This technique has been used to evaluate prediction of wall motion or “strain” with blood pressure load and has demonstrated that the finite element model we are currently using predicts wall motion relatively well when compared with “dynamic” CT or MRI studies.

Developing Techniques to Allow Widespread Use of FEA in a Simple Manner

More realistic finite element models are a worthwhile goal but will not be helpful if the clinician has to be able to perform this task. An international multicenter study is now underway that allows any interested center to obtain automated aneurysm wall stress analysis without cost over and above the three-dimensional reconstruction and without requiring any knowledge of the finite element method. The process creates a “rupture risk report,” which reports on modifiable risk factors for rupture, such as smoking and blood pressure, as well as how blood pressure affects aneurysm wall stress and rupture risk. A number of centers have already joined the study group, but adequate capacity is available to add new centers (Fillinger MF, 2004). Enrollment is going well, with over 200 patients enrolled. Early investigation with limited follow-up indicates that the method is not ideal yet, but trends are encouraging.

Methods to Evaluate Rupture Risk Based on Conventional Two-Dimensional Imaging

Although three-dimensional techniques are quite promising, two-dimensional analysis is more practical for the short term as the more sophisticated methods evolve. We have evaluated the conventional CT morphology of ruptured aneurysms in the context of selectively imaged AAAs, matching patients for AAA size and patient gender and age in an effort to isolate key anatomic variables. Records were reviewed to identify all CT scans at Dartmouth-Hitchcock Medical Center or the referring hospital prior to emergency AAA repair for rupture or acute severe pain (RUP). CT scans prior to elective AAA repair (ELEC) were reviewed for age and gender matches to RUP patients. Over 40 variables were measured on each CT scan. Diameter matching was achieved by consecutively deleting the largest RUP and the smallest ELEC to avoid bias. CT scans were analyzed for 259 patients with AAAs: 122 RUP and 137 ELEC. Patients were well matched for age, gender, and other demographic variables or risk factors.

Maximum AAA diameter was significantly different in the comparison of all patients (RUP 6.5 ± 2 cm vs ELEC 5.6 ± 1 cm, p < .0001), and the mean diameter for rupture was 5 mm lower in females (6.1 ± 2 cm vs 6.6 ± 2 cm, p = .007). Matching for diameter, gender, and age was possible for 200 patients (100 from each group; maximum AAA diameter 6.0 ± 1 cm vs 6.0 ± 1 cm). Analysis of diameter-matched AAAs indicated that most variables were statistically similar for the two groups, including infrarenal neck length (17.1 ± 19.1 mm, p = .3), maximum thrombus thickness (25.1 ± 23.1 mm, p = 4), and indices of body habitus, such as [(maximum AAA diameter)/(normal suprarenal aorta diameter)] or [(maximum AAA diameter)/(lumbar vertebral L3 transverse diameter)]. Multivariate analysis controlling for gender indicated that the most significant variables were aortic tortuosity (odds ratio [OR] 3.3, indicating no/mild tortuosity has greater rupture risk), diameter asymmetry (OR 3.2 for a 1 cm difference in major-minor axis), and current smoking (OR 2.7, greater risk for current smokers).

In this study, we found that when matched for age, gender, and diameter, ruptured AAAs tend to be less tortuous and yet have greater cross-sectional diameter asymmetry. On conventional two-dimensional CT axial slices, when diameter asymmetry is associated with low aortic tortuosity, the larger diameter on axial slices more accurately reflects rupture risk. When diameter asymmetry is associated with moderate or severe aortic tortuosity, the smaller diameter on axial slices more accurately reflects rupture risk. Current smoking is significantly associated with rupture, even when controlling for gender and AAA morphology. This type of information can be used without relying on “high-tech” methodology or participation in a multicenter study.

Conclusions

Progress continues in developing better tools for estimating aneurysm rupture risk using noninvasive methods. Some of these tools are not yet ready for regular clinical use, but others can be used in a practical manner now.

References


XXXIV.7 Endovascular Aneurysm Repair Reduces the Risk of Rupture Despite Persisting Type I Endoleak: How Can This Possibly Be True?

Christopher K. Zarrins, MD
Stanford, CA

Introduction

Type I endoleaks following endovascular aneurysm repair (EVAR) are considered to be evidence of unsuccessful endovascular repair with a continuing risk of aneurysm rupture, similar to untreated aneurysms. Type I endoleaks are of particular concern in patients with aneurysms larger than 5.5 cm where the annual risk of rupture of untreated aneurysms exceeds 10%. Type I endoleaks can be present in up to 7% of patients on completion angiography and are usually treated with secondary endovascular procedures. Unfortunately, these secondary treatments are not always successful, leaving some patients with persisting type I endoleaks with open surgical conversion as the only treatment option. Since patients in this situation are elderly and often are at very high risk for open surgery, many elect to have ongoing monitoring rather than surgical conversion. The risk of rupture under these circumstances, while assumed to be high, has never been well documented. We sought to determine whether EVAR of large abdominal aortic aneurysms (AAA) reduces the risk of rupture despite the presence of persistent type I endoleaks in patients considered too high risk for open surgery.

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Persistent Type I Endoleak

Over 400 patients were treated with EVAR over a 7-year period at Stanford University and monitored in a prospectively defined protocol of clinical and image-based follow-up. Among patients with large (≥5.5 cm) aneurysms, 21 had evidence of persistent postprocedure type I endoleak documented by serial CT scanning and duplex ultrasonography. Eleven patients underwent one or more endovascular treatments to resolve the type I endoleak, with ultimate resolution in three patients; three patients underwent surgical conversion. In 15 patients the type I endoleak persisted, and these patients were considered to be unfit for elective surgical conversion due to multiple comorbidities. The duration of type I endoleak in these patients was 10 months to 4 years (mean 28 months). The 15 patients with persistent type I endoleak had a mean age of 79 years. Preoperative AAA diameter was 6.1 cm. Aneurysm enlargement occurred in 73% of patients during the follow-up period. There have been no aneurysm ruptures and no AAA-related deaths in the patients with persistent type I endoleak. Overall survival was 73%. There were four deaths, one each due to cardiac failure, respiratory failure, renal failure, and cancer.

No AAA Treatment

Retrospective review of all patients evaluated for AAA in a well-defined geographic region in Finland during an 8-year period revealed 24 patients with large aneurysms (≥5.5 cm) who were not treated because of high surgical risk or patient refusal. These 24 patients underwent routine surveillance studies but no treatment of the aneurysm. Sixteen patients had suitable anatomy for endovascular repair and were compared with the type I endoleak group. There were no significant differences in age or baseline aneurysm size compared with the type I endoleak group and follow-up time was similar. During the 23-month follow-up, 7 of 16 patients with large aneurysms and no treatment (44%) sustained aneurysm rupture and died. Two patients underwent emergent operative repair at the time of rupture but neither of them survived emergency surgery. Freedom from AAA-related death was 80% at 12 months and 69% at 24 months in the no-treatment group compared with freedom from AAA-related death of 100% at 12 and 24 months in the type I endoleak group. Overall survival in untreated patients with large aneurysms was 19% compared with 73% in the type I endoleak group.

Conclusions and Discussion

It appears that patients with large aneurysms treated with EVAR have a lower risk of aneurysm rupture and AAA-related death than untreated patients and that this reduced risk of rupture may extend to patients with persisting type I endoleaks following endovascular treatment. This does not mean that type I endoleaks are unimportant but suggests that all type I endoleaks may not be the same and that in some patients the risk of surgical conversion may be higher than the risk of ongoing monitoring of type I endoleaks. Continued close surveillance and ongoing long-term monitoring of such patients are needed to confirm these results.

Reference


XXXIV.8 The VALOR Trial of Talent Endografts for a Variety of Thoracic Aortic Lesions in High-Risk Patients: The Real-World Experience

Ronald M. Fairman, Mark A. Farber, MD, Rodney A. White, J. Michael Tuchek, Frank J. Criado
Chapel Hill, NC

Objective

The objective of this study was to evaluate the safety and efficacy of the Medtronic Vascular Talent Thoracic Stent Graft System for patients with thoracic aortic disease who were at high risk for open surgery (SVS 3) and/or nonsurgical candidates not associated with SVS scoring. The proximal and distal aortic nonaneurysmal neck diameter requirement was within the range of 18 to 42 mm.

Methods

The study was a prospective, nonrandomized, multicenter, consecutive, observational trial with descriptive components. The safety primary end point was all-cause mortality, and the efficacy primary end point was the proportion of patients with successful aneurysm treatment. The secondary 30-day end points evaluated the percentage of patients who experienced successful deployment and delivery of the stent graft, death, paraplegia/paraparesis, secondary procedures due to endoleak, and one or more major adverse clinical events (MACE). End points beyond 30 days included secondary procedures, open conversion, device migration, loss of patency, rupture, endoleaks, and one or more MACE. Supplementary clinical utility measures were also recorded. Standard follow-up interval examinations were prescribed at 1 month, 6 months, 1 year, and annually thereafter. There were no external controls. Outcomes were summarized by descriptive statistics.

Results

There were 137 patients treated, of whom 59% were male, and the median age was 75 years. Thoracic aortic pathologies treated included thoracic aortic aneurysm (75%), dissection (12%), pseudoaneurysm (7%), and traumatic injury (6%). The median maximum aneurysm diameter at treatment was 64 mm and the median aneurysm length was 108 mm. Procedural success was 98%. The 30-day all-cause mortality was 7.3%, with a paraplegia/paraparesis rate of <1% at 1 month. Fourteen percent of the procedures required a conduit for access. The 1- and 8-month endoleak rates were 9% and 6%, respectively. The 30-day stroke incidence was 7.3%. There were no cases of aneurysm rupture, loss of stent graft patency, or open conversions at 8 months; however, 7% required secondary procedures during this interval. Clinical utility measures included mean duration of procedure (2.9 hours), volume of contrast used (166 cc), estimated blood loss (363 cc), and hospital length of stay (9.9 days).

Conclusions

These results demonstrate highly favorable preliminary outcomes in a high-risk/nonsurgical population of patients with heterogeneous thoracic aortic pathology who would have been historically managed with "watchful waiting." Procedural success was high, whereas operative mortality, stroke incidence, and paraplegia/paraparesis rates were particularly low. Long-term follow-up will be required to demonstrate durability and prevention of aneurysm-related mortality.