

Selected Abstracts from the February Issues of the Journal of Vascular Surgery [☆]

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Outcomes of the GORE Iliac Branch Endoprosthesis in clinical trial and real-world registry settings

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Background: We report midterm outcomes with the GORE Iliac Branch Endoprosthesis (IBE; W. L. Gore & Associates, Flagstaff, Ariz) in the U.S. investigational device exemption (IDE) trial and comparatively assess outcomes in the IDE trial with outcomes in a real-world population of patients treated in the Gore Global Registry for Endovascular Aortic Treatment (GREAT).

Methods: From 2013 to 2016, the IDE trial enrolled 99 patients treated with the IBE for common iliac artery (CIA) aneurysms or aortoiliac aneurysms. Bilateral IBE treatment was allowed only in the continued access phase. From 2013 to 2016, there were 92 patients treated with the IBE in the GREAT registry. Baseline characteristics, procedural variables, and reinterventions through 6 months were compared in the IDE trial and GREAT registry. Clinical and core laboratory-assessed imaging outcomes were assessed in the IDE trial through 2 years.

Results: GREAT patients were significantly older ($P = .01$) and of shorter height ($P < .001$) and lower weight ($P < .001$). There were also significantly more women treated in GREAT vs the IDE trial (8% vs 1%; $P = .02$). Thirteen GREAT patients (14%) and 4 of 35 continued access IDE patients (11%) had bilateral IBE placement ($P = .70$). IDE patients were more likely to be treated with percutaneous access methods (55% vs 40%; $P = .04$). Three IDE patients and three GREAT patients underwent 1-month reintervention, with two IDE reinterventions (2.1%) and one GREAT reintervention (1.6%) for thrombotic events. Five additional patients in each study underwent reintervention through 6 months (5% vs 5%; $P = .92$), all for nonthrombotic events. Internal iliac limb patency was 93.6% (95% confidence interval, 86.4%-97.1%) at 12 and 24 months in the IDE study. Subset analyses of the 10 IDE and GREAT patients with ≤ 6 -month reintervention vs 181 intervention-free patients found that acute myocardial infarction ($P = .01$), nonpercutaneous access ($P = .01$), and surgical conduit use ($P < .001$) were associated with reintervention through 6 months. In the IDE trial, 3.4% and 4.1% of patients underwent reintervention at 12 months and 24 months, respectively, all for treatment of type II endoleaks. At 24 months, 8.7% of IDE patients exhibited abdominal aortic aneurysm sac expansion; 21.7% exhibited abdominal aortic

aneurysm sac regression. No patients exhibited CIA aneurysm sac expansion; 45% exhibited CIA aneurysm sac regression.

Conclusions: Midterm IDE outcomes and 6-month outcomes in the worldwide GREAT registry suggest that endovascular aortic aneurysm repair with concomitant CIA aneurysm repair with the IBE device is safe and effective. Thrombotic events are uncommon and are concentrated in the first month after the index procedure, and they typically can be resolved with endovascular reintervention.

Epidemiology of fatal ruptured aortic aneurysms in the United States (1999-2016)

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Objective: Ruptured aortic aneurysms (rAAs) are associated with high mortality. The purpose of this study was to describe the trends of deaths due to rAA in the United States.

Methods: A retrospective review of the national death certificate data from the U.S. National Vital Statistics System was done to identify deaths due to rAAs in the United States between 1999 and 2016. Patients aged 15 years or older with rAA as the underlying cause of death as defined by *International Classification of Diseases, Tenth Revision* codes I71.1 (ruptured thoracic aortic aneurysm [rTAA]), I71.3 (ruptured abdominal aortic aneurysm [rAAA]), I71.5 (ruptured thoracoabdominal aortic aneurysm), and I71.8 (rAA of unspecified site) were included and standardized to U.S. Census data.

Results: A total of 104,458 deaths due to rAAs occurred during the study period. The overall age-adjusted incidence of fatal rAA was 23.3 per 1 million (rAAA, 15.1; rTAA, 3.1; thoracoabdominal, 0.4; and unspecified site, 4.8). The annual incidence of rAA decreased by 68% from 40.0 (1999) to 12.8 (2016) per 1 million (rTAA by -67% from 5.5 to 1.8 and rAAA by -70% from 26.3 to 7.89 per 1 million; $P < .001$ for all comparisons). These trends were consistent across age groups, sexes, and races. There was a significant seasonal variation in rAA mortality, with higher deaths in winter months compared with summer months. The incidence of rAA is highest in Midwest states (27.1 per 1 million), followed by Northeast (23.8 per 1 million) and West (14 per 1 million) states, and lowest in Southern states (13.6 per 1 million). Only 57% of rAAA deaths occurred in men ≥ 65 years.

Conclusions: The incidence of fatal rAA, rTAA, and rAAA drastically decreased in the United States between 1999 and 2016, a trend that was consistent across age groups,

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sexes, and races. A significant percentage of fatal rAAAs occurred in patients who are not eligible for the current screening program.

Inability of conventional imaging findings to predict response to laparoscopic release of the median arcuate ligament in patients with celiac artery compression

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Objective: The objective of this study was to identify duplex ultrasound (DUS) or computed tomography angiography (CTA) imaging findings that can predict clinical response to laparoscopic release of the median arcuate ligament (MAL) in patients with celiac artery compression.

Methods: There were 299 patients who were evaluated for MAL syndrome (MALS) between January 2009 and November 2015. Of these, 29 underwent laparoscopic MAL release and completed 1-year follow-up. The patients' preoperative and postoperative symptoms, use of analgesics, and body mass index were recorded. Patients' demographics and DUS and CTA findings were reviewed. Fisher exact and Student *t*-tests were used to identify correlation between patient or imaging variables and clinical outcomes.

Results: There were 19 patients (66%) who reported improvement in symptoms, and 18 (62%) decreased their use of analgesics; average body mass index increased by 0.2 (standard deviation, 1.97; range, -3.35 to 5.11). No celiac artery DUS finding (peak celiac artery velocity, angle of deflection, or change in preoperative to postoperative velocity) was predictive of successful clinical outcomes ($P > .05$). Similarly, no CTA finding (characteristic morphology, cross-sectional area, diameter, or location of the focal stenosis of the celiac artery) was associated with clinical outcomes ($P > .05$).

Conclusions: Clinical response to laparoscopic MAL release was favorable in two-thirds of patients; however, no specific imaging finding of stenosis was predictive of this response. Given that the severity of stenosis on conventional imaging had no impact on treatment efficacy, vascular compromise may not be the primary cause of pain in patients presenting with this syndrome. Future investigation incorporating the neurogenic basis of MALS pain, such as with diagnostic celiac ganglion blockade, would be helpful in further elucidating the enigmatic pathophysiologic process of MALS.

In-hospital versus postdischarge major adverse events within 30 days following lower extremity revascularization

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Objective: Studies using hospital discharge data likely underestimate postoperative morbidity and mortality after lower extremity revascularization because they fail to

capture postdischarge events. However, the degree of underestimation and the timing of postdischarge complications are not well-characterized.

Methods: We used the American College of Surgeons National Surgical Quality Improvement Program procedure-targeted vascular databases from 2011 to 2015 to tabulate 30-day adverse events (in hospital and after discharge) for lower extremity bypass (LEB) and percutaneous vascular interventions (PVI) performed for claudication and chronic limb-threatening ischemia (CLTI).

Results: A total of 14,125 patients underwent lower extremity revascularization, 8909 patients (63%) with LEB and 5216 (37%) with PVI. For CLTI, total 30-day mortality was similar between PVI and LEB (2.3% vs 2.1%; $P = .61$), but in-hospital deaths only accounted for 43% of PVI mortality and only 65% of LEB mortality ($P \leq .001$). Major adverse cardiac events occurred in 2.9% of PVI patients and 4.6% of LEB patients ($P < .001$), with postdischarge events accounting for 37% of PVI events and 18% of LEB ($P \leq .001$). Although the 30-day reoperation rates were 14% for PVI and 18% for LEB ($P < .001$), almost one-half occurred after discharge (PVI 46% vs LEB 44%; $P = .55$). Any postoperative major adverse events (MAEs) occurred in 22% of patients after PVI and 31% after LEB, with more than one-half occurring after discharge (PVI 56% vs LEB 53%; $P = .17$). For claudicants, total 30-day mortality was 0.4% for PVI and 0.7% for LEB ($P = .32$), with the vast majority of events occurring after discharge (PVI 90% vs LEB 50%; $P = .049$). The 30-day reoperation rates were 5.2% for PVI and 8.0% for LEB ($P < .001$), with more than one-half occurring after discharge (PVI 63% vs LEB 53%; $P = .09$). Any MAEs occurred in 7.0% of patients after PVI and 17% after bypass, with the majority occurring after discharge (PVI 65% vs LEB 63%; $P = .66$).

Conclusions: Most MAEs occur less frequently after PVI than LEB. However, a significant number of major adverse events after lower extremity revascularization occur after leaving the hospital, especially after PVI, which may overestimate its benefits compared with LEB if only in-hospital data are evaluated. These data demonstrate the importance of reporting 30-day rather than in-hospital outcomes when evaluating postoperative adverse events.

Near-instant noninvasive optical imaging of tissue perfusion for vascular assessment

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Background: Noninvasive vascular tests are critical for identifying patients who may benefit from surgical revascularization, but current tests have significant limitations in people with diabetes. This study aimed to evaluate the ability of spatial frequency domain imaging (SFDI), an optical imaging method capable of measuring tissue oxygen saturation (StO₂) and tissue hemoglobin, to assess lower extremity blood supply.

Methods: Ankle-brachial index, toe-brachial index, pedal Doppler waveforms, and SFDI images were prospectively evaluated in 47 consecutive patients with and without diabetes in whom there was concern for peripheral artery disease (PAD). SFDI is a noncontact optical imaging technology that uses structured illumination to quantify sub-surface (2-3 mm in depth) StO_2 and tissue hemoglobin in the dermal microcirculation (HbT_1) and macrocirculation (HbT_2) over a large field of view (15×20 cm) within 10 seconds.

Results: This demonstrates the ability of SFDI to capture reliable clinical measurements of perfusion in plantar aspects of the feet. SFDI StO_2 values differentiate nondiabetic patients with and without arterial disease, defined as ankle-brachial index <0.9 ($P = .06$), but are limited in those with diabetes ($P = .43$). An elevated StO_2 and reduced HbT_1 are observed in people with diabetes compared with nondiabetic patients ($P < .05$). An SFDI-derived $\text{HbT}_2/\text{HbT}_1$ index differentiates diabetics with PAD vs no PAD ($P < .01$) using toe-brachial index <0.7 as a cutoff for PAD in diabetes.

Conclusions: SFDI is a feasible, rapid, and easy to use widefield measurement of perfusion in a clinical setting. This first-of-use study suggests that the technology has potential to evaluate lower extremity perfusion in people with and without diabetes. Further studies with increased numbers of patients and end points including wound healing will need to be designed to fully evaluate the applicability of this new technology.

A systematic review and meta-analysis of the efficacy of aortic anastomotic devices

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Objective: One of the factors contributing to complications related to open repair of the aorta is the construction of a hand-sewn anastomosis. Aortic anastomotic devices (AADs), such as the intraluminal ringed graft (IRG), and the anastomotic stenting technique have been developed to

perform a sutureless and less complicated anastomosis. This study performed a systematic review and meta-analysis of the literature reporting clinical use of AADs and aimed to assess, primarily, the effect of each device on 30-day overall and operation-related mortality and aortic cross-clamping time and, secondarily, the rate of successful two-sided application of the IRG device and the operation-related morbidity for each device.

Methods: An electronic search was performed using MEDLINE, Scopus, ScienceDirect, and Cochrane Library by two independent authors. Our exclusion criteria included studies incorporating fewer than three patients and studies reporting results solely from animals or in vitro testing, results solely from end-to-side anastomosis, and results solely from endarterectomy procedures. The last search date was February 1, 2018.

Results: A total of 41 studies were identified that reported outcomes for the use of three different device types: IRG, anastomotic stenting technique, and surgical staplers. The last two types were classified together as the non-IRG group. The meta-analysis included 27 studies with 50 cohorts incorporating 1260 patients. The median age of the incorporated patients was 61.4 years (range, 51-73 years), and 68.9% were male. The operations were performed for the treatment of acute aortic dissection in 82.3%. The pooled overall 30-day mortality rate varied by device type; IRG devices had a mean rate of all-cause mortality of 9.71%, whereas non-IRG devices were associated with a significantly ($I^2 = 15.78\%$; P for Cochrane Q test $< .19$) lower rate of death (1.47%). The pooled mean aortic cross-clamping time was 35.83 minutes. Metaregression showed that the performance of two-sided anastomosis with the IRG device significantly decreased the aortic cross-clamping time. However, a successful two-sided ringed anastomosis was performed in approximately half of the cases.

Conclusions: Taking into account that the majority of operations were performed for the treatment of acute aortic dissection, AADs had a relatively low rate of 30-day mortality. Despite the observed heterogeneity in study protocols and the small sample size in the non-IRG group, the non-IRG group presented with the lowest 30-day mortality rate. Specific device-related complications between the different device types need further investigation.