



AMERICAN COLLEGE OF SURGEONS

SURGERY NEWS



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Study collaborators Dr. Gregory J. Jurkovich (L) and Dr. Douglas F. Zatzick advocate routine screening of trauma patients.

Data Find PTSD Common Among Injured Patients

BY BRUCE JANCIN
Elsevier Global Medical News

NEW YORK — Posttraumatic stress disorder and depression are extremely common a full year following hospitalization for injury and are associated with up to a nearly sixfold increased likelihood of failure to return to work, according to the largest-ever U.S. study evaluating the multiple impacts of trauma.

With an estimated 2.5 million hospital admissions for injury per year in the United States, the National Study of Costs and Outcomes of Trauma (NSCOT) data suggest 500,000 of these patients will have debilitating posttraumatic stress disorder (PTSD) 1 year later, Dr. Douglas F. Zatzick

said at the annual meeting of the American Surgical Association.

The economic, social, and health costs of this problem are such that screening for early signs of PTSD and depression should become routine during the acute hospitalization of all trauma patients, regardless of injury severity, according to Dr. Zatzick, a psychiatrist at the University of Washington, Seattle.

He reported on 2,707 NSCOT participants hospitalized for injuries requiring surgery at 69 U.S. hospitals, including 18 level 1 trauma centers. The patients, who were followed for 1 year, represented the broad spectrum of trauma with the exception of burn

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Hyperglycemia Hikes Postop Infection Rates

Monitor blood glucose after surgery.

BY BRUCE JANCIN
Elsevier Global Medical News

NEW YORK — Postoperative hyperglycemia boosts the 30-day risk of infectious complications—regardless of preoperative glucose level or whether a patient has diabetes—according to a study of 995 patients undergoing general or vascular surgery in non-ICU settings.

Postoperative blood glucose monitoring should be a routine part of patient management, and maintaining euglycemia postoperatively is a simple intervention that could significantly reduce postoperative infection rates, Dr. Selwyn O. Rogers Jr., said at the annual meeting of the American Surgical Association.

More than 2 million postoperative infections occur annually in U.S. patients. Tight postoperative glucose control has previously been shown to reduce the risk of wound infection in diabetic patients and to

lower morbidity and mortality in cardiac surgery patients, as well as in critically ill patients in surgical ICUs. But the impact of perioperative hyperglycemia on postoperative infection risk hadn't previously been studied in noncardiac surgery patients in non-ICU settings—the sort of patients general surgeons see every day, said Dr. Rogers, an ACS Fellow with Brigham and Women's Hospital, Boston.

Dr. Rogers reported on 995 consecutive patients who underwent major general or vascular surgery at Brigham and Women's Hospital, Boston. The program's stated goal is to reduce preventable surgical morbidity and mortality by 25% by 2010.

Postoperative infections—including wound infections, pneumonia, sepsis, urinary tract

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Work Hours

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ACS Presses for a Short-Term Fee Fix

BY MARY ELLEN
SCHNEIDER

Elsevier Global Medical News

With less than a month to go before a 10.6% Medicare payment cut takes effect, the American College of Surgeons and others in the physician community are pushing Congress to take action.

At a recent hearing of the House Committee on Small Business, Dr. Charles D. Mabry, chairman of the ACS Health Policy Steering Committee, told members of Congress that short-term legislation is needed to stop the scheduled cut from taking effect on July 1 and to replace the 5.4% cut set for Jan. 2009 with a reasonable increase in Medicare physician payments.

By acting to stop payment cuts for the next 18 months, sur-

geons will be able to budget their expenses and Congress will have time to look at more permanent solutions, said Dr. Mabry, an ACS Fellow.

A short-term fix appears to have support in Congress. The Senate has outlined a plan to delay the cuts for 18 months, and Rep. Nydia M. Velazquez (D-N.Y.), chairwoman of the House Committee on Small Business, said it was one of the top prior-

ities of Congress to address the scheduled payment cuts. But the clock is ticking. Congress should act by mid-June to ensure that there is not a disruption in payments, according to the Centers for Medicare Medicaid Services.

Rep. Velazquez said she is also interested in looking for a permanent fix to how Medicare payments are calculated that

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VITAL SIGNS

Top 10 Most Expensive Health Conditions (in billions of dollars)

Heart conditions	\$76
Trauma disorders	\$72
Cancer	\$70
Mental disorders, including depression	\$56
Asthma and COPD	\$54
High blood pressure	\$42
Type 2 diabetes	\$34
Joint diseases*	\$34
Back problems	\$32
Normal childbirth	\$32

*Includes osteoarthritis.

Note: Based on 2005 data for visits to doctors' offices, clinics, and emergency departments, and for hospital stays, home health care, and prescription drugs.

Source: Agency for Healthcare Research and Quality

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Routine Screening Recommended

PTSD • from page 1

injuries, an exclusion criterion.

One year post injury, 20.7% of subjects met diagnostic criteria for PTSD using the validated 17-item PTSD checklist. Another 6.6% met criteria for depression using the Center for Epidemiologic Studies Depression Scale, and 4.9% had both psychiatric disorders. After 1 year, 45% of patients employed preinjury had not returned to work. The rate varied significantly depending upon whether a patient had neither psychiatric disorder, one, or both (see box).

In a multivariate analysis adjusting for injury severity, pre-

morbid psychiatric disorders, and preinjury health status and functioning, having either PTSD or depression was an independent risk factor associated with a 3.2-fold greater likelihood of failure to return to work than for those with neither disorder. Patients with both depression and PTSD were at a 5.6-fold increased risk.

A similar stepwise relationship was observed between the number of psychiatric diagnoses present and other measures of functional impairment collected in the study, including return to usual activities as well as physical and mental health status as assessed using the Short Form 36, Dr. Zatzick continued.

The prevalence of PTSD and depression was similar in patients treated at level 1 trauma centers and those treated at community hospitals. So were adjusted return-to-work rates.

“As a trauma community, we are largely ignoring this problem currently,” said Dr. David B. Hoyt, an ACS Fellow who is professor of surgery and chief of the division of trauma, burns, and critical care at the University of California, San Diego.

“It’s hard to get psychiatric consults for in-

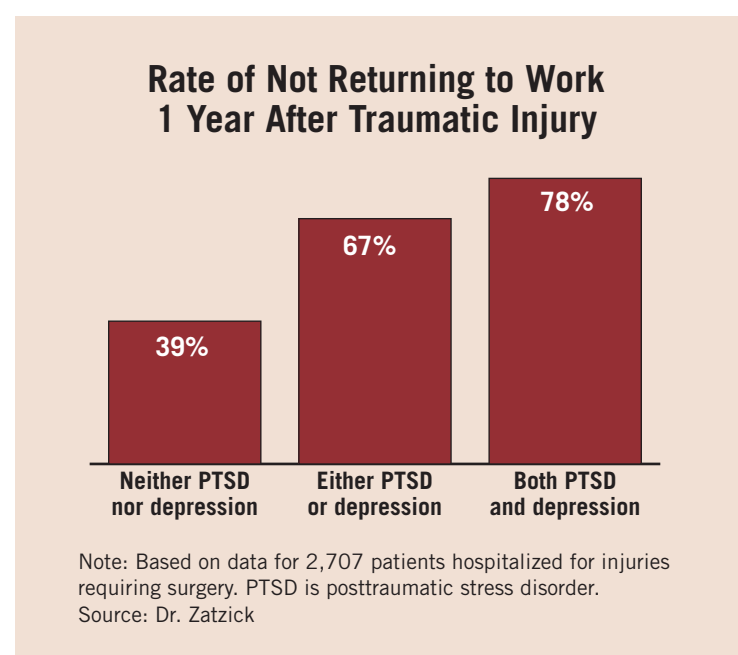
patient trauma patients,” he said, pondering the daunting prospect of screening 2.5 million patients per year. “Will the psychiatric community step up to help? Who will be available to help manage this complicated problem?”

Col. John B. Holcomb, MC, USA, commented that the prevalence of PTSD and depression documented in NSCOT is “exactly the same” as what he and others have found in both military and civilian trauma populations.

“Just screen everybody. I don’t think PTSD is related to your family or work status. And we find it’s not related to severity of injury; what we would consider a minor injury the patient may consider a major injury,” said Dr. Holcomb, an ACS Fellow and commander of the U.S. Army Institute of Surgical Research, Brooke Army Medical Center, San Antonio.

NSCOT copresenter Dr. Gregory J. Jurkovich said the nation’s major trauma centers must bear most of the responsibility for screening for psychiatric morbidity in injured patients.

“They have really become the linchpin of managing trauma patients, much more so than community hospitals, and that will become even more true as regionalization of trauma care continues. But with that status as the centerpiece of care comes the responsibility for broad-based care involving collaborative effort between psychiatrists, psychologists,



rehabilitation specialists, and others,” said Dr. Jurkovich, an ACS Fellow who is professor of surgery at the University of Washington and chief of trauma services at Harborview Medical Center, both in Seattle.

What should one look for when screening for PTSD? The disorder can’t be formally diagnosed until at least 1 month after the traumatic event. But the strongest predictor of subsequent PTSD is development of an acute stress disorder during the hospitalization. This acute stress response is marked by the same three classes of symptoms that define PTSD: intrusive symptoms such as flashbacks and nightmares, avoidance behavior, and hyperarousal as evidenced by insomnia, inability to concentrate, and an exaggerated startle response.

Other indicators of increased

likelihood of PTSD occurring in trauma patients include a history of more than four prior hospitalizations for trauma, female gender, and a positive urine toxicology screen, Dr. Jurkovich said.

Prevention and treatment of PTSD are “somewhat problematic” and warrant far more research, he noted. One theory holds that the disorder results from imprinting of the trauma in patients with elevated catecholamines at the time of injury. Consistent with this theory is the finding that trauma patients who are more tachycardic are at increased risk for later PTSD. But prophylactic β -blocker therapy has proved ineffective. Moreover, the use of SSRIs in patients with PTSD has been disappointing. The best treatment at present is cognitive-behavioral therapy, he concluded. ■

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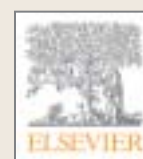
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Aprotinin Found Unsafe for High-Risk Cardiac Surgery

BY MARY ANN MOON
Elsevier Global Medical News

A large randomized trial was terminated early when an interim analysis showed “a strong trend” toward death in high-risk cardiac surgical patients who received aprotinin, compared with two lysine analogues.

On the basis of the trial’s results, Bayer HealthCare Pharmaceuticals recalled its remaining U.S. supplies of the drug (see sidebar).

“Despite the possibility of a modest reduction in the risk of massive bleeding, the strong and consistent negative mortality trend associated with aprotinin as compared with lysine analogues precludes its use in patients undergoing high-risk cardiac surgery,” said Dr. Dean A. Fergusson of the Ottawa Health Research Institute and his associates (*N. Engl. J. Med.* 2008;358:2319-31).

The Blood Conservation Using Antifibrinolytics in a Randomized Trial (BART) research group compared the serine protease inhibitor aprotinin with two lysine analogues, tranexamic acid and aminocaproic acid, to determine which agent better reduced the risk of massive postoperative bleeding among high-risk cardiac surgery patients. The BART study enrolled 2,468 patients undergoing high-risk elective or urgent surgery requiring cardiopulmonary bypass at 19 Canadian medical centers in 2002-2007. These subjects were randomly assigned in roughly equal numbers to receive one of the three hemostatic drugs. Of the 2,331 patients in the intention-to-treat analysis, 781 received aprotinin, 770 received tranex-

amic acid, and 780 received aminocaproic acid.

The trial was terminated early after an interim analysis of data on more than 2,000 participants showed “a strong trend toward higher mortality in the aprotinin group than in the other two groups.”

Aprotinin did curb massive bleeding. Nine percent of the aprotinin group had this complication, compared with 12% in each of the other two groups. However, 30-day mortality from any cause in 2,328 patients analyzed was 6% with aprotinin, compared with 3.9% with each of the two lysine analogues. “When we compared the combined mortality rates in the lysine-analogue groups with the rate in the aprotinin group, we noted a significant absolute increase of 2.1%, or a relative increase of 54%, in the number of deaths in the aprotinin group,” the researchers said.

Further data analysis showed that the drug doubled the risk of death from cardiac causes specifically, including cardiogenic shock, right ventricular failure, heart failure, or MI.

In an accompanying editorial, Dr. Wayne A. Ray and Dr. C. Michael Stein of Vanderbilt University, Nashville, Tenn., wrote BART provided “modest” evidence that aprotinin was more effective at maintaining hemostasis, although the difference between it and the lysine analogues was only of borderline statistical significance. Aprotinin patients had slightly less need for blood products postoperatively than the other two groups (*N. Engl. J. Med.* 2008;358:2398-400).

None of the drug manufacturers contributed medications or financial support to the study. Three study authors reported receiving consulting or lecture fees from Bayer. Dr. Ray has received grant support from Pfizer Inc. ■

BART Study Prompts Aprotinin Recall

Bayer HealthCare Pharmaceuticals notified the Food and Drug Administration in May that it would recall all remaining supplies of aprotinin (Trasylol) in the United States, according to an FDA statement. Results from a randomized study of more than 2,000 patients found that the risk of death associated with the antifibrinolytic drug outweighed the benefits of controlling bleeding in high-risk cardiac surgery patients (see story).

Trasylol, which was approved to help control bleeding and reduce the need for blood transfusions during cardiac surgery, will remain available to investigators on a limited basis for use in patients who meet strict criteria, the FDA said in a statement. Investigators who want access to the drug must submit a protocol for FDA review.

Bayer agreed to an FDA request to suspend marketing of the drug in November 2007 based on preliminary findings from the Blood Conservation Using Antifibrinolytics in a Randomized Trial (BART) study.

To see the FDA statement, visit www.fda.gov/bbs/topics/NEWS/2008/NEW01834.html.

—Heidi Splete

Glucose Control

Infections • from page 1

infections, and septic shock—occurred within 30 days in 117 of the 995 study participants, or 11.7%. The incidence was 15.3% among the 13% of subjects who had diabetes and 8.8% in nondiabetic patients. Patients who developed postoperative infections had a mean postoperative blood glucose level of 142 mg/dL and were significantly older as well as more likely to have received more than two units of RBCs intraoperatively.

A multivariate regression analysis showed only three significant predictors of postoperative infections: emergent surgery and a higher American Society of Anesthesiologists classification—which are factors beyond control—and postoperative hyperglycemia, which is readily manageable. A postoperative blood glucose level 40 mg/dL higher than normal was independently associated with a 30% increased risk of postop infection. And a postop blood glucose greater than 180 mg/dL was associated with an adjusted two-fold increase in infection risk.

Preoperative blood glucose level, race, age, and diabetes status were not related to the risk of postoperative infection, he said.

There was a strong relationship between postoperative hyperglycemia and the risk of surgical site infections, which account for about one-quarter of all postoperative infections occurring annually in U.S. patients. Prevention and prompt treatment of postop hyperglycemia could therefore have a major favorable impact on the quality of surgical services, he noted.

Dr. Hiram C. Polk Jr. observed that the fascination with tight blood glucose control in surgical patients is only 7 or 8 years old. The pendulum has recently begun to swing away from tight control, but this careful study will push it back, he predicted.

Dr. Polk said in his own ongoing prospective study of surgical practices at small community hospitals, he has been struck by the contrast between the careful attention given to avoiding hypothermia versus the spotty performance in perioperative blood glucose monitoring.



Prompt treatment of postop hyperglycemia could favorably impact quality of surgical care.
DR. ROGERS

“Hypothermia is being avoided in 98% of cases. On the other hand, nearly one-third of all diabetics are not monitored for intraoperative glucose during long surgical procedures. And 29% of people with very high glucose in the holding area don’t get their blood glucose monitored at all,” said Dr. Polk, an ACS Fellow and senior professor of surgery at the University of Louisville (Ky.).

Strict perioperative blood glucose control is routine only in cardiac surgery, because of the abundant evidence that it influences outcomes, Dr. E. Patchen

Dellinger pointed out, adding that it’s irrational not to apply the same practice in other fields of surgery.

“Clearly the biology is the same,” argued Dr. Dellinger, an ACS Fellow who is professor and vice chairman of surgery and chief of the general surgery division at University of Washington Medical Center, Seattle.

“There are still nonbelievers who are unconvinced of this important relationship,” commented Dr. Dana K. Andersen, an ACS Fellow who is professor and vice chair of surgery at Johns Hopkins University, Baltimore. ■

SGR Alternative

Fee Fix • from page 1

would reflect increasing practice costs.

Currently, Medicare physician payments are calculated using the Sustainable Growth Rate (SGR), which sets a spending target based on the gross domestic product. Whenever the spending target is exceeded, Medicare payments must be cut. Physician groups have objected to the use of this formula for years, saying that it fails to track rising practice costs. And surgeons in particular are opposed because surgery has a relatively low rate of growth but is cut at the same rate as are other rapidly growing physician services.

“There’s no question that the SGR is broken and we’re in dire straits,” said Dr. Mabry, a general surgeon in Pine Bluff, Ark.

The constant Medicare payment cuts not only make it hard for surgeons to keep budgets on track, but also force some to retire early, creating an access problem for the entire community, he said. Between 1997 and 2004, seven counties in Arkansas lost all of their general surgeons, which led to significantly reduced services at five hospitals and the closing of two in those areas, Dr. Mabry noted. This experience is being mirrored in other rural areas, he added.

As Congress considers long-term reform to Medicare payments, he offered a proposal developed by the ACS in conjunction with the American Osteo-

pathic Association in which Medicare would replace the current SGR with a system of six separate physician service categories: primary and preventive care, other evaluation and management services, major procedures, anesthesia services, imaging and diagnostic services, and minor procedures and all other physician services.

Spending targets would be based on the current SGR factors, such as trends in physician spending and beneficiary enrollment, but would not include the gross domestic product. The GDP would be replaced with a statutorily set percentage point growth allowance for each service category.

Establishing separate physician service categories would allow policy makers to adjust targets and payments to each service area, rather than making across-the-board cuts. “We feel that this will allow Congress and the administration to better control the management of those individual services,” he said.

But representatives from other physician groups voiced concerns about the ACS alternative. The proposal would create “mini SGRs” and would require careful study to ensure that it didn’t just compound the current problem, Dr. Cecil B. Wilson, immediate past chair of the board of trustees of the American Medical Association, testified at the hearing.

The ACS proposal has received some support within Congress and was included in legislation last summer that failed to move forward. ■



Payment cuts make it hard for surgeons to keep budgets on track, and force some to retire early.
DR. MABRY

THE 20/20 VISION

Evolutionary Changes in Surgical Practice

McCain Health Plan Relies on Tax Changes

While the Democrats continue to debate the need for individual mandates for health coverage, Sen. John McCain proposes a plan to eliminate the tax exclusion that allows employees to avoid paying income tax on the value of their health benefits.

Sen. McCain, the presumptive Republican presidential nominee, would replace that tax break with a refundable tax credit of \$2,500 for individuals and \$5,000 for families.

For those who remain in their employer-sponsored plan, the tax credit would roughly offset the increased income tax burden. For those seeking to buy their own health coverage, the tax credit would be used to pay their premiums, according to Sen. McCain's plan.

"Insurance companies could no longer take your business for granted, offering narrow plans with escalating costs," Sen. McCain said in a speech.

For those with preexisting conditions, Sen. McCain is proposing a Guaranteed Access Plan. The GAP would reflect the best practices of the more than 30 states that have a "high-risk" pool for individuals who cannot obtain health insurance. He pledged to work with industry and the government to ensure adequate funding for the initiative the inclusion of disease management programs, individual case management, and health and wellness programs.

Eliminating the employee health benefits tax exclusion would be an excuse for employers to avoid providing health insurance, said Roger Hickey, codirector of the Campaign for America's Future, a progressive think tank. And a \$5,000 tax credit wouldn't be enough for family coverage.

Dr. Jack Lewin, chief executive officer of the American College of Cardiology, called on Sen. McCain to rethink his tax proposal.

To see a side-by-side comparison, go to www.acponline.org/advocacy/where_we_stand/election/.

—Mary Ellen Schneider

ACS Urges IOM to Weigh Impact Of Fewer Duty Hours in the Future

BY JANE ANDERSON
Elsevier Global Medical News

Patient safety cannot be achieved by arbitrarily decreasing surgical resident work hours, and the Institute of Medicine needs to carefully study the implications of the 80-hour work week before recommending any further changes, an American College of Surgeons panel told the IOM committee studying reductions in resident work hours.

The report from the ACS Task Force on the Resident 80-Hour Work Week urged the IOM to recommend a fully funded, multi-institutional study to evaluate the impact of further reductions in duty hours and the optimal number needed to achieve curriculum objectives, maintain continuity of care, and address team training efforts.

"We should not make any additional changes until a complete analysis has been made of the changes we've already made," Dr. L.D. Britt said in an interview. Dr. Britt, an ACS Fellow, is chairman of the department of surgery at Eastern Vir-

ginia Medical School, Norfolk, and chairman of the ACS task force. "We cannot train a good surgeon in less than an 80-hour work week, and before we entertain that, we should look at some outcomes."

The ACS report is intended to help guide the IOM Committee on Optimizing Graduate Medical Trainee Hours and Work Schedules, which was formed at the request of Rep. John D. Dingell (D-Mich.) and colleagues on the House Committee on Energy and Commerce as part of an investigation into preventable medical errors.

The IOM will publish a report including strategies and actions for implementing safe work schedules in February 2009, Dr. Britt said. The report may recommend additional work hour reductions.

European countries have cut back further than 80 hours, Dr. Britt pointed out. In the United Kingdom, for example, surgical residents work 54-hour weeks, while those in the Netherlands put in less than 40 hours, he said. The reduced hours have led to problems with handoffs

and medical mistakes, he said, adding, "they're not being adequately trained."

"You can train a good surgeon in 80 hours, but it has to be more streamlined. Why implement anything else when you haven't looked at the impact of that? In all fairness, no organization should institute a work-hour reduction without analyzing and investigating what already has been done," he said.

The ACS task force, which represents several surgical subspecialties, reminded the IOM in the report that there has been no evidence-based study linking surgery resident duty hours with improved patient safety. Efforts to improve care should focus on optimal use of information technology, electronic health records, telemedicine, and simulation.

The report raised several questions for the IOM to consider, including the optimal balance between resident duty hours and rest and whether "any gains in patient safety from less-fatigued residents would be overshadowed by the consequences of increased errors generally associated with handoffs."

The IOM should consider how training programs can provide adequate clinical/operative activity to ensure future availability of well-qualified surgeons, and examine the "unintended consequences of duty hour limitations on undergraduate medical education," as well as funding for graduate medical education.

The task force recommended establishing team training initiatives with an emphasis on patient safety and advised integrating advanced information technology and simulation into "all aspects of surgical residency training and healthcare delivery in order to enhance educational experiences and ensure patient safety."

Chief surgery residents should be exempt from the duty hour limitation "to allow a more realistic transition to a postgraduate career, and to acquire the knowledge and skills for practice," the report said.

The report advised removing the restrictive "cap" on graduate medical education positions funded by the Centers for Medicare & Medicaid Services, saying it would be "counterproductive to the current efforts to expand the undergraduate medical student pool in order to meet the future workforce needs." ■

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Quality Improvement Incentives May Backfire on 'Safety Net' Hospitals



BY MIRIAM E. TUCKER
Elsevier Global Medical News

PITTSBURGH — The initiation of public reporting and pay-for-performance measures, designed as incentives to improve the quality of care at hospitals, may actually have the opposite effect on those institutions that serve lower-income populations.

That conclusion was based on an analysis of performance data on acute myocardial infarction, heart failure, and pneumonia from 3,600 hospitals in the Web site www.hospitalcompare.com, the performance measure and public reporting system instituted in 2004 by the Centers for Medicare and Medicaid Services (CMS). Between 2004 and 2006, the hospitals with the highest proportion of Medicaid patients—which had the

worst performance on the three measures to begin with—also saw the least improvements in quality. Hospitals that achieved the most improvements had the smallest proportion of Medicaid patients, Dr. Rachel Werner reported at



There is concern about rich hospitals becoming richer and poor hospitals becoming poorer.
DR. WERNER

the annual meeting of the Society of General Internal Medicine.

These "safety net" hospitals were generally worse off financially at baseline, and would have fewer resources to invest in quality improvement. They could receive lower bonus payments and incur penalties for not meeting standards.

"There is concern that reporting and pay for performance could set up a system where rich hospitals become richer and poor hospitals become poorer," said Dr. Werner of the Center for Health Equity Research and Promotion at the Philadelphia Veterans Affairs Medical Center.

After controlling for baseline performance and variables such as teaching status, bed size, and hospital ownership, investigators found that the percentage point improvements from 2004 through 2006 for the hospitals with the highest quartile of Medicaid population (mean, 40%) were 2.3 for composite measures of acute MI, 6.6 for heart failure, and 8.0 for pneumonia, compared with 3.8, 8.0, and 9.3, respectively, for hospitals with the lowest quartile of Medicaid population (mean, 5%). The differences for

acute MI and heart failure were significant.

These differences mean that safety-net hospitals are far less likely to rank among the top two deciles for clinical quality scores, designations that earn hospitals bonus incentive payments in the CMS pay-for-performance demonstration.

The findings suggest a need to minimize the unintended consequences of pay for performance and public reporting, said Dr. Werner, who is also with the division of general internal medicine at the University of Pennsylvania, Philadelphia. Steps might include providing subsidies

specifically for quality improvement and rewarding hospitals for absolute improvements in care rather than for relative rank.

The study was funded by a Career Development Award from the Health Services Research and Development Service of the Department of Veterans Affairs. ■

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EDITORIAL

Shifting Down



BY LAZAR J.
GREENFIELD, M.D., FACS

Back when ships were made of wood and men were made of steel, I was an intern at a hospital that didn't worry much about duty hours. On call responsibility was simple: you were on call 24/7, but you could sign out to another intern for a few hours on weekends if your

patients were stable. Some patients required minimal care, because hernias and breast biopsies kept them in the hospital for a few days. Others were very sick, however, and ICUs had not been invented.

Living in a hospital apartment, we never worried about a phone bill because our number was a hospital extension. Interns did all routine lab work, started IVs, and scrubbed in on all elective and emergency

cases. To say we were sleep deprived is an understatement. We fell asleep holding retractors in the OR and during conferences. Did this system need reform? You bet. Succeeding programs demonstrated that excellent clinical experience could be obtained with scheduled time off, and that residents learned more while awake.

The reform process became a public issue in 1986 after 18-year-old Libby Zion

died of a drug interaction in New York under the care of poorly supervised and inexperienced residents. Her father, a newspaper columnist, believed fatigue was the problem, and embarked on a crusade resulting in state laws enacted in 1989 that restricted resident duty to 80 hours per week, on-call duty to every third night, and individual shifts to 24 hours.

These restrictions became national after Public Citizen, a Washington-based nonprofit public interest organization, petitioned the Occupational Safety and Health Administration on behalf of several medical resident and student organizations in 2001 to take control of residency programs. Rep. John Dingell (D-Mich.) supported legislation advocating unionization of all residents. The Accreditation Council for Graduate Medical Education responded quickly by endorsing the restrictions and applying them to all training programs in 2003 to avoid federal control.

The restrictions facilitated recruitment of medical students to surgical programs and forced programs to eliminate much of the noneducational busywork. But continuity of care under shift management and overall clinical experience were challenged. Fatigue-related errors declined, errors related to miscommunication, continuity of care, and cross-coverage availability increased (*J. Surg. Res.* 2006;135:275-81). Studies of overall operative experience generally showed little change—although residents knew less about their patients (*Am. Surg.* 2005;71:552-5).

Rep. Dingell has asked the Institute of Medicine to form a committee to propose new guidelines in 2009 further reducing resident workload. The committee has heard testimony about fatigue-related errors, sleep deprivation, and the increase in auto accidents. An American College of Surgeons task force developed a report and presented it to the IOM in March (see p. 4). Among other recommendations, the report emphasized the need for a multi-institutional study to fully understand the impact of further duty hour limitations before changing current requirements.

On an emotional level, the plight of residents is appealing. But the core issues of patient safety and adequacy of clinical experience are inadequately documented.

Regardless of the issue, when reformers seek change, the pendulum is pushed as far as it will go. Then the effects are measured, and the pendulum usually swings back. In August 2009, the European Working Time Directive will reduce duty hours from the current 56 to 48 per week. Program directors there, concerned about adequacy of clinical experience, are considering extending the length of training.

No one knows the optimal range of duty hours, but we do know the consequences of inadequate training and passerby patient care. So who do you want standing over you when you're on an OR table—a smiling, inexperienced surgeon or a tired surgeon with experience? ■

DR. GREENFIELD is editor in chief of SURGERY NEWS.

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LETTERS

Get Real About Operative Experience

As an elderly, retired, rural surgeon, I have followed the issue of restricted work hours for residents to reduce management errors seemingly related to sleep deprivation ("IOM Committee Looks Into Safety of Work Schedules," February 2008, p. 1).

The progressive flagellations toward more controlled management of work time I find interesting, but none of the debate addresses the real issues.

The obvious solution is to limit the work week to three and a half to four 12-hour shifts per week; do away with the weekend concept, with each day serving as a full service work day for the facility; and extend the general surgery residency to 10 years to ensure adequate clinical and operative experience.

Certainly, reducing work hours reduces the clinical experience obtained by trainees in the past. But there are other bases for error or poor performance. First, factors such as lack of supervision, fatiguing activities engaged in during trainees' own time, family distress or tragedy, social disturbance, recreational drug use, and responsibility for a critically ill patient may enter into the equation. These issues seem not to be considered in the published information that I've seen. Second, especially in the rural setting, an element of deprivation is unavoidable, and lack of experience in this arena when good oversight and guidance are available does not "train" the surgeon in managing, avoiding, or recognizing the potential for errors. Family and social influences are also factors that may lead to errors, and will never be resolved.

Perhaps the breadth of investigation should be widened to also include the real world.

*Stuart A. Reynolds M.D., FACS
Havre, Mont.*

In Support of General Surgery

SURGERY NEWS is replete with articles warning of the crisis in general surgical manpower. The consensus is that we need more general surgeons, that they need to be better distributed geographically, and that they need to be available to take call in our increasingly crowded emergency departments.

Yet forces conspire against this. Residents gain less experience in an 80-hour work week than they did in a 110-hour work week: 5 years of training equals only 700-800 cases—less than half the number of cases they did 2 decades ago. And fellowship training takes the general surgeon out of the workforce.

We now have breast, hand, pancreatic/biliary, endocrine, colorectal, vascular, minimally invasive, bariatric, trauma, and acute care surgeons, as well as surgical intensivists. Each specialty has its own fellowship and professional societies. Each has its own self-serving proponents who will tell audiences at CME meetings that "this procedure should only be performed by fellowship-trained surgeons practicing at a designated center of excellence."

This subspecialization limits the places where general surgeons can live and work. Most require a city of more than 100,000 and a drawing area exceeding 250,000. That leaves a lot of territory uncovered by

general surgeons. And many subspecialists apply for a narrower scope of clinical privileges in a thinly veiled attempt to escape emergency department on-call duty.

Reimbursement reductions affect all physicians, but the hammer falls hardest on the general surgeon. I don't know the answer, but I've got some ideas.

► Beef up the general surgical residencies. By partnering with private hospitals, all university-based programs should be able to supply their residents with experience approaching 2,000 cases in 5 years.

► Stop glorifying surgical subspecializa-

tion. Would we pay homage to the internist who treats hypertensive patients in the fourth decade of life to the exclusion of all other maladies?

► Spread the talent around. Let residents know about towns with populations under 50,000 that would welcome them.

► Show us some love. If general surgeons are needed and wanted, stop the pay cuts.

► Change your rhetoric. Lighten up on the talk about fellowship-trained surgeons doing certain procedures in certain locations. No one should have to apologize for being just a general surgeon.

*David J. Farrell, M.D., FACS
Porterville, Calif.*

LETTERS TO THE EDITOR

SURGERY NEWS is your publication, and we're eager to share your opinions. Please send correspondence, including your name and address, to surgerynews@facs.org or to:

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NEWS FROM THE COLLEGE

College Breaks Ground for Office Building on Capitol Hill

The ACS broke ground on May 9 for a Washington, D.C., office that will serve as the College's centerpiece presence on Capitol Hill. The 10-story, class A office building, located at 20 F Street, NW, will be completed in the first quarter of 2010. ACS headquarters will remain in its current location in Chicago.

The College's Board of Regents believes that the proximity of the building to Capitol Hill will provide a more visible presence for the College and the surgeons it represents.

"It is becoming increasingly important for all of surgery to speak with one voice," Thomas R. Russell, M.D., FACS, ACS executive director, said during the groundbreaking ceremony. "The new Washington office will be a physical representation of the College as the 'house of surgery' and will present a united front to lawmakers on Capitol Hill on behalf of surgeons and their patients. This building represents the American College of Surgeons' commitment to working with policymakers to improve patient care, measure outcomes of that care, and work collaboratively with all other organizations and groups representing the overall health care team to create a better health care system."

In addition to housing the College's Division of



Helping to break ground were (L to R) J. David Richardson, M.D., FACS; Josef E. Fischer, M.D., FACS; William A. Liggins from Mayor Adrian M. Fenty's office; John L. Cameron, M.D., FACS; and Thomas R. Russell, M.D., FACS.

Advocacy and Health Policy, which is currently located in Georgetown, the new office will be home to the ACS's new Health Policy and Research Institute, currently located in North Carolina, and several surgical specialty societies.

The new building will allow the College to add more experts in congressional and regulatory affairs to its staff without physical restriction, and will include meeting areas large enough to host conferences sponsored by building tenants and other interested groups.

Physician Practice Survey Seeks Input From Surgeons

The results of a comprehensive multispecialty survey of America's physician practices will be used to educate national decision makers about the importance of ensuring accurate and fair representation of all physicians and patients in the development of health policy. Data from the 2008 Physician Information and Practice Expense Survey, which is being conducted by the ACS, the American Medical Association, and more than 70 other organizations, also will be used to articulate the challenges of running a practice that provides expert patient care and is financially sustainable.

The Centers for Medicare & Medicaid Services has indicated it will use the results of this study to help determine physician payment.

The survey firm, dmrkynetec, has been contacting randomly selected physicians and practice managers over the past several months to collect responses.

As of April 25, only 30% of the general surgery practices sought for participation had completed the study, whereas a much higher response rate is desirable.

Surgeons are encouraged to alert their staff regarding their willingness to participate in this confidential survey and to accept incoming calls, faxes, or e-mails from the survey firm.

If your practice has been selected to participate in this important effort and you have questions about it, please call toll-free 877-816-8940, and ask to speak with one of dmrkynetec's executive interviewers about the survey. All responses will remain confidential.

ACS Cosponsors K08/K23 NIH Supplement Awards

The ACS has announced a program that will supplement funding for up to five individuals who receive a National Institutes of Health (NIH) Mentored Clinical Scientist Development Award (K08/K23).

This award is directed at surgeon-scientists who are working in the early stages of their research careers.

The award requires cosponsorship with an approved surgical society of a period of supervised research experience for 3, 4, or 5 years that may integrate didactic studies with laboratory or clinically based research. Participating surgical societies include the American Association of Plastic Surgeons, American Head and Neck Society, American

Society of Transplant Surgeons, American Vascular Association, Society of Gynecologic Oncologists, Society of University Surgeons, and Thoracic Surgery Foundation for Research and Education.

The program helps facilitate research careers by enhancing salary support over and above that offered by the K08/K23 mechanism. Awardees must be members in good standing of the College and the cosponsoring surgical society.

Applications are due June 12, 2008; funding begins July 1, 2009. Interested individuals should submit a copy of the NIH application to the College. For more details, contact Kate Early at kearly@facs.org.

Acute Care CME Program Offered

The ACS Eastern States Committees on Trauma will host Point/Counterpoint XXVII—Acute Care Surgery June 8-11, 2008, in Baltimore. This continuing medical education program, to be chaired by L.D. Britt, M.D., MPH, FACS, will provide informa-

tion and continuing education in the area of trauma/critical care and non-trauma surgical emergencies. A maximum of 25 CME credits are offered. Details about the program can be viewed at www.facs.org/trauma/cme/pointcp.html.

Dr. Camins Selected as AANS Vice President

Martin B. Camins, M.D., FACS, was named vice president of the American Association of Neurological Surgeons at its annual meeting in Chicago in April.

Dr. Camins, a clinical professor of neurosurgery at Mount Sinai Hospital, an attending neurosurgeon at Lenox Hill Hospital, and an ACS Regent, has been a member of the AANS since 1980 and is a member of the bylaws, executive, finance, long-range planning, and professional conduct committees and the NeurosurgeryPAC Board of Directors.

After receiving his medical degree from Chicago Medical School/University of the Health Sciences in 1969, he did an internship in general surgery at New York University-Bellevue Medical Center in 1970. He completed his residency in neurosurgery at The Neurological Institute of New York, Columbia-Presbyterian Medical Center in 1975.

During his residency, Dr. Camins was an International College of Surgeons Fellow at the National Hospital for Nervous Diseases, Queens Square, London, England. After his residency, he undertook a fellowship in electron

microscopy at the department of neurosurgery, New York University-Bellevue Medical Center.

In 1994 he received the Distinguished Alumnus Award from Chicago Medical School.

Dr. Camins served on the executive committee of the Congress of Neurological Surgeons from 1985 to 1991 and was the organization's vice president in 1988. He is past president of the American Academy of Neurological Surgeons and of the New York City Society of Neurosurgeons. Dr. Camins is also a member of the administrative committee of the World Federation of Neurological Surgeons and a member of the Neurosurgical Society of America and the Society of Neurological Surgeons.

He served on the ACS Executive Committee of the Board of Governors from 1992 to 1997 and as the chair for the Advisory Council of Neurological Surgery from 1998 to 2001.

The AANS, which is dedicated to advancing the highest-quality neurosurgical care for the public, has more than 7,200 members worldwide.



MARTIN B. CAMINS, M.D., FACS

NEWS FROM THE COLLEGE

Surgeon Shares Experience in State Advocacy

BY MELINDA BAKER

Hugh Gamble II, M.D., FACS, has been an ACS Fellow since 1985. A graduate of the University of Mississippi Medical Center (where he did both his surgical internship and residencies), Dr. Gamble has held many leadership positions in the College: governor, chapter president, and chair of the Committee on Trauma, as well as his current post as a member of the Health Policy Steering Committee. In addition, Dr. Gamble is past president of the Mississippi State Medical Association, and currently he serves as the MSMA's delegate to the American Medical Association's House of Delegates.

Dr. Gamble is a thoracic and cardiovascular surgeon at Gamble Brothers & Archer Clinic, a subsidiary of Delta Regional Medical Center in Greenville, Miss. He was asked to share his experiences in advocacy in hopes of encouraging other Fellows to think about how they can assist in advocating for their profession.

How did you get involved in advocacy?

I grew up in advocacy. My grandfather, great-uncle, and father were all presidents of the MSMA. Mississippi is a relatively small state, especially for specialty societies, so most legislative activity in health care involves MSMA. My great-grandfather was also in the first candidate group of the College in 1913. I have his certificate, which is dated November 13, 1913. His brother, Paul Gaston Gamble, was initiated a few years later.

You were president of the Mississippi Medical Association during the "medical liability wars." What was that like?

Within 2 months of my becoming president of the MSMA, liability companies across the state started to increase premiums by up to 70%. Almost immediately, the amount of time required to deal with legislators, the press, and other tort reform partners increased dramatically. For almost a year, this was a second job in addition to my private practice.



HUGH GAMBLE II,
M.D., FACS

What do you see as the biggest issue affecting surgery today?

How is that different from when you began practicing?

The biggest issues today are the ones that the ACS is trying to address. Patient safety, manpower, liability, and reimbursement are always at the top of the list. These issues never change. I remember hearing discussions about all of these issues as a child at

my family dinner table. The battles end only if we allow others to make all the decisions for us.

Why should surgeons become involved in advocacy?

No one else can or will speak for us. We are the only ones with the insight to be advocates for surgical patients.

What do you think holds surgeons back from becoming involved in advocacy?

I think people, surgeons in particular, don't think they can have an impact. That's just not true. You can't always be asking for something; sometimes you just need to show up and listen. The pressures of practice, family, and personal interests all provide excuses to avoid becoming involved. "Showing up" really is 90% of the battle.

Are there any specific skills that surgeons tend to possess that make them more suited for advocacy?

Surgeons tend to be good advocates because they are able to direct their focus on specific issues. Persistence is a surgical virtue that is essential to adequately address problems that require long-term involvement.

How can chapters get more surgeons involved?

Do you have any suggestions for recruiting younger surgeons?

The major thing that chapters can do is communicate with their respective members. There are many national forums to address national issues, but individual states need to focus on their own local issues. Whether at the state or national level, the projected changes in our health care delivery system are far too important to be left to bureaucrats and politicians. Their objectives may be good, but the input of real-world practitioners is essential.

Every resident in any surgical training program should be exposed to the benefits and programs that the College offers. Program directors, local chapters, and governors should carry the message of the ACS. We should consider making every resident a member of the candidate group upon acceptance into a training program. Physicians in training need to understand that while they are primarily focused on learning their craft, the impact of outside influences can be overwhelming. If we do not speak up, others who have a stake in the health care system will move on without us. Such an occurrence will be to the detriment of our profession and our patients. ■

Ms. Baker is State Affairs Associate in the ACS Division of Advocacy and Health Policy.

First Lady of Georgia Visits ATLS Program

Sandra Elisabeth Roelofs, the First Lady of the Eurasian country of Georgia, and Georgian Embassy staff visited the College in March to meet with representatives of the Advanced Trauma Life Support program. They discussed health care in her nation and the reforms she believes are necessary.

This visit with International ATLS Director Christoph Kaufmann, M.D., FACS, and

ATLS Program Manager Will Chapleau was partially inspired by plans that are in place for ATLS to be launched in Georgia. The country's application was approved at the ATLS annual meeting, and the first site visit will take place this summer.

While visiting the College, First Lady Roelofs and her delegation were given a tour of the trauma center at Northwestern University Hospital by Michael West, M.D., FACS. Members of the delegation included Mikheil Dolidze, M.D., who is involved in establishing the first Georgian trauma center, and Levan Jugeli, M.D., who works on health initiatives with First Lady Roelofs. ■



Dr. Jugeli, Dr. Kaufmann, First Lady Roelofs, Mr. Chapleau, and Dr. Dolidze tour Northwestern's trauma center.

Scholarships Start in July For Resident Research

The Board of Regents has awarded six ACS Resident Research Scholarships for 2008. The scholarships begin July 1, 2008, and carry awards of \$30,000 for each of 2 years to encourage residents to pursue careers in academic surgery. Unless otherwise noted, scholarships are sponsored by the Scholarship Endowment Fund of the College. Recipients and their respective research projects are as follows:

Matthew Santore, M.D., resident in surgery, University of Pennsylvania, Philadelphia.

Research project: Developing effective in utero hematopoietic cell transplantation using intrathymic injection to facilitate engraftment in order to treat genetic disorders.

Sae Hee Ko, M.D., resident in surgery, University of Pittsburgh, Pittsburgh, Pa.

Research project: The role of HIF overexpression in bone marrow mesenchymal stem cells on wound healing. (Dr. Ko's scholarship is sponsored by Ethicon and will be conducted at Stanford University.)

Johannes E. Kratz, M.D., resident in

surgery, Massachusetts General Hospital, Boston.

Research project: Linking inflammation and lung adenocarcinoma: Aberrant Wnt/Shh signaling in lung cancer stem cells. (Dr. Kratz's scholarship is sponsored by Wyeth Pharmaceuticals and will be conducted at the University of California, San Francisco.)

Joshua J. Short, M.D., resident in surgery, University of Alabama at Birmingham.

Research project: Development of fluorophore labeled advanced generation pancreatic adenocarcinoma targeted conditionally replicative adenovirus (CRAd).

Sam C. Wang, M.D., resident in neurosurgery, University of California, San Francisco.

Research project: Defining the contributions of pancreatic ductal and acinar cells to tumorigenesis.

Isam W. Nasr, M.D., resident in surgery, University of Pittsburgh, Pittsburgh, Pa.

Research project: Role of tertiary lymphoid organs in chronic allograft rejection. ■

Hemodilution Technique a Plus for Liver Resection

BY BRUCE JANCIN
Elsevier Global Medical News

NEW YORK — Acute normovolemic hemodilution markedly reduced the need for blood products, compared with standard intraoperative management in a randomized trial of patients undergoing major hepatic resection.

In the 130-patient study, the red blood cell transfusion rate in patients managed with ANH was half that of patients who received standard management, Dr.

William H. Jarnagin reported at the annual meeting of the American Surgical Association.

ANH “should be used routinely when moderate to high blood loss is anticipated,” concluded Dr. Jarnagin, vice chair of surgical services and chief of the hepatopancreatobiliary service at Memorial Sloan-Kettering Cancer Center, New York.

Hepatic resection often entails major blood loss. While transfusion of allogeneic blood products can often be lifesaving, it has numerous downsides, among them in-

creased risks of blood-borne infection, acute lung injury, transfusion reactions, and immunomodulation, as well as much higher direct and indirect costs of care.

ANH is a low-tech blood conservation technique that avoids exposing patients to the risks of allogeneic transfusion while preserving blood bank supplies for the situations where they are truly needed.

ANH involves intraoperative removal of whole blood by gravity collection prior to starting the resection. The lost volume is replaced with crystalloid and colloid. That

way a smaller volume of the patient’s red blood cell (RBC) mass is lost per volume of surgical blood lost. At the end of the operation, after hemostasis is attained, the patient’s blood is transfused back.

“Compared with other blood conservation strategies, ANH has several advantages: It is technically and logistically simple; and there are minimal equipment requirements, no storage or administrative

costs, no delay in procedure scheduling, and no waste of autologous units,” Dr. Jarnagin said.

He presented a single-center prospective trial involving 130 patients undergoing resection of three or more hepatic segments who were randomized to ANH or standard intraoperative management.

In the ANH group, blood was removed

to a target hemoglobin of 8.0 g/dL. Patients had a median of 2,250 mL of blood removed; the hemodilution took 37 minutes on average to complete.

The RBC transfusion rate was 25.4% in controls and 12.7% with ANH, for a 50% reduction. Intraoperatively, a hemoglobin below 7.0 g/dL required transfusion; only 1.6% of patients managed with ANH required an intraoperative transfusion, versus 10.4% with standard management.

Historically, roughly 50% of patients at Sloan-Kettering undergoing major hepatic resection have required allogeneic transfusions. With contemporary techniques, the rate in the usual-care group in this study was just half that. “In fact, ANH was not necessary in many of our patients,” the surgeon noted.

ANH proved most useful for patients with an operative blood loss of at least 800 mL, which was actually the median blood loss in the study. Among that population, 42.4% of controls required allogeneic RBC transfusion, compared with 18.2% in the ANH group. Moreover, only 21.1% of patients in the ANH group required fresh frozen plasma, compared with 48.3% on standard intraoperative management.

Sixty-day major morbidity rates were similar at about 30% in the two study arms.

Discussant Dr. William C. Chapman, an ACS Fellow, said the well-designed study provides convincing evidence that ANH is safe and effective. As a result, ANH will be instituted at many centers in selected high-risk patients, said Dr. Chapman, professor of surgery and chief of the section of transplantation at Washington University, St. Louis.



The red blood cell transfusion rate was 25.4% in controls and 12.7% with ANH, a 50% reduction.

DR. JARNAGIN



The well-designed study provides convincing evidence that ANH is safe and effective.

DR. CHAPMAN

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For more information about SDIF, please contact Tom Kiley at 312/202-5019, tkiley@facs.org, or Savi Pai at 312/202-5056, spai@facs.org.



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4-D CT Pinpoints Parathyroid Gland Preoperatively

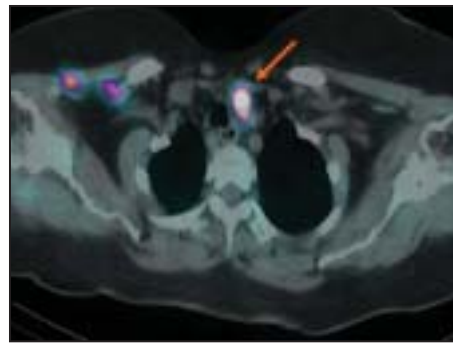
BY JEFF EVANS
Elsevier Global Medical News

HOT SPRINGS, VA. — Four-dimensional computed tomography scanning prior to reoperative parathyroid surgery may help endocrine surgeons localize the parathyroid gland amid scar tissue and distorted anatomy better than sestamibi or ultrasound imaging, according to the results of a retrospective study.

A review of 45 patients who had previous neck surgery showed that 4-D CT correctly localized hyperfunctioning parathyroid glands in 80% of the patients before their reoperation, compared with 50% for sestamibi and 21% for ultrasound, Dr. Kelly K. Hunt reported at the annual meeting of the Southern Surgical Association.

Reoperative parathyroid surgery can be more difficult than the first operation because scar tissue that forms from the previous surgery can distort the anatomy in the neck, said Dr. Hunt, an ACS Fellow who is professor of surgical oncology and experimental radiation oncology at the University of Texas M.D. Anderson Cancer Center, Houston. Reoperation also carries the risk of failing to cure the patient of hyperparathyroidism and causing morbidity from recurrent laryngeal nerve injury or hypoparathyroidism.

Four-dimensional CT scanning has the potential to improve the localization of hyperfunctioning parathyroid glands by combining 3-D CT with the fourth “dimension” of perfusion, which provides information similar to what is obtained with CT angiography. The addition of perfu-



This image was derived from fusion of sestamibi SPECT with conventional CT.

sion shows a rapid uptake and washout that are “suggestive of hyperfunctioning glands, allowing for improved localization,” said Dr. Hunt, who presented the study for the endocrine surgery group at M.D. Anderson.

The same group previously reported a sensitivity of 70% for 4-D CT in localizing the gland in the correct quadrant of the neck in a series of 75 patients with primary hyperparathyroidism. However, only 16% of the patients had undergone a reoperation (Surgery 2006;140:932-40).

To determine the ability of 4-D CT to localize hyperfunctioning parathyroid glands in patients who had previous neck surgery, Dr. Hunt and her colleagues reviewed the cases of 45 patients with a biochemical diagnosis of sporadic primary hyperparathyroidism who underwent 4-D CT before reoperative neck surgery during 2004-2007. The study included three groups: patients with prior neck surgery for reasons other than hyperparathyroidism (group 1), prior unsuccessful ex-



4-D CT imaging identified a left inferior adenoma (left image) and a right superior adenoma (right image) in this patient.

ploration of the neck for hyperparathyroidism without any removal of hyperfunctioning tissue (group 2), and prior exploration of the neck for hyperparathyroidism with resection of hyperfunctioning tissue (group 3).

The review showed that 4-D CT correctly localized hyperfunctioning glands more often than did sestamibi or ultrasound imaging. The investigators defined localization not only as the lateralization of the gland but also as the specific neck quadrant in which it was located. Four-dimensional CT correctly localized hyperfunctioning glands in 36 of 45 patients (80%), compared with 22 of 44 patients (50%) for sestamibi and 9 of 42 (21%) for ultrasound.

Four-dimensional CT proved to have significantly better overall sensitivity (88%) than did sestamibi (54%) or ultrasound

(21%). It also had the greatest sensitivity in each of the three groups.

In 42 patients with at least 6 months of follow-up data available, 39 were surgically cured of their hyperparathyroidism (21 patients in group 1, 8 in group 2, and 10 in group 3). Hypercalcemia remained in one patient in group 2 and in two patients in group 3.

Three cases of permanent hypoparathyroidism occurred in group 2, but recurrent laryngeal nerve injury was not seen in any patients.

Dr. Hunt said that patients in group 1 appear to have the best outcomes, whereas the glands in the group 3 patients were the most difficult to localize and cure. Patients in group 2 should be “approached with caution” because they appear to have a significant risk for permanent hypoparathyroidism,” she said. ■

Thyroid Uptake Helped Limit Biopsies in Multinodular Disease

BY JEFF EVANS
Elsevier Global Medical News

CINCINNATI — A thyroid uptake scan might be useful for limiting the number of biopsies that need to be taken from patients who have multinodular thyroid disease on ultrasound without any dominant pathological features, according to a small retrospective study.

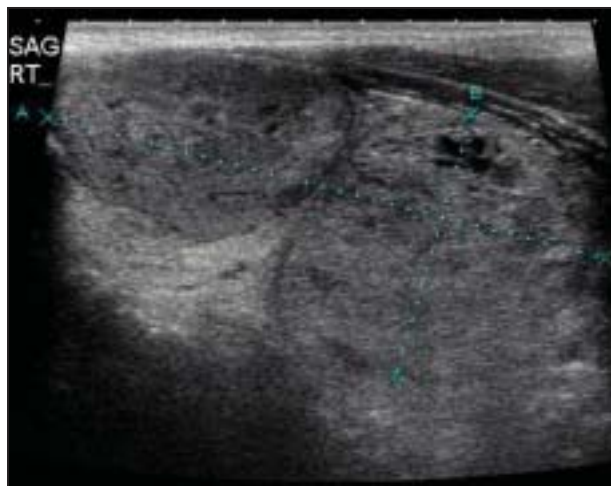
The results point out a beneficial use for thyroid uptake scanning (TUS), which has had a very limited role in the diagnosis of thyroid disease because of its inferiority to fine-needle aspiration biopsy (FNAB) in predicting the malignancy of thyroid nodules. TUS limited the number of FNABs that were necessary in 71% of patients, Dr. Scott M. Wilhelm reported at the annual meeting of the Central Surgical Association.

Incidental thyroid nodules are generally nonpalpable and are typically discovered on diagnostic radiologic procedures performed for other reasons. Many patients with incidentally discovered disease have a single nodule.

“Most of these patients really do not have previously known thyroid disease, but there is a caveat that sometimes, once a study has been done, if you palpate the neck you may actually be able to feel the nodule,” said Dr. Wilhelm, an endocrinologic surgeon in the division of surgical oncology at Case Western Reserve University, Cleveland.

These nodules are commonly evaluated by testing thyroid-stimulating hormone levels and by ultrasound imaging of the thyroid. An FNAB can then confirm if they are benign or malignant. Some clinicians advocate doing FNAB on both “warm” and “cold” nodules, recommending against TUS, especially for a solitary nodule.

“This leaves the role of thyroid uptake scanning for hyperparathyroidism and occasionally in patients with follicu-



Sagittal ultrasound of a right thyroid lobe shows two nodules, each 3.5 cm, without any worrisome features.

lar neoplasms or nondiagnostic biopsies to try to avoid a surgical procedure,” noted Dr. Wilhelm, an ACS Fellow.

But a rising number of patients who presented to Dr. Wilhelm’s clinic with incidentally discovered thyroid disease led him to try to determine whether TUS could be used to decide which nodules should be biopsied.

Ultrasound detected multinodular thyroid glands without any dominant nodule to biopsy in 14 (20%) of 71 patients who had been referred to Dr. Wilhelm’s clinic during 2005-2007 with an incidentally discovered thyroid nodule. These 14 patients had similar-size nodules without features of malignancy on ultrasound. They had an average of about five nodules; most nodules 1 cm or greater in size varied by an average of only 4 mm.

The 14 patients had ¹²³I TUS, followed by FNAB of cold

nodules. Patients with “hot” nodules, which are typically hyperfunctioning and “not overly worrisome for cancer,” were initially excluded from biopsy. If the nodules showed normal ¹²³I uptake, Dr. Wilhelm used his discretion to decide which ones to biopsy. Nonbiopsied nodules were monitored for growth that might indicate malignancy with serial ultrasounds. All surgery was based on biopsy results.

Overall, 9 patients had a cold nodule and 1 patient had a hot nodule, thereby reducing the number of biopsies performed on 10 (71%) of the patients. Of the nine cold nodules, three (33%) were malignant. Biopsies of the four patients with normal, uniform ¹²³I uptake were benign. There was about 85% correlation between the nodules biopsied on ultrasound with those seen on TUS, he said.

The three patients with malignant biopsies underwent thyroidectomy. Three of the remaining 11 patients were lost to follow-up. Another seven patients had one or two follow-up ultrasound tests (spaced about 6 months apart) without growth in any nodule. A growing nodule in the one remaining patient that had not been previously biopsied turned out to be benign.

Cold nodules detected thyroid cancer with 100% sensitivity and 45% specificity. A cold nodule gave a positive likelihood ratio of 1.83, which reflects a slight increase in the chance of a cold nodule representing cancer. A cold nodule also gave a negative likelihood ratio of zero; a negative likelihood ratio of less than 0.1 represents a large and often conclusive decrease in the likelihood of papillary thyroid carcinoma occurring, Dr. Wilhelm said.

The 33% rate of malignancy in cold nodules was higher than the traditionally expected rate of 5% seen in palpable nodules, but this might be explained by the fact that published studies have reported finding cancer in 7%-29% of incidentally discovered nodules, he said. ■

Pump Prolongs Heart Transplant Candidates' Survival

BY MITCHEL L. ZOLER
Elsevier Global Medical News

BOSTON — The continuous-flow HeartMate II left ventricular assist device was effective and generally safe during 1-year follow-up in expanded clinical experience with 279 patients.

Patients who received the HeartMate II had a 75% actuarial survival rate after 12 months, with an "acceptable risk profile," Dr. Leslie Miller said at the annual meeting of the International Society for

Heart and Lung Transplantation.

After 18 months, the actuarial survival rate was 74%, a 1% drop in survival with an additional 6 months of follow-up. Previously reported experience with the HeartMate XVE—a first-generation, pulsatile-flow left ventricular (LV) assist device—had a 69% survival rate after 12 months and a 54% rate after 18 months. The change in long-term survival between the two devices is a "dramatic difference," said Dr. Miller, chief of the integrated divisions of cardiology at Georgetown Uni-

versity and Washington Hospital Center.

Another notable finding was that the subgroup of patients who received the HeartMate II between May 2006 and March 2007 as part of a continued-access protocol had a 10% increased survival rate after 6 months and 4% greater survival after 12 months, compared with the first subgroup of patients, who received the device during March 2005–May 2006. The improved outcomes seemed linked to surgeons' increased experience with placing the device, Dr. Miller said.

The HeartMate II, approved by the Food and Drug Administration in April for use as a bridge to transplantation in cardiac transplant candidates at risk of imminent death from nonreversible LV heart failure, is a "brand new technology. This played a role in the improvement" seen with greater experience in placing the new pump, said Dr. Miller, who has received research grants and honoraria from Thoratec Corp., maker of the device.

The average age of patients receiving the axial-flow device was 55 years (range 15-70 years), and their average LV ejection fraction prior to device placement was 16%. The series included women with body surface areas as low as 1.33 m². At the time of placement, 56% were listed for a heart transplant with the United Network for Organ Sharing with a 1A status, and the

other 44% were listed with 1B status.

Once they received the device, 87% of patients were discharged from the hospital. During the year following placement, 51% of the patients subsequently received a transplant, 28% still had their device in place, and 1% recovered sufficiently to have the device removed.

Taken together, this



At 18 months, the actuarial survival rate was 74%, vs. 54% for an earlier-generation device.

DR. MILLER

meant an overall successful support rate of 80%. A total of 19% of patients died, and 1% had their axial-flow device removed and replaced with another LV assist device.

The patients who received a device had, on average, a nearly 10-fold increase in their 6-minute walk distance by 6 months after placement, compared with their baseline performance. Also by 6 months, 83% of patients had improved to New York Heart Association class 1 or 2 heart failure.

Adverse events included bleeding that required surgical intervention in 26% of patients and infections in 30%. "Infection remains a substantial cause of death" in patients getting the device, Dr. Miller said. But significant bleeding episodes were reduced by about two-thirds, and the rate of strokes and other neurologic events was reduced by more than a third, compared with patients who received pulsatile-flow devices. Device-related infections occurred in 15%, but pump-pocket infections occurred in 1%, also an improvement over the rate seen with pulsatile-flow devices.

"At this point, the HeartMate II appears to offer significant advantages over the HeartMate XVE," said Dr. Fred A. Crawford Jr., an ACS Fellow who commented on the study. Dr. Crawford, chair of the surgery department at the Medical University of South Carolina, Charleston, said that the intermediate term durability of the HeartMate II has been excellent, and suggested that "perhaps it will have its greatest impact as a destination therapy device, eventually replacing the HeartMate XVE, which has been limited to larger adults because of its size." ■

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Burn Patients May Benefit From Insulin Therapy

BY JEFF EVANS
Elsevier Global Medical News

CINCINNATI — Control of blood glucose levels through intensive insulin therapy has been shown to reduce morbidity in both surgical and medical ICU patients, as well as mortality in surgical ICU patients. Results of a retrospective study now suggest that implementation of this therapy in burn patients may reduce the rate of infectious complications but not mortality.

Maintaining mean blood glucose levels of less than 140 mg/dL reduced the rate of pneumonia, ventilator-associated pneumonia, and urinary tract infections in 71 burn patients who received intensive insulin therapy, compared with 81 burn patients in the same ICU during the year before the protocol was implemented, Dr. Mark R. Hemmila said at the annual meeting of the Central Surgical Association.

But some discussants at the meeting questioned whether certain weaknesses in the study's design and differences in patient characteristics may have contributed to its results.

During the first year of an intensive insulin therapy protocol (July 2005 to June 2006), Dr. Hemmila and his colleagues at the University of Michigan, Ann Arbor, sought to bring burn patients' blood glucose levels to less than 140 mg/dL. In the previous year (July 2004 to June 2005), burn patients whose blood glucose levels exceeded 150 mg/dL had received an insulin drip protocol.

The patients in each group had a mean age in the early 40s, and close to three-fourths in each group were men. The investigators excluded patients with concomitant trauma and burn injuries or desquamating skin diseases.

The control and intensive insulin therapy groups had similar blood glucose levels upon admission (142 mg/dL vs. 130 mg/dL, respectively) and in terms of daily average (135 mg/dL vs. 129 mg/dL) as well as overall mean during their hospital stay (127 mg/dL vs. 126 mg/dL). The intensive insulin-treated and control groups each spent a similar percentage of time in the hospital with a mean daily blood glucose level greater than 140 mg/dL (22% vs. 35%, respectively). But compared with the control group, patients who were treated with intensive insulin therapy spent significantly less time in the hospital with a maximum mean daily blood glucose level greater than 200 mg/dL (11% vs. 17%).

In multivariate analyses that adjusted for age, gender, the percentage of total body surface area burned, and inhalation injury, adding intensive insulin therapy did not significantly improve the outcomes obtained in burn patients in the year before the therapy was implemented. There were no improvements in mortality (7% vs. 9%, respectively), among intensive insulin vs. control patients), mean length of stay in the ICU (5 vs. 9 days), mean length of stay in the hospital overall (10 vs. 17 days), and mean number of days requiring ventilation (3 vs. 6 days).

But intensive insulin therapy significantly reduced rates of pneumonia overall (16% vs. 37%), ventilator-associated pneumonia (10% vs. 31%), and urinary tract infection (6% vs. 22%).

The odds of developing infection were more than 11 times higher in patients with a maximum mean glucose of greater than 140 mg/dL than in those with a maximum blood glucose level of 140 mg/dL or less. Of the patients with maximum blood glucose levels higher than

140 mg/dL, 61 had an infection and 32 did not, whereas those with blood glucose levels of 140 mg/dL comprised 6 with infection and 53 without. Based on these values, a maximum blood glucose level greater than 140 mg/dL predicted the development of infectious complications with 91% sensitivity and 62% specificity, said Dr. Hemmila, an ACS Fellow.

"Measurement of a blood glucose level greater than 140 mg/dL should heighten the clinical suspicion for presence of an infection in patients with burn injury," he said.

Dr. Peter J. Fabri of the University of South Florida, Tampa, a discussant at the meeting, noted a recent study suggesting that the complication rate of tight blood glucose control may actually negate its benefits (N. Engl. J. Med. 2008;358:125-39). "We have to be very careful being critical when we look at these studies," said Dr. Fabri, an ACS Fellow. "It's very rare that one thing is the only thing that changes in a busy, successful critical care unit over a 2-year period of time."

Dr. Fabri said that the median length of stay was 4 days in the intensive insulin group and 12 days in the control group, which "suggests that there may, in fact, be other changes that are going on getting patients out of the unit quicker." He also noted that the control group had a (non-significant) higher incidence of inhalation injury than did the intensive insulin-treated group (37% vs. 31%), as well as a higher rate of second- and third-degree burns. Dr. Hemmila said he was unaware of any particular ICU protocol changes that were made during the study period.

Other discussants commented that the average total body surface area of the burns was small (19% in controls and 15% in intensive insulin-treated patients).

Dr. Hemmila and some of the discussants noted that the "chicken or the egg" question of what came first—hyperglycemia or infection—is still unresolved. ■



A blood glucose level greater than 140 mg/dL should raise suspicion for an infection in burn patients.

DR. HEMMILA

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Guidelines Allow DCIS Patients to Opt Out of Radiation

BY FRAN LOWRY
Elsevier Global Medical News

HOLLYWOOD, FLA. — All women with ductal carcinoma in situ should have the choice of foregoing radiation therapy, according to updated breast cancer guidelines announced at the annual conference of the National Comprehensive Cancer Network.

Previously, the guidelines distinguished between the majority of women who have a typical ductal carcinoma in situ (DCIS) and those few women who have a very small DCIS that is less than 0.5 centimeters, unicentric, and of low grade, said Dr. Stephen B. Edge.

For that small subset of women, the guidelines had stipulated treatment by lumpectomy alone with omission of ra-

dations about postmastectomy radiation, an issue neglected in past years.

The breast cancer guidelines committee now urges the use of radiation therapy for women who have 1-3 positive nodes. The committee stopped short of making this a category 1 recommendation.

“Previously we said that patients should consider this, but now we’ve gone so far as to say that women should strongly consider radiation therapy after mastectomy,” Dr. Edge said.

Also new are recommendations on the

use of breast reconstruction. The guidelines now warn that reconstruction has the potential to affect delivery of radiation therapy.

In one study (Int. J. Radiat. Oncol. Biol. Phys. 2006;66:76-82), 52% of women who received radiation after reconstruction had some compromise in the application of radiation, either in terms of the field or the dosing to underlying structures.

“Consideration of this must be brought to the patient’s attention,” Dr. Edge said.

In general, women undergoing autolo-

gous tissue reconstruction should strongly consider delaying reconstruction until after radiation, because reconstruction before radiation may lead to a worse cosmetic outcome.

For women who are undergoing implant reconstruction, the guidelines advise that reconstruction before radiation can spare expansion of nonirradiated skin, but they also caution that radiation may lead to capsular contraction.

Dr. Edge said he had no financial conflicts of interest to disclose.

THE ONUS IS ON THE PHYSICIAN TO DISCUSS WITH THE PATIENT WHETHER TO CHOOSE RADIATION THERAPY FOR DCIS.

diation therapy. It was recommended that all other women with DCIS were to be treated with total mastectomy without lymph node dissection or by lumpectomy plus radiation therapy.

The updated guidelines incorporate lumpectomy without radiation therapy as an option for all women with DCIS. “This is a major change,” announced Dr. Edge, interim chair of the department of surgical oncology, and chair of the department of health services and outcomes research at Roswell Park Cancer Institute in Buffalo, N.Y.

The three treatment options for early stage DCIS with no nodal involvement now comprise the following:

- ▶ Lumpectomy without lymph node surgery, plus whole breast radiation therapy (offered as a category 1 recommendation).
- ▶ Total mastectomy with or without sentinel node biopsy, and with or without breast reconstruction.
- ▶ Lumpectomy alone, with no lymph node surgery and no radiation therapy (offered as a category 2b recommendation).

The new guidelines place the onus on the physician to have an appropriate discussion with the patient as to whether or not to choose radiation therapy for DCIS, said Dr. Edge, who is also a professor of surgery at the State University of New York at Buffalo.

The guidelines also make recommen-

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.

WARNINGS

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 ^d	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 cSSSI 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 including 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 cSSSI, 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 therapy 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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TYGACIL

A POWERFUL PARTNER

A first-in-class antibiotic

- Expanded broad spectrum of in vitro activity against many gram positives, gram negatives, anaerobes, and methicillin-resistant *Staphylococcus aureus* (MRSA)^{1*}

Simplified empiric management of polymicrobial infections

- No dosage modifications necessary for patients with renal impairment¹
- Low potential for drug interactions—not metabolized by, and does not inhibit or induce, cytochrome P450¹

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*

***The clinical significance of in vitro activity is unknown.**
www.TYGACIL.com

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.



Tygacil[®]
tigecycline IV

Reducing treatment complexity