Endovascular Aneurysm Repair Should Be the Gold Standard for All Abdominal Aortic Aneurysms with Reasonable Anatomy and Even Some 4.0 cm Abdominal Aortic Aneurysms

Kenneth Ouriel, MD, Cleveland, OH

NOTES

The choice between two therapeutic choices rests on an approximation of the risks and benefits associated with each. In the case of abdominal aortic aneurysms (AAA), there exist three alternatives; open surgical repair, endovascular repair, and observation alone. When comparing any invasive or even semi-invasive intervention with an observational choice, the morbidity and mortality of the procedure must be made up over time as the risks of nonintervention accrue. For instance, even in the best of hands, the 1 to 2% mortality rate of open surgical AAA repair must be "repaid" as the risk of rupture and death accumulate in patients who are observed without repair. For this reason, repair of an aneurysm in a patient with limited life expectancy is unlikely to be fruitful; the mortality cost of the procedure itself will not be repaid by a sufficiently high cumulative risk of death from rupture.

Some simple hypothetical numbers will illustrate this point. If the risk of rupture-associated death without treatment is 0.5% per year for a given sized AAA, and if the risk of death from the procedure is 2%, it will take approximately 4 years (2% ÷ 0.5%) to repay the mortality from repair (assuming the aneurysm doesn't grow to a size associated with an increased risk of rupture). Patients with less than 4 years life expectancy should not be offered repair since, on the average, they will not live long enough to realize the benefits of the procedure. Now let us assume that the aneurysm is smaller and the risk of rupture is only 0.25% per year. Clearly, a much lower threshold of comorbid conditions would be used to decide whether repair should be offered; these patients must be predicted to live more than 8 years (2% ÷ 0.25%) for repair to be beneficial. Adjusting the numbers slightly will alter our clinical decision making; for example, assume that we now have a therapy with lower periprocedural mortality, say, 0.5%. Now, this therapy might be offered to the same subset of patients with smaller aneurysms (0.25% yearly risk of rupture-associated death) as long as their life-expectancy is more than only 2 years (0.5% ÷ 0.25%). While these calculations are approximate and not based on precise, actuarial-adjusted risk, they do illustrate the caveat that smaller aneurysms should be considered for repair in healthier individuals; one should wait until the aneurysm is larger as the level of comorbidity increases. As well, endovascular repair, if durable, may be applicable in smaller aneurysms or in individuals with a shorter life expectancy—as long as the periprocedural mortality of endovascular repair is sufficiently low.

The recently reported DREAM and EVAR studies, for the first time, provide objective data to sort these issues out. These two studies randomized patients with > 5.5 cm diameter AAA to endovascular or open surgical repair. Both DREAM and EVAR-1 confirmed lower periprocedural mortality with endovascular repair; a benefit that did not, in either study, persist over longer-term follow-up. In fact, in both studies, the long-term survival after endovascular or open surgical repair was virtually identical. If outcome is similar with two therapeutic options, it is natural that patients will opt for the less invasive therapy. Thus, DREAM and EVAR-1 offer good data that patients with > 5.5 cm aneurysms can safely be offered endovascular therapy as a primary treatment option.

The surprise came from EVAR-2. This study randomized more ill, higher-risk patients to endovascular repair or observation. Even in this group of patients with larger aneurysms, endovascular repair was not associated with significant improvement in survival compared with observation. This finding could be explained by two findings. First, the periprocedural mortality of endovascular repair was very high in this subset of patients averaging 9%. Second, the long-term survival of this cohort of patients was very low due to death from causes not associated with the aneurysm. Roughly two-thirds of the patients succumbed, principally as a result of their comorbidities, over just 4 years of follow-up. One might speculate that the results of open surgery would have been even worse in this group of patients; the perioperative mortality rate would have likely been even higher; thereafter the fall off in survival should have roughly paralleled that in the endovascular group.

The last issue that needs to be considered is whether smaller AAA should be repaired with endovascular techniques. We know from the ADAM and the UK small aneurysm trials that open repair is not indicated in most aneurysms less than 5.5 cm in diameter. And, data from the Cleveland Clinic series of endovascular treatment of small AAA would suggest that the therapy is remarkably safe in smaller AAAs. Whether endovascular therapy is sufficiently better than open surgery and, by transitive logic, better than observation, remains to be seen. In mid-2005 a multicenter randomized trial of endovascular AAA repair versus observation, the PIVOTAL trial, was begun. This study, funded by Medtronic, plans to enroll 1,680 patients with aneurysms between 4 and 5 cm in diameter and follow them for the occurrence of rupture or aneurysm-related death (primary end point determined after 3-years of follow-up). A second trial, the CESEAR trial, was also recently begun, funded by Cook. The primary end point of this trial is all-cause mortality. It will be several years before even preliminary results from these trials are forthcoming.