose an individual insurance mandate, but would cap premiums at 5% of income for low-income individuals and 10% for those in higher income tax brackets. It would also require employers to either offer coverage or contribute about 7% of payroll into a coverage trust fund.

The Commonwealth Fund proposal endorses moving away from the current fee-for-service system and replacing it with reforms such as bundling payments for acute care episodes, increasing pay-

ment for primary care while decreasing payment for specialty and procedural care, and providing additional payments for practices that provide a patient-centered medical home.

Under the proposal, all payment reforms would apply to Medicare, Medicaid, and the new public health plan. The proposal would also raise Medicaid rates to Medicare levels and invest in health information technology, population health, and comparative effectiveness research.

The proposal would not lower current costs but could slow the rate of health care spending, according to the Commonwealth Fund. Instead of health care spending rising 6.7% each year over the next 11 years, as predicted by current trends, the increase in spending would slow to about 5.5% per year if the reforms were implemented in 2010. The combination of the proposed insurance and payment system reforms could slow spending by nearly \$3 trillion by 2020.

Costs incurred by the federal government would climb sharply during the first years of implementing these changes, but could be largely recouped by 2020, according to the report.

Under the proposal, the number of uninsured Americans would drop from about 48 million this year to about 4 million by 2012. Without reforms, the uninsured would increase to about 61 million by 2020, according to the Commonwealth Fund. ■

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New Tool Tested as Predictor of AAA Rupture Risk

BY MITCHEL L. ZOLER
Elsevier Global Medical News

HOLLYWOOD, FLA. — A more quantifiable and precise strategy for gauging the risk that an abdominal aortic aneurysm will rupture is on the verge of becoming a clinically useful tool.

Dr. Mark F. Fillinger and his associates at Dartmouth-Hitchcock Medical Center in Lebanon, N.H., have been developing a method for measuring the vascular

wall stress within abdominal aortic aneurysms (AAA) for more than 10 years.

They take structural data collected by either CT or MRI to produce a three-dimensional image of a patient's abdominal aorta and the aneurysm within it, and then factor in the patient's peripheral blood pressure. Using both commercial software and a special program developed by Dr. Fillinger and his group, they take this information and create a mod-

el showing the wall stress exerted on each square millimeter of vessel wall.

AAA diameter "works pretty well" for identifying patients who have a high risk for aneurysm rupture "but it fails in some patients. What we're trying to do is make a better differentiation" between the AAAs that will rupture and those that won't, Dr. Fillinger said at ISET 2009, an international symposium on endovascular therapy.

Because most physicians cannot read-

ily interpret the significance of wall-stress force as a raw number (in units of newtons/cm²), a recent innovation of Dr. Fillinger's has been to translate the force into a functional diameter for each AAA.

Conversion of the wall stress into a functional AAA diameter "allows us to say that the wall stress is higher or lower than is typical for a particular diameter. ... All clinicians know the significance when you say an aneurysm has a wall stress that's typical for a 5.5-cm diameter AAA," said Dr. Fillinger, an ACS Fellow, during an interview.

Translating the results this way into a more easily interpretable result also "takes out the need for an expert reviewer" and may allow the measure to be more widely used, explained Dr. Fill-

inger, a professor of surgery at Dartmouth and program director in vascular surgery.

The wall stress of "most AAAs [is] in the typical range" for the actual diameter of the aneurysms. But in about 10%-20% of patients, the wall stress defines an AAA that is functionally much wider, and much more likely

The wall stress defines an AAA that is much more likely to rupture than the actual diameter suggests.
DR. FILLINGER

to rupture than the actual diameter suggests. These outlier AAAs have functional diameters of 5.5 cm or greater, making them prime candidates for repair, even though their actual diameters are less than 5.5 cm, which would otherwise make them questionable repair candidates.

Dr. Fillinger found the reverse situation as well. About 10%-20% of patients with AAAs that have actual diameters of 5.5 cm or greater have wall stress readings that make their functional diameter less than 5.5 cm, thereby making these aneurysms poor candidates for repair. This is especially true for patients who are old or frail, and have a relatively short life expectancy.

The Dartmouth group has produced wall stress analyses for more than 300 AAAs. He anticipates evaluating the rupture predictions that his team has made for these AAAs later this year to conclusively decide if the analysis has become reliable enough for routine use. If so, they will submit their findings to the Food and Drug Administration, Dr. Fillinger said. A very similar method has been validated in a separate group of patients by researchers at Hull Royal Infirmary, England.

The software that Dr. Fillinger uses to make a three-dimensional model of the patient's abdominal aorta and the program used to calculate AAA wall stress are both commercially available.

Software that eliminates artifacts has also been developed, but it has yet to be commercialized. ■

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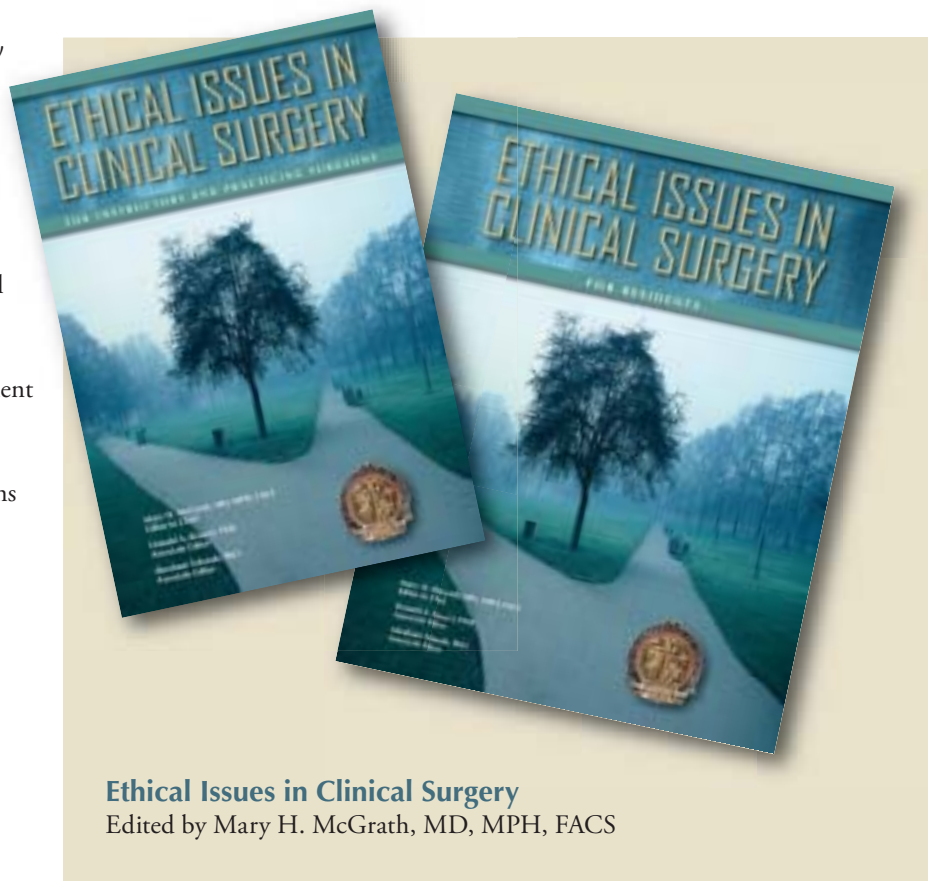
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VTE Drug Prophylaxis for Gastric Bypass Challenged

BY DAMIAN McNAMARA
Elsevier Global Medical News

PALM BEACH, FLA. — Pharmacologic prophylaxis against venous thromboembolism is not mandatory for average-risk patients undergoing laparoscopic Roux-en-Y gastric bypass, according to data on more than 900 procedures.

“Pneumatic compression devices, early ambulation, and a relatively short operative time are effective prophylaxes against VTE,” Dr. Ronald H. Clements said.

As a follow-up to their earlier report of one deep vein thrombosis (DVT) among 380 patients (*Surg. Endosc.* 2004;18:1082-4), Dr. Clements and his associates continued to collect data on 957 consecutive laparoscopic Roux-en-Y gastric bypasses performed at the University of Alabama at Birmingham since 2000. Dr. Clements, an ACS Fellow and laparoscopic surgeon, presented the findings at the annual meeting of the Southern Surgical Association.

The study cohort was 83% women and 80% white. Mean age was 41 years, mean body mass index was 49 kg/m², and mean operative time was 106 minutes, according to Dr. Clements, who performed all of the procedures.

Calf-length pneumatic compression devices were placed on all patients before anesthesia. Early ambulation was compulsory: Patients were expected to walk on the evening of the day of surgery, Dr. Clements said.

The researchers followed all but one patient for 30 days. Among the 956 patients, there were three DVTs, one non-fatal pulmonary thromboembolism, and seven instances of major bleeding. Two patients with bleeding required reoperation, four had transfusions, and one required no intervention. One patient died of causes unrelated to DVT.

Venous thromboembolism (VTE) is a leading cause of postoperative mortality following bariatric surgery, but it is relatively uncommon. Rates are 3-7 in every 1,000 patients, said study discussant Dr. Hiram C. Polk Jr. He cited an unpublished study of 966,000 patients in his hospital consortium database. Elastic stockings were the most common intervention in his study. “The dangers of prophylaxis outweigh the risks of what you are trying to prevent,” said Dr. Polk, an ACS Fellow and professor of surgery at the University of Louisville (Ky.).

The study “is important for the bariatric surgeon who chooses to use compression and early ambulation alone. You don’t have to always use heparin,” said Dr. Bruce D. Schirmer, an ACS Fellow and general surgeon at the University of Virginia, Charlottesville, who was another study discussant. Chemoprophylaxis is still warranted for high-risk patients, he added.

But Dr. Spence M. Taylor, an ACS Fellow who is chair and clinical professor of surgery at the University of South Carolina, Greenville, took a different view. “I’m aware of at least six consensus statements for prophylaxis for DVT, and without fail, they all say chemoprophylaxis is the treatment of choice.”

Dr. Clements replied, “I don’t think these obese patients fall into all those guidelines. I don’t think most of you would use prophylaxis for the morbidly obese [patient undergoing] removal of a gallbladder, so I don’t think you should do it for bypass, either.”

The consensus statements overlook or include only level II evidence for gastric bypass, he said, reiterating that his findings do not apply to the highest-risk patients. “I’m talking about the average

person who comes to me for gastric bypass who is not at high risk” for VTE.

Citing the low incidence (0.1%-0.8%) of pulmonary embolism in this study, Dr. Taylor said, “It’s conceivable you don’t have enough patients yet.” Dr. Clements responded, “It’s a low incidence, and that is the point of the paper. We are not saying compression devices are superior; simply that they are equivalent.”

Good follow-up and applicability of the findings to most patients undergoing

gastric bypass are strengths of the study, Dr. Clements said. Limitations include the retrospective design and detection of VTE as clinically evident disease only.

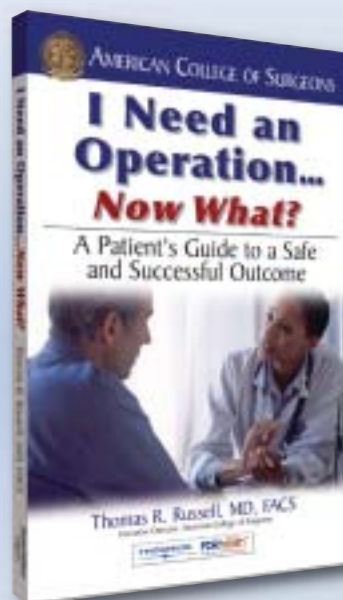
“The biggest problem with your manuscript is physical examination for DVT,” Dr. Taylor said. “Don’t some patients get swollen legs after surgery [even without VTE]? Don’t some get shortness of breath?” Still, “from an objective standpoint, 106 minutes for bariatric procedures is an accomplishment.” ■

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Statement Issued on Emergency Surgical Call

This statement was developed by the Board of Governors' Committee on Socioeconomic Issues in collaboration with the Board of Governors' Committee on Surgical Practice in Hospitals and Ambulatory Settings. The statement was approved by the Board of Governors and the Board of Regents in October 2008.

Issue

Compassion and our professional ethics mandate that all patients faced with a surgical emergency are provided care. The American College of Surgeons fully supports access for all Americans to emergency care, but major issues of surgical manpower and resource utilization represent a threat to continued access. The American College of Surgeons presents the following analyses and recommendations.

Historical Perspective

Emergency surgical call serves to meet patient needs. The Emergency Medical Treatment and Active Labor Act regulations support this patient care by Medicare-participating hospitals and provide a funding stream to the hospitals by means of the Medicare system. By means of cost shifting and sharing the burden with other surgeons, surgi-

cal practices generally have been able to provide such service.

Current Environment

Our population has aged steadily. The more elderly the population, the more health care required, both emergent and nonemergent. In addition, an ever-increasing population of indigent patients uses the emergency room as the sole avenue to medical care. At the same time, the number of surgeons produced by our graduate medical education programs has remained stable for nearly 30 years. (Statement on the surgical workforce [ST-57]. Bull. Am. Coll. Surg. 2007;92(8):34-35.) In general surgery, the ratio of surgeon to population has been steadily declining since 1985. Other specialties with even fewer providers feel they can no longer meet the community demands for their services. (Statement on the surgical workforce [ST-57]. Bull. Am. Coll. Surg. 2007;92(8):34-35.) As a result, there exists an increasing chasm between expectations for access to emergency surgical care and the surgeon workforce available to provide such care.

The College recognizes the need for emergency surgical care. (Statement on emergency surgical care [ST-56].

Bull. Am. Coll. Surg. 2007;92(5):27.)

The hospital, mandated by the government, has entered into a contract with the community to provide care without involving the actual care provider in the negotiations. The surgeon feels deeply obligated to care for all individuals who require care. However, the surgeon attempting to provide this care is forced to be practical in the face of increasing demands.

To provide this care, the surgical practice must remain fiscally viable, professionally attractive, and competitive in retaining and hiring colleague surgeons for the community. The challenges to this effort are many and varied. Emergency surgical care detracts from this ability to recruit in many communities because emergency call involves greater risks than care provided during elective, scheduled operations. Operations often must be accomplished under conditions that do not allow for standard preoperative preparations. These patients often have the highest risk for complications due to advanced disease states and associated risk factors.

Patient expectations frequently reflect what can be expected with proper preoperative preparation and planning

even when this is not the case. Such unrealistic expectations can lead to an increased malpractice risk. Being available for emergency call may appear innocuous, yet excessively frequent on-call duty has a negative impact on the surgeon's time with family and the ability to provide community service outside of the profession.

Unfortunately, this surgical service is increasingly mandated without appropriate compensation. The obligation to provide care must be balanced by the means to do so; cost shifting to the surgeon is an unacceptable option.

Recommendations

The College recommends that health care payors and institutions commit necessary and appropriate support to surgeons for emergency coverage of surgical care. (Statement on emergency surgical care [ST-56]. Bull. Am. Coll. Surg. 2007;92(5):27.)

Whatever the model chosen to provide this patient service, it must account for the disruption involved with being on call when actual service may or may not be required. Compensation for the service provided must be based on fair value for the risks involved and time allocated. ■

Portal Is Rich Resource For Rural Surgeons

Are you a rural surgeon looking for an easier way to stay current on topics of interest? Look no further than the Rural Surgeons Community on e-FACS.org, the College's members-only Web portal, where you will find many useful features and resources. For starters, the "Latest from PubMed" feature provides scrolling links to the most recent journal articles relating to surgery in rural areas. See something you like but don't have time to read it right away? Just click the "Add to Bookmarks" button to save the item to the portal's "My Bookmarks" page for later reading.

As an example of the type of useful information you will find in this community, check out the article, "Trends in Adoption of Laparoscopic Cholecystectomy in Rural Versus Urban Hospitals," by Randall S. Zuckerman, M.D., FACS (Co-Community Editor, Rural Surgeons) and his colleagues.

Herbert Chen, M.D., FACS, an endocrine surgeon, has provided an excellent review of the current state of parathyroid surgery. This article should help in studying for recertification or for exploring the options for patients with parathyroid disease.

The community also includes a link to the rural surgeons discussion forum, where members of the College can share ideas or ask questions.

You can even subscribe to the forum to receive an e-mail when new postings are added. As an extension of this forum, Tyler G. Hughes, M.D., FACS (Co-Community Editor, Rural Surgeons), has created the Rural Surgeons' Network for those who wish to be alerted to postings and events on rural surgery. The alerts are noncommercial, brief, and transmitted only when a new subject of interest is posted.

To access the Rural Surgeons community, visit <http://efacs.org/rural>.

To join the community or to submit material, photos, or ideas, send your preferred e-mail address to Dr. Hughes at tylerh@mcphersonmemorial.org. ■

Interactive Symposium Coaches Surgeons on End-of-Life Issues

Physicians will learn about the cultural, spiritual, and practical aspects of the physician-patient relationship at the end of life during "The Art of Medicine at the End of Life," a continuing medical education (CME) annual symposium to be held May 8, 2009, at The New York Academy of Medicine (NYAM).

Geoffrey Dunn, M.D., FACS, medical director, Palliative Care Consultation Service, Hamot Medical Center, Erie, Pa., and chair of the College's Surgical Palliative Care Task Force, will join Arthur Caplan, Ph.D., a well-known expert on bioethics, and other experts participating in this highly interactive course. The course is sponsored by the Cunniff-Dixon Foundation and the NYAM.

Using short, didactic lectures, discussions, and case presentations, speakers will address the following objectives for the course:

- ▶ Prepare patients and their families for the transition to the end of life.
- ▶ Implement a strategy to provide a more personal and informed level of patient care, thus en-

hancing the quality of life for terminally ill patients.

- ▶ Recognize the appropriate time to suggest palliative care or hospice for terminally ill patients, and facilitate the process.

- ▶ Anticipate common ethical and legal issues that arise in the context of end-of-life medical care.

- ▶ Apply an understanding of the psychiatric aspects of mortality to improve the quality of interactions with terminally ill patients and their families.

- ▶ Recognize and accommodate the needs of patients and families from various cultures and religions coping with the end of life.

- ▶ Understand research and policy trends in palliative care.

The fee for the course is \$225 for physicians and \$125 for resident physicians who register before April 1, 2009. Fees will increase after the registration deadline and again on site. For detailed course information and to register, visit www.nyam.org/events/?id=494. ■

2009 PQRI Program Changes Listed on Web Site

The recently updated Physician Quality Reporting Initiative (PQRI) Web site, www.facs.org/ahp/pqri/, includes information about the 2009 program. Surgeons will find an introduction to PQRI, results and payment information for participants in the 2007 initiative, valuable resources and tools for participating in PQRI, and links to other useful Web sites.

Previous PQRI participants should note that some of the performance measures that have car-

ried over from 2008 may have changed. It is important to look closely at the measure specifications for 2009 even if you are reporting a measure from a previous year. The ACS Web site lists the changes made to the perioperative measures under the 2009 PQRI performance measures section with a link titled "Code Changes to 2008 Perioperative Measures Specifications."

More information may be obtained by contacting cburley@facs.org. ■

RAS Essay Contest Honors Mentors

The following article is the first in a series of brief essays written for an ACS Resident and Associate Society (RAS) essay contest. Residents, fellows, and new faculty have been asked to describe in 500 words or less the role that a mentor has played in their development. The RAS leadership believes that these mentors not only are role models, but also are pillars of strength and good examples for future generations of surgeons who are attaining technical and clinical skills, while also advancing their interest in research, education, and outreach in an increasingly challenging health care environment. The winner of this year's essay contest will be announced at the 2009 Clinical Congress in Chicago.

My Mentor

Faith in the Journey: Julie Freischlag, M.D., FACS
by Jonathan Bath, M.D.

I have recently started as a third-year postgraduate student in general surgery at University of California–Los Angeles. My rotations will be a rigorous but standard mixture of trauma and gastrointestinal, thoracic, and vascular surgery, which is an expected training pathway for a U.S. graduate in surgery. However, I am not a U.S. graduate, and my career pathway has been anything but standard.

I attribute a large part of my surgical career in the U.S. to an extraordinary mentor in Julie Freischlag, M.D., FACS, professor of surgery at Johns Hopkins University, Baltimore. Applying to surgical residency 3 years ago, I had sent my application to many top-ranked programs. By January, I had been invited to interview at only two programs. Departing the interview in Professor Freischlag's office in drizzling January rain, all I felt was hope; her positive and encouraging tones were like a bright torch of light in a damp and emotionally turbulent few months.

I matched as a preliminary surgical resident at Johns Hopkins in the intern class of 2006–2007. Professor Freischlag recognized the sacrifices and emotional and financial hardship I had endured in coming here and had the open-mindedness and strength

of character that it takes to bring one's professional reputation into question for the sake of someone else's aspirations.

Without a social security number, automobile, cellular phone, or apartment, I would steam my shirt in the hotel shower, hail a cab in the morning and evening, and use a pay phone to call internationally to my parents. Through those trying first few months, I called upon my mentor for advice and direction. Professor Freischlag encouraged, sympathized, and ultimately had enough faith in me to smooth the edges of a raw transition into residency in the U.S.

Two years into residency, I was about to enter probably the most important interview of my career: a categorical surgery position at University of California–Los Angeles (UCLA). I was reminded when I met the program director how historically UCLA has not taken an international medical graduate into its categorical program. Two weeks passed with no word. I called my mentor and uttered superlatives regarding the position. The job signified my transition from passive onlooker to part of the process, and Professor Freischlag understood the significance of this in my life.

It was after a call from the program director at UCLA that I realized the full extent of my mentor's dedication to my cause. Sitting near the chairman of surgery at a surgical meeting in California, conversation turned to the opening at UCLA. Professor Freischlag handed a folded napkin across the table. "This is the person you need to take in your program. He is perfect for the job."

As I tried to remain composed when replying to the one position that validated the past 5 years of hard work, the lasting words of the program director at UCLA could not have more greatly underlined the compassion and understanding extended to me by Professor Freischlag. "I look forward to working with you at UCLA. I am expecting great things from a man with such stellar support from his chair." ■

DR. BATH is a third-year postgraduate student in general surgery at University of California–Los Angeles.



JULIE
FREISCHLAG, M.D., FACS

Symposium Helps Perioperative Team Improve Safety

The Council on Surgical & Perioperative Safety (CSPS) and Joint Commission Resources, Inc. will cosponsor the symposium "Improving, Enhancing, and Sustaining Positive Patient Outcomes" May 8-9 at the Sheraton Chicago Hotel and Towers.

Aimed at surgeons, anesthesiologists, nurse anesthetists, perianesthesia and perioperative nurses, surgical physicians' assistants, surgical technologists, pharmacists, and all others who provide care and services in the field of surgery, the conference focuses on teamwork and improved communication—topics that also interest business leaders and risk management professionals. Participants will leave the conference with the ability to:

- ▶ Describe the current state of perioperative safety and prioritize strategies for improvement within their respective organizations.
- ▶ Analyze the methods presented to determine which would most effectively enhance the interdisciplinary care model at their organization.
- ▶ Evaluate and apply interdisciplinary approaches designed for specialty patients and situations.
- ▶ Examine tenets of and advocate for medication safety in the perioperative area.
- ▶ Investigate causes of surgical and anesthesia errors as a means to develop preventive processes.

The CSPS is a unique collation of professional organizations representing the perioperative team: the American Association of Nurse Anesthetists, the American Association of Surgical Physician Assistants, the American College of Surgeons, the Association of periOperative Registered Nurses, the American Society of Anesthesiologists, the American Society of PeriAnesthesia Nurses, and the Association of Surgical Technologists.

To register or obtain more information, visit www.jcinc.com/Conferences-and-Seminars/Perioperative-Safety-Symposium/1512/. To learn more about the CSPS, go to www.cspsteam.org or contact dgoode@facs.org. ■

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In the current issue of SRGS (Vascular Trauma/Venous Disease, Volume No. 35, No. 3), you will find a review and clarification of the controversies surrounding optimum prevention of thromboembolic complications in trauma patients.

To review this issue, sign up for a trial subscription. Go to www.facs.org/srgs/subscribe/order.html. Click on the link labeled "Order, renew, or sign up for a free 30-day online subscription." The online trial subscription offer is the third item listed on that page. Click on the "Details" button to the right, and then "Add to Cart." Before checking out, please login as a member of the College.

SRGS offers online, print, and CD-ROM subscription formats. An optional continuing medical education (CME) program can be used to satisfy the requirements for maintenance of certification, licensure, and privileges.

More information is available at www.facs.org/srgs. ■

SAGES To Offer Endoscopy Web Cast

The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) will present a comprehensive postgraduate course in flexible endoscopy that will also be Web cast at its annual meeting April 22, 2009, in Phoenix.

The course will cover basic diagnostic and therapeutic upper and lower gastrointestinal endoscopic techniques as well as management of difficult scenarios and complications. A brief overview of endoscopic retrograde cholangiopancreatography and advanced upper endoscopy techniques will also be presented.

This course is designed to address the needs of practicing general surgeons who perform flexible endoscopy as a part of their practice, but it is also appropriate for surgical residents and fellows in training.

To view the Web cast, send an e-mail to jacqueline@sages.org. Please include your name, institution, e-mail address, and phone number.

Register by Thursday, April 16. Login instructions will be sent on Friday, April 17.

To learn more, visit www.sages.org/meetings/annual_meeting/2009/. ■

Add Your Photo to Your ACS Profile

Did you know that you can upload your photo into your profile in the ACS database? By using the ACS Web Portal's "My Profile" feature, you can easily insert your photo into the profile that patients and others see when they search the ACS Member Directory via the College's public Web site. Simply go to http://efacs.org/portal/page/portal/ACS_Content/MYPAGE/MYPROFILE and click on "Update My Profile." Go to "Edit SECTION VI," where you can upload your photo,

describe your practice, and provide the URL for your personal Web site if you have one.

While visting the "My Profile" area, you may also wish to list your specialty, year of birth, phone and fax numbers, e-mail address, medical school attended, graduation year, hospital appointment(s), academic appointment(s), degrees, board certification(s), society memberships, and areas of special interest. In addition, you can select which information you would like to be available to the public. ■

Contralateral Prophylactic Mastectomy Rate Doubles

If the trend continues, 'we may have a problem with access to reconstruction,' an expert cautions.

BY BRUCE JANCIN
Elsevier Global Medical News

SAN ANTONIO — The recent marked increase in contralateral prophylactic mastectomies—most of them unnecessary—is a trend that could bring adverse consequences for overall breast cancer care, a prominent surgeon cautioned at the San Antonio Breast Cancer Symposium.

"In the time it takes a surgeon to perform a bilateral skin-sparing mastectomy with immediate reconstruction, a surgeon can probably do about three breast-sparing surgical procedures. As a result, I worry that with increasing demands on the breast surgeons' time, there are going to be potential delays for many patients in the time from diagnosis of cancer to ultimate surgical treatment," said Dr. Todd M. Tuttle, chief of surgical oncology at the University of Minnesota, Minneapolis.

"If these trends continue we may have a problem with access to reconstruction; we already have a shortage of breast reconstructive surgeons in the U.S.," he noted.

Using data from the National Cancer Institute's Surveillance, Epidemiology, and End Results registry, Dr. Tuttle and his coworkers have shown that the annual rate of contralateral prophylactic

mastectomy (CPM) in women with unilateral invasive breast cancer more than doubled from 1998 to 2003 (J. Clin. Oncol. 2007;25:5203-9). He estimated that at least 10,000 women per year now undergo CPM.

In a separate study soon to be published in the Journal of Clinical Oncology, Dr. Tuttle and his coinvestigators showed that the trend for a recent steep rise in CPM also applies to women with ductal carcinoma in situ. Among 51,229 patients diagnosed with DCIS in the SEER database for 1998-2005, there were 2,082 CPMs. The CPM rate for these patients climbed by 147% during the study period.

Unlike the case for some other operations, there were no broad regional trends in CPM rates in women with invasive breast cancer. Among the highest rates in 2003 were those in metropolitan Atlanta (13.5%), Iowa (10.5%), and California (9.6%). Rates were lowest in Utah (3.7%), Connecticut (4.7%), and Hawaii (4.8%), according to Dr. Tuttle.

The best estimate is that CPM reduces the risk of contralateral breast cancer by 95%-97%. But Dr. Tuttle considers most CPM unnecessary because there is no evidence that the surgery improves overall survival. For most patients, the risk of systemic metastases from their known breast cancer far exceeds the risk of de-

veloping metachronous contralateral breast cancer, which remains constant at about 0.7% per year in women with unilateral invasive breast cancer and 0.5% per year in those with DCIS.

Moreover, CPM is irreversible and not risk free. In a series of 239 patients who underwent CPM, most with immediate reconstruction, at M.D. Anderson Cancer Center, Houston, the overall complication rate was 16.3%, with about half of the complications occurring in the contralateral breast (Cancer 2004;101:1977-86).

For most patients—those not at high genetic risk—surveillance and adjuvant endocrine therapy are a good alternative to CPM, the surgeon continued.

A U.K. physician in the audience said he believes there has been a sea change in the attitude of British patients toward CPM. Back when the major clinical trials of breast-conserving therapy were being done, there was strong, widespread opposition to mastectomy. Now more and more patients embrace it for the peace of mind they anticipate. Is the same thing happening in the United States? he asked.

"I do think there has been a shift toward being more aggressive, and I think it's largely been driven by patients," Dr. Tuttle replied. "In talking to my plastic surgery colleagues, they tell me that the most important aspect of breast reconstruction is symmetry, and I think many women view bilateral mastectomy with or without reconstruction as being able

to effectively achieve symmetry."

When should a physician initiate discussion of CPM for a clinically normal breast? Dr. Tuttle doesn't do so in average-risk patients who are good candidates for breast-conserving surgery. He does bring up CPM selectively in average-risk women who want a mastectomy and are obese or have extremely large breasts, for it may be difficult to achieve symmetry in such patients. He routinely initiates discussion of CPM in women at high risk for contralateral breast cancer because of a BRCA mutation or a history of radiotherapy to the chest earlier in life. But he actively dissuades women with advanced-stage breast cancer from undergoing CPM because their risk of systemic metastases from their known cancer vastly exceeds their risk of contralateral breast cancer.

"I think the major challenge surgeons face is in dealing with the patient who's at average risk of developing contralateral breast cancer and wants to have CPM. I have no data to support my opinion, but I believe that most women grossly overestimate their risk of developing contralateral breast cancer. So I spend some time telling them about what the risk really is, I talk about the side effects of CPM, and I talk about the surveillance options.

"Usually after a 30-minute discussion, the patient thanks me for my advice and asks when we can schedule the CPM with immediate reconstruction," Dr. Tuttle said. ■

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ACOSOG Seeks Trial Participants

BY DAVID M. OTA, M.D., FACS
ACOSOG Group Co-Chair

The American College of Surgeons Oncology Group, which is dedicated to procedure-oriented cancer trials, encourages surgeons to consider participating in two recently activated cancer trials: Z1072, a phase II trial of cryoablation of T1 breast cancers; and Z6051, a phase III, prospective randomized trial comparing laparoscopic-assisted resection to open resection for rectal cancer.

The breast study (Rache Simmons, M.D., FACS, chair) is designed to determine the rate of complete tumor ablation. Secondary objectives include evaluation of the use of magnetic resonance imaging in the postablation setting to determine residual disease, identification of adverse events associated with cryoabla-

THE BREAST CANCER TRIAL SEEKS TO DEFINE THE TUMOR ABLATION RATE. THE RECTAL CANCER TRIAL COMPARES OPEN VERSUS LAPAROSCOPIC SPECIMEN RESECTION.

tion, assessment of pain following cryoablation and surgical resection, and identification of technical variables that affect the success of cryoablation.

Patients with unifocal primary invasive ductal carcinoma and who have tumors less than 2.0 cm in greatest diameter with no evidence of multicentric disease are eligible.

After protocol informed consent is obtained, patients will undergo cryoablation of their primary tumor using ultrasound guidance and the Sanarus V2 ablation system. The procedure can be performed in an office-based setting. An MRI is performed after the ablation and prior to surgical resection. The surgical resection will allow assessment of the pathology and residual tumor.

Credentialed criteria for surgeons, radiologists, and pathologists are available on the ACOSOG Web site at www.acosog.org. This trial is supported through a grant from the National Cancer Institute.

Laparoscopic approaches to low anterior resection, coloanal resection, and abdominoperineal resection are known to be feasible, but can we achieve the same local cancer control rate of open resec-

tion? The rectal cancer trial is designed to determine whether pathologic analysis of the resected specimen is the same for laparoscopic and open procedures. The pathologic variables to be assessed are circumferential tumor margin greater than 1 mm, distal resection margin greater than 2 cm (or greater than 1 cm with clear frozen section in the low rectum), and completeness of transmesorectal excision. Secondary objectives include perioperative benefit, as-

essment of disease control, and assessment of quality of life.

Patient eligibility criteria include the following:

► Histologic diagnosis of adenocarcinoma of the rectum (less than 12 cm from the anal verge).

► T3N0M0, TanyN1M0 disease as determined by pretreatment CT scans and pelvic MRI or transrectal ultrasound; patients with T4 disease extending to the circumferential margin of the rectum or

invading adjacent organs are not eligible.

► Completion of preoperative 5-fluorouracil-based chemotherapy and/or radiation therapy; capecitabine may be substituted for 5FU.

For more information, go to www.acosog.org, or send an e-mail to Dr. James Fleshman, protocol study chair, at fleshman@wudosis.wustl.edu. Surgeons who are interested in being credentialed can also contact Helen Harbett at helen.harbett@duke.edu. ■

TYGACIL® (tigecycline) Brief Summary

See package insert for full Prescribing Information. For further product information and current package insert, please visit www.wyeth.com or call our medical communications department toll-free at 1-800-934-5556.

CONTRAINDICATIONS

TYGACIL is contraindicated for use in patients who have known hypersensitivity to tigecycline.

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Anaphylaxis/anaphylactoid reactions have been reported with nearly all antibacterial agents, including tigecycline, and may be life-threatening. Glycylcycline class antibiotics are structurally similar to tetracycline class antibiotics and may have similar adverse effects. TYGACIL should be administered with caution in patients with known hypersensitivity to tetracycline class antibiotics.

TYGACIL may cause fetal harm when administered to a pregnant woman. If the patient becomes pregnant while taking tigecycline, the patient should be apprised of the potential hazard to the fetus. Results of animal studies indicate that tigecycline crosses the placenta and is found in fetal tissues. Decreased fetal weights in rats and rabbits (with associated delays in ossification) and fetal loss in rabbits have been observed with tigecycline. (See **PRECAUTIONS, Pregnancy**.)

The use of TYGACIL during tooth development (last half of pregnancy, infancy, and childhood to the age of 8 years) may cause permanent discoloration of the teeth (yellow-gray-brown). Results of studies in rats with TYGACIL have shown bone discoloration. TYGACIL should not be used during tooth development unless other drugs are not likely to be effective or are contraindicated.

Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including TYGACIL, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile*. *C. difficile* produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing strains of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.

If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated.

PRECAUTIONS

General

Caution should be exercised when considering TYGACIL monotherapy in patients with complicated intra-abdominal infections (cIA) secondary to clinically apparent intestinal perforation. (See **ADVERSE REACTIONS**.) In Phase 3 cIA studies (n=1642), 6 patients treated with TYGACIL and 2 patients treated with imipenem/cilastatin presented with intestinal perforations and developed sepsis/septic shock. The 6 patients treated with TYGACIL had higher APACHE II scores (median = 13) vs the 2 patients treated with imipenem/cilastatin (APACHE II scores = 4 and 6). Due to differences in baseline APACHE II scores between treatment groups and small overall numbers, the relationship of this outcome to treatment cannot be established.

Glycylcycline class antibiotics are structurally similar to tetracycline class antibiotics and may have similar adverse effects. Such effects may include: photosensitivity, pseudotumor cerebri, and anti-anabolic action (which has led to increased BUN, azotemia, acidosis, and hyperphosphatemia). As with tetracyclines, pancreatitis has been reported with the use of TYGACIL.

The safety and efficacy of TYGACIL in patients with hospital acquired pneumonia have not been established. In a study of patients with hospital acquired pneumonia, patients were randomized to receive TYGACIL (100 mg initially, then 50 mg every 12 hours) or a comparator. In addition, patients were allowed to receive specified adjunctive therapies. The sub-group of patients with ventilator-associated pneumonia who received TYGACIL had lower cure rates (47.9% versus 70.1% for the clinically evaluable population) and greater mortality (25/131 [19.1%] versus 15/122 [12.3%]) than the comparator.

As with other antibacterial drugs, use of TYGACIL may result in overgrowth of non-susceptible organisms, including fungi. Patients should be carefully monitored during therapy. If superinfection occurs, appropriate measures should be taken.

Prescribing TYGACIL in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Information for Patients

Patients should be counseled that antibacterial drugs including TYGACIL should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When TYGACIL is prescribed to treat a bacterial infection, patients should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by TYGACIL or other antibacterial drugs in the future. Diarrhea is a common problem caused by antibiotics which usually ends when the antibiotic is discontinued. Sometimes after starting treatment with antibiotics, patients can develop watery and bloody stools (with or without stomach cramps and fever) even as late as two or more months after having taken the last dose of the antibiotic. If this occurs, patients should contact their physician as soon as possible.

Drug Interactions

Prothrombin time or other suitable anticoagulation test should be monitored if tigecycline is administered with warfarin. (See **CLINICAL PHARMACOLOGY, Drug-drug Interactions** in full prescribing information.)

Concurrent use of antibacterial drugs with oral contraceptives may render oral contraceptives less effective.

Drug/Laboratory Test Interactions

There are no reported drug-laboratory test interactions.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Lifetime studies in animals have not been performed to evaluate the carcinogenic potential of tigecycline. No mutagenic or clastogenic potential was found in a battery of tests, including in vitro chromosome aberration assay in Chinese hamster ovary (CHO) cells, in vitro forward mutation assay in CHO cells (HGPRT locus), in vitro forward mutation assays in mouse lymphoma cells, and in vivo mouse micronucleus assay. Tigecycline did not affect mating or fertility in rats at exposures up to 5 times the human daily dose based on AUC. In female rats, there were no compound-related effects on ovaries or estrous cycles at exposures up to 5 times the human daily dose based on AUC.

Pregnancy

Teratogenic Effects—Pregnancy Category D

Tigecycline was not teratogenic in the rat or rabbit. In preclinical safety studies, ¹⁴C-labeled tigecycline crossed the placenta and was found in fetal tissues, including fetal bony structures. The administration of tigecycline was associated with slight reductions in fetal weights and an increased incidence of minor skeletal anomalies (delays in bone ossification) at exposures of 5 times and 1 times the human daily dose based on AUC in rats and rabbits, respectively. An increased incidence of fetal loss was observed at maternotoxic doses in the rabbits with exposure equivalent to human dose.

There are no adequate and well-controlled studies of tigecycline in pregnant women. TYGACIL should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. (See **WARNINGS**.)

Labor and Delivery

TYGACIL has not been studied for use during labor and delivery.

Nursing Mothers

Results from animal studies using ¹⁴C-labeled tigecycline indicate that tigecycline is excreted readily via the milk of lactating rats. Consistent with the limited oral bioavailability of tigecycline, there is little or no systemic exposure to tigecycline in nursing pups as a result of exposure via maternal milk.

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when TYGACIL is administered to a nursing woman. (See **WARNINGS**.)

Use in Patients with Hepatic Impairment

No dosage adjustment is warranted in patients with mild to moderate hepatic impairment (Child Pugh A and Child Pugh B). In patients with severe hepatic impairment (Child Pugh C), the initial dose of tigecycline should be 100 mg followed by a reduced maintenance dose of 25 mg every 12 hours. Patients with severe hepatic impairment (Child Pugh C) should be treated with caution and monitored for treatment response. (See **CLINICAL PHARMACOLOGY, Special Populations, Use in Patients with Hepatic Impairment and DOSAGE AND ADMINISTRATION** in full prescribing information.)

Pediatric Use

Safety and effectiveness in pediatric patients below the age of 18 years have not been established. (See **WARNINGS**.) Therefore, use in patients under 18 years of age is not recommended.

Geriatric Use

Of the total number of subjects who received TYGACIL in Phase 3 clinical studies (n=1415), 278 were 65 and over, while 110 were 75 and over. No unexpected overall differences in safety or effectiveness were observed between these subjects and younger subjects, but greater sensitivity to adverse events of some older individuals cannot be ruled out.

ADVERSE REACTIONS

Because clinical studies are conducted under varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug and may not reflect the rates observed in practice. The adverse reaction information from clinical studies does, however, provide a basis for identifying the adverse events that appear to be related to drug use and for approximating rates.

Phase 3 clinical studies enrolled 1415 patients treated with TYGACIL. TYGACIL was discontinued due to treatment-emergent adverse events in 5.0% of patients compared to 4.7% for all comparators (5.3% for vancomycin/aztreonam and 4.4% for imipenem/cilastatin). Table 4 shows the incidence of treatment-emergent adverse events through test of cure reported in ≥2% of patients in these studies regardless of causality.

Table 4. Incidence (%) of Treatment-Emergent Adverse Events Through Test of Cure Reported in ≥2% of Patients Treated in Phase 3 Clinical Studies

Body System Adverse Events	TYGACIL ^a (N=1415)	Comparators ^b (N=1382)
Body as a Whole		
Abdominal pain	6.8	5.7
Abscess	3.2	2.6
Asthenia	2.5	1.7
Back Pain	1.2	2.3
Fever	7.1	9.8
Headache	5.9	6.5
Infection	8.3	5.4
Pain	3.7	2.9
Cardiovascular System		
Hypertension	4.9	5.6
Hypotension	2.3	1.7
Phlebitis	1.8	3.8
Digestive System		
Constipation	2.8	4.1
Diarrhea	12.7	10.8
Dyspepsia	2.9	1.6
Nausea	29.5	15.8
Vomiting	19.7	10.8
Hemic and Lymphatic System		
Anemia	4.2	4.8
Leukocytosis	3.7	2.5
Thrombocytopenia	6.1	6.2
Metabolic and Nutritional		
Alkaline Phosphatase Increased	3.5	2.6
Amylase Increased	3.1	1.4
Bilirubinemia	2.3	0.9
BUN Increased	2.1	0.2
Healing Abnormal	3.5	2.6
Hyperglycemia	1.8	2.9
Hypokalemia	2.1	2.9
Hypoproteinemia	4.5	3.0
Lactic Dehydrogenase Increased	4.0	3.5
Peripheral Edema	3.3	3.3
SGOT Increased ^c	4.3	4.4
SGPT Increased ^c	5.6	4.7
Nervous System		
Dizziness	3.5	2.7
Insomnia	2.3	3.3
Respiratory System		
Cough Increased	3.7	3.8
Dyspnea	2.9	2.7
Pulmonary Physical Finding	1.9	2.2
Skin and Appendages		
Pruritus	2.6	4.1
Rash	2.4	4.1
Sweating	2.3	1.6
Other		
Local Reaction to Procedure	9.0	9.1

^a 100 mg initially, followed by 50 mg every 12 hours

^b Vancomycin/Aztreonam, Imipenem/Cilastatin, Linezolid

^c LFT abnormalities in TYGACIL-treated patients were reported more frequently in the post therapy period than those in comparator-treated patients, which occurred more often on therapy.

In Phase 3 cSSI and cIAI studies, death occurred in 2.3% (32/1383) of patients receiving TYGACIL and 1.6% (22/1375) of patients receiving comparator drugs; this difference is not statistically significant and relationship to treatment cannot be established. In all treatment groups, mortality was associated with higher baseline comorbidity and/or greater severity of baseline infections.

In Phase 3 clinical studies, infection-related serious adverse events were more frequently reported for subjects treated with TYGACIL (6.7%) vs comparators (4.6%). Significant differences in sepsis/septic shock with TYGACIL (1.5%) vs comparators (0.5%) were observed. Due to baseline differences between treatment groups in this subset of patients, the relationship of this outcome to treatment cannot be established. (See **PRECAUTIONS**.) Other events included nonsignificant differences in abscess (1.8% vs 1.6%) and infections, including wound infections (1.7% vs 1.1%) for TYGACIL vs comparators, respectively.

The most common treatment-emergent adverse events were nausea and vomiting which generally occurred during the first 1–2 days of therapy. The majority of cases of nausea and vomiting associated with TYGACIL and comparators were either mild or moderate in severity. In patients treated with TYGACIL, nausea incidence was 29.5% (19.6% mild, 8.5% moderate, 1.4% severe) and vomiting incidence was 19.7% (12.3% mild, 6.3% moderate, 1.1% severe). In patients treated for cSSI, nausea incidence was 35.0% for TYGACIL and 8.9% for vancomycin/aztreonam; vomiting incidence was 20.0% for TYGACIL and 4.2% for vancomycin/aztreonam. In patients treated for cIAI, nausea incidence was 25.3% for TYGACIL and 20.5% for imipenem/cilastatin; vomiting incidence was 19.5% for TYGACIL and 15.3% for imipenem/cilastatin.

Discontinuation from tigecycline was most frequently associated with nausea (1.3%) and vomiting (1.0%). For comparators, discontinuations were most frequently associated with rash (1.1%), vancomycin/aztreonam and nausea (1.0%), imipenem/cilastatin).

The following drug-related adverse events were reported infrequently (≥0.2% and <2%) in patients receiving TYGACIL in Phase 3 clinical studies:

Body as a Whole: injection site inflammation, injection site pain, injection site reaction, septic shock, allergic reaction, chills, injection site edema, injection site phlebitis

Cardiovascular System: thrombophlebitis, bradycardia, tachycardia, vasodilatation

Digestive System: anorexia, dry mouth, jaundice, abnormal stools

Metabolic/Nutritional System: increased creatinine, hypocalcemia, hypoglycemia, hyponatremia

Nervous System: somnolence

Special Senses: taste perversion

Hemic and Lymphatic System: prolonged activated partial thromboplastin time (aPTT), prolonged prothrombin time (PT), eosinophilia, increased international normalized ratio (INR), thrombocytopenia

Urogenital System: vaginal moniliasis, vaginitis, leukorrhea

Post-Marketing Experience

Worldwide post-marketing adverse events not previously listed in the product label include: anaphylaxis/anaphylactoid reactions, acute pancreatitis.

OVERDOSAGE

No specific information is available on the treatment of overdosage with tigecycline. Intravenous administration of TYGACIL at a single dose of 300 mg over 60 minutes in healthy volunteers resulted in an increased incidence of nausea and vomiting. In single-dose IV toxicity studies conducted with tigecycline in mice, the estimated median lethal dose (LD₅₀) was 124 mg/kg in males and 98 mg/kg in females. In rats, the estimated LD₅₀ was 106 mg/kg for both sexes. Tigecycline is not removed in significant quantities by hemodialysis.

This Brief Summary is based on TYGACIL direction circular W10521C002 ET01, revised 06/07.

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Expanded broad-spectrum
coverage is on your side^{1*†}

Gram positives
Gram negatives
Anaerobes
Resistant gram positives
Resistant gram negatives

*The clinical significance of in vitro activity is unknown.

† TYGACIL does not cover *Pseudomonas aeruginosa*.

TYGACIL is indicated for

- The treatment of adults with complicated skin and skin structure infections caused by *E. coli*, *E. faecalis* (vancomycin-susceptible isolates only), *S. aureus* (methicillin-susceptible and -resistant isolates), *S. agalactiae*, *S. anginosus* grp. (includes *S. anginosus*, *S. intermedius*, and *S. constellatus*), *S. pyogenes*, and *B. fragilis*
- The treatment of adults with complicated intra-abdominal infections caused by *C. freundii*, *E. cloacae*, *E. coli*, *K. oxytoca*, *K. pneumoniae*, *E. faecalis* (vancomycin-susceptible isolates only), *S. aureus* (methicillin-susceptible isolates only), *S. anginosus* grp. (includes *S. anginosus*, *S. intermedius*, and *S. constellatus*), *B. fragilis*, *B. thetaiotaomicron*, *B. uniformis*, *B. vulgatus*, *C. perfringens*, and *P. micros*

Important Safety Information

- To reduce the development of drug-resistant bacteria and maintain the effectiveness of TYGACIL and other antibacterial drugs, TYGACIL should be used only to treat infections proven or strongly suspected to be caused by susceptible bacteria
- Anaphylaxis/anaphylactoid reactions have been reported with nearly all antibacterial agents, including tigecycline, and may be life-threatening
- TYGACIL is contraindicated in patients with known hypersensitivity to tigecycline
- TYGACIL should be administered with caution in patients with known hypersensitivity to tetracycline class antibiotics
- Glycylcycline class antibiotics are structurally similar to tetracycline class antibiotics and may have similar adverse effects. Such effects may include: photosensitivity, pseudotumor cerebri, and anti-anabolic action (which has led to increased BUN, azotemia, acidosis, and hyperphosphatemia). As with tetracyclines, pancreatitis has been reported with the use of TYGACIL
- The safety and efficacy of TYGACIL in patients with hospital-acquired pneumonia have not been established
- In clinical trials, the most common treatment-emergent adverse events in patients treated with TYGACIL were nausea (29.5%) and vomiting (19.7%)
- **TYGACIL may cause fetal harm when administered to a pregnant woman**
- The safety and effectiveness of TYGACIL in patients below age 18 and lactating women have not been established
- *Clostridium difficile*-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including TYGACIL, and may range in severity from mild diarrhea to fatal colitis
- **The use of TYGACIL during tooth development may cause permanent discoloration of the teeth.** TYGACIL should not be used during tooth development unless other drugs are not likely to be effective or are contraindicated

Please see brief summary of Prescribing Information on adjacent page.

Reference: 1. TYGACIL® (tigecycline) Prescribing Information, Wyeth Pharmaceuticals Inc.

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Tygacil[®]
tigecycline IV

Expanded coverage for resistant pathogens