British Data Back Efficacy of Selective EVAR Use

BY MITCHEL L. ZOLER
Philadelphia Bureau

Midterm findings from two British studies of endovascular repair of abdominal aortic aneurysms may have limited relevance to U.S. practice because the aneurysms were relatively large and the wait for surgery was long.

Still, the findings offer another boost to the documented efficacy and safety of endovascular aneurysm repair (EVAR), which already is the preferred repair option in the United States, experts said. The findings also underscore the importance of reserving EVAR for patients with aortic anatomy that's amenable to placement of an endovascular-repair device.

For elderly and higher-risk patients, the results "shift the balance in favor of EVAR, and many younger, lower-risk patients will now also shift toward EVAR to avoid the short-term morbidity of open repair," said Jack L. Cronenwett, M.D., chief of vascular surgery at Dartmouth-Hitchcock Medical Center, Lebanon, N.H.

"These data will be very helpful for giving patients a perspective on how the treatment works long-term," said Thomas S. Riles, M.D., chairman of the department of surgery and a vascular surgeon at New York University. "We currently do about 80% of our abdominal aortic aneurysm [AAA] repairs with EVAR, and as I look at these data, I think that maybe we should be a little more conservative. But if a group now does about 50% of their repairs with EVAR, maybe the results will push them to use EVAR more," he said in an interview.

According to Dr. Cronenwett, most American centers now use EVAR in about 60% of patients with AAAs that are large enough to warrant repair.

William D. Jordan, M.D., chief of vascular surgery at the University of Alabama, Birmingham, questioned the relevance of the two studies because the aneurysms were often large at the time of randomization (all AAAs had a diameter of at least 5.5 cm) and because many patients had long delays before surgery.

The standard of care in the United States is to offer repair once an AAA reaches 5.0 cm in diameter; with increasing use of routine surveillance, more patients are being diagnosed with even smaller AAAs. Although the efficacy and safety of AAA repair for aneurysms that are 4.0-4.9 cm in diameter are now being studied in two trials, Dr. Jordan will repair an AAA of this size if the patient asks for it and is a suitable candidate, he said in an interview.

The EVAR trials 1 and 2 were done at 34 hospitals in the United Kingdom, which assessed 4,799 patients with an AAA from September 1999 through December 2003. From this group, 1,423 patients had an AAA at least 5.5 cm in diameter and were judged eligible for either EVAR or open repair, and from this group a total of 1,082 were randomized and included in the primary end point analysis for trial 1.

Of the more than 3,000 patients ineligible for randomization, 457 were eligible for EVAR with an AAA at least 5.5 cm in diameter but unfit for open repair. Of these, 338 enrolled in trial 2 and were randomized to EVAR or medical management.

The average age of patients in trial 1 was 74 years, and their median aneurysm diameter was 6.2 cm. The median time from randomization to surgery was 43 days for EVAR and 36 days for open repair.

By 30 days after surgery, patients treated with EVAR had 1.7% mortality, compared with 4.7% in those who got an open repair (Lancet 2004;364:843-8).

By the end of 2004, all patients had been followed for 1 year, 70% for 2 years, 47% for 3 years, and 24% for 4 years. At that point, the incidence of death from all causes was 100 out of 543 in the EVAR group (18.4%), and 109 out of 539 in the open-repair group (20.2%), a difference that was not statistically significant.

But aneurysm-related deaths occurred in 19 of the EVAR patients (3.5%), compared with 34 in the open-repair group (6.3%) a statistically significant difference. When the rate of aneurysm-related deaths was adjusted for clinical and demographic differences at baseline, EVAR was associated with a 49% drop in the rate of aneurysm-related deaths, compared with open repairs (Lancet 2005;365:2179-86).

Although aneurysm-related survival was better with EVAR, the procedure also led to more complications. By 4 years, 41% of patients in the EVAR group had at least one complication, compared with 9% among those who got open repair.

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In EVAR trial 2, the 166 patients randomized to EVAR had a median aneurysm diameter of 6.4 cm and waited a median of 57 days from randomization until their procedure was done. While awaiting EVAR, nine patients experienced aneurysm rupture. Among the 172 patients randomized to medical management, 47 (27%) eventually had their aneurysm treated by EVAR or open repair.

During up to 4 years of follow-up in trial 2, there was no statistically significant difference between the two study groups in total mortality or in aneurysm-related mortality (Lancet 2005; 365:2187-92).

The performance of EVAR in trial 2 was handicapped by two factors, Dr. Cronenwett said in an editorial. First was the lag between randomization and EVAR—a delay that probably led to the ruptures in nine patients. Second was the high rate of aneurysm repairs in the patients randomized to medical management. These two factors "bias the study against EVAR," he wrote (Lancet 2005;365:2156-8).

Nonetheless, trial 2 shows that in patients with a relatively short life expectancy, EVAR should be targeted to carefully selected patients, he said.

Trial 1 also shows that patients with low operative risk are the best candidates for open repair and should be considered for EVAR only if they have excellent anatomic suitability. According to Dr. Riles, that would mean a long, proximal, aortic neck, 1.5 cm or longer, and a width that's ideally no more than 28 mm.

A relatively small fraction of patients with marginal anatomic suitability and a short life expectancy are best managed medically with no aneurysm repair. But a sizable fraction of patients fall into a gray area, where there is no clear advantage of EVAR or open repair. In these cases, patient preference is an important factor, Dr. Cronenwett wrote.

Dr. Riles noted that the data from the British trials will be useful for tempering the enthusiasm of some patients for EVAR by showing them that after EVAR, they face an ongoing risk that a follow-up procedure will be needed in the future. ■

New Resuscitation Guidelines to Emphasize Compression

BY KATE JOHNSON
Montreal Bureau

MONTREAL — Although the content of new resuscitation guidelines will not be released until December, the elimination of interruptions to chest compression during CPR is likely to be one of the major issues that is addressed.

The International Liaison Committee on Resuscitation (ILCOR) plans to publish an international consensus on the science for CPR and emergency cardiovascular care (ECC) in November, on which its member countries will base their resuscitation guidelines, said Marc Gay, who serves on the resuscitation policy advisory committee for the Heart and Stroke Foundation of Canada.

Although he would not hint at how the new guidelines will differ from current ones, he did suggest that CPR priorities need to change.

"There are certain things we need to do better," he said in an interview at the International Interdisciplinary Conference on Emergencies.

"There have been recent studies showing that both in-hospital and out-of-hospital resuscitation attempts by paramedics are not good because there are too many distractions and interruptions."

The last guideline update, in 2000, eliminated the recommendation of pulse checks for laypeople performing CPR in an attempt to improve efficiency, and cut down on their division of time, he said.

"Certainly, common sense says that even for health care professionals, there is a similar time limit," he said.

Because 90% of all cardiac arrests are of cardiac etiology only, there is growing support for the idea that chest compression should take precedence over almost everything else in CPR, Mr. Gay said.

To that end, the fire department in Tucson, Ariz., working with the University of Arizona's Sarver Heart Center, recently abandoned current resuscitation guidelines in favor of a new CPR protocol that de-emphasizes many of the interruptions (rhythm analysis, defibrillation, tracheal intubation, and placement of intravenous catheters) and focuses on chest compressions (Resuscitation 2005;64:261-8).

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Using data from their own controlled animal experiments, published clinical studies, and data from the 17-year-old fire department database, the researchers identified four main issues contributing to stagnant out-of-hospital cardiac arrest survival rates: lack of bystander CPR efforts; the complexity of CPR education for lay rescuers; an emphasis on defibrillation first, regardless of the duration of ventricular fibrillation; and frequent interruptions of chest compressions resulting in a marked compromise in circulatory support during resuscitation efforts.

An evaluation of the outcome of their protocol changes has not yet been done, but there is no doubt of the authors' political intent.

"A formalized, evidence-based process has been adopted by the International Liaison Committee on Resuscitation in formulating [its] guidelines," the investigators wrote. "Currently, randomized clinical trials are considered optimal evidence, and very few major changes in the Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care are made without such. An alternative approach is to allow externally controlled clinical trials more weight in Guideline formulation and resuscitation protocol adoption." ■