Endovascular Aneurysm Repair for High-Risk Patients: Weighing Controversial EVAR2 Evidence

Endovascular aneurysm repair (EVAR) was developed to address the needs of high-risk aortic aneurysm patients found unfit to undergo open surgery. To study its effectiveness, the Health Technology Assessment program (a branch of the United Kingdom's National Health Service) commissioned wide-ranging EVAR 1 and 2 trials. Although EVAR 1 showed that endovascular repair of abdominal aortic aneurysms provided a 3% mortality benefit, EVAR 2 showed that for high-risk patients there was no demonstrable mortality benefit, and further that 7% of patients died within 30 days of the procedure. Today at the 33rd annual VEITHsymposium™, renowned vascular surgeons discussed the implications of these findings, in the process raising serious questions about the methodology and findings of EVAR 2.

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Sir Peter R.F. Bell, Professor of Surgery at the University of Leicester (Leicester, UK), made a compelling case that the EVAR 2 trial had major design flaws. Addressing the issue of 30-day mortality benefit, Dr. Bell pointed out that nine patients who were awaiting open repair died from rupture while waiting for their procedures, raising the question of whether these numbers were properly weighted in the EVAR 2 analysis.

Additionally, Dr. Bell noted that 47 patients crossed over in the trial and had open surgery, rendering the trial results speculative, and also claimed that EVAR 2 used unclear criteria for determining what constituted a high-risk patient. Pointing out that abdominal aortic aneurysm patients are typically at risk from dying from multiple causes, Dr. Bell stated that the most immediate and non-invasive possible treatment of these aneurysms is of significant benefit. Dr. Bell said, "If your patient has seven reasons why he may die at any minute and one of those is rupture of his aneurysm, he always wants to improve his odds by reducing that to six and having the aneurysm repaired."

Other physicians disagreed, presenting solid evidence in support of the EVAR 2 findings. For EVAR 1, patients were classified into three groups of fitness: good, moderate and poor (high-risk). In terms of 30-day mortality, there was some evidence to suggest that all three fitness groups fared better with EVAR than with open repair; however, the benefit was only statistically significant in the fittest group. Other benefits reported for these high-risk patients were shown, after customized probability analysis, to be statistically insignificant. Ultimately, only the most fit patients were found to benefit from EVAR. The high-risk patients for whom the procedure was designed did not show significant benefit.

These sharply different interpretations of the EVAR 2 findings reflect a continuing debate among vascular
surgeons that may only be resolvable with additional study.

About VEITHsymposium™: Now entering its fourth decade, VEITHsymposium™ provides vascular surgeons, interventional radiologists, interventional cardiologists and other vascular specialists with a unique and exciting format to learn the most current information about what is new and important in the treatment of vascular disease. The 5-day event features 300 rapid-fire presentations from the world's most renowned vascular specialists with emphasis on the latest advances, changing concepts in diagnosis and management, pressing controversies and new techniques.

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