



## AMERICAN COLLEGE OF SURGEONS

## SURGERY NEWS

## Patient Benchmarks Defined for Revascularization

BY BRUCE JANCIN

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TUCSON, ARIZ. — Clinical success following lower-extremity revascularization for ischemic tissue loss is determined by key intrinsic patient factors, not by the revascularization method used, according to a retrospective study of 677 patients.

“We need to get over debating ‘Is endovascular better than open, is open better than endo?’ Everybody’s using both now. We have to assume we’re providing the best form of revascularization and ... select patients [who] are really going to benefit from either one or both approaches if we’re to improve our outcomes,” Dr. John W. York said at the annual meeting of the Southern Association for Vascular Surgery.

The traditional surgeon-defined measures for successful lower-extremity revascularization, such as graft patency and limb salvage rates, provide an unrealistic picture of what the actual benefit to the patient will be, according to Dr. York, an ACS Fellow with the Greenville (S.C.) Hospital System University Medical Center.

For this reason, he and his colleagues have come up with patient-oriented benchmarks for procedural success to help patients make fully informed treatment decisions based on realistic expectations. These four benchmarks are patency of the reconstruction until wound healing has occurred, limb salvage and maintenance of ambulation for 1 year, and survival for 6 months.

These represent a goal that anyone undergoing surgery could reasonably expect. Successful outcome requires achievement of all four, he said.

Dr. York applied this definition of clinical success in a study of 677 consecutive patients with lower-extremity ischemic tissue loss. Of those, 361 underwent open repair and 316 endovascular revascularization.

The overall clinical success rate in achieving all four benchmarks was a “somewhat sobering” 41%, he said, with no significant difference between patients undergoing endovascular versus open procedures. The 1-year limb salvage rate was 76%. Both the 1-year ambulation rate and the survival rate for at least 6 months was 85%. But the rate of reconstruction patency to the point of wound healing was only 44%.

The type of revascularization used was 1 of 20 factors evaluated as potential predictors of clinical success. In a multivariate analysis, five intrinsic patient variables emerged as independent predictors of clinical failure. Impaired ambulation at presentation was the strongest of the five.

Vascular surgery patients with none of the five predictors were “elusively rare,” according to Dr. York, but this group had a 65% probability of clinical success as defined by meeting all four benchmarks. The success rate dropped to about 40% in patients with two independent predictors of failure and to 18% in those with three predictors. Patients who possessed all five predictors had only a 7% success rate; such patients—even if somewhat ambulatory at baseline—might have been better served by not being offered revascularization and receiving symptomatic medical management and eventual primary amputation instead, he continued.

The 41% clinical success rate based on these benchmarks was so disconcertingly low, that discussant Dr. David J. Minion quipped that he found himself repeating, “My whole existence is a sham.” More seriously, he suggested that the study underscores the fact that limb salvage and wound healing are two distinct entities. While the patency and 1-year limb salvage

rates were good, most wounds were not healing.

“Vascular surgeons need to focus more research efforts on advancing wound care in order to achieve further success with these patients,” concluded Dr. Minion, an ACS Fellow at the University of Kentucky, Lexington.

The Greenville data spurred spirited audience discussion on amputation in patients with lower limb ischemic tissue loss. Dr. Jacob G. Robison said that, while primary amputation is a reasonable option in nonambulatory patients, in many ambulatory ones it is tantamount to throwing the baby out with the bath water.

“If you look at the challenging group of ambulatory patients with both tissue necrosis and end-stage renal disease, in our experience, even though half of those patients aren’t alive in 5 years, half of those who are have a functioning lower-extremity reconstruction.” If you view it as patient-oriented, cost-effective care measured in quality-adjusted life years, lower-extremity bypass or endovascular revascularization is better than primary amputation, said Dr. Robison, an ACS Fellow with the Medical University of South Carolina, Charleston.

In contrast, Dr. Stuart I. Myers argued that “Amputation is not a failure of treatment, it’s another treatment; there are a lot of patients who benefit from that. If a prosthesis enables a patient to get up out of a wheelchair to go to the bathroom, I think that’s a success.”

Dr. Myers, an ACS Fellow with the University of Tennessee at Chattanooga, added that he found the study “very thought provoking.”

“It points to objective criteria—something beyond the eyeball test—for determining who’s going to need primary amputation,” said Dr. Myers. ■



**Graft patency and limb salvage rates provide an unrealistic picture of what the patient benefit will be.**

DR. YORK

## Colon Resection Patients Fare Well at Nonteaching Hospitals

BY KERRI WACHTER

*Elsevier Global Medical News*

Mortality and length of stay following colon resection are significantly reduced at nonteaching hospitals, compared with teaching hospitals, according to a retrospective analysis of 6 years’ data in the National Inpatient Sample.

Following risk and volume adjustment, teaching hospitals were associated with a 14% increased risk of operative mortality, Dr. Awori J. Hayanga reported at the annual Academic Surgical Congress in Fort Myers, Fla. There also was a significant increase in length of stay—10.4 days at teaching hospitals versus 8.5 days at nonteaching hospitals—and a trend toward an increase in total charges from about \$6,000 to more than \$8,000.

“The assumption is that teaching hospitals have higher volumes for all procedures, and that’s not the case ... most colon resections in the United States are

not performed in teaching hospitals,” Dr. Hayanga said in an interview. “Cancer makes up the minority of resections that are performed on the colon. More resections are performed for benign disease.” The bulk of resections for benign colon disease are performed at nonteaching hospitals.

“We are postulating that there might be a tipping point in the volume-outcome ratio that shifts in favor of nonteaching hospitals—once you hit the critical volume of procedures,” said Dr. Hayanga, a surgical resident at the University of Michigan in Ann Arbor.

The analysis conducted by Dr. Hayanga and his colleagues was supplemented with data from the Area Resource File and the National Inpatient Sample. Logistic regression analysis was used to estimate 30-day mortality while linear regression analysis was used to estimate both length of stay and total charges. A teaching hospital met the definition by

the American Hospital Association and was affiliated with either an Accreditation Council for Graduate Medical Education-accredited general surgery residency and/or colon fellowship at the institution.

The analysis included patients over the age of 18 who had undergone a colon resection as classified by ICD-9 codes. Covariates included age, sex, race, insurance status, geographical region, institutional volume and urban/suburban/rural status, median county income, and percentage of county residents living below the federal poverty level.

“Teaching hospitals—with their propensity for performing rare and specialized surgery—tend to see sicker patients, who require the resources that are available only at these tertiary centers to get these patients better,” said Dr. Hayanga. “There is a feeling that there is a qualitatively different patient who comes to teaching hospitals.”

To attempt to control for possible differences in the types of patients seen at teaching versus nonteaching hospitals, the investigators included the Charlson comorbidity index as a covariate.

In all, 115,250 patients underwent colon resection during the time period at more than 2,000 hospitals. Most patients (60%) received care at nonteaching hospitals. Overall, the mortality rate was 3.8%.

The researchers concluded that teaching hospitals may offer improved outcomes for complex oncologic surgical resections but may have worse outcomes for less complex surgery. Most of the less complex procedures are performed at nonteaching hospitals.

The databases have some limitations, and the study raises more questions than it answers, Dr. Hayanga acknowledged, adding that to accurately determine this relationship, a randomized prospective study would be needed for further clarification. ■



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## Refused Pediatric Donor Hearts Found Acceptable

BY SHERRY BOSCHERT  
Elsevier Global Medical News

SAN FRANCISCO — Transplanting pediatric hearts that had been refused by at least one other transplantation program produced survival rates similar to transplants using newly offered hearts in a study of 141 patients.

Hearts previously refused on the basis of quality were transplanted in 29 children, 27 (93%) of whom survived the operation, and 24 (83%) of whom are alive today. The operative survival rate was identical (93%) in 112 children who received primarily offered hearts, with 81% (91 patients) alive today, a review of all pediatric heart transplants at one institution during the past 8 years found.

Similar results were achieved despite the previously declined hearts having had a longer graft cold ischemic time (384 minutes on average), compared with primarily offered hearts (289 minutes), and being less likely to come from

local organ procurement organizations.

"This suggests that pediatric donor hearts should seldom be declined on the basis of organ quality or projected graft cold ischemic time," Dr. Leonard L. Bailey said at the annual meeting of the Society of Thoracic Surgeons.

Actuarial survival rates also were similar. Of those with previously refused hearts, 79% could expect to live 7 years, compared with 74% with primarily offered hearts, the researchers reported.

Among 6,000 donor hearts offered through the United Network for Organ Sharing (UNOS) in the United States during 2000-2008, only 3,943 were transplanted, noted Dr. Bailey, an ACS Fellow and distinguished professor of surgery at Loma Linda (Calif.) University. Approximately a third of pediatric donor hearts are lost to transplantation yearly, often because they are refused on the basis of graft quality (UNOS Code 830).

The previously refused hearts in the study fell under UNOS Code 830 and

were more likely to have suffered anoxia, compared with the primarily offered hearts, which were more likely to come from donors with head trauma. The surgeons transplanted a total of 115 hearts into 112 patients.

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

Dr. Hillel Laks, an ACS Fellow and professor of surgery at the University of California, Los Angeles, who commented on the study, compared results with outcomes at his institution after transplanting 266 hearts into 244 children from 1984 to 2009. "We, too, have accepted hearts at a distance," with donor ischemic times longer than 8 hours in 1 patient, 6-8 hours in 3 patients, 4-6 hours in 28 patients, and shorter ischemic times in 52 patients, he said.

About 5% of the patients died within 30 days of transplant. "Our patients were older than the Loma Linda group, with a mean age of 7 years, as opposed to the 2.1 years for Dr. Bailey's primar-

ily accepted group and 1.5 years for the refused hearts," Dr. Laks explained.

He asked how many of Dr. Bailey's patients had mildly or moderately impaired ventricular function or ejection fractions below 25%. Donor hearts with combined risk factors such as these or a slight size mismatch might be refused by his program. "We found that additive factors should be avoided in trying to minimize the risk in borderline recipients," he said.

Dr. Bailey said his institution uses a shortened ejection fraction of around 20% as a cutoff for rejecting pediatric donor hearts. "If we can't get above that with inotropic support, then we won't accept it," he said.

UCLA created an "alternate" transplant list for adult high-risk patients in need of a new heart (who might not qualify for transplant) who may be matched with "marginal" donor hearts. He suggested that this might be helpful for pediatric patients, an idea that Dr. Bailey called "excellent." ■

## Weigh Risk of Bleeding vs. Clotting in Warfarin Use

BY DAMIAN McNAMARA  
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MIAMI BEACH — The perioperative risk of thromboembolism is small but real for warfarin patients who discontinue anticoagulation to undergo non-cardiac surgery or other procedures. Bridging therapy can reduce this risk, but it increases the likelihood of postoperative bleeding, so clinical judgment, guideline recommendations, and individual patient and surgical factors remain paramount, Dr. Amir K. Jaffer said.

"This whole area lacks randomized, controlled trials, and management is guided by observational data and consensus," Dr. Jaffer said at a meeting on perioperative medicine sponsored by the University of Miami. "You have to balance risk of bleeding against the risk of clotting."

Patients often require an individualized approach. For example, the population of patients with older-generation mechanical heart valves or mechanical valves in the mitral position are at higher risk for thromboembolic events, according to the most recent guidelines on peri-

operative management of antithrombotic therapy from the American College of Chest Physicians (Chest 2008;133:299S-339S). The valve type and its position are two important factors

to consider, Dr. Jaffer said. Risk is generally greater among patients with a mitral valve or older device (for example, ball-in-cage type), compared with patients who have an atrial bileaflet valve (Circulation 1994;89:635-41).

"Warfarin is a tricky drug," said Dr. Jaffer, chief of the division of hospital medicine at the University of Miami, and a coauthor of the ACCP guidelines. "It is a highly litigated area of perioperative medicine. Every week or so, I have an attorney calling me to serve as an expert; the plaintiffs' attorneys are always going after these types of cases."

One reason warfarin is big business for lawyers is that almost 3 million patients are taking the drug in North America,

and 400,000 of these are evaluated for bridging therapy each year, according to the American Heart Association 2002 Heart and Stroke Statistical Update.

Although the dangers are clinically significant, they affect only a minority of patients. "The risk of thromboembolism is low. It's not zero; it is about 1%," Dr. Jaffer said. For example, 2 of 224 (0.9%) of warfarin patients experienced cardiac thromboembolism in one study (Circulation 2004;110:1658-63).

The risk of major bleeding in this series was 6.9%. However, the average risk of

major bleeding is 3%-3.5% across studies in the literature for patients with a valve or other indication who have warfarin discontinued and receive low-molecular-weight heparin (LMWH) as a bridge. For example, major bleeding occurred in 3.5% of 260 patients in one study (J. Thromb. Haemost. 2007;5:2211-8) and 3.3% of 721

patients in another (J. Thromb. Haemost. 2006;4:1246-52).

There can be increased bleeding immediately postoperatively with full-dose LMWH or unfractionated heparin, "but this can likely be minimized by delaying reinitiation of full-dose heparin ... for up to 48 hours, depending on the type of surgery," Dr. Jaffer said. In the interim, lower prophylactic doses may be warranted. "Those centers who dose everyone with full doses were at [six times] higher risk for major bleeding than those who did not give full doses," according to unpublished data on 500 patients.

Guidelines support bridging patients with therapeutic doses of subcutaneous LMWH, rather than intravenous unfractionated heparin, as there is a paucity of data for intravenous unfractionated heparin, said Dr. Jaffer. He is a consultant for Sanofi-Aventis, AstraZeneca, Bristol-Myers Squibb, and Boehringer-Ingelheim. In addition, he receives research and grant support from AstraZeneca and is on the speakers bureau for Sanofi-Aventis and Roche Diagnostics.

Although both thromboem-

bolic events and major bleeding can be fatal, mortality and morbidity rates differ for the two conditions. "With bleeding, patients can be resuscitated; with a thromboembolic event, they can have long-lasting disability," Dr. Jaffer said. A total of 9%-13% of major bleeding events are fatal but rarely result in permanent disability (Ann. Intern. Med. 2003;139:893-900). In contrast, an estimated 20% of arterial thromboembolic events are fatal, and more than 50% result in permanent disability (Arch. Intern. Med. 1994;154:1449-57).

Ultimately, the decision on perioperatively managing warfarin patients relies on individual patient and surgical risk factors. The patients' indication for anticoagulation, their risk profile for thromboembolism, the type of surgery, and the likely amount of time they will be off warfarin therapy are important considerations, Dr. Jaffer said. "Weigh the consequences of thromboembolism and bleeding and then determine the need for bridging therapy ... and include patient and provider preferences in decision making." ■



**'Warfarin is a tricky drug. It is a highly litigated area of perioperative medicine.'**  
DR. JAFFER