Patient Selection for Endovascular Abdominal Aortic Aneurysm Repair

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Because the US device trials were not randomized and were not matched for either anatomic or clinical criteria, we do not have Level I evidence of efficacy when endovascular treatments are compared with conventional aortic aneurysm (AAA) repair. Consequently, creating a clear, detailed algorithm for patient selection is not possible at this time. Instead, the decision to recommend one type of aneurysm repair over another is quite subjective, will vary from institution to institution, and is governed by a number of factors including anatomy, medical comorbidity, operator skills, and access to the devices. Ideally, the UK EndoVascular Aneurysm Repair, the Dutch DREAM Trial, and the French ACE Project, when completed, will provide more objective guidance for patient selection for each of the two procedures. These trials will not only compare the two operative approaches but will also evaluate best medical treatment in inoperable cases. Although I believe that young, healthy patients should have conventional repair, in properly selected patients, endovascular repair appears to be comparable to conventional repair, using rupture and death as end points within the first year after deployment.1,3

Because most patients, given a choice, would opt for the simpler, less invasive procedure, the fundamental question each of us must ask is how to select those most suitable for each of the two approaches given the limited data available. There are two distinct aspects to this recommendation—first, the physiologic condition of the patient, taking into account the patient’s life expectancy and his or her risk for conventional operation, and second, the anatomic factors that make endovascular repair possible or impossible, safe or risky.

EARLY RESULTS OF ENDOVASCULAR ANEURYSM REPAIR

Vascular surgeons are psychologically uncomfortable with palliation of aneurysms as opposed to cure, probably for good reason. Endovascular repair does not provide freedom from rupture in every case. Rupture has been reported in 25 patients in the AneuRx Trials (1,112 patients treated).4 In contrast to conventional repair, the need for lifelong surveillance is costly in dollars, staff resources, and patient time. Reintervention rates for a variety of problems are alarmingly high and over an intermediate time may result in longer cumulative hospital days and expenditures than conventional repair. The largest data set is the EUROSTAR registry begun in 1996. Voluntary reporting from 88 institutions deploying over 3,000 endografts indicates that the 30-day mortality rate is 2.1%, freedom from persistent endoleak at 18 months is 90%, the rate of rupture approaches 1.5% per year, and the conversion rate to open repair is 3% per year.5 The voluntary reporting requirements of this registry probably underestimate the incidence of complications, but the fact that the incidence of graft-related complications does not decrease over time is worthy of note and concern. Nonetheless, in an older, sicker population, any lack of certainty about a longterm cure after endovascular repair seems less relevant.

ASSESSING THE RISK OF CONVENTIONAL REPAIR

Critical reviews of conventional repair indicate that the risk may be higher than most surgeons believe. Single-center studies exceeding 100 patients report the most favorable results (mortality rates of 0% to 3.7%).6−8 Operative mortality rates from multiinstitutional series of more than 300 patients are higher, ranging from 3.6% to 4.9%. Population-based studies report still higher mortality rates, ranging from 6% to 7.3%.9 Patients randomized to operation in the UK Small Aneurysm Trial had a 30-day mortality rate of 5.8%, although a mortality rate of only 2% was predicted during study design.10 In 1992, the Society for Vascular Surgery/International
Society for Cardiovascular Surgery defined age, cardiac function, pulmonary function, and renal function as the predictors of medical risk for elective aneurysm repair.11 Other factors are now known to affect mortality rates, namely the experience of the surgeon and the hospital. Dardik and colleagues12 reviewed all patients undergoing elective aneurysm repair in the state of Maryland between 1990 and 1995. There were 2,335 operations performed by 219 surgeons in 46 hospitals, and the in-hospital overall mortality rate was 3.5%. A medical complexity score was created from a computer-based analysis of comorbidities that included hospital volume, surgeon volume, and patient age. A multivariate analysis of these data showed that patient age (0.0002), low hospital volume (0.039), and very low-volume surgeons (0.01) were independent variables of mortality. Specifically, patients older than 80 years had a mortality rate of 7.3% after aneurysm repair, as compared with a rate of 2.2% for patients less than 65 years. The mortality rates for hospitals with high volumes (>50 during study period) and surgeons with very high volumes (>100 during study period) were roughly one-half the rates of hospitals and surgeons with little experience in aneurysm repair. It appears that the reported experience with endografts, and in particular the data from the Investigational Device Exemption (IDE) trials, come from precisely those surgeons and institutions with high-volume aortic surgical practices. It stands to reason that the best comparison to date may be these data from Maryland, the UK Small Aneurysm Trial, and like experiences.7-10,12,13

SHOULD AN ENDOVASCULAR OPTION LOWER THE THRESHOLD FOR REPAIR?

Elective repair has one goal: to prolong life. Certainly the size of the aneurysm at the time of diagnosis is a primary determinant of need for treatment. There is a temptation to lower the threshold for aneurysm repair because the morbidity and mortality rates of endovascular repair may be lower than those associated with conventional repair and because the procedure is less invasive and more readily accepted by patients. Mathematical models (Markov) have been created to examine whether the optimal diameter for elective aneurysm repair in average- and high-risk patients should be different for the two treatment modalities.13 Assumptions were made from published reports and were as follows: the annual rupture rates for infrarenal aortic aneurysms smaller than 4 cm, 4.5 cm, 5.5 cm, and 6.5 cm were 0%, 1%, 11%, and 26%, respectively; the mortality rates were 1% for endovascular repair and 3.5% for conventional repair (age 70 years); the immediate conversion rate from endovascular repair to open repair was 5% and was 1% per year thereafter. The benefit of aneurysm repair was then calculated in quality-adjusted life-years. The benefit of endovascular repair increased with increasing patient age and disappeared with procedural mortality rates exceeding 3.5% and longterm endovascular graft failure rates exceeding 6% per year. The quality-adjusted life-years benefits were small, and these authors concluded that lowering the threshold for endovascular AAA repair was not justified except for patients more than 80 years of age who were in poor health; for these patients, the data supported reducing the diameter threshold from 8.1 cm to 5.7 cm.

Longterm survival is reduced in patients with coronary artery disease, renal insufficiency, COPD (reduced forced expiratory volume in 1 second), hypertension, and peripheral vascular disease (reduced ankle brachial index [ABI]). Those patients who met the size criteria for operation in the UK Small Aneurysm Trial but who were medically unfit had a mortality rate of 22% at 10 months and 50% at 2 years.14 Recent EUROSTAR data analyzing older, sicker patients who underwent endovascular repair showed a cumulative survival of 58% at 3 years, suggesting limited advantage for repair in this high-risk group of patients.

ANATOMIC CONSIDERATIONS IN PATIENT SELECTION

Anatomic factors affecting patient selection include the length, shape, and angulation of the infrarenal neck; any involvement of the common iliac arteries with either aneurysmal or occlusive disease; occlusive disease or marked tortuosity of the iliofemoral access vessels; or intrinsically small iliac arteries.

Because the flexibility to alter course during an endovascular aneurysm repair is limited, preoperative images must provide accurate measurements of the diameters, lengths, and angulations of the attachment sites and information about the suitability of the access vessels and the presence of important nutrient vessels such as accessory renal arteries or large inferior mesenteric arteries. Although ultrasound images give accurate measurements of the diameter of the aneurysm, they provide no other useful data in planning an endovascular repair. Likewise, screening CT scans with images at 10-mm
intervals are inadequate in the majority of cases. Occasionally a patient will be referred with one of these images, and rather than repeating a spiral CT scan with 3-mm cuts, we go directly to an arteriogram, recognizing its limitations as well. The magnification artifact requires the use of a graduated radiopaque marker catheter (Fig. 1). Additionally, length measurements may be artificially short because tortuosity in the plane of an arteriogram causes a foreshortened appearance that diminishes the apparent length of the vessel, thereby underestimating the length requirements of the device. This can be avoided by appropriate oblique views. Intravascular ultrasound is an adjunct method that can be used when there are questions about access vessel disease and diameter (but not length).

Stable proximal fixation is the key to longterm durability. The downward force on the proximal attachment site is related to the diameter and curvature of the aorta. There is minimal drag in a straight aorta; the principle disrupting force on the device is that of the curve, which tends to cause migration from proximal to distal ends. The stress on the endograft is further related to the diameter of the aorta. The downward force in a 30-mm neck on a bifurcated graft is 10 newtons and is twice that of a 24-mm neck, where it is only 5 newtons (ML Brown, personal communication, November 2000). Increasing angulation of the proximal neck is associated with significant Type I endoleaks. As the angulation increases, the proximal attachment area must lengthen. A conservative approach would be as follows: a length of 2 cm is sufficient in the absence of proximal angulation. If there is angulation greater than 15 degrees, a length of 2.5 cm is required, and patients should be excluded if the angulation exceeds 30 degrees. This is a much more conservative approach than is advocated by some manufacturers who will accept angulations less than 60 degrees. Patients who fall in the 30- to 60-degree range are not anatomically ideal and should receive an endograft only when other options are even less desirable. Patients should be excluded if the proximal diameter progressively increases (conical neck) or if filling defects are present indicating thrombus or atheroma. Figures 2 through 4 illustrate problems with the proximal attachment site that should preclude endovascular repair with currently available devices.

The iliac arteries must obviously be of sufficient diameter to allow access to the aneurysm yet still provide suitable deployment sites within the ranges of the available devices. The distal attachment sites should not interfere with the existing internal iliac arteries (Fig. 5).
The angle between the longitudinal axis of the aorta and the common iliac arteries should be less than 45 degrees for successful deployment of a bifurcated endograft. If this measurement is exceeded, a bifurcated system should be excluded and an aorto-uniiliac system should be considered, with balloon occlusion of the contralateral iliac artery and creation of a femoral to femoral bypass graft. These procedures are not recommended for heavily calcified iliac arteries. The presence of a single aneurysm of a common iliac artery is not a contraindication as long as one hypogastric artery can be preserved and the possible complications of intentional sacrifice of a hypogastric artery are acceptable to the patient. As the size of the aneurysm increases and the medical comorbidities worsen, one may be justified in offering endovascular repair to those patients with anatomically less favorable situations, provided that an experienced team is on hand to deal with any untoward events.

Current devices require an access vessel diameter of at least 7 mm. Distal deployment sites up to 20 mm can usually be used provided that reverse tapering of the iliac limb is achieved (bell-bottom technique). Iliac vessels greater than 20 mm in diameter can be excluded by deploying the device into the external iliac artery and occluding the ipsilateral hypogastric artery. Review of our own experience with hypogastric embolization is not encouraging. We found that 39% of our patients had complications directly attributable to interruption of internal iliac artery flow. Buttock, thigh, and pelvic claudication or ischemia were the major morbidities, and they occurred in 30% of patients. Although we try to place coils only in the proximal internal iliac artery, no

Figure 3. These three CT scans at 3-mm intervals demonstrate the short, angulated neck. Longterm stability is not a realistic expectation in this situation even with suprarenal fixation, and these patients should not be offered endovascular repair with currently available devices.

Figure 4. This CT scan demonstrates extreme angulation of the proximal neck that regardless of length (which in this particular case is more than adequate) should be rejected for endovascular repair.
difference was found in claudication symptoms when coils were placed in the distal artery or in the anterior or posterior divisions. We now consider direct surgical reconstruction of iliac anatomy to preserve hypogastric artery flow and have performed this procedure in selected cases rather than sacrifice both hypogastric arteries. Parodi and Ferreira and Chuter and Reilly have reported results with surgical relocation of the iliac bifurcation in five patients with good results. Although hip claudication is a common occurrence after hypogastric artery coiling, unilateral occlusion has not been associated with colon or spinal cord ischemia unless inadvertent occlusion of the contralateral hypogastric artery occurs. Bilateral hypogastric occlusion should be avoided.

It is dangerous to liberalize the anatomic inclusion criteria particular to each device. In those cases where deviations intentionally occur, there should be reasons such as large or symptomatic aneurysms in otherwise inoperable patients. It appears that shortterm proximal fixation can be achieved in proximal necks that are smaller than 10 mm when suprarenal, bare-stent fixation is used. Larger series evaluating the impact on renal function will be required before this approach is adopted, and no currently available device accommodates the short proximal neck. Our own series of “stretched” anatomic indications has led to a significant number of complications, and we would not offer endoluminal therapy if there were other options.

Our estimates of the impact of current devices on clinical practice suggest that only a small percentage of aneurysms will be anatomically suitable for the AneuRx or Ancure devices. I am surprised at the number of implants that have been marketed since FDA approval was obtained, and I have concerns that the anatomic criteria are not strictly followed. Our analysis was conducted after a review of preoperative CT scans from 299 recent patients undergoing open repair of infrarenal AAA. Eligibility for AneuRx and Ancure devices was determined by each device’s specific anatomic inclusion and exclusion criteria. Only 28 patients (10%) of those operated on were suitable for an Ancure device. The remainder were excluded either because the iliac landing zones exceeded the device size (67%) or because the diameter of the proximal aortic neck was too large (39%). The use of the aorto-uniiliac device with contralateral iliac occlusion and femoral to femoral bypass increased the usage of the Ancure device to 24%. The AneuRx device would have been suitable in 80 patients (27%). Iliac arteries that exceeded the dimensions of the device were again the most important reason for exclusion (61%). Too large a proximal cuff was a problem in 80 patients (27%). Techniques to increase the size of the iliac limbs by using proximal cuff extensions (the bell-bottom technique) increased suitability to 51%. Interestingly, this is the exact percentage of patients found to be suitable for AneuRx grafts in the Stanford experience recently reported by Zarins and colleagues. The Talent graft was the most flexible in its requirements and could be deployed in 180 patients (60%), but a decision to submit the IDE data for post-market approval usage has apparently not been made because of possible structural problems that have recently been identified. The iliac landing area precluded Talent deployment in 55 patients (18%), and retrograde femoral access was not possible because of small iliac arteries in 29 patients (10%). Widespread usage will not be possible until devices become available that can accommodate the larger proximal and distal attachment sites, shorter necks, and smaller access vessels.
CURRENT SUGGESTIONS

A reasonable algorithm separates patients into those who require treatment or observation based on established criteria for size that should not be influenced by the choice of technique. For me that size is 5.0 cm or greater. Conventional repair should be considered in patients with an expected peroperative mortality chance of less than 5% and a life expectancy that exceeds 5 years. Endovascular repair should be considered when the expected operative mortality rate exceeds 5%, when the patient has shortened life expectancy, and when other factors such as a hostile abdomen are present. Once the patient is considered physiologically appropriate for endovascular repair, anatomic suitability becomes the determining issue.

Patients who receive endografts must understand the palliative nature of this procedure and must be willing to trade the proved longer term security of an open repair against the hopes of the lesser procedure. Our experience has been that patients quickly tire of the frequent imaging necessary in the current followup protocols and require a considerable amount of emotional support. The surgeon must be certain that the patient is psychologically able to accept the much greater frequency of postoperative interventions.

Whether or not we will ever have a prospective randomized trial that matches patients with similar risks and aneurysm morphology to open and endoluminal treatments is irrelevant. I would argue that such a trial at the time of completion will be outdated, because the devices are constantly changing and improving, and the marketplace will ultimately dictate the most appropriate therapy. There is a fundamental difference between indiscriminate application and careful, watchful usage of an evolving technology. Surgeons must stay involved in this evolution toward less invasive management of aortic aneurysms as the longterm effects of aneurysm remodeling on device integrity are used to redesign better products.

One has only to discharge a patient with a symptomatic AAA on home oxygen on the second postoperative day to appreciate the giant step forward that endoluminal therapy has made. On the other hand, pessimism is understandable when this same patient requires multiple interventions for endoleak and ultimately ruptures his aneurysm because of a fabric tear. I believe the great advantage of conventional repair is its longterm durability. Hallett and colleagues reported on a recent population-based study extending over 36 years. These data confirmed that conventional operative repair remains free of any significant graft-related complications over a 10-year period. The great advantage of endovascular repair is its low peroperative morbidity. These benefits must be balanced in the first case with significant peroperative morbidity and in the latter with significant reintervention rates, which may approach 20%. The process has moved rapidly, and “surgery” of the aorta will be altered forever. Surgeons need to be expert with each of the procedures and apply them judiciously.

REFERENCES


