Preliminary Results of the Medtronics Vascular Thoracic Stent Graft System for Patients with Thoracic Aortic Disease. The Valor Trial: High-Risk/Nonsurgical Arm

NOTES

Ronald M. Fairman, MD, Philadelphia, PA

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

Methods
The study was a prospective, non-randomized, 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 owing to endoleak, and one or more major adverse clinical events (MACEs). End points beyond 30 days included secondary procedures, open conversion, device migration, loss of patency, rupture, endoleaks, and one or more MACEs. 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
One hundred and thirty-seven patients were treated, 59% of the patients were male, and the mean age was 75 years. Thoracic aortic pathology treated included fusiform or saccular TAA (75%), dissecting TAA (4%), chronic dissection (4%), pseudoaneurysm (7%), traumatic injury (6%), and complicated acute type B dissection (4%). Mean maximum aneurysm diameter at treatment was 63.5 mm, and mean aneurysm length was 108 mm. Procedural success was 98%. The 30-day all cause mortality was 7.3%, and the 8-month midterm mortality was 25%. The paraplegia/paraparesis rate was less than 1% at 1 month. Fourteen percent of the procedures required a conduit for access. The endoleak rate was 9% at 1 month and 6% at 8 months. The 30-day stroke incidence was 7.3% (10 patients). There were no cases of aneurysm rupture, 1 case of open conversion at the time of initial implant, and 2 cases of device migration. The midterm secondary procedure rate was 7%. Clinical utility measures included mean duration of procedure (2.9 hours), volume of contrast used (167 cc), estimated blood loss (360 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.