

Should Your Father Have a Stent-Graft?

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From their inception, it was hoped that endografts would be less expensive than conventional open surgery, cause less morbidity and mortality, and provide an alternative to patients too sick to undergo standard therapy. Their role, however, has yet to be clearly defined. Several questions must be answered before this technology can be routinely considered for elective aneurysm repair:

Compared to open repair...

Can stent-grafts be placed with equal success?

Do they exclude AAA?

Do they decrease periop morbidity & mortality?

Do they prevent rupture?

Do they improve survival?

Do they decrease hospitalization and cost?

Do they provide increased access to repair for high-risk patients? If so, is mortality improved?

Initial technical success for implantation varies among studies but is as high as 98%. The AneuRx trial cites a one year patency of 99%.⁽⁴⁾ Nonetheless, specific questions regarding the durability of endografts and in particular, the role of endoleaks need to be answered. In a meta-analysis, Schurink found that the prevalence of endoleaks was 24%.⁽⁵⁾ Spontaneous thrombosis was seen in only 21% of endoleaks and in patients with endoleaks, aneurysms grew in a majority and failed to shrink in many patients. These results are in distinction to aneurysms with no endoleak, in which none grew. This data suggests inadequate aneurysm exclusion if an endoleak is detected. Clearly, given the incidence of endoleaks, their management and role in aneurysm growth needs to be explored. Problems may also occur in grafts with successfully excluded aneurysms. At one year, anatomic changes caused by aneurysm shrinkage may lead to kinking and migration of the endograft in up to 69% of patients.^(6,7) Most alarming are increasing reports of aneurysm rupture in the absence of a documented endoleak. Of seven patients with rupture after successful placement of an AneuRx graft, five had no endoleak and no evidence of aneurysm enlargement prior to rupture.⁽⁴⁾ Rupture in these cases was attributed to acute failure of graft fixation. Late ruptures have also been attributed to graft material fatigue, and to the concept of "endotension": persistence of systemic pressure within the aneurysm sac without a documented leak.^(8,9) Rupture has occurred even in the setting of a shrinking aneurysm. Long term studies defining the durability of grafts will help determine their role as an alternative to conventional therapy.⁽¹⁰⁾

In support of the endovascular method, studies have shown that colonic ischemia, which has been proposed as a cause of multisystem organ failure is decreased with endovascular repair. Data from clinical trials have also shown a significant decrease in

blood loss and peri-operative major adverse cardiac and respiratory events. This was associated with decreased intubation time, and a decrease in ICU and total hospital stay. Patients in the endovascular group lost less blood, recovered more quickly and returned to normal function faster. However, most of the large case-controlled series failed to show a statistically significant decrease in 30-day morbidity or mortality, and the four-year Ancure data shows no difference in mortality or long-term cardiopulmonary morbidity.

Endovascular repair has been suggested as a less invasive option for high risk patients. In one study, technical success in such a group was found to be approximately 90%. (2) Despite the technical feasibility, long term data for such groups of patients is limited. When outcomes are examined, a significant perioperative mortality exists and potential benefit in terms of increased survival beyond 17 months is not clear.(3) Well controlled prospective trials investigating the outcomes for high risk patients comparing medical, conventional, and endovascular therapies are needed.

A potential advantage of endovascular therapy that is often cited is that of reduced cost. However, this procedure may be more costly than originally thought. Intensive care unit admissions are shorter and recovery time is less with endovascular repair versus surgery. However, a reduced stay does not, necessarily, lead to lower cost because endovascular repair of aortic aneurysms requires multiple pre and post procedure diagnostic and therapeutic radiological procedures not required for surgical repair. Also, the cost of the devices has risen dramatically as commercial interest in the technology has grown. Approximately 68% of aneurysm repairs are paid by Medicare and are therefore reimbursed at rates determined by the Health Care Finance Administration Diagnostic Related Group. In such a system, hospitals are reimbursed a set amount for a procedure inclusive of the cost of the device. The estimated price of an endovascular device is approximately \$10,000 to \$15,000 in comparison to \$653 for a standard surgically placed graft. In order for a savings to be realized in the endovascular group, there would have to be a significant reduction in other hospital costs to offset the cost of the device. Despite significant savings related to recovery time and shorter ICU stays, the overall hospital costs are significantly higher in the endovascular group than in the open repair group (\$21,000 vs. \$12,000). (11) With current reimbursement practices, it has been estimated that costs for endovascular repair alone rival that of standard therapy only when device cost is reduced to \$5,000. Such an estimation includes a higher diagnostic hospital costs for the endovascular group, but does not take into account the added costs of follow up imaging and estimated costs for treating complications such as endoleaks. In a recent study that compared relative value units (RVU) for radiological studies between matched groups of patients undergoing standard repair versus endovascular repair, researchers found 5.4 times higher RVUs in the endovascular group.(12) Without significant changes in reimbursement policies or in the number of adjunctive studies, endovascular repair may not be an economically advantageous alternative for patients who are candidates for open repair. For high risk patients unfit for open repair, the long term benefit of the procedure over medical therapy remains to be shown.

CONCLUSION

Endovascular aneurysm repair represents an emerging technology that has the potential to treat approximately 50% of patients with infrarenal aneurysms, and may be performed successfully in patients deemed to be too high of a risk for an open procedure. Morbidity and mortality rates of endovascular therapy compare favorably with those of standard therapy, but diligent follow up is required in the endovascular group. Questions concerning the durability of endografts, the significance of endoleaks, the long term effects of aneurysm shrinkage, and the benefits of endovascular repair need to be studied in prospective randomized trials to determine appropriate therapy in high and low risk patients. Although some aspects of endovascular repair are cheaper than conventional therapy, the economic impact of this less invasive therapy needs to be studied and reconciled with current payment policies before this therapy can be considered routine.

References

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