New Tool May Aid In Comparison of Hospital Outcomes

Risk index is available in public domain.

BY JANE ANDERSON
Elsevier Global Medical News

A research team based at the Cleveland Clinic has released a new risk assessment tool designed to allow fair comparison of hospital outcomes across institutions. The tool provides a reliable way for hospitals to predict length of stay and mortality for surgical patients using only administrative data, the researchers said.

The tool, called the Risk Stratification Index, is in the public domain. It was detailed in the journal Anesthesiology in November (Anesthesiology 2010;113:1026-37), and the Cleveland Clinic currently uses it to stratify risk in its internal outcomes analyses, according to Dr. Daniel Sessler, lead author of the article and chair of the department of anesthesiology.

"Hospitals are already being compared," Dr. Sessler said in an interview. "But comparisons only make sense after adjusting for baseline and the risk associated with different operations. Our Risk Stratification Index allows for an accurate and fair comparison among hospitals using only publicly available data."

Dr. Sessler said it was necessary to develop a new risk assessment tool because institutions use various systems to evaluate outcomes, and many of these systems are proprietary and nontransparent.

"Available systems are either inaccurate or require special clinical data that are not generally or publicly available," he said, adding that the Risk Stratification Index is "reasonably reasonable, according to Health and Human Services Secretary Kathleen Sebelius. The effort will be conducted in collaboration with the states."

The initial threshold for review is set at 10% for next year. Ms. Sebelius said that the states will have the responsibility to keep insurance rates in check, and that the federal government is "not going to be sitting on state commissioners' shoulders and question what it is that they're doing."

Feds Want Transparent Insurance Costs

BY NASEEM S. MILLER
Elsevier Global Medical News

In an effort to control rising health insurance rates and to bring transparency to the market, the federal government has proposed rules requiring insurers to publicly disclose and justify large rate increases.

Beginning this year, proposed rate increases of 10% or more are to be publicly disclosed and reviewed to determine if the rate increase is reasonable, according to Health and Human Services Secretary Kathleen Sebelius. The effort will be conducted in collaboration with the states.

The initial threshold for review is set at 10% for next year. Ms. Sebelius said; however, starting in 2012, the states will set their own thresholds based on data and trends they gather. If a state is unable to do so, the proposed rule allows the HHS to do so.

Beginning in 2014, the states will be able to exclude from the new health insurance exchanges any health plans that show a pattern of excessive or unjustified premium increases.

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Over the past decade, the average health insurance premiums for family coverage have risen 131%, according to the HHS. Some states such as Connecticut and Rhode Island already have the power to review and reject excessive rate increases, but not all, and some lack the legal authority or resources to do so.

“The proposed rate review policy will empower consumers, promote competition, encourage insurers to do more with existing health care costs and disease, and allow consumers from charging premiums which are unjustified,” Jay Angoff, director of the HHS Office of Consumer Information and Insurance Oversight, said in a statement.

The Affordable Care Act makes $250 million available to states to take action against insurers seeking unreasonable rate hikes, and so far $46 million has been awarded to 45 states and the District of Columbia for improving oversight of health insurance rate increases, according to the HHS.

The proposed rules will also work in conjunction with medical loss ratio regulations, which were released in November. In a statement, Karen Ignani, president and CEO of the insurance trade group America’s Health Insurance Plans, said, “while the proposed rules give consideration to the impact of rising medical costs, it also establishes a threshold for review that is incomplete because it does not adequately factor in all of the components that determine premiums, including the cost of new benefit mandates and the impact of younger and healthier people dropping coverage. Premium review must consider the unique circumstances of small employers that are struggling to afford coverage for their employees, and of the individual market in which people are moving in and out of coverage depending on whether they anticipate needing medical services.” She added, “It is also important to remember that the new federal law already caps health plans’ administrative costs and profits. We welcome the opportunity to submit comments on this proposed rule.”

A final rule could be issued in 6 months. For more information, visit www.hhs.gov/octi.html.

Insurance Costs

WASHINGTON – Health care spending growth at its slowest rate in 50 years in 2009, as the recession caused Americans, especially those with lower incomes and less insurance coverage, to cut back on their use of physician, hospital, and other health services, according to a report issued by federal analysts.

The data indicated that Americans significantly reduced their physician office visits in 2009.

The overall 4% rate of health spending growth followed an increase of 4.7% in 2008. In 2009, the nation’s total health tab topped $2.4 trillion, or $8,086 per person, according to the annual analysis of a federal data set called the National Health Expenditures Accounts by CMS.

The analysts found that even with a low rate of health care spending growth, spending remained increased as a share of the nation’s gross domestic product. Health care costs accounted for 17.6% of the GDP, up a record 1% from the previous year. The recession depressed spending, which was 15% of the GDP, and thus allowed health care to gobble up a larger share, said the federal analysts at a press briefing announcing their findings.

The analysis was published in the journal Health Affairs (2011:11-22 [doi:10.1377/hfaff.2010.1032]).

The economists and statisticians painted a picture of a nation stunned by job loss and declining incomes. In the past, there has been a lag between a recession and any impact on health costs, largely because it has been thought that people will always need health care, Anne Martin, an economist at the HHS Office of the Secretary, said.

But in 2009, the impact was almost immediate, Ms. Martin said.

Seventy-one percent of the nation’s health spending was covered by insurance from private or public payers, according to the report.

Medicare spending remained steady from 2008 to 2009, but there was a large reduction in spending by private insurers. The government analysts said that this was due in part to a reduction in private coverage. They estimated that private insurance enrollment declined by 4.1%.

Medicaid, on the other hand, saw its rate of spending grow by 4%, in part offsetting the slowdown by other payers, said Ms. Martin. More children and working-age adults enrolled in Medicaid as the economy continued to flatten, she said, and also because of provisions of the stimulus bill, or American Recovery and Reinvestment Act. There was a 7.4% increase in enrollment in 2009, compared with a 3% increase in 2008.

The federal government bore most of the burden for the spending increase, she said.

Americans also vastly curbed their out-of-pocket spending on health – another reflection of the poorly performing economy, the federal analysts noted.

Hospital care continues to be the largest segment of health spending. At $760 billion, it accounted for at least a third of the nation’s health bill. Medicaid’s spending growth accelerated from 1993 to 1999, in part because enrollees used emergency departments for primary care, said the analysts.

Pharmaceutical spending was the second-biggest category, at $505 billion in 2009. The 4% increase from 2008 was the slowest rate of growth since 1996 – partly a result of fewer Americans going to see the doctor. The analysts cited data showing that 36% of Americans said they had fewer health professional visits in 2009, and 59% of that group said the visit they’d skipped was with the primary care physician.

Instead, they might have gone to outpatient or retail clinics, according to the report. Spending for “clinical services,” which is included in the physician services category, grew at double the rate of all physician spending, according to the report. The analysts wrote that the growth is “consistent with recent reports that retail clinics (a subset of all clinics) have increased in popularity because of their convenience and costs.”

Finally, prescription drug spending, which reached $210 billion, grew 5.3% in 2009, compared with the 3.1% growth rate in 2008.
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1. 2009 Ventral Hernia Market Tracking Study, n=200, based on evaluation of 10 brands
2. 2009 Ventral Hernia Market Tracking Study, n=200, based on evaluation of 10 brands
4. Data on file (in vitro tests)

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Hospital Outcomes Comparison

New Tool • from page 1

Stratification Index (RSI) is more accurate than other generally available nonproprietary systems, and uses only publicly available information. To develop the index, Dr. Sessler and his colleagues used more than 35 million patient stay records from 2001 to 2006 Medicare Provider Analysis and Review files, randomly choosing them into development and validation sets. RSI lengths for length of stay and mortality end points were derived from aggregate risk associated with individual diagnostic and procedure codes.

Next, the researchers tested performance of the RSI prospectively on the validation database, as well as on a single-institution registry of 103,324 adult surgical patients, and compared the results with an index designed to predict 1-year mortality.

The researchers found that the risk stratification model accurately predicted 30-day and 1-year postdischarge mortal- ity, while separate risk stratification models predicted length of stay and in-hospital mortality. The risk predic- tions are accurate for as few as 2,000 patients, meaning the system can be used effectively by small hospitals.

“RSI is a broadly applicable and robust system for assessing hospital length of stay and mortality for groups of surgical patients based solely on administrative data,” Dr. Sessler and his colleagues concluded in their article.

The research team wanted to make the RSI available to any hospital that wants to use it, so it put it in the public domain, Dr. Sessler explained. He anticipates that it will be adopted rapidly because it’s objective, transparent, requires only billing codes, and is free to use. Details of how to use the system and sample files are available at www.clevelandclinic.org/RSI.

The tool shows good promise but also has some drawbacks, noted Dr. Charles Mabry, an ACS Fellow from the University of Arkansas in Pine Bluff, in an interview. “Like many risk adjustment methods, this relies upon the administrative data set, which is submitted with hospital bills to insurers. As such, many clinical factors, such as weight, blood pressure, drugs used, socioeconomic status, etc., aren’t reported, and thus are unavailable to help with risk stratification.”

For large numbers of patients, the administrative data set can help reveal major differences in such factors as treatment and medications, Dr. Mabry said. However, for smaller numbers of patients – for example, the number in a group that had one particular surgical procedure – it becomes weaker, he said.

Other large organizations, along with Medicare and Medicaid Services, already are using the administrative data set for their own risk-adjusted payment codes. However, the Physician Quality Reporting Initiative (PQRI) primarily measures process as opposed to outcomes, Dr. Mabry said. “I think PQRI is a waste of time and effort,” he said. “Many feel that outcomes measurement is really what we need to be aiming for, rather than process compliance.”

Dr. Chad Rubin, an ACS Fellow and general surgeon in Columbia, S.C., agreed that the Risk Stratification Index is limited through its use of the administra- tive data set. “While it appears to be a useful tool, I am always reticent to give credence to something so important as hospital (and maybe doctor) outcomes when the original data may be flawed,” he said in an interview.

NSQIP meanwhile, “may be more relevant to quality. For instance, the definition of skin and soft tissue infection, while a very common diagnosis/com- plication, varies widely in the claims data but has a strict definition by NSQIP.” Dr. Rubin said. “While NSQIP is expensive (both the enrollment and PTU required), it depends on the quality of the data as to whether it is too re- source-intensive. I’m sure hospitals have spent a lot more on SCIP (Surgical Care Improvement Project) than on NSQIP for a lot less improvement in quality.”

NSQIP remains the gold standard, Dr. Rubin said. “The use of good clinical data carefully collected and carefully risk-adjusted is, in my opinion, the way to go,” he said. “I’m worried that lesser claims data will not be accurate but will be acted upon as if it were.”

Dr. Sessler said he agrees that the NSQIP registry is a valuable resource, but notes that it applies to a limited number of hospitals, and fewer than 1% of U.S. surgical patients.

“Specially trained nurses must ab- stract clinical details from the records of each NSQIP patient,” he said. “Because NSQIP applies to so few patients in so few hospitals, it cannot be used to compare hospital performance.” In contrast, he said, the Risk Stratification Index can be used for all patients and all hospitals.

Circulating Tumor Cells Prognostic in Early Breast Cancer

BY BRUCE JANCIN
Elsevier Global Medical News

SAN ANTONIO – The presence of even a single circulating tumor cell in a 23-mL sample of peripheral blood taken prior to chemotherapy for early breast cancer predicts significantly higher 3-year rates of recurrence, distant metastasis, and all-cause mortality, according to a prospective German study.

Circulating tumor cells (CTCs) are thus clearly an independent marker of prognosis in patients with early breast cancer. But it’s decidedly not yet time to start looking for CTCs in such patients outside of clinical tri- als, Dr. Brittgte Rack stressed at San Antonio Breast Cancer Symposium.

The Veridex CellSearch CTC detection technology used in this study was approved by the Food and Drug Administration for patients with metastatic breast cancer, but before it can reasonably be applied in early breast cancer, it will be necessary to await results of ongoing or planned clinical trials that were designed to show whether counting CTCs actually affects outcomes, either by serv- ing as an early predictor of treatment efficacy or by permitting individualized therapy based upon phenotyping of the minimal residual disease that’s escaping treatment, explained Dr. Rack, head of the department of gynecologic oncology at the Women’s Hospital of Ludwig-Maximilians University of Munich.

She presented the first results of serial blood sampling for CTCs in the SUCCESS trial, a 241-center, German phase III randomized trial. All participants had stage I-III breast cancer and required chemotherapy because of positive lymph nodes or other high-risk features.

One or more CTCs were found in a 23-mL sample of peripheral blood in 21.5% of 2,026 patients follow- ing complete tumor resection but prior to che- motherapy. These patients fared significantly worse over the next 3 years than did patients with no CTCs. (See box.)

Far fewer CTCs are present in patients with early breast cancer than in those with metastatic disease. For that reason, the investigators took a blood sample that was three times larger than the sample taken when CellSearch is used in patients with metastatic disease. Then the researchers used an enrichment procedure to reduce the five 7.5 mL blood samples that were required for the system’s automated preparation and analysis.

CTC-positive patients had a median 1.3 cells per sam- ple. Only 2.3% of subjects had six or more CTCs. The more CTCs a patient had prior to chemotherapy, the greater the negative downstream impact. In terms of dis- ease-free survival, for example, multivariate analysis showed that patients with one or more CTCs were 1.9-fold more likely to experience disease recurrence than were those with no CTCs, whereas patients with two or more CTCs were at 2.8-fold greater risk than were those with zero or one CTC. Women with five or more CTCs were at four- fold increased risk, compared with those who had zero to four CTCs.

In the SUCCESS trial, blood sampling for CTC detection is also being conducted after chemotherapy and after 2 and 5 years of endocrine/zoledronic acid therapy. The investiga- tors anticipate reporting on the prognostic impact of postchemotherapy CTCs next year.

Dr. Rack and coworkers also have launched SUCCESS-C, a follow-up study in which CTC counts will be used to prospectively guide treatment in women with postmenopausal hormone receptor-positive breast cancer.

In a conference-closing review of the past year’s major developments in translational breast cancer research, Dr. Mitchell Dowsett singled out the SUCCESS investigators for showing that CTCs ex- ist in early breast cancer and are clinically meaningful in terms of outcome. Put the reproducibility of the CTC detection system in the setting of early breast can- cer hasn’t been established, and that’s a critical issue for a testing method that hinges upon the presence or absence of a single cell in 23 mL of blood.

“Before we take this forward for use in monitoring or changing therapy we need to know about the reproducibility of this methodology,” said Dr. Dowsett, pro- fessor of translational research at the Breakthrough Breast Cancer Center and Royal Marsden Hospital, London.

Dr. Rack disclosed that she receives grant support from Veride and is a speaker for Chugai and Sanofi- Aventis.

Prognostic Relevance of Circulating Tumor Cells in Early Breast Cancer

Dr. Rack et al. demonstrated that the presence of CTCs is highly predictive of disease-free survival and distant disease-free survival, as compared with patients with no detectable CTCs.

Note: These 3-year rates are based on a study of 2,026 patients. Source: Dr. Rack.
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1. 2009 Vental Hernia Market Tracking Study, Millennium Research Group (n=200), based on evaluation of 10 brands.
2. IMS Data Sept-Nov 2009 & LifeCell™ TTR Analysis

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Early Data on Dual Anti-HER2 Therapies Look Promising

BY BRUCE JANCIN
Elsevier Global Medical News

SAN ANTONIO – The combination of two anti-
HER2 therapies, together with chemotherapy, may be
markedly better than one, according to watershed
randomized clinical trials presented at the San Anto-
nio Breast Cancer Symposium.

“This is data that is preliminary; it’s not to be used
today in practice. But this is the way things are
going to go,” predicted Dr. Jose Baselga, chief of hemato-
logy/oncology at Massachusetts General Hospital, Boston,
and professor of medicine at Harvard Medical
School and the Autonomous University of
Barcelona.

He presented the results of the Neo-ALTTO trial, a
phase III, open-label, triple-arm study that ran-
odomized 455 women with HER2-positive early breast
cancer to 18 weeks of neoadjuvant anti-HER2 ther-
apy with trastuzumab (Herceptin), lapatinib (Tykerb),
or both. After the first 6 weeks of anti-HER2 thera-
py, 12 weeks of paclitaxel was added to each study
arm prior to surgery.

Pathological complete re-
response (pCR), which was the primary study end point, oc-
curred in 73.3% of patients in the lapatinib/paclitaxel arm,
29.5% in the trastuzumab/pa-
clitaxel arm, and a signifi-
cantly higher 51.3% in the
trastuzumab/paclitaxel
arm.

Grade 3 or worse adverse events occurred most
frequently in the two lapatinib-containing arms.
The most common of these was grade 3 or higher
diarrhea, which occurred in 21% of the dual anti-
HER2 group, 23% in the lapatinib arm, and just 2%
in the trastuzumab arm. Grade 3 or higher hepa-
totoxicity occurred in 9% on dual anti-HER2 therapy,
13% on lapatinib, and 1% on trastuzumab. Grade 3 or
higher granulocytopenia and skin rash followed the
same pattern.

Largely as a result of toxicities, 39% and 34% of pa-
tients in the dual anti-HER2 and lapatinib arms, re-
spectively, didn’t complete neoadjuvant treatment as planned. This was the case for only 8% in the
trastuzumab arm.

Based upon the success of Neo-ALTTO, Dr. Baselga
and coinvestigators have launched the companion
ALTTO trial. Nearly 8,200 of a planned 8,400 patients
with HER2-positive breast cancer have been enrolled
in the trial, which will feature four adjuvant therapy
arms: lapatinib, trastuzumab, both agents, and se-
quential trastuzumab followed by lapatinib. Study end
points will include overall and disease-free survival.

Although no statistically significant pCR rate differen-
tials were observed, the combination of trastuzumab/
paclitaxel, compared with lapa-
tinib/paclitaxel, didn’t achieve statistical significance in Neo-ALTTO, it did in another randomized trial that was presented during the same session. Dr. Michael Untch of the Helios Clinic in Berlin pre-
sented the results of the phase II GeparQuinto study
led by the German Breast Group, in which 620 pa-
tients with HER2-positive primary breast cancer were
randomized to neoadjuvant therapy with either trastuzumab/ paclitaxel, both given in conju-
cation with neoadjuvant anthracycline/taxane-based
chemotherapy.

The pCR rate (defined as no invasive or noninvasive
residual disease in the breast or nodes) was 31.3% in the
tрастузумаб-лапатиниб therapy arm, compared with
21.7% with lapatinib/chemotherapy (P < .05). These
study results prompted extensive discussion
during the conference. Dr. Eric P. Winer served as for-
mal discussant of Neo-ALTTO, GeparQuinto, and a
third neoadjuvant trial – NeoSphere – in which doc-
texel plus dual anti-HER2 therapy with trastuzum-
ab and the investigational agent pertuzumab produced a significantly higher pCR rate than did do-
cetaxel plus either anti-HER2 biologic agent alone.

Dr. Winer argued that even though Neo-ALTTO is a
phase III trial, he doesn’t consider pCR rate an ap-
propriate end point for drug approval or change in
clinical practice. As a surrogate for the key end points
of overall and disease-free survival, pCR simply isn’t
reliable enough, he said. A classic case in point was
the NSABP (National Surgical Adjuvant Breast and
Bowel Project) B-27 trial, in which a doubling of the
pCR rate didn’t lead to improvement in overall or
disease-free survival.

“In my view, the combination of trastuzumab, la-
patinib, and paclitaxel looks like a regimen of great
interest. It’s not ready for adjuvant therapy. It isn’t
ready for neoadjuvant therapy outside of a clinical tri-
al. But we all eagerly await the results of ALTTO,” said Dr. Winer, director of the breast oncology center at the Dana-Farber Cancer Institute and professor of medicine at Harvard Medical School, both in Boston.

As for trastuzumab vs. lapa-
tinib as single-agent anti-HER2 neoadjuvant therapy in con-
junction with neoadjuvant
chemotherapy, the evidence
from Neo-ALTTO and GeparQuinto makes it “hard
to escape the conclusion that [the combination of] la-
patinib and chemotherapy is a little less active and a
little more toxic than trastuzumab and chemothera-
py,” the oncologist observed.

Dr. Baselga later commented that clinical practice
in the management of metastasis HER2-positive
breast cancer could change as early as next year, when the results of the Neo-ALTTO trial are due
to be reported. That study is comparing first-line ther-
apy with trastuzumab plus docetaxel vs. trastuzum-
ab, pertuzumab, and docetaxel.

In a plenary lecture, Dr. Neil L. Spector of Duke University argued that anti-HER2 Drugs are better than one, it’s entirely possible that
total blockade may be feasible, but we’re going to
total blockade of HER2 via triple therapy with
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Mortality of Critical Care Patients Not Linked to Poverty

BY DOUG BRUNK
Elsevier Global Medical News

SAN DIEGO – There is no apparent relationship between the neighborhood poverty rate, based on patient address, and mortality following critical care, results from a large, 10-year analysis showed.

“Our findings are in contrast to data in other arenas of health care that have established an inverse relationship between socioeconomic status and mortality,” Sam Zager said at the annual congress of the Society of Critical Care Medicine.

“The few studies that examine economic disparities and mortality in the critically ill are contradictory.”

Using 1990 census and hospital administration data, Mr. Zager, a fourth-year student at Harvard Medical School, Boston, and his associates performed an observational study of 18,917 patients aged 18 years and older who received critical care at Brigham and Women’s Hospital and Massachusetts General Hospital, both in Boston, in 1997-2007.

Neighborhood poverty rate was defined as the percentage of each neighborhood’s residents with incomes below the federal poverty line, categorized as 5%-10%, 10%-20%, 20%-40%, or greater than 40%.

The researchers used logistic regression to examine the rate of death by day 30, day 90, and day 365 post ICU, as well as in-hospital mortality, and adjusted the data for age, sex, race, admission year, patient type (medical vs. surgical), Charlson-Deyo index, sepsis, CABG, myocardial infarction, hematocrit, white blood cell count, creatinine, and blood urea nitrogen.

Mr. Zager and his colleagues also performed a sensitivity analysis for 1-year postdischarge mortality among patients discharged to home, as well as mortality among patients who lived less than 50 miles from the hospital of care.

The mean age of patients was 62 years, 42% were women, and 78% were white. After multivariable adjustment of the data, Mr. Zager and his associates found no statistically significant relationship between neighborhood poverty rate and all-cause 30-day mortality.

The odds ratio was 1.05 for those who resided in neighborhoods in which 5%-10% of residents lived below the federal poverty line ($P = .2$), 0.96 for those who resided in neighborhoods in which 10%-20% of residents lived below the federal poverty line ($P = .5$), 1.08 for those who resided in neighborhoods in which 20%-40% of residents lived below the federal poverty line ($P = .2$), and 1.20 for those who resided in neighborhoods in which more than 40% of residents lived below the federal poverty line ($P = .2$).

Similar nonsignificant associations were observed for 90-day and 365-day mortality post ICU admission and for in-hospital mortality.

In addition, neighborhood poverty rate was not significantly associated with 1-year postdischarge mortality in patients who were discharged to home or in patients who resided less than 50 miles from the hospital of care.

Mr. Zager also reported that patients from neighborhoods in which 20% or more of residents lived below the federal poverty line were more likely to be black, Hispanic, or young; to have a hematocrit of less than 36%; and to live 5 miles or less from the hospital.

He acknowledged certain limitations of the study, including its observational design and the fact that the researchers were unable to fully exclude patients who received critical care only in the emergency department.

Also, “our study focuses on neighborhood poverty at the time of critical care initiation, which may not fully reveal the contribution of socioeconomic status to mortality risk,” he said.

The study was supported by the National Institutes of Health. The researchers said that they had no relevant financial conflicts to disclose.

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Hernia Repair

Continued from page 1

Hernias, return to the hospital or operating room, and mortality.

A quarter of the cohort (36%) required a subsequent abdominal operation. Most of these (65%) were redo hernia repairs, complications from hernia repair, or another procedure combined with a hernia repair. The remainder were other abdominal procedures – including small bowel, colorectal, biliary, gastric, or duodenal – or esophageal, urologic, or gynecologic procedures.

Most subsequent procedures (77%) were elective. The remainder were emergent repairs, which were significantly more common in patients undergoing a redo hernia repair that had been done with absorbable or biologic mesh.

About one-third of the subsequent procedures (38%) showed extensive or difficult adhesions. The rate of enterotomy or unplanned bowel resection was 10%, as was the necessity of removing the initial repair mesh. The mean operating time was 126 minutes, and the postoperative length of stay averaged 4 days.

Postoperative morbidity included surgical site infections (6%), return to the OR within 30 days (9%), and hospital readmission within 30 days (13%). There were 16 deaths within 30 days of the admission.

The study found no significant associations between any characteristics of the initial hernia repair (mesh position or type) when difficult or extensive adhesions were involved. However, the need for mesh removal was significantly associated with both open and laparoscopic placement of expanded polytetrafluoroethylene (ePTFE) mesh (24% and 16%, respectively). The rate of unplanned enterotomy or unplanned bowel resection did not differ significantly, regardless of mesh positions or types (ePTFE, polypropylene, or absorbable/biologic meshes). A multivariate analysis found that the most important factors influencing risk for enterotomy or bowel resection were older age (odds ratio 1.04) and previous incisional hernia repair, which was associated with more than a fourfold increased risk of enterotomy or bowel resection. Both associations were statistically significant.

Operative time was used as a surrogate for the difficulty of the operation. "We found that after adjusting for patient variables, those with an overlay or inlay polypropylene or biologic mesh had significantly longer operative times," during the subsequent surgery, Dr. Hawn said.

A multivariate analysis found that the mean operative times were 176 minutes for underlay mesh, 207 minutes for inlay mesh, and 143 minutes for onlay mesh. Absorbable/biologic meshes required a mean operating time of 190 minutes – significantly shorter than the time needed to place polypropylene or ePTFE mesh.

The indication for the subsequent operation also significantly affected operating time. A nonincisional hernia repair (mean 212 minutes) took significantly longer than either a redo of an incisional hernia repair (139 minutes) or a redo hernia repair plus another procedure (159 minutes). Although Dr. Hawn did not provide specific data, he said that, compared with polypropylene, ePTFE mesh that had been applied in an open repair had a significantly higher explantation rate, a lower operative time, and a similar enterotomy rate.

In laparoscopic repair, ePTFE had a lower rate of explantation than did polypropylene, but this finding could have been confounded because of the low number of patients whose index hernia was laparoscopically repaired.

"Also, the patients selected for laparoscopy during that initial operation probably had less of a chance of having had prior surgery, so less of a chance of adhesions," she said.

Discussant Dr. Todd Hemiford, an ACS Fellow with the Carolinas Medical Center, Charlotte, N.C., emphasized the take-home message: "Surgeons should do whatever is needed to perform the best hernia repair they can … to avoid reoperations."

Dr. Jones said. It's really important that we start thinking about how to prevent the problem as opposed to how to manage it after it occurs.”

He credits the laparoscope for revolutionizing bariatric surgery in the late 1990s, although initial acceptance was slow. In fact, being overweight was once considered a contraindication to laparoscopy. “That all turned upside down,” Dr. Jones said. “The bariatric surgeons at the time knew that obese persons would most benefit from laparoscopy. An incision on a larger patient is very big, because you have to get through all the fat, down into the fascia and to the target. Whereas someone might do a 10-cm incision on a thin person, that same incision might be 50 cm on an obese patient. But the poke holes of laparoscopy are the same small size.”

Dr. Jones discussed the most common bariatric surgery procedures being performed today:

- Roux-en-Y. Commonly referred to as gastric bypass, this procedure involves reducing the stomach from the size of a football to the size of a golf ball. “The gastric bypass is then attached to the ileum, bypassing about 60% of the small intestine. While there can be long-term complications, such as B12, calcium, iron, and folate deficiency if there is not a nutritional deficiency in the future, the most part it’s reasonably safe,” he said. “You’re going to achieve loss of 50%-70% of your extra body weight. So if you’re 100 pounds overweight, on average you’re going to lose 50-70 of those pounds. If you’re 200 pounds overweight, you might lose 100-plus pounds.”

Dr. Jones generally performs open gastric bypass in patients who weigh more than 350 pounds because the visualization is better and he believes this procedure is safer for a person of that size. “Other surgeons modify their technique a bit to offset the fact that people are bigger,” he said.

He reserves laparoscopic gastric bypass for patients who weigh less than 350 pounds because it generally produces less scarring and shortens hospital stay – usually 1-2 days versus up to 3-5 days in patients undergoing an open procedure. “When I came to Boston, people would say, laparoscopic gastric bypass is not known, not proven,” Dr. Jones said. “That was only 8 years ago. Now, surgeons ask, ‘why would you ever do the open approach in this patient population?’ I’ve parked in the middle of that debate for a long time.”

Women of childbearing age who undergo gastric bypass should avoid pregnancy in the first 2 years after surgery because they’re going to compete nutritionally with the growing fetus, he said. And patients should keep postoperative alcohol consumption in check. “If you drink half a glass of wine after gastric bypass surgery, you may be legally drunk because alcohol gets absorbed so fast in the reconfiguration of the stomach,” he explained. “It may also be easier to get addicted to alcohol after the surgery because feelers get so high so fast. Alcohol needs to be on the back burner if you’re thinking about gastric bypass surgery.”

According to the ASMBS, the gastric bypass procedure costs between $14,000 and $26,000, but Dr. Jones puts the cost of this and other weight loss procedures in the range of $30,000.

- Laparoscopic adjustable gastric banding (LAGB). In this procedure, surgeons place a silicone band filled with saline around the upper part of the stomach.

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Bariatric Surgery Effective in Minorities With Diabetes

By 1 year, all patients achieved normal blood glucose, which remained steady through 3 years.

BY MICHELE G. SULLIVAN
Elsevier Global Medical News

PALM BEACH, FLA.—Bariatric surgery resulted in complete remission of type 2 diabetes and prediabetes in a group of patients most of whom were Hispanic or black.

Within 1 year of surgery, 100% of patients with those disorders experienced normalization of fasting blood glucose and hemoglobin A1c, and they lost a mean of 40 kg. Dr. Alan Livingstone said at the annual meeting of the Southern Surgical Association. By the end of the 3-year follow-up period, all patients still had normal levels of blood glucose and insulin.

"Uncontrolled type 2 diabetes is highly prevalent among ethnic minorities," said Dr. Livingstone, an ACS Fellow who is the Lucille and DeWitt Daughtery Professor and Chairman of Surgery, University of Miami Miller School of Medicine, as well as chief of surgery, Jackson Memorial Hospital, Miami. "Bariatric surgery helps to effectively treat these diverse minority groups and is a safe and effective option for permanent weight loss and chronic disease risk improvement in this population." Dr. Livingstone reported on a cohort of 1,603 adult bariatric surgery patients, of whom 66% were Hispanic, 17% were black, and rest were other ethnicities. The patients were prospectively entered into a research database and then retrospectively studied.

"Minorities are at a particularly high risk for type 2 diabetes and its associated complications," Dr. Livingstone said. "While only 6% of whites have [the disorder], it’s present in 10% of Hispanics and 12% of blacks—a huge burden of disease.

"The patients’ mean age was 45 years, most (77%) were female. The mean preoperative weight was 130 kg, and the mean body mass index, 47 kg/m^2."

Most of the group already had some insulin abnormality; 377 had diagnosed type 2 diabetes, 107 had un-diagnosed type 2 (fasting blood glucose of more than 126 mg/dL), and 276 had prediabetes (fasting blood glucose of 100-125 mg/dL). Among those with elevated blood glucose, the mean BMI was 45 kg/m^2.

The inclusion criteria for patients was "reasonable assurance" that they would remain on the Lap-Band procedure for at least 3 years and that they would commit to lifelong dietary modifications.

"We’re leveling off on the number of operations our surgeons and hospitals can address, yet our obesity problem continues to rise."

On Dec. 3, 2010, the Food and Drug Administration’s Gastroenterology and Urology Devices Panel recommended the use of the Lap-Band procedure for people who don’t meet the clinical criteria for obesity. Allergan Inc., which makes the device, proposed that the Lap-Band be approved for weight reduction in patients with BMI 35 kg/m^2 and an HbA1c of 6% or below. Dr. Livingstone said. "Within the first year, all of these patients had normal fasting blood glucose and an HbA1c of 6% or below. Again these values remained steady and in the normal range in the entire 3-year follow-up cohort. "This is a tremendous accomplishment," he said.

However, Dr. Bruce Schirmer, an ACS Fellow with the University of Virginia, Charlottesville, cautioned that a 3-year follow-up period may not be long enough to proclaim bariatric surgery as a cure for type 2 diabetes in any population. "In mostly Caucasian populations, if you follow the patients for up to 5 years, you see that 15%-20%, at least, have some weight regain and with it, a return to diabetes. So to make this statement that there is no weight regain and no return to the disorder is a little premature," Dr. Livingstone had no financial disclosures. Coauthor Nestor F. De La Cruz-Munoz Jr., an ACS Fellow and chief of laparoscopic and bariatric surgery at the University of Miami, is a consultant and proctor for Ethicon.

Continued from previous page

ach, creating a small pouch which causes restriction. The band can be tightened or loosened through a port.

Ideal candidates include patients with a body mass index of 40 kg/m^2 or more, or those with a BMI of 35 kg/m^2 plus a serious medical condition such as diabetes that might improve with weight loss.

"The band operation itself is not that difficult to perform, yet you’re still around some real estate," said Dr. Jones, coauthor with Dr. Mark J. Watson of the "Lap-Band Companion" handbook (Woodbury, Conn.: Ciné-Med Inc., 2007), which is intended for patients.

"There’s the esophagus, the aorta, the stomach, and the diaphragm. There are plenty of opportunities for very serious, life-threatening complications. The band is deceptively simple, but there is plenty of room for problems. Many severely overweight people come to us who have other significant comorbid conditions: coronary artery disease, hypertension, sleep apnea. All of these things may put patients at very high risk for heart attack or respiratory arrest, or [deep vein thrombosis]."

Slippage ranks as the most common reason for needing to remove bands. Dr. Jones tells patients that there is a 40% chance that their band may need to be repaired, revised, or removed at some point in their lives. "That band may be there forever, or it may come out because they have prolapse and it’s in the wrong spot, or maybe they had an appendicitis and the band was getting infected," he said.

"The things I see most are breakdowns in the tubing or hub, from say, a needle stick during the port adjustment. Early on, a port can flip over, and long term, these bands can get out of position."
Using RFA for High-Risk or Inoperable NSCLC

SBRT and RFA may be problematic compared with lobectomy, but they are often the only alternative.

by Mark S. Lesney
Elsevier Global Medical News

Locoregional approaches in the treatment of surgically curable patients with stage I NSCLC using radical intent have become standard. In these patients, survival is similar whether surgery is performed or not. In nonoperable patients, however, it is not as clear whether the approach should be surgical or non-surgical. This study details their experience with 303 consecutive patients who were treated with SBRT for stage I NSCLC and compares the outcomes with the goal of identifying patient characteristics that are associated with improved outcomes.

PERSPECTIVE

Historically, lung cancer treatment has been complicated by the delicate balance between therapeutic morbidity and efficacy. There is little doubt that patients with lung cancer present with co-migrating illnesses that are more formidable than those commonly encountered for other cancer patients. Specifically, lung cancer is highly associated with the presence of advanced chronic obstructive pulmonary disease (COPD) and other illnesses that track long-term tobacco use (coronary artery disease, peripheral vascular disease, and stroke). Another problem confounding treatment options is that most treatments for lung cancer, specifically, non-small cell lung cancer (NSCLC), consume respiratory reserve in patients already saddled with some degree of respiratory insufficiency. Consequently, and not surprisingly, lung cancer resection (lobectomy) carries operative morbidity/mortality rates that reflect the fact that there are fewer lymph nodes available to retrieve in older patients. The proportion of patients meeting the 12-node benchmark is also significantly higher in the youngest group (62%) than in the oldest (33%) (P < .001). Compliance with the 12-node benchmark improved significantly for all age groups during the study, from 33% in 1992 to 40% in 2004, and from 49% to 71% among the youngest age group. A Kaplan-Meier survival analysis among stage II colon cancer patients aged 40 and 65 revealed significantly lower overall survival among patients in each age group who had fewer than 12 vs. more than 12 lymph nodes harvested (P values less than .001 for each age group). Similarly, among stage II patients aged 65 years and over, there was a significant difference in survival based on the number of nodes retrieved.

In stage III colon cancer, survival was significantly lower based on the number of nodes retrieved among patients aged 65 and 85 years, but not among those under age 65, Dr. Bilchik said.

The reason for the negative correlation between advancing age and lymph node yield is likely multifactorial, possibly related to the surgeon, the pathologist, or the patient’s own biology, he said.

During the discussion, attendees suggested that variance in lymph-node yield may reflect the fact that there are fewer lymph nodes available to retrieve in older patients. Dr. Bilchik said it’s unclear whether lymph nodes correlate with age, and stressed that measuring the 12-node benchmark indeed improves survival. He also cited a recent study showing that older patients with resected stage III colon cancer appear to tolerate adjuvant chemotherapy better than do younger patients, as evidenced by a lower incidence of late clinical adverse events (JAMA 2010;303:1037-45).

Dr. Theodore Saclariades, an ACS Fellow with Rush University Medical Center in Chicago, was the invited discussant. “Most concerning to me was that for the entire cohort, only 40% of patients had (12 or more) lymph nodes harvested in the specimen—an observation that is discouraging and suggests we are falling short of our role as surgeons. However, this effect was offset by noting that at the end of the study, lymph-node harvest increased, suggesting we are paying more attention to the principles of oncologic surgery.” Dr. Saclariades said.

He also questioned whether the SEER database allows for identification of patients with a positive familial history of colon cancer or a way to parse out the circumstances of the surgery. He pointed out that an elderly patient brought in during the middle of the night for emergency surgery differs greatly from a 50-year-old whose cancer is detected via colonoscopy and follows on from a battery of imaging studies are available at the time of surgery. Dr. Bilchik said they were unaware of family history and the circumstances of surgery, but agreed that research suggests elderly cancer patients are more likely to receive emergency surgery.

Dr. Bilchik and his coauthors, along with Dr. Saclariades, disclosed no conflicts of interest.

Lymph Node Harvest in Colon Cancer Decreases With Age

by Patrice Wendling
Elsevier Global Medical News

CHICAGO—Mean lymph node yield decreased significantly with advancing age and was associated with adequacy of colon cancer resection.

Using the SEER (Surveillance Epidemiology and End Results) database, the researchers led by Dr. Scott Steele, an ACS Fellow with the Madigan Army Medical Center in Fort Lewis, Wash., calculated the lymph-node yield for 101,767 patients with nonmetastatic stage III colon adenocarcinoma who underwent colon resection from 1992 to 2004. Overall, 61,159 or 60% of patients had fewer than 12 lymph nodes harvested, said Dr. Bilchik, an ACS Fellow with the University of California, Los Angeles.

The mean number of lymph nodes harvested was significantly lower in 14.2 nodes when the primary tumor was in the right colon, compared with 12.7 nodes in the transverse colon, 11.9 in the left colon, and 10.4 in the sigmoid (P values less than .001 for all sites).

When patients were stratified into 5-year increments based on age, the mean lymph-node yield was higher for younger than for older patients in each year studied. Dr. Bilchik said.

Mean lymph-node yield was significantly higher at 18.7 nodes in patients aged 40 years or younger, vs. 11.4 nodes among those aged 86 years or older (P less than .001). The proportion of patients meeting the 12-node benchmark was also significantly higher in the youngest group (62%) than in the oldest (33%) (P less than .001).

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Dr. Bilchik and his coauthors, along with Dr. Saclariades, disclosed no conflicts of interest.
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Dr. Huang, who is from the Fourth Military Medical University in Xi an, China, found that progression-free survival in all of these patients was directly related to tumor size.

Local progression occurred in 27% of patients with tumors measuring less than 3 cm and in 27.1% of patients with tumors of 3-4 cm, a nonsignificant difference. However, 42% of patients with tumors larger than 4 cm had a local recurrence, which was a significant difference. Based upon their findings, they recommended that RFA should not be used in patients with tumors larger than 4 cm.

Tumor size was also seen as a significant factor in prognosis by Dr. Penathur’s group (Ann. Thorac. Surg. 2009;87:1030-9).

‘NONOPERATIVE TECHNIQUES... HAVE THE INHERENT RISK OF NOT TREATING THE COMPLETE TUMOR AND CAN MISS OCCULT NODAL DISEASE.’

With nonoperative techniques, it is always a question as to whether recurrence was truly recurrence. “It must be acknowledged that local tumor progression seen in this series most likely represents incomplete tumor treatment,” stated Dr. Huang and colleagues.

This is a good example of how nonoperative techniques, despite their benefits, have the inherent risk of not treating the complete tumor and can miss occult nodal disease (which has been determined to have around a 7% incidence even with peripheral tumors of 1 cm or smaller). This leads to undertreatment, according to Dr. Hiran C. Fernando and colleagues from the University of Pittsburgh, who object to current trends to recommend SBRT for high-risk (but not surgically inoperable) patients and even for patients considered eligible for lobectomy (Ann. Thorac. Surg. 2010;89:S213-7).

“Nonoperative therapies such as RFA and SBRT should be reserved for medically inoperable patients,” according to Dr. Fernando and his group.

Compared with surgical approaches, there are other considerations with both SBRT and RFA, they indicated.

Both approaches leave a scar that can interfere with future imaging assessment, making serial imaging and long-term follow-up a requisite to differentiate scar from recurring tumor. For SBRT, “the optimal method of delivery has not been determined with respect to the system used, the dose, and the fractionation schedule,” according to Dr. Fernando and his colleagues. This was found to make comparisons and determination of optimal treatment difficult.

There are other differences between an operative and nonoperative approach that may be even more important in the future, as tailored cancer therapies become more available. Sublobar resection, compared with SBRT or RFA, provides adequate tissue for molecular profiling and for chemoresistance and sensitivity testing of tumors, all of which may be helpful in directing adjuvant chemotherapy if indicated, Dr. Fernando said.

In addition, the results of sublobar resection can be greatly improved by close attention to the surgical margin and lymph node assessment, taking advantage of the benefits of adjuvant brachytherapy to improve the surgical margins. “With these approaches, local recurrence can be reduced from the 17.2% reported in [an earlier] lung cancer group study to 5% or less,” according to Dr. Fernando.

However, despite all this, there is still no clear-cut solution to making the decision in patients for whom sublobar resection is possible.

For high-risk patients, those for whom lobectomy is not appropriate, “RFA or SBRT may be clinically equivalent to resection because they may be associated with a lower complication profile and quicker return to normal function and quality of life. Randomized studies are needed to determine whether this is true, but these studies must be limited to high-risk patients rather than lobectomy candidates until further data are available,” concluded Dr. Fernando.

None of the authors of the referenced articles in this report indicated that they had any relevant conflicts. A portion of Dr. Penathur’s research was funded by research grants from RITA Medical/Angiodynamics to the University of Pittsburgh.

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O
one of the legends of St. Valentine says that he was a priest arrested by Roman Emperor Claudius II for secretly performing marriages. Claudius wanted to enrage his army and believed that married men did not make good soldiers, rather like Haldes’s feelings about surgical residents. But Valentine’s Day is about love, and if you remember a romantic gut feeling when you met your significant other, it might have a physiological basis. It has long been known that Drosophila raised on starch media are more likely to mate with other starch-raised flies, whereas those fed maltose have similar preferences. In a study published online in the November issue of the Proceedings of the National Academy of Sciences, investigators explored the mechanism for this preference by treating flies with antibiotics to sterilize the gut and saw the preferences disappear [(Proc. Natl. Acad. Sci. U.S.A. 2010 Nov 1 [doi 10.1073/pnas.1009906107]). In cultures of untreated flies, the bacterium L. plantarum was more common in those on starch, and sure enough, when L. plantarum was returned to the sterile groups, the mating preference returned. The best explanation for this revelation is in the significant differences in their sex pheromones. ‘These experiments also support the hologenome theory of evolution wherein the unit of natural selection is the “holobiont”, or combination of organism and its microorganisms, that determines mating preferences.’

Mating gets more interesting when you have an organism that can choose between sexual and asexual reproduction, like the rotifer. Biologists say that it’s more advantageous for a rotifer to remain asexual and pass 100% of its genetic information to the next generation. But if the environment changes, rotifers must adapt quickly in order to survive and reproduce with new gene combinations that have an advantage over existing genotypes. So in this new situation, the stressed rotifers, all of which are female, begin sending messages to each other to produce males for the switch to sexual reproduction [(Nature 2010 Oct. 13 [doi 10.1038/nature09449]). You can draw your own inference about males not being needed until there’s trouble in the environment. As far as humans are concerned, you may think you know all about sexual signals, but you’d be surprised by new findings. It’s been known since the 1990s that heterosexual women living together synchronize their menstrual cycles because of pheromones, but when a study of lesbians showed that they do not synchronize, the researchers suspected that semen played a role. In fact, they found ingredients in semen that include mood enhancers like estrone, cortisol, prolanct, oxytocin, and serotonin; a sleep enhancer, melatonin; and of course, sperm, which makes up only 1%-5%. Delivering these compounds into the richly vascularized vagina also turns out to have major salutary effects for the recipient. Female college students having unprotected sex were significantly less depressed than those whose partners used condoms [(Arch. Sex. Behav. 2002;31:289-93)]. Their better moods were not just a feature of promiscuity, because women using condoms were just as depressed as those practicing total abstinence. The benefits of semen contact also were seen in fewer suicide attempts and better performance on cognition tests. So there’s a deeper bond between men and women than St. Valentine would have suspected, and now we know there’s a better gift for that day than chocolates.

—Dr. Greenfield is Editor in Chief of SURGERY NEWS.

FROM THE COLLEGE

ACS: A Legacy of Leadership

Editor’s Note: The following is a summary of the Presidential Address delivered by L.D. Britt, M.D., M.P.H., FACS, during Convocation at the 96th annual Clinical Congress in Washington, D.C. The full text of the address will be published in the February 2011 issue of the Journal of the American College of Surgeons.

I enthusiastically dedicate this Presidential Address to the patient,” said L.D. Britt, M.D., M.P.H., FACS, newly installed ACS President, to the College’s 1,467 Initiates on October 3, during the Convocation ceremony in Washington, D.C.

Framing his address with a historical perspective of both the Clinical Congress and the American College of Surgeons, Dr. Britt noted the historical benchmarks of the College, while acknowledging the importance of strong leadership in the past and the present day.

“The American College of Surgeons has a legacy of leaders who put the interest of patients first,” Dr. Britt said, “even when such an emphasis conflicted with the economic interests of the surgery. It is a legacy that no amount of advertisement can create. Today, the American College of Surgeons has leaders who transcend gender, ethnicity, race, and professional specialty orientation.”

Although Dr. Britt emphasized the importance of the College’s “legacy of leadership,” he urged the Initiates not to “bash in nostalgic euphoria” and he stressed the importance of adapting to change “without compromising [the College’s] core values.”

In speaking about the challenges surgeons will face over the next several months, Dr. Britt underscored the importance of access to quality health care, and the College’s role as a beacon for quality and patient safety with “unwavering emphasis on professionalism and ethics.”

He specifically noted the Advanced Trauma Life Support® course—which is celebrating its 30th anniversary this year—as a prototype for best practices in the management of the surgical patient.

“There has been no better steward of quality care and safety than the American College of Surgeons,” said Dr. Britt. “The American College of Surgeons has never needed any other authority to define its mission.”

Dr. Britt noted three ways the College—as well as the individual surgeon—“must fulfill their professional responsibilities to society.” These duties include ensuring excellent patient outcomes, wise resource allocation, and effective self-regulation.

“Whether we consider ourselves members of the ‘House of Surgery’ or citizens of the ‘Village of Surgery’ [where there are housing neighborhoods], we have an unbreakable contract with society to provide optimal care for the surgical patient,” said Dr. Britt.

In closing, Dr. Britt noted that “the gathering today marks the 100th year since the inception of the Clinical Congress, [and combined with] the fact that we are just 3 years shy of the centennial anniversary of the American College of Surgeons, it seems only fitting that we all renew our commitment to the original tenets of this great organization.”

He called for everyone to demonstrate “the leadership that’s required” to meet the challenges of one of the most turbulent and labile periods that this nation has faced.”

THE CUTTING EDGE

Gut Feelings

Skeptical About SIL

1) I object to the article “Single-Incision Approach Deemed Safe for Colectomy,” because its headline promotes a position not supported by the data [(SURGERY NEWS, December 2010, p. 1). The study described in this article was a review of three minimally invasive colectomy groups with 29 patients each, and the study eager to derive support from Covidien. While a systematic review of 20 such studies might be able to draw some valid conclusions, this is one small, nonrandomized study, so a headline implying that the single-incision laparoscopic approach is safe for colectomy is somewhat irresponsible. Interestingly, two patients in the single-incision laparoscopy (SIL) group had nonocclusive portal vein thrombosis. This complication is uncommon, and one wonders if these two occurrences were just coincident.

Over the past two decades, it has been difficult to demonstrate meaningful differences in outcome between open and laparoscopic procedures (aside from cosmesis and short-term recovery). I say this as a proponent of minimally invasive surgery (MIS). Now we have a newer approach (that is, SIL and other equivalents), which many investigators eager to compare with “traditional” MIS. If it has been difficult to tease out differences in outcome between open and laparoscopic surgery, where preconceived notions had predicted the easy superiority of the latter, how much more difficult will it be to find differences in outcome between SIL and traditional MIS? (Incidentally, the development of SIL has been driven by industries that would benefit from retooling hospitals and surgeons to use the SIL approach.)

This article headline grabs attention but does not do justice to surgical science. Studies like this one can be presented and discussed at a surgical society meeting, and published in an appropriate peer-reviewed journal, but they should not be emblazoned across the front page of a medical newspaper.

Mark A. Carlton, M.D., FACS
Omaha, Neb.

Dr. Lazar J. Greenfield replies: The study was presented at the annual meeting of the Western Surgical Association in November 2010 and included the comments of a discussant. There is also additional information available in a reported series of more than 300 patients that was presented at the Clinical Congress of the American College of Surgeons [(SURGERY NEWS, January 2011, p. 6)].

The editors have confidence in the judgment of readers to put new and controversial concepts into perspective.
The National Cancer Data Base

The Commission on Cancer is a consortium of professional organizations that are dedicated to improving survival and quality of life for cancer patients. Established by the American College of Surgeons in 1922, it has evolved into its current composition of more than 100 individuals representing the American College and nearly 50 other national professional organizations in cancer care.

The Commission on Cancer (CoC) is devoted in part to establishing standards by which accredited facilities are regularly evaluated. These standards represent a consensus of the necessary structural resources and procedural characteristics that demonstrate adequate care for cancer patients. In 1988, the CoC initiated the National Cancer Data Base (NCDB) with the aid of an initial 4-year planning grant from the American Cancer Society. The initial intent was to “(1) provide a scientific resource suitable for assessing patient care and outcome nationally and to disseminate this information to the medical community; (2) enhance ongoing cancer programs among hospitals [accredited] by the CoC ... by providing annual reports of national, regional, and hospital data; and improve the process by which cancer patient care and research advances are translated into physician practice” (CA Cancer J. Clin. 1998;48:131-133). The NCDB currently contains data on more than 26 million cancer cases, and data is captured on some 70% of all newly diagnosed U.S. cancer cases.

The existence of the NCDB has generated new opportunities for utilization of the data. Emphasis is on increasing the capability to generate automated facility-specific reports, allowing comparison with hospital subsets (national, state, region, or facility type). These reports constitute carefully designed indicators based on a formal consensus-building process.

The first such report, offered in 2005, measured cancer program compliance with the standard of administering chemotherapy to stage III colon cancer patients. Metrics now include measures on the use of chemotherapy, hormonal therapy, and radiation therapy in certain subsets of breast cancer patients, as well as use of chemotherapy in certain rectal cancer cases. Also, a surveillance measure evaluating the frequency of identifying 12 or more lymph nodes in colon cancer cases has been added. Each accredited facility accesses Web-based reports on their individual performance for these measures, compared with national, state, or other aggregate groups.

In the current format, these measures are reported using data that may be 2 years old, a consequence of cancer registry data collection and reporting processes. This time lag is problematic, because any case for which care is clearly documented as noncompliant is beyond the point of “rescue.” Additionally, physicians and program staff feel less compelled to take action based on historical performance data. This issue is being addressed through the development of the Rapid Quality Reporting System (RQRS). The RQRS collects a subset of data elements for each new cancer that can be reported as soon as the definitive surgical procedure is performed. The RQRS software can then track the documentation of specified anticipated treatments in near real time – such as the administration of radiation therapy after breast-conserving surgery. This tracking activity can be used to identify cases that might be “rescued” to receive recommended treatment before the therapeutic window closes. Plans are underway to expand the dashboard of quality indicators to include other disease sites. The refinements introduced through the initiatives spearheaded by NCDB, it is hoped, will both simplify and enhance the delivery of recommended therapy, according to accepted standards of care, to each patient.

DR. KENNEDY is with DeKalb Surgical Associates in Decatur, Ga.
**Nominations Due March 11 For 2011 Jacobson Award**

The ACS is accepting nominations for the seventh Joan L. and Julius H. Jacobson II Promising Investigator Award, to be conferred in 2011. The annual award recognizes outstanding surgeons engaged in research advancing the art and science of surgery who have shown early promise of significant contribution to the practice of surgery and the safety of surgical patients.

Award criteria and information about the nomination procedure are posted on the ACS website at www.facs.org/cqj/src/jacobsonpi.html. Special consideration will be given to surgeons who are at the “tipping point” of their research careers with a track record indicative of early promise and potential (such as a degree program in research or K-award). Surgeon-scientists who are well established (for example, funded by NIH RO-1 grants) are not eligible candidates.

To be considered for the award in 2011, submissions must be e-mailed or (sent on a CD) postmarked no later than March 11, 2011. Award criteria documentation compiled in an electronic format may be submitted via e-mail to jacobsonpi@facs.org. Nomination materials can also be submitted on a CD-ROM to Mary Fitzgerald at American College of Surgeons, 633 N. Saint Clair St., 22nd Floor, Chicago, IL 60611. Applicants are encouraged to verify that all necessary documentation has been received before the March 11 deadline. For additional information, call 312-202-5319 or e-mail jacobsonpi@facs.org.

**‘Surgeons As Leaders’ Course Slated for June**

The “Surgeons as Leaders: From Operating Room to Boardroom” course will be held June 5-8 at ACS headquarters in Chicago. Surgeons who aspire to meet the challenges of exemplary leadership across all settings are encouraged to join senior surgical leaders in the 3-day course.

The faculty will include Course Chair Layton F. Rikkers, M.D., FACS; Bruce L. Gewertz, M.D., FACS;Wi ley W. Souba, M.D., FACS, ScD, MBA; and Gayle E. Woodson, M.D., FACS. Carlos A. Pellegreni, M.D., FACS, FRCSI (Hon), Chair of the Board of Regents, will deliver the keynote speech, Julie A. Freischlag, M.D., FACS, a Regents of the College, and Charles F. Rinker II, M.D., FACS, will serve as special invited faculty. Debra A. DaRosa, Ph.D., will serve as professional educator.

Organized by the College’s Division of Education, the course will help surgeons exhibit leadership attributes; use consensus development and vision to set, align, and achieve goals; build and maintain effective teams; cultivate leadership capacities; change culture, resolve conflict, and balance demands within the larger environment, and translate the principles of leadership into action.

For details and to obtain an application form, visit www.facs.org/education/surgeonsasleaders.html, e-mail apalmski@facs.org, or phone 312-202-5018. The application deadline is Monday, April 4.
Statement on US Guidance for CVC Placement Revisited

Revisions to this statement were developed by the American College of Surgeons Committee on Perioperative Care and approved by the Board of Regents in October 2010.


The Guidance on the Use of Ultrasound Locating Devices for Placing Central Venous Catheters from the National Institute for Clinical Excellence had the following major recommendations (National Institute for Clinical Excellence [NICE]). Guidance on the Use of Ultrasound Locating Devices for Placing Central Venous Catheters.

1. Two-dimensional (2-D) imaging ultrasound guidance is recommended as the primary imaging technique for ultrasound-guided placement of CVCs.
2. Ultrasound guidance should be used for all catheterizations, including those performed in emergency settings.
3. Ultrasound imaging should be used to confirm proper placement of the catheter tip within the central circulation before making a cutdown or placing the catheter in a large vein.

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preferred method for insertion of CVCs into the internal jugular vein in adults and children in elective situations.

The use of 2-D imaging ultrasound guidance should be considered in most clinical circumstances where CVC insertion is necessary either electively or in an emergency situation.

It is recommended that all those involved in placing CVCs using 2-D imaging ultrasound guidance should undertake appropriate training to achieve competence.

Audio-guided Doppler ultrasound guidance is not recommended for CVC insertion.

The American College of Surgeons (ACS) supports the use of real-time ultrasound guidance for the placement of central venous catheters.

The ACS encourages health care systems to provide for the education, training, and resources required. Additional Resources


Sign Up for Rural Surgery Symposium

Registration is now open for a two-part educational program on rural surgery, sponsored by the ACS and the Nora Institute for Surgical Patient Safety. Co-sponsored by the Mithoefer Center for Rural Surgery, Cooperstown, N.Y., the Rural Surgery Symposium, which will be held May 5-8, in Chicago, will address issues that impact rural surgery, trends in rural surgery practice, and ACS resources available for the rural surgeon. A skills course workshop, “Patient Safety and Quality in Rural Surgery: Advanced Skills Training for the Rural Surgeon,” will follow the symposium. The course will combine online learning and self-assessment with hands-on mentored practice in the areas of endoscopy, plastic surgery, gynecology, and urology.

This live activity has been approved for AMA PRA Category 1 Credit™.

To learn more and to register, visit www.surgicalpatientsafety.facs.org/surgical/symposium.html.

Fellowship Offered For Surgical Outcomes Research

The ACS is offering a 2-year onsite fellowship in surgical outcomes research, health services research, and health care policy, which will allow a Clinical Scholar to conduct research and participate in ACS quality improvement initiatives. These projects will include the National Surgical Quality Improvement Program, the National Cancer Data Base, and the Trauma Quality Improvement Program. The Scholar will also have the opportunity to complete a Master of Science degree in Clinical Investigation, Health Services and Outcomes Research, or Healthcare Quality and Patient Safety through Northwestern University. Applications are due March 15. To learn more, go to www.facs.org/ropc/clinicalscholars.html.

Clinical Congress Abstract Site Open

The electronic abstract submission site for the ACS 97th annual Clinical Congress, which will be held Oct. 23-27 in San Francisco, is now open.

The deadline for abstract submissions, which must be submitted online, is 5 p.m. (CT) on Tuesday, March 1. Revisions to the abstracts can be made until the March 1 deadline. There is no late-breaking abstract deadline.

For more information, go to http://web2.facs.org/Abstracts/Call_For_Abstracts.cfm.
Better Survival After EVAR Versus Open AAA Surgery

BY DAMIAN McNAMARA
Elseror Global Medical News

NAPLES, FLA. - Endovascular aneurysm repair is associated with better long-term survival compared with open abdominal aortic aneurysm surgery, although re-intervention rates for the two techniques were similar in a single-center, retrospective study.

In a registry of 1,066 endovascular aneurysm repair (EVAR) and 920 open abdominal aortic aneurysm (AAA) procedures, all-cause mortality in the first 100 months was 23% after EVAR and 39% after open repair. The mortality disparity was significant, even though the EVAR patients tended to be older and had more comorbidities, such as hypertension or diabetes, Dr. Brenton E. Quinney said at the annual meeting of the Southern Association for Vascular Surgery.

One-year mortality was 16% in the EVAR group and 28% in the open-repair group. At 5 years, mortality rose to 36% and 48%, respectively. "EVAR had better immediate, mid-term, and long-term survival out to 9 years," said Dr. Quinney, a vascular surgery fellow at the University of Alabama at Birmingham.

To compare durability of EVAR vs. open AAA, they examined EVAR cases performed from 1999 to 2009 and open repairs from 1985 to 2009 at the University of Alabama.

Secondary interventions were vascular (aortic graft-related or remote procedures, such as carotid surgery) or nonvascular (incisional or gastrointestinal surgery). "Patients required more secondary vascular procedures after EVAR," Dr. Quinney said. In contrast, "patients required more nonvascular procedures after open AAA repair."

Also, 12.8% of EVAR versus 5.1% of open surgery cases required graft-related subsequent procedures. However, when we add GI complications and laparotomy complications, both groups are virtually identical with overall re-intervention rates," Dr. Quinney said. Specifically, 21.9% of the EVAR and 21.1% of the open cases required a re-intervention during the 290-month follow-up (mean, 27 months).

In the EVAR group, the graft-related secondary interventions were mostly minimally invasive transfemoral procedures (131 cases, or 56%). Subsequent nonaortic vascular procedures included 63 cases of infrainguinal bypass, 13 thoracic aortic aneurysms (TAAs), and 4 gastrointestinal bleed repairs, Dr. Quinney said.

In the open-surgery group, graft-related re-interventions were mostly secondary aneurysm repairs (23 cases). There were also 34 infrainguinal bypass procedures and 22 TAA repairs in this group. All 97 nonvascular secondary surgeries in the study occurred in patients who initially underwent open surgery.

"What would be your preferred approach to a healthy 54-year-old male patient when this man wants you to make the decision?" asked study discussant Dr. Karthikeshwar Kasirajan, FACS, director of clinical research, division of vascular surgery, at Emory University in Atlanta. "In a 54-year-old with suitable anatomy for AAA, we would probably recommend an EVAR," Dr. Quinney replied.

Potential limitations include the retrospective study design based on nonvascular procedures from medical records and patient reports. Also, the registry tracks only procedures, not patients, so "one patient could have had multiple procedures," Dr. Quinney said.

The current finding of a long-term survival benefit with EVAR differs from results of the Dutch Randomized Endovascular Aneurysm Management (DREAM) trial (N. Engl. J. Med. 2005;352:2398-405). EVAR showed an early postoperative survival advantage versus open repair in the DREAM trial, but "mortality equalized at 1 year," Dr. Quinney said.

Secondary intervention rates in this patient population vary, partly because of different follow-up times, Dr. Quinney said, noting that a comparison of 444 EVAR and 437 open-repair outcomes during a mean 1.8-year follow-up found essentially equivalent rates of secondary interventions (JAMA 2009;302:1335-42). Another study showed a 9.8% re-intervention rate among 543 EVAR cases, compared with 5.8% of 539 open repairs over 4 years (Lancet 2004;364:843-8).

Dr. Quinney said that he had no relevant disclosures. Dr. Kasirajan receives research support from W.L. Gore and Medtronic.

MARCH 26–29, 2011

2011 Leadership Conference & Joint Surgical Advocacy Conference (JSAC)

The 2011 Leadership Conference is sponsored by the Young Fellows Association for young surgeons and chapter leaders. Join them on Sunday, March 27, for an educational program devoted to leadership topics. The JSAC conference gives attendees from the surgical community the opportunity to join their peers in a collaborative advocacy effort.
Medical residents have expressed deep ambivalence toward the 16-hour cap on first-year residents’ duty hours that is scheduled to take effect in July 2011, responses to a new survey indicate.

Although many survey respondents agreed that the new rules would improve their quality of life, others expressed skepticism about their effects on patient safety, as well as concern about their effect on training and acquisition of skills.

In 2003, the Accreditation Council for Graduate Medical Education established an 80-hour cap on residents’ workweeks in response to concerns about patient safety and resident fatigue. In June 2010, the rules were tightened further, with a new proposal to shrink first-year residents’ work periods to 16 continuous hours with on-site supervision by an upper-level resident or attending physician.

The idea was immediately challenged. A July editorial in the New England Journal of Medicine cautioned that the 2003 rules had already resulted in “the adoption of a ‘shift mentality’ during residency,” and that further restrictions could “conflict with physicians’ moral and professional responsibility to their patients [and] leave residents unfamiliar with and unprepared for the hours and professional obligations of practicing physicians” (N. Engl. J. Med. 2010;363:e3).

And a survey of residency program directors published in August revealed that only 14% of 429 respondents agreed with capping duty periods at 16 hours for first-postgraduate-year (PGY-1) residents (N. Engl. J. Med. 2010 Aug. 19 [doi:10.1056/NEJMep1008305]). But that rule – along with others intended to leave residents better rested and supervised – was adopted by the ACGME in September.

The new survey was conducted by Dr. Brian C. Drolet, a surgery resident and lead author, Dr. Lucy B. Spalluto, a radiology resident, and Dr. Staci A. Fischer, director of graduate medical education, all with Rhode Island Hospital in Providence (N. Engl. J. Med. 2010 Dec. 2 [doi:10.1056/NEJMep1011413]).

They sent surveys electronically to 11,617 trainees at 75 institutions in the United States. Some 22% responded from more than 12 branches of medicine and in all program years, providing what the investigators considered a good representation of residents across the United States. Most respondents were in their first 3 program years.

The residents were evenly divided on whether the new rules would improve patient safety, with 34% saying they wouldn’t, 39% saying that they would, and the rest undecided. A slight majority (51%) agreed that the new rules would improve their quality of life, although only 35% thought that their working hours would in fact be reduced.

When asked whether the changes would improve education, experience, and fund of knowledge, 54% of respondents disagreed and just 24% agreed with that statement.

Half of the respondents said they thought that the length of residency and fellowship training would increase as a result of the rules, which Dr. Spalluto said was not surprising. “Residency programs are for a certain number of years, and if work hours are decreased and the required knowledge base remains the same, something will have to bridge that gap.”

No one knows, she said, whether to expect longer training as a result of the shorter hours in the first year.

Dr. Spalluto added that the responses reflect concern rather than dismay; residents are eager to learn as quickly as possible, and learning is traditionally accomplished by long periods of continuous work. “These are people who have worked their whole lives to be able to do this, and they want to practice medicine,” she said in an interview. “Patient care doesn’t follow a time schedule.”

The investigators also solicited open, anonymous comments from respondents to their survey. Dr. Spalluto said that about 1,000 of these have been received, and these as-yet-unpublished comments shed even more light on residents’ concerns, which vary by clinical specialty. In addition, she said, “we’re hoping in a further paper to divide up the specialties and see how that affected residents’ perceptions” of the new rules.

The investigators reported having no relevant financial disclosures.
# Overnight Call Implicated in Poorer Cognitive Function

**By Patrice Wendling**
Elsevier Global Medical News

Chicago – Overnight call taken by surgical residents impairs psychomotor and cognitive function, judging by a small study of EEG data and virtual task performance.

The quantitative data support qualitative outcomes from several previous studies as well as years of physician experience demonstrating that fatigue has a negative impact on surgical proficiency.

The seven postgraduate-year 1 surgical residents in the current study wore motion-tracking gloves and a wireless EEG cap and then completed a series of virtual ring-transfer tasks during three weekly sessions over 4 weeks. The tasks are part of a validated basic laparoscopic course and require moving a series of virtual rings onto randomly highlighted points using a haptic joystick. The tasks were performed prior to and following an in-hospital overnight “24 + 6” call.

They experienced significant postcall changes in psychomotor function, hand and movement smoothness, cognitive errors, time elapsed, attention, distraction, and workload (P value less than .01). Dr. John Ferrara reported at the annual meeting of the Western Surgical Association.

Notably, postcall errors increased by 28%, while EEG data revealed a 40% decrease in attention, a 91% increase in distraction/drowsiness scores, and a 51% increase in workload scores measuring overall mental effort.

“EEG data prove there are physiological changes in residents post call and that these changes mostly manifest in the underlying neurophysiology,” said Dr. Ferrara, an ACS Fellow and adjunct faculty in the school of biological and health systems engineering, Arizona State University, Phoenix.

The time to complete tasks was 12% shorter post call, suggesting that there is a haste to accomplish tasks that is detrimental to performance. The ability to perform pure psychomotor tasks, however, was not significantly affected post call.

“What we have seen is that with psychomotor exams that just require psychomotor tasks, there is not much change in any proficiency stuff, but exams that combine cognitive and psychomotor tasks are where we see a lot of change,” co-author Dr. Kanar Kahol, also with Arizona State, said in an interview. “What is interesting is that a cognitive exam when you start failing, the psychomotor performance also suffers.”

The researchers previously reported that fatigue and sleep deprivation impair residents’ surgical proficiency, but that study did not address the impact of overnight call (Ann. J. Surg. 2008;196:813-20).

During a discussion, audience members expressed concern that the data could be used to further curtail residents’ training, particularly by nonmedical entities. Dr. Karen Borman, an ACS Fellow with the Abington Memorial Hospital in Abington, Pa., questioned how it correlates with clinical outcomes.

“We know fatigue is out there, but is there enough redundancy to buffer patients?” asked “What is the ideal, the target, in resident duty and sleep hours?” Dr. Ferrara said that the ideal resident number hours is the “Holy Grail” of their research and that the research needs to be taken into the OR in order to pick up intraoperative technical errors earlier.

Dr. Ferrara and his co-authors disclosed no relevant conflicts of interest.

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# Outcomes in Select Cases Linked to Resident Involvement

**By Patrice Wendling**
Elsevier Global Medical News

Chicago – The involvement of surgical residents in seven common general surgery procedures as a proxy for other things at an institution is associated with higher morbidity, but lower mortality in an analysis of 37,907 operations. Absolute 30-day mortality for all cases was 3% in those with surgical residents and 1% in those without surgical resident involvement (SRI).

Absolute 30-day mortality rates for all cases with and without SRI were 0.1% and 0.08%, respectively. Dr. Warren Tseng and his colleagues at the University of California, Davis, reported at the annual meeting of the Western Surgical Association.

In risk-adjusted analyses, SRI was associated with significantly lower mortality for open right colectomies (OR, 0.32), a 68% increase in workday (76%), 2,940 laparoscopic right colectomies (74%), 2,614 total thyroidectomies (82%), and 2,940 laparoscopic Nissen fundoplication cases (79%).

In a 51% increase in workday, there is not much difference that is detrimental to performance. The ability to perform pure psychomotor tasks, however, was not significantly affected post call.

“What we have seen is that with psychomotor exams that just require psychomotor tasks, there is not much change in any proficiency stuff, but exams that combine cognitive and psychomotor tasks are where we see a lot of change,” co-author Dr. Kanar Kahol, also with Arizona State, said in an interview. “What is interesting is that a cognitive exam when you start failing, the psychomotor performance also suffers.”

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Dr. Ferrara and his co-authors disclosed no relevant conflicts of interest.

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The second sentence sets the tone; it seems to say, “everybody agrees that call is bad for surgical proficiency.” I think the data speak for themselves, but the jump from decreased performance on a simulator to poor clinical performance is not proven. I think that point should be more clear, especially since pure psychomotor tasks were not affected, and speed to complete tasks was improved.

Dr. Mark Savarise is an ACS Fellow and a general surgeon in private practice, Selkirk General Surgery, Sandpoint, Idaho.

Like many studies of this nature, this one fails to address the safety balance involved in patient care: well-rested individuals vs. individuals who have had to time the intimate details about their patients. Perhaps the study that needs to be performed is the simulation of an emergent situation after 2 hours of patient care (when the resident is well rested vs. after 20 hours more fatigued). I suspect that post-call residents likely finished tasks more quickly because they were trying to finish the study so that they could go home (while the pre-call residents only had patient care responsibilities to look forward to after finishing the study).

Dr. Joshua M.V. Mammen is assistant professor at the University of Kansas.

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I am puzzled as to how mortality rates were halved with resident involvement while morbidity increased. Furthermore, I suspect that the differences seen are more likely due to resident-related (not resident involved) rather than resident related (as Karen Borman pointed out, it may be a proxy for what is actually measured).

I am a little concerned that if the secular media sees on the results of the study, that they may misinterpret the results. I wonder if the resources are available for the division of continuous quality improvement of the college to rigorously look at the data and control for important variables like the number of patients and the number of residents involved. (Higher risk patients are more likely to be at hospitals that train residents.)

Dr. Joshua M.V. Mammen is assistant professor at the University of Kansas.
SEATTLE – An adjustment in emergency department protocols to ensure that suspected sepsis patients get antibiotics quickly saved an estimated 120 lives at Intermountain Healthcare in 2009, and improved the Salt Lake City–based health system’s bottom line by $40 million.

Under the new system, every patient who presents to an Intermountain emergency department (ED) with an elevated temperature has blood drawn for a white blood cell count. If the count is elevated, the hospital lab automatically completes a lactic acid level. If that too is elevated, the ED staff is informed immediately and the patient is started on intravenous antibiotics and admitted to the ICU, Dr. Christopher Wood explained at the 2010 Swedish Medical Center health care symposium.

Patients don’t wait in the ED to undergo an exam or other procedures that delay antibiotics. In fact, the whole process can happen under the guidance of nursing staff, before a physician even sees the patient, said Dr. Wood. Intermountain’s information systems medical director.

The protocol has cut the time it takes for suspected sepsis patients to get antibiotics from about 9 hours to fewer than 4. “We now detect [sepsis] even before a physician sees the patient in the ED,” Dr. Wood said in an interview. The 120 lives saved in 2009 is an estimate based on sepsis deaths at Intermountain in 2008. Sepsis mortality there now hovers around 8%, down from about 25% only 5 years ago. Nation-wide, sepsis mortality ranges from 30% to 70%.

The $40 million bottom line improvement taken into account not only savings from reduced long-term hospitalizations and surgical complications, but also nursing days saved, increased revenue from ICU admissions, and other savings spread across the 15 Intermountain hospitals that have ICUs, Dr. Wood said.

Quicker sepsis antibiotic administration wasn’t a new idea; rapid administration is, in fact, a cornerstone of sepsis guidelines from several groups, including the Surviving Sepsis Campaign, launched in 2002 by the Society of Critical Care Medicine, among others (Intensive Care Med. 2010;36:222-31). Intermountain’s antibiotic-selection computer program has also helped by narrowing antimicrobial options before culture results are known. The program considers patient demographics, insurance coverage, renal function, and medical history, along with community epidemiologic patterns, and presents “the clinician with a list of what the best and most cost-effective antibiotics would be,” Dr. Wood said.

Clinical judgment comes into play when the patient has an obvious source of infection, such as a urinary tract infection or meningitis.

Overall, the system has made “quite a bit of difference in what [antibiotics] we pick,” Dr. Wood said.

Intermountain has made other sepsis care improvements in recent years, in keeping with strategies recommended by the Surviving Sepsis Campaign and other sources, including tighter glucose control and protecting the lungs with a standardized ventilator strategy.

But it’s the rapid identification and treatment of sepsis patients “that’s really the foundation piece of the protocol and the thing that is having such a great impact on mortality,” Dr. Wood said.
Patients with COPD were 29% more likely to die and 35% more likely to have complications.

BY SUSAN LONDON
Elsevier Global Medical News

VANCOUVER, B.C. – Patients with chronic obstructive pulmonary disease are more likely to die after surgery than are those without COPD, even after controlling for comorbidities and type of surgery, according to a cross-sectional study of nearly half a million patients undergoing surgery in the United States.

The researchers found that patients with COPD were 29% more likely to die and 35% more likely to experience complications, compared with similar patients without the disease, said presenting investigator Dr. Prateek K. Gupta, a surgeon at Creighton University in Omaha, Neb. In addition, hospital length of stay was four times longer for the COPD group.

“Knowledge of the increased risk associated with COPD may improve patient selection and the informed consent process,” Dr. Gupta said at the annual meeting of the American College of Chest Physicians.

“Perioperative optimization of these patients may help in improving outcomes and health care costs, and there is a need to study such strategies in multi-center, randomized, prospective trials,” he added. These strategies might include, for example, giving patients respiratory exercises and encouraging them to quit smoking, he said.

Dr. Gupta and his colleagues used the NSQIP (National Surgical Quality Improvement Program) database, which collects data from more than 250 hospitals nationwide, to identify patients who underwent surgery in 2007 and 2008.

They then compared 30-day postoperative outcomes between patients who did and did not have COPD, defined in the database as GOLD (Global Initiative for Chronic Obstructive Lung Disease) stage II, III, or IV, or a prior hospitalization for COPD.

Analyses included 468,795 patients who underwent surgery. The types of surgery were typical of patients seen in the general population, with a predominance of cholecystectomy, appendectomy, hernia repair, and vascular and breast surgery.

A total of 5% of the patients had COPD. Relative to their unaffected peers, patients with COPD had a higher mean body mass index (29 vs. 28 kg/m²) and an older median age (69 vs. 55 years), were more likely to be male (52% vs. 42%), white (82% vs. 72%), smokers (41% vs. 20%), and alcoholics (5% vs. 2%); and were more likely to be taking corticosteroids (10% vs. 5%).

The group with COPD also had higher prevalences of more than a dozen co-morbidities, especially hypertension (74% vs. 44%), dependent functional status (20% vs. 6%), diabetes (23% vs. 14%), and an American Society of Anesthesiologists score of 3 or 4 (55% vs. 22%).

The median length of hospital stay was much longer for the patients with COPD than for their unaffected peers, at 4 days vs. 1 day (P less than .0001), Dr. Gupta reported. And the 30-day rate of postoperative mortality was higher, at 6.7% vs. 1.4% (P less than .0001).

After the investigators took into account more than 30 comorbidities and the type of surgery (including whether it was laparoscopic or open), patients with COPD still had higher risks of postoperative morbidity (odds ratio, 1.35; P less than .0001) and mortality (OR, 1.29; P less than .0001).

The odds of nine postoperative complications analyzed individually were also elevated for the COPD group, with the greatest increases seen for pneumonia (OR, 1.71), reintubation (OR, 1.54), and failure to wean from the ventilator within 48 hours (OR, 1.45) (all P less than .0001).

The study was limited by a lack of detailed information on therapies that patients were receiving, Dr. Gupta acknowledged. “We just know that they had this surgery (and) that they had COPD prior. We don’t know what medication or what preoperative optimization they underwent,” he said.

In addition, the study did not specifically assess any influence of the urgency of the surgery (emergency vs. elective) and did not assess the potential impact of mild COPD.

GOLD stage II-IV COPD is “common among patients undergoing surgery and is associated with increased morbidity, mortality, and length of stay,” Dr. Gupta concluded. Physicians may be able to use this information to help guide selection of appropriate surgical candidates, counsel patients about risks, and target interventions to improve outcomes, he said.

Dr. Gupta reported having no conflicts of interest related to the research.

Mortality Up With Higher Perioperative Oxygen

San Diego – Giving a high perioperative inspiratory oxygen fraction in the hopes of preventing wound infections was associated with significantly increased long-term mortality in a study of 1,382 patients.

At a mean follow-up of 2 years after abdominal surgery, patients who had been randomized to receive a high inspiratory oxygen fraction (80%) during surgery and for 2 hours afterward had a 28% higher risk for death compared with patients randomized to a lower oxygen fraction (30%). The difference between groups was statistically significant (P = .04). Christian S. Meyhoff and his associates reported at the annual meeting of the American Society of Anesthesiologists.

The mortality rate already was slightly higher in the 80%-oxygen group with in 30 days of surgery, and started to diverge more distinctly from the 30%-oxygen group 8 months after surgery, said Dr. Meyhoff of Copenhagen University Hospital, Denmark.

The difference in mortality between groups was most pronounced among 714 patients undergoing surgery for cancer, a subanalysis found. Cancer surgery patients in the 80%-oxygen group were 41% more likely to have died than were those in the 30%-oxygen group (P = .02).

The study is a follow-up to a randomized, double-blind PROXI trial in which Dr. Meyhoff and his colleagues analyzed wound infection rates in 1,386 adults undergoing acute or elective laparotomy. The wound infection rate was not significantly different between oxygen groups, but there was a nonsignificant trend toward higher 30-day mortality in the 80%-oxygen group (4.4%) compared with the 30%-oxygen group (2.9%), Dr. Meyhoff said (JAMA 2009;302:1543-50).

In the current study, the investigators gathered follow-up data on all but four patients in the PROXI trial.

Dr. Meyhoff suggested three possible explanations for the mortality difference, none of which have been studied. The results could be a statistical type 1 error. Patients in the two groups had similar characteristics, but there may be some unknown factor that created an imbalance, he added.

Alternatively, 80% oxygen may have some negative effect on survival. “Could it be that the perioperative immunosuppression is somehow changed so that elimination of minimal residual disease could be decreased or neovascularization increased?” Dr. Meyhoff asked.

“We can only say that a high inspiratory oxygen fraction given during and for 2 hours after abdominal surgery is associated with increased long-term mortality,” he concluded.

Dr. Meyhoff said he has no relevant interest related to the research.

Studies Conflict on Perioperative Oxygen and Wound Infections

The benefit of giving a high perioperative oxygen fraction during surgery to prevent wound infections is not clear cut, judging by conflicting data from several studies.

High tissue oxygenation reduces the risk of wound infection by improving the ability of neutrophils to kill bacteria, so surgical patients often receive extra oxygen inspired to boost tissue oxygen. However, conflicting results were seen in four randomized, controlled studies comparing surgical patients given a high inspiratory oxygen fraction (80%) with those who received a more conventional, lower oxygen fraction (30%) during surgery and for 2 hours afterward, said Dr. Daniel I. Sessler at the meeting.

In one randomized study of 500 patients undergoing colorectal resection, surgical wound infections occurred in 5% of the 80%-oxygen group and 11% of the 30%-oxygen group (N. Engl. J. Med. 2000;342:161-7). Another study of 165 surgical patients reported that the wound infection rate more than doubled in the 80%-oxygen group compared with the 30%-oxygen group – 25% vs. 11%, respectively (JAMA 2004;291:79-87).

In a third study of 291 colorectal surgery patients, the surgical wound infection rate was 13% in the 80%-oxygen group vs. 24% in the 30%-oxygen group (JAMA 2005;294:2035-42). The differences between groups in those studies were statistically significant, said Dr. Sessler, professor and chair of Anesthesiology at the Cleveland Clinic.

Among 1,386 adult patients undergoing abdominal surgery (acute or elective laparotomy) in the PROXI trial, wound infection rates were 19% in the 80%-oxygen group and 20% in the 30%-oxygen group (JAMA 2009;302:1543-50). Investigators gave very little fluid to patients, so patients may have been well oxygenated but not well perfused. Factors like this may help explain the conflicting results, Dr. Sessler noted, but more research is needed.

Dr. Sessler has had financial relationships with Arizant, Dynahearrm, Aspect Medical System (Covidien), Hutchinson Technology, Merck Pharmaceuticals, Cardinal Health, King Systems, and Velomedix.
SAN DIEGO – Since 2007, the use of preoperative beta-blockers has been a quality standard for patients undergoing coronary artery bypass graft surgery. However, a study by Dr. William T. Brinkman of the Cardiopulmonary Research Science and Technology Institute, Dallas, and colleagues found no evidence that perioperative beta-blocker usage before CABG was beneficial.

Using data from the STS National Database for 2000-2008, the researchers compared outcomes between two propensity-matched groups obtained from their overall study group: 4,474 patients received preoperative beta-blockers and 4,474 did not. There was no difference in event rates between patients treated with beta-blockers and those who were not, but significantly more beta-blocker-treated patients required intraoperative blood product use. The preoperative use of beta-blockers was not an independent predictor of mortality. Dr. Brinkman said at the annual meeting of the Society of Thoracic Surgeons.

“We were unable to substantiate any benefit to routine use of preoperative beta-blocker therapy. Our findings do not support continued use of preoperative beta-blockade as a quality indicator for CABG,” Dr. Brinkman said in an interview.

Discussant Dr. David M. Shahian, an ACS Fellow and chair of the STS National Database Workforce — which has advocated beta-blocker use as a quality control measure — disagreed with Dr. Brinkman’s conclusions. “There are now almost 30 randomized clinical trials that demonstrate on average a 60% reduction in the odds of postoperative atrial fibrillation with the use of perioperative beta-blockade. ... Because of this and other benefits for patients with various heart conditions, the use of these drugs has had long-standing support, unless contraindicated,” Dr. Shahian said.

Dr. Brinkman reported being on the speakers bureau of the Medicines Company; all authors had an ownership interest in the Heart Hospital Baylor Plano. Some of the authors had a financial relationship with heart device companies. Dr. Shahian had no relevant disclosures regarding his comments.
DENVER – Black children who receive kidney transplants appear more likely to lose their transplants sooner, compared with whites, results from a large analysis showed.

In addition, black pediatric patients living in high poverty neighborhoods face a more than twofold risk of transplant failure, compared with white patients.

“It has been reported that kidney transplants in blacks do not last as long as in whites, but we don’t really understand why this happens,” Dr. Amanda Amaral said during a press briefing at the annual meeting of the American Society of Nephrology.

Black patients were 2.3 times more likely to experience organ failure, compared with non-Hispanic whites to experience organ failure.

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We think part of it is biologic; there are genetic differences between races, differences in diseases, and differences in our immune systems. But we also think that there may be socioeconomic differences,” she said.

Dr. Amaral, an assistant professor of medicine at Emory University, Atlanta, and her associates studied outcomes from the United States Renal Data System (USRDS).

The patients were aged 21 years, and they received a kidney transplant between 2000 and 2006.

The researchers followed the patients for transplant outcomes through September 2008 and then linked their residential zip codes with poverty data obtained from the 2000 United States Census.

Dr. Amaral reported that 18.3% of the patients experienced organ failure during a mean follow-up of 3.6 years.

Black patients were 2.3 times more likely to experience organ failure, compared with non-Hispanic white patients (hazard ratio = 0.76).

After the researchers adjusted for demographic, clinical, and socioeconomic factors, they found that blacks were more likely to experience organ failure, compared with non-Hispanic whites. Furthermore, the degree of disparity varied by patient’s residential neighborhood.

Poverty also played a role in adverse outcomes in all patients. However, black patients were 4.0 times more likely to experience transplant failure, compared with their white counterparts.

This relationship was also apparent in the wealthiest neighborhoods (those in which fewer than 5% lived below the federal poverty line), where black patients were 40% more likely to experience organ failure, compared with women.

It looks like poverty makes a difference,” Dr. Amaral said. “It makes it harder for you to have a successful transplant.

She acknowledged certain limitations of the study, including the fact that the USRDS is unable to capture the specific barriers that get in the way of better transplant survival. “Is it because patients have more comorbid conditions, or is it because they can’t get to their appointments? she asked. “Are there other things that get in the way of them being successful?” This is an area for further study.

Dr. Amaral said that she had no relevant financial disclosures.
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- Complicated intra-abdominal infections caused by Citrobacter freundii, Enterobacter cloacae, Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Enterococcus faecalis (vancomycin-susceptible isolates), Staphylococcus aureus (methicillin-susceptible and -resistant isolates), Streptococcus anginosus grp. (includes S. anginosus, S. intermedius, and S. constellatus), Bacteroides fragilis, Bacteroides thetaiotaomicron, Bacteroides uniformis, Bacteroides vulgatus, Clostridium perfringens, and Peptostreptococcus micros
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Important Safety Information

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- Anaphylaxis/anaphylactoid reactions have been reported with nearly all antibacterial agents, including tigecycline, and may be life-threatening. TYGACIL should be administered with caution in patients with known hypersensitivity to tetracycline-class antibiotics
- Isolated cases of significant hepatic dysfunction and hepatic failure have been reported in patients being treated with tigecycline. Some of these patients were receiving multiple concomitant medications. Patients who develop abnormal liver function tests during tigecycline therapy should be monitored for evidence of worsening hepatic function. Adverse events may occur after the drug has been discontinued
- The safety and efficacy of TYGACIL in patients with hospital-acquired pneumonia have not been established
- An increase in all-cause mortality has been observed across phase 3 and 4 clinical studies in TYGACIL-treated patients versus comparator-treated patients. The cause of this increase has not been established. This increase in all-cause mortality should be considered when selecting among treatment options
- TYGACIL may cause fetal harm when administered to a pregnant woman
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- Acute pancreatitis, including fatal cases, has occurred in association with tigecycline treatment. Consideration should be given to the cessation of the treatment with tigecycline in cases suspected of having developed pancreatitis
- 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
- Monotherapy should be used with caution in patients with clinically apparent intestinal perforation
- TYGACIL is 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
- 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. As with other antibacterial drugs, use of TYGACIL may result in overgrowth of non-susceptible organisms, including fungi
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- Prothrombin time or other suitable anticoagulant test should be monitored if TYGACIL is administered with warfarin
- Concurrent use of antibacterial drugs with oral contraceptives may render oral contraceptives less effective
- The safety and effectiveness of TYGACIL in patients below age 18 and lactating women have not been established

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