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Results of a prospective multicenter trial of CTAG thoracic endograft

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Objective: As thoracic aortic aneurysms (TAAs) are more frequently being treated with endografts, the anatomic challenges of the thoracic aorta have led to design modifications of endografts. The Conformable GORE TAG (CTAG) device (W. L. Gore & Associates, Flagstaff, Ariz) was specifically designed to be more conformable in tortuous anatomy, more resistant to compression, and more accommodating to various aortic diameters compared with the original GORE TAG device. This prospective, multicenter study evaluated the safety and effectiveness of the CTAG endograft in the repair of descending TAA.

Methods: This was a prospective, multicenter regulatory study with a primary end point of freedom from major device event through 1 month after treatment. Two-year outcomes included aneurysm-related morbidity (endoleaks and morphology changes), aneurysm-related mortality, and all-cause mortality.

Results: Fifty-one patients were enrolled between October 2009 and October 2010, with at least one endograft implanted in 50 patients. After the regulatory study successfully completed its primary end point and expanded to a continued-access phase, 15 additional patients were enrolled in the continued-access arm of the study from February 2011 until September 2011, for a total treatment group of 66 patients for the early results and 65 patients for the long-term clinical results with imaging evaluation. There was one 30-day death (1.5%), two patients (3%) with spinal cord ischemia, and two central strokes (3%) $\leq$30 days. Five patients (7.6%) died $\leq$1 year; one of ascending aortic aneurysm rupture, two of cardiac disease, and two of respiratory failure. The core laboratory adjudicated 1-month imaging in 60 patients (92.3%), where nine endoleaks (15.0%) were identified (one type Ia, four type II, and four indeterminate). Forty-five patients (69.2%) had 2-year imaging with five endoleaks (11.1%; two type II and three indeterminate), and one patient had a distal aortic dilatation that required a secondary intervention. At 2 years, 20 of 38 imaged patients (52.6%) had aneurysm shrinkage $\geq$5 mm, 15 (39.5%) had no change in diameter, and three patients (7.9%) had an increase in aneurysm diameter of $\geq$5 mm. There were no conversions, fractures, compressions, or aneurysm ruptures of the treated segment through 2 years.

Conclusions: This next-generation thoracic endograft has a low rate of major device events through 2 years, with no graft compressions or device failures. The data for this new endograft demonstrate favorable outcomes and confirm low risks for treatment for patients with TAA. Follow-up will be continued for 5 years.

Cost analysis of endovascular versus open repair in the treatment of thoracic aortic aneurysms

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Objective: For descending thoracic aortic aneurysms (TAAs), it is generally considered that thoracic endovascular aortic repairs (TEVARs) reduce operative morbidity and mortality compared with open surgical repair. However, long-term differences in survival of patients have not been demonstrated, and an increased need for aortic reintervention has been observed. Many assume that TEVAR becomes less cost-effective through time because of higher rates of reintervention and surveillance imaging. This study investigated midterm outcomes and hospital costs of TEVAR compared with open TAA repair.

Methods: This was a retrospective, single-institution review of elective TAA repairs between 2005 and 2012. Patient demographics, operative outcomes, reintervention rates, and hospital costs were assessed. The literature was also reviewed to determine commonly observed complication and reintervention rates for TEVAR and open repair. Monte Carlo simulation was used to model and to forecast hospital costs for TEVAR and open TAA repair up to 3 years after intervention.

Results: Our cohort consisted of 131 TEVARs and 27 open repairs. TEVAR patients were significantly older (67.2 vs 58.7 years old; P = .02) and trended toward a more severe comorbidity profile. Operative mortality for TEVAR and open repair was 5.3% and 3.7%, respectively (P = 1.0). There was a trend toward more complications in the TEVAR group, although not statistically significant (all $P > .05$). In-hospital costs were significantly greater in the TEVAR group ($52,008 vs $37,172; P = .001). However, cost modeling by use of reported complication and reintervention rates from the literature overlaid with our cost data produced a higher cost for the open group in-hospital ($55,109 vs $48,006) and at 3 years ($58,426 vs $52,825). Interestingly, TEVAR hospital costs, not reintervention rates, were the most significant driver of cost in the TEVAR group.

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Conclusions: Our institutional data showed a trend toward lower mortality and complication rates with open TAA repair, with significantly lower costs within this cohort compared with TEVAR. These findings were likely, at least in part, to be due to the milder comorbidity profile of these patients. In contrast, cost modeling by Monte Carlo simulation demonstrated lower costs with TEVAR compared with open repair at all time points up to 3 years after intervention. Our institutional data show that with appropriate selection of patients, open repair can be performed safely with low complication rates comparable to those of TEVAR. The cost model argues that despite the costs associated with more frequent surveillance imaging and reinterventions, TEVAR remains the more cost-effective option even years after TAA repair.

Durability and survival are similar after elective endovascular and open repair of abdominal aortic aneurysms in younger patients

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Objective: The role of endovascular repair (EVAR) of aortic aneurysms in young patients is controversial. The purpose of this study was to determine the long-term outcomes and reintervention rates in patients 60 years of age or younger who underwent elective open or endovascular repair of an abdominal aortic aneurysm.

Methods: Retrospective review of a prospectively collected vascular surgery database at a university-affiliated medical center was performed to identify all patients who underwent elective repair of an abdominal aortic aneurysm between 2000 and 2013 and were 60 years of age or younger at the time of the repair. Preoperative anatomic measurements were performed and compared with instructions for use (IFU) criteria for the endografts.

Results: The study cohort comprised 169 patients 60 years of age or younger (mean age, 56.7 $\pm$ 2.8 years) who underwent elective repair (119 open repair, 50 EVAR). Patients treated with open repair and EVAR had similar comorbidities, except that EVAR patients were more likely to have hypertension (P = .03) and poor left ventricular function (P = .04). The open repair group had significantly larger suprarenal (P = .004) and infrarenal (P = .005) neck angles, shorter neck lengths ($P < .001$), and larger maximum aneurysm diameter (P = .02) compared with the EVAR group. Only five patients (13%) in the EVAR group did not meet all IFU criteria. The overall in-hospital mortality rate was 1.8% (0% EVAR, 2.5% open repair; P = .56). Overall mean life expectancy was 11.5 years (9.8 years EVAR, 11.9 years open repair; P = .09). The 1-year (98% EVAR, 96% open repair), 5-year (86% EVAR, 88% open repair), and 10-year (54% EVAR, 75% open repair) survival did not differ between EVAR and open repair (P = .16). Long-term survival (78% EVAR, 85% open repair; P = .09) and reintervention rates (12% EVAR, 16% open repair; P = .80) did not differ. No late aneurysm rupture or aneurysm-related deaths were observed. The most common causes of long-term mortality were malignant disease and cardiovascular events. Reinterventions in the open repair group were exclusively laparotomy related (incisional hernia repairs), whereas all reinterventions in the EVAR group were aortic related, including one conversion to open repair.

Conclusions: After elective aneurysm repair, younger patients have a moderate life expectancy related to malignant disease and cardiovascular health. EVAR offers durability and long-term survival similar to those with open repair in these younger patients as long as aneurysm anatomy and IFU are adhered to.

Abdominal compartment syndrome associated with endovascular and open repair of ruptured abdominal aortic aneurysms

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Background: Abdominal compartment syndrome (ACS) is a known complication of ruptured abdominal aortic aneurysm (rAAA) repair and can occur with either endovascular (EVAR) or open repair. We hypothesize that the underlying mechanism for the development of ACS may differ for patients treated with EVAR or open operation.

Methods: All patients who presented with rAAA at a tertiary care medical center between January 2005 and December 2010 were included in the study. Demographic factors, type of repair (open vs EVAR), development of ACS, intraoperative and postoperative fluid requirements, estimated blood loss, length of stay, and morbidity and mortality were recorded. Student t-test and Fisher exact test were performed. A P value $< .05$ was considered significant.

Results: Seventy-three patients, 62 men and 11 women with an average age of 70.5 years, were treated for rAAA. Forty-four (60%) underwent open repair; 29 (40%) had EVAR. Overall mortality was 42% (31 of 73), with mortality being 31% (9 of 29) in EVAR and 48% (21 of 44) in open repair. ACS developed in 21 patients (29%), more frequently in open repair than in EVAR (15 of 44 [34%] vs 6 of 29 [21%]; P = NS). Mortality was higher in patients who developed ACS compared with those without ACS (13 of 21 [62%] vs 17 of 52 [33%]; P = .022). This finding was especially pronounced in the EVAR group, in which mortality in patients with ACS was 83% (5 of 6) compared with 17% (4 of 23) without ACS (P = .005). Intraoperative fluid requirements were significantly higher in EVAR patients who developed ACS compared with those without ACS, including packed red blood cells (5600 mL vs 1100 mL; $P < .0001$), total blood products (9300 mL vs 1500 mL; $P < .001$), crystalloid (11,200 mL vs 4500 mL; $P < .001$), and estimated blood loss (5000 mL vs 660 mL; P = .006). In patients treated with open repair, there were no significant differences in intraoperative fluid requirements between those who developed ACS and those without ACS. However, patients who developed ACS after open repair required significantly