

# Results of the Phase II Multicenter Trial of the Gore TAG Endoprosthesis in the Treatment of Descending Thoracic Aneurysms

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Results are presented from the first completed multicenter trial directed at gaining approval from the US Food and Drug Administration of endovascular versus open surgical repair of descending thoracic aortic aneurysms. The primary objectives of this study were to (1) compare the safety of endovascular repair with the Gore TAG Endoprosthesis to open surgical repair when used in the primary treatment of DTA aneurysms, and (2) estimate the efficacy of the TAG device in test subjects. The secondary objectives of this study were to compare the test and control groups for procedural blood loss, length of intensive care unit and hospital stay after the procedure, and time to return to normal daily activities.

The multicenter, pivotal study assessed the safety and efficacy of the endoprosthesis in 140 test subjects who underwent endovascular repair and 94 control subjects who underwent open surgical repair; subjects were enrolled at 17 investigational sites between September 1999 and May 2001. Subjects were assessed at pretreatment, treatment, and hospital discharge and returned for follow-up visits at 1, 6, and 12 months, and annually through 5 years post-treatment. (Currently data have been collected and analyzed through 2 years post-treatment.)

Baseline characteristics were similar between the treatment groups. Two hundred thirty-three endoprostheses were implanted in 137 subjects (1.7/subject, range 1 to 4). An endoprosthesis was not implanted in three subjects because of access failure. The test group had a shorter median stay in the intensive care unit (1 vs 3 days,  $p < .001$ ) and hospital (3 vs 10 days,  $p < .001$ ) than did the control group. The proportion of subjects who experienced  $\geq 1$  MAE through 1 year post-treatment was lower ( $p < .001$ ) in the test group (42%) than in the control group (77%). The incidences of major bleeding (11% vs 54%,  $p < .001$ ) and pulmonary (14% vs 38%,  $p < .001$ ), renal (4% vs 15%,  $p = .004$ ), wound (6% vs 15%,  $p = .03$ ), and neurologic (12% vs 33%,  $p < .001$ ) complications were lower in the test group through 1 year post-treatment. However, the test group experienced more major vascular complications than did the control group (18% vs 6%,  $p = .01$ ), largely owing to injuries of the access vasculature. The benefit of endovascular treatment was observed within 30 days post-treatment as 41 (29%) of the test subjects versus 66 (70%) of the control subjects reported  $\geq 1$  MAE ( $p < .001$ ). This difference was maintained for the 24-month follow-up period.

No statistically significant differences were observed in all-cause mortality through 1 year post-treatment. Mortality in the first 30 days post-treatment was 1% in the test group and 6% in the control group. In-hospital mortality was 2% versus 6%. Spinal cord ischemia was also lower in the TAG group, at 3% versus 14%. Strokes occurred in 4% of both groups. Aneurysm-related mortality was lower ( $p = .01$ ) in the test group (3%) than in the control group (11%) through 1 year post-treatment.

Eight test subjects (5.7%) experienced more than one major device-related event through the 12-month follow-up visit.

## Conclusions

These data demonstrate that the treatment of DTA aneurysms with the TAG device is safe and efficacious. Early outcomes with descending aortic endovascular stent grafting were encouraging when compared with outcome in a well-matched surgical cohort.