

## Selected Abstracts from the August Issues of the Journal of Vascular Surgery and the Journal of Vascular Surgery: Venous and Lymphatic Disorders<sup>☆</sup>

Editors: Peter Gloviczki and Peter F. Lawrence

### Technical aspects and 30-day outcomes of the prospective early feasibility study of the GORE EXCLUDER Thoracoabdominal Branched Endoprosthesis (TAMBE) to treat pararenal and extent IV thoracoabdominal aortic aneurysms

Gustavo S. Oderich, MD, Mark A. Farber, MD, Pierre Galvagni Silveira, MD, Rami Tadros, MD, Michael Marin, MD, Mark Fillinger, MD, Michel Makaroun, MD, Jason Hemmer, PhD and Meghan Madden, BS

**Objective:** This study reports the technical aspects and 30-day outcomes of the prospective, multicenter early feasibility study designed to evaluate the GORE EXCLUDER Thoracoabdominal Branch Endoprosthesis (TAMBE; W. L. Gore & Associates, Flagstaff, Ariz).

**Methods:** Thirteen patients with pararenal or extent IV thoracoabdominal aortic aneurysms were prospectively enrolled at five U.S sites and one non-U.S. site from 2014 to 2016. The TAMBE included four portals with either retrograde or antegrade renal portal configuration and used GORE VIABAHN Balloon-Expandable Endoprosthesis (W. L. Gore & Associates) for stenting of the renal and mesenteric arteries. The primary end point was procedural safety at 30 days, defined by absence of major adverse events, including any-cause mortality, myocardial infarction, stroke, paraplegia, bowel ischemia, respiratory failure, severe acute kidney injury (>50% decline in estimated glomerular filtration rate), dialysis, and procedural blood loss >1000 mL.

**Results:** There were 11 male and 2 female patients with a mean age of  $69 \pm 8$  years. Mean aneurysm diameter was  $61 \pm 13$  mm. A total of 52 renal and mesenteric arteries were incorporated (4 vessels/patient). Technical success was achieved in 12 patients (92%). One patient had inadvertent occlusion of a right renal artery due to dissection. There was no mortality, aneurysm rupture, conversion to open repair, dialysis, or spinal cord injury. Mean length of hospital stay was  $5 \pm 3$  days. At 30 days, four patients (31%) had major adverse events, all due to procedural blood loss >1000 mL. One patient had a type I endoleak at the distal renal branch, which was successfully treated by placement of an additional renal stent before dismissal. Computed tomography angiography at 30 days showed patent target vessels and no type I or type III endoleak.

**Conclusions:** This study confirms the early feasibility of the TAMBE for treatment of pararenal and extent IV thoracoabdominal aortic aneurysms. The high technical success,

no mortality, and low morbidity rate support continuation of clinical investigation in a larger population of patients.

### The state of complex endovascular abdominal aortic aneurysm repairs in the Vascular Quality Initiative

Thomas F.X. O'Donnell, MD, Virendra I. Patel, MD, MPH, Sarah E. Deery, MD, MPH, Chun Li, MD, Nicholas J. Swerdlow, MD, Patric Liang, MD, Adam W. Beck, MD and Marc L. Schermerhorn, MD

**Background:** Endovascular repair of complex abdominal aortic aneurysms has become increasingly common, but reports have mostly been limited to single centers and single devices.

**Methods:** We studied all endovascular repairs of complex abdominal aortic aneurysms (zone 6 or caudal) from 2014 to 2018 in the Vascular Quality Initiative. This included all commercially available fenestrated endovascular aneurysm repair (FEVAR), chimney/snorkel repairs, and physician-modified endografts (PMEGs), exclusive of investigational device exemptions and clinical trial devices. We used inverse probability-weighted multilevel logistic regression to compare rates of perioperative outcomes including death, acute kidney injury (AKI), and major adverse cardiac events (MACEs; the composite of death/stroke/myocardial infarction) and Cox regression for long-term mortality.

**Results:** During the study period, surgeons performed 1396 complex endovascular repairs: 1308 (94%) elective, 63 (4.5%) for symptomatic aneurysms, and 25 (1.8%) for rupture. The number of centers performing complex endovascular repairs expanded steadily from 39 in 2014 to 81 in 2017. There were 880 FEVAR (63%), 256 PMEG (18%), and 260 chimney/snorkel repairs (19%). In elective cases, 3214 visceral vessels were incorporated and revascularized; 120 repairs (9%) involved one vessel, 481 (38%) repairs involved two vessels, 560 (44%) involved three vessels, and 113 (9%) involved four vessels. The mean number of arteries incorporated was  $2.5 \pm 0.8$ , with PMEGs involving the most arteries ( $3.3 \pm 0.8$  for PMEG vs  $2.5 \pm 0.6$  for FEVAR and  $1.9 \pm 0.9$  for chimney/snorkel;  $P < .001$ ). PMEGs were used to treat more extensive aneurysms, and more incorporated the celiac and superior mesenteric arteries. There was no change in aneurysm extent, but the length of proximal seal extended over time. Chimney/snorkel cases employed more arm or neck access, had longer procedure times, and used more contrast material. Rates of perioperative death (3.4% for FEVAR vs 2.7% for PMEG vs 6.1% for chimney/snorkel;  $P = .13$ ) and AKI (17% vs 18% vs 19%;  $P = .42$ ) were similar,

<sup>☆</sup>Full articles available online at [www.jvascsurg.org](http://www.jvascsurg.org)  
1078-5884/  
[http://dx.doi.org/10.1016/S1078-5884\(19\)31066-4](http://dx.doi.org/10.1016/S1078-5884(19)31066-4)

but chimney/snorkel was associated with higher rates of stroke (0.8% vs 0.9% vs 3.3%;  $P = .03$ ) and MACEs (6.1% vs 5.4% vs 11.7%;  $P = .02$ ). After adjustment, rates of perioperative death, AKI, and overall complications remained similar, but chimney/snorkel was associated with significantly higher odds of stroke (odds ratio [OR], 7.3 [1.5-36.4];  $P = .015$ ), myocardial infarction (OR, 18.7 [2.6-136.8];  $P = .004$ ), and MACEs (OR, 11.1 [2.1-58.9];  $P = .005$ ). Overall survival after elective repair was 91% at 1 year and 88% at 3 years, with no difference between repair types in crude or adjusted analysis.

**Conclusions:** The Vascular Quality Initiative provides a unique opportunity to study the real-world application and outcomes of complex endovascular aneurysm repair. Perioperative morbidity appears to be higher after chimney/snorkel repair, but further study is needed to confirm these findings and to establish the durability of these novel technologies.

---

#### The GORE TAG conformable thoracic stent graft with the new ACTIVE CONTROL deployment system

Carlo Mariani, MD, Emma van der Weijde, MD, Tim Smith, PhD, Henri Gerard Smeenk, MD, PhD, Jan Albert Vos, MD, PhD and Robin Hendricus Heijmen, MD, PhD

**Objective:** The aim of this study was to describe single-center intraoperative details and early outcome of the new GORE TAG conformable stent graft with ACTIVE CONTROL (C-TAG ACTIVE CONTROL; W. L. Gore & Associates, Flagstaff, Ariz).

**Methods:** Between September 2017 and June 2018, a consecutive 30 patients underwent thoracic endovascular aortic repair with C-TAG ACTIVE CONTROL. This new system provides an intermediate deployment step at 50% and optional angulation control of the proximal part of the stent graft. Indications for thoracic endovascular aortic repair varied widely, including chronic postdissection and degenerative aneurysms, complicated acute dissections, and intramural hematomas, among others, in an elective (63.3%), urgent (13.3%), or emergent (23.3%) setting. The proximal landing zone (LZ) was LZ 2 in 23.3%, LZ 3 in 43.3%, and LZ 4 in 33.3%. Data were collected retrospectively and analyzed for technical and clinical success.

**Results:** In all patients, the stent graft was successfully introduced and deployed at the intended position, with complete exclusion of aortic disease and without intraoperative mortality (primary technical success, 100%). One emergent patient died at 2 days of ongoing septic shock (clinical success at 30 days, 96.6%). Median follow-up was 107 days (range, 33-271 days); late mortality was 3.4% (one patient died of stent graft infection at 40 days). Freedom from type I and type III endoleak at the early follow-up was 100%. No patients required other surgical or endovascular procedures for the primary treated aortic disease.

**Conclusions:** Our reported initial experience in 30 patients with the C-TAG ACTIVE CONTROL showed excellent early results, with high deployment accuracy and conformability.

The additional features of staged deployment and angulation control may be of great help in challenging aortic arch diseases, allowing precise positioning and preventing bird-beak effect.

---

#### Validation of a preoperative prediction model for mortality within 1 year after endovascular aortic aneurysm repair of intact aneurysms

Dan Neal, MS, Adam W. Beck, MD, Mohammed Eslami, MD, MS, Marc L. Schermerhorn, MD, Jack L. Cronenwett, MD, Kristina A. Giles, MD, Alfio Carroccio, MD, Omid Jazaeri, MD, Thomas S. Huber, MD, PhD, Gilbert R. Upchurch Jr., MD and Salvatore T. Scali, MD

**Objective:** Most would agree that at least 1-year survival is necessary after intact abdominal aortic aneurysm (AAA) repair to appropriately justify the cost and risk of the procedure. No validated clinical decision instruments exist to predict survival after endovascular aneurysm repair (EVAR) beyond the perioperative period. The purpose of this analysis was to create a preoperative prediction model for 1-year mortality after EVAR for intact AAA in the Society for Vascular Surgery Vascular Quality Initiative.

**Methods:** All intact EVARs in the Society for Vascular Surgery Vascular Quality Initiative from 2011 to 2015 were randomly divided into training ( $n = 17,836$ ) and validation ( $n = 2500$ ) data sets, and 31 preoperative candidate predictors were identified. A logistic regression model for 1-year mortality was created, and bootstrapped stepwise variable elimination was used to reduce this model to a best subset of predictors. Penalized maximum likelihood estimation was used to correct for potential overfitting. The final model was internally validated by bootstrapping the area under the curve (AUC) and the calibration slope and intercept, and its performance when applied to the training and validation data sets was compared.

**Results:** After elective and nonelective (symptomatic, intact) EVAR, 1-year mortality was 5.5% ( $n = 900/16,411$ ) and 11.4% ( $n = 162/1425$ ), respectively. The mean probability of 1-year mortality was 6.0% ( $n = 1062$ ) in the training set and 5.7% ( $n = 143$ ) in the validation cohort ( $P = .12$ ). Significant preoperative predictors of 1-year mortality included chronic obstructive pulmonary disease, age, preoperative renal insufficiency (creatinine concentration  $\geq 1.8$  mg/dL or on hemodialysis), ejection fraction  $< 50\%$ , transfer status, body mass index  $< 24$  kg/m<sup>2</sup>, preoperative beta-blocker exposure, larger AAA diameter, and lower admission hemoglobin level. Preoperative statin use was found to be protective. The bias-corrected AUC was 0.759 (Hosmer-Lemeshow goodness-of-fit  $P$  value of 0.36; calibration intercept,  $-0.003$ ; slope, 0.999). When applied to the validation data set, the model had AUC of 0.724 (95% confidence interval, 0.676-0.768; calibration intercept, 0.0009; slope, 0.970), which was in excellent agreement with the original data set bias-corrected AUC. Notably,  $\sim 27.5\%$  ( $n = 4902$ ) had four or more risk factors with a predicted 1-year post-EVAR mortality risk of 10% to 22%

despite that 33.2% of these patients had AAA diameters *below* recommended treatment guideline minimum thresholds.

**Conclusions:** This validated preoperative prediction model for 1-year mortality identifies patients less likely to benefit from EVAR. Appropriateness of intact AAA EVAR care delivery can be improved by use of this clinical decision aid to determine which high-risk patients have lower probability of mortality within the first postoperative year relative to their predicted annualized rupture risk.

---

#### Cost-effectiveness analysis of endovascular versus open repair of abdominal aortic aneurysm in a high-volume center

Patrick Canning, MBBCh, Wael Tawfick, MBBCh, MSc, MRCS, Nicola Whelan, MBBCh, Niamh Hynes, MRCS, MMSc, MD and Sherif Sultan, MCh, MD, FRCS, PhD

**Objective:** Endovascular aneurysm repair (EVAR) for abdominal aortic aneurysms (AAAs) is the standard treatment for anatomically suitable patients. EVAR has been associated with a lower perioperative morbidity and mortality compared with open surgical repair (OSR) at the expense of increased reinterventions and costs. We aimed to compare the outcomes of EVAR and OSR for elective AAA repair. The primary end point was cost per QALY at 3 years. Secondary end points were perioperative morbidity and mortality; freedom from reintervention; length of hospital, high-dependency unit, and intensive care unit stay; and freedom from all-cause mortality.

**Methods:** The project was approved by the Galway Clinical Research Ethics Committee. This project followed the Declaration of Helsinki. This was an audit of interventions that had already taken place. No active clinical intervention was undertaken, and patients' anonymity was preserved; thus, individual patient consent was not obtained. Data on all elective AAA repairs at a tertiary referral vascular center were collected from 2002 to 2015. Demographics and outcomes were reported according to the Society for Vascular Surgery guidelines. QALY was measured on the basis of a quality-adjusted time without symptoms or toxicity assessment. Data were analyzed using parametric and nonparametric tests.

**Results:** Between 2002 and 2015, a total of 494 patients required elective AAA surgery; 401 underwent EVAR and 93 underwent OSR. Demographics and vascular-related risk factors were similar in both groups. Median (interquartile range) cost per QALY at 3 years was €5776 (€5541-€6481) for EVAR vs €7101 (€5812-€8952) for OSR ( $P < .001$ ). EVAR was associated with reduced perioperative morbidity (12.2% vs 50%;  $P < .001$ ). There was no significant association between procedure and perioperative mortality

(EVAR, 1.7%; OSR, 4.3%;  $P = .130$ ). There was no significant association found between the procedure and reintervention ( $P = .502$ ). Our subgroup analysis found no association between procedure and improvement in all-cause mortality, QALYs, costs, or cost per QALY.

**Conclusions:** EVAR is cost-effective with improved cost per QALY compared with OSR.

---

#### Statin use improves limb salvage after intervention for peripheral arterial disease

Gaurav M. Parmar, MD, MPH, Zdenek Novak, MD, PhD, MSHI, Emily Spangler, MD, Mark Patterson, MD, Marc A. Passman, MD, Adam W. Beck, MD and Benjamin J. Pearce, MD

**Background:** Statin use is recommended in all patients with peripheral arterial disease (PAD) owing to its morbidity and mortality benefits. However, the effect of statin use on limb salvage in patients with PAD after intervention is unclear. We examined the effect of statin use on limb salvage and survival among patients with PAD undergoing surgical or endovascular intervention.

**Methods:** A total of 488 patients with PAD were identified who underwent surgical ( $n = 297$ ) or endovascular ( $n = 191$ ) intervention between 2009 and 2010. Information was collected from electronic medical records and the Social Security Death Index. Predictors of ongoing statin use were identified first by univariate analysis and then via multivariable logistic regression. Survival and freedom from amputation were identified using Kaplan-Meier plots and adjusted hazard ratios by Cox regression.

**Results:** Of the 488 patients with PAD with intervention, 39% were non-whites, 44% were females, 41% received statins, 56% received antiplatelets, 26% received oral anti-coagulants, 9% required a major amputation, and 11% died during follow-up of up to 88 months. Statin users were more often male ( $P = .03$ ), white ( $P = .03$ ), smokers ( $P < .01$ ), and had higher comorbidities such as coronary artery disease ( $P < .01$ ), hypertension ( $P < .01$ ), and diabetes ( $P < .01$ ). Antiplatelet use was not associated with limb salvage ( $P = .13$ ), but did improve survival ( $P < .01$ ). Dual antiplatelet therapy did not show any benefit over monotherapy for limb salvage ( $P = .4$ ) or survival ( $P = .3$ ). Statin use was associated with improved survival ( $P = .04$ ), and improved limb salvage (hazard ratio, 0.3; 95% confidence interval, 0.1-0.7) after adjusting for severity of disease, traditional risk factors, and concurrent antiplatelet use.

**Conclusions:** Statin use in patients with PAD with interventions was associated with improved limb salvage and survival. Despite existing guidelines, statin therapy was low in our PAD population, and efforts are ongoing to increase their use across the health care system.