Formulas Identify Best Patients for AAA Repair

BY MITCHEL L. ZOLER
Philadelphia Bureau

PHILADELPHIA — Some patients with abdominal aortic aneurysms are simply too sick to safely undergo aneurysm repair, be it by open surgery or with an endovascular procedure. Evidence is now starting to accumulate on how to identify patients for whom aneurysm repair is too risky.

New data suggest that only a few patients, perhaps less than 3%, fall into the high-risk group that shouldn't undergo repair of an abdominal aortic aneurysm (AAA). And new findings also indicate that, contrary to prior belief, it's the fittest patients who gain the biggest advantage from undergoing endovascular aneurysm repair (EVAR) instead of open surgery.

"The trend is toward the fitter the patient, the more EVAR may benefit over open repair," Dr. Roger M. Greenhalgh said at the Vascular Annual Meeting, sponsored by the Society for Vascular Surgery. "At the other end, in extremely unfit patients, you eventually get to a point where the unfitness is so great that EVAR won't help at all," added Dr. Greenhalgh, professor of surgery and head of vascular surgery at Imperial College, London. "It's sensible to use a scoring method to assess fitness."

One formula for measuring preoperative fitness was derived empirically by looking at all of the AAA repair patients in the more than 41 million patients of the Medicare data set from 2000 to 2004. In this group were 39,792 patients who underwent an elective, first-time AAA repair using EVAR. Overall in this group, the rate of death during

the first 30 days after treatment was 1.73%, said Dr. K. Craig Kent, chief of vascular surgery at New York-Presbyterian Hospital.

Use of EVAR rose throughout the 5 years examined, from 1,500 patients in 2000 to 12,000 in 2004. And the 30-day mortality rate was cut in half, from 2.5% in 2000 down to 1.25% in 2004.

Based on a multivariate analysis that assessed the role of a variety of comorbidities in 30-day

mortality, Dr. Kent and his associates calculated a very preliminary scoring system to assess the risk of perioperative death that a patient faces from EVAR.

Renal failure emerged as the single most important comorbidity, scoring five points in the system Dr. Kent presented. (See upper part of box.)

When this comorbidity scoring system was applied to the Medicare cohort, scores could be associated with specific perioperative mortality rates. (See lower part of box.) Finally, Dr. Kent

maining 97.7% of the AAA patients had a lower score and hence a lower risk of 30-day death.

Until now, "we had thought that high-risk patients might be 20%-30%" of all patients with an AAA. Dr. Kent said.

A different approach to risk assessment was tested by Dr. Greenhalgh and his associates using data they had collected on patients in the landmark EVAR tri-

used was a modified form of a previously reported scoring system that had been developed to assess perioperative mortality in patients undergoing vascular surgery by researchers at Erasmus Medical Center, Rotterdam, Netherlands (Arch. Intern. Med. 2005;165:898-904).

The modified Rotterdam formula is called the customized probability index (CPI), and uses seven clinical characteristics: re-

fined as a serum creatinine level of 2 mg/dL or greater) adds 16 points, uncontrolled heart failure adds 14 points, ischemic heart disease adds 13 points, hypertension adds 7 points, and chronic pulmonary disease (defined as a forced expiratory volume of less than 60% of predicted) also adds 7 points. Treatment with either of two medications was considered to cut the mortality risk and therefore subtracts points. Treatment with a β-blocker subtracts 15 points, and treatment with a statin pares 10 points off the total.

nal dysfunction (de-

The result is a CPI point total that can range from -25 to +57, said Louise C. Brown, a statistician who works with Dr. Greenhalgh at Imperial College.

When the researchers applied the CPI to 1,174 patients in EVAR Trial 1 studies, they found that 47% fell into a category with good fitness for surgery, having a

CPI score ranging from –25 to 0. Another 26% had a moderate CPI score of 1-10, and 27% had poor fitness, with a score of 11 to 36. The average CPI score for all patients was 3.7 in EVAR trial 1, and it was 10.1 in EVAR trial 2.

The London team then analyzed the 30-day operative mortality rates for patients in the three fitness categories based on whether the patients had been treated with EVAR or open surgery.

Patients with good fitness were 83% less likely to die when they underwent EVAR, compared with open surgery, a statistically significant difference. Patients with moderate fitness had an 11% drop in mortality with EVAR, compared with open surgery, and poor fitness patients had a 53% reduced mortality, but a test for any difference across all the fitness ranges did now show any strongly significant results.

All-cause mortality during 5 years after surgery was roughly similar between the EVAR and open surgery groups for all three fitness subgroups. Although aneurysm-related deaths during 5-year follow-up were reduced by 52% in patients who were repaired by EVAR in the good fitness group, there was little evidence of difference across the fitness spectrum.

In short, the analysis showed no fitness group for which open surgery was superior to EVAR, but there was some evidence that EVAR may be a better option for patients who were most fit for AAA repair, Dr. Greenhalgh said. In addition, "there is a small but potentially definable group of patients for whom open surgery is not possible [because of the high risk that surgery poses], and EVAR will not save the day."

Risk Scoring for Patients With Abdominal Aortic Aneurysm

Clinical Feature	Points
Renal failure	5
Cardiac arrhythmia	2
Neurologic comorbidity	2
Age 75 or older	2
Female	2
Chronic pulmonary disease	1
Heart failure	1
Absence of hypertension	1

Representative Scores and Mortality 30 Days After AAA Repair

Score	Mortality
0	0.5%
5	2.6%
10	12.5%
15	42.0%

Source: Dr. Ker

and his associates selected a representative high-risk score of 9, linked with a 9.3% risk of death, to determine how many of the Medicare patients met or exceeded this arbitrarily selected high-risk threshold. They found that 2.3% of the more than 39,000 patients in the group had a score of 9 or more. The re-

al 1 (Lancet 2005;365:2179-86) and EVAR trial 2 (Lancet 2005;365:2187-92). EVAR trial 1 randomized nearly 1,100 patients to EVAR or open surgical repair; EVAR trial 2 included 338 patients judged unfit for open surgery who were then randomized to EVAR or to no repair.

The risk assessment tool they

EVAR Better Than Open AAA Repair in High-Risk Patients

BY MITCHEL L. ZOLER
Philadelphia Bureau

PHILADELPHIA — Endovascular repair for abdominal aortic aneurysms appeared safer than open repair in a retrospective analysis of more than 2,000 high-risk patients who underwent aneurysm repair in the Veterans Affairs' health system.

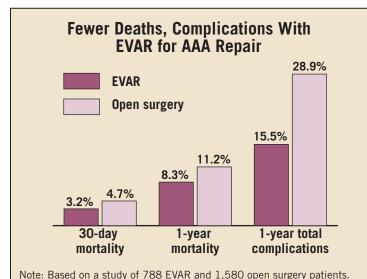
"EVAR [endovascular aneurysm repair] should be considered the alternative of choice for patients at high risk for aneurysm repair," Dr. Ruth L. Bush said at the Vascular Annual Meeting.

The study used data from the U.S. Department of Veterans Affairs' National Surgical Quality Improvement Program, which is the largest prospectively collected and validated U.S. surgical database. The analysis focused on the approximately 3,400 patients who underwent abdominal aortic aneurysm (AAA) repair during May 2001-December 2004.

From this group, Dr. Bush, a vascular surgeon at

Baylor College of Medicine, Houston, and her associates analyzed data on 2,368 high-risk patients. The researchers' definition of high risk included patients aged 60 or older who were classified as having grade III or IV disease by the criteria of the American Society of Anesthesiologists. The high-risk subgroup was further defined as having at least one of these additional conditions: a history of cardiac, respiratory, or hepatic disease; a history of coronary revascularization; renal dysfunction; or a serum albumin level of less than $3.4~\rm g/dL$.

The outcomes of 788 EVAR patients were analyzed, and compared with those of 1,580 open surgery patients with regard to 30-day mortality rate, 1-year death rate, and total complications rate. (See box.) In an analysis that adjusted for baseline differences between the two treatment groups, EVAR was associated with statistically significant reductions for all three measures, compared with the open-surgery group, Dr. Bush said.



Note: Based on a study of 788 EVAR and 1,580 open surgery patients. Source: Dr. Bush