Late outcomes after endovascular and open repair of large abdominal aortic aneurysms

Livia E. V. M. de Guerre, MD, Kirsten Dansey, MD, Chun Li, MD, Jinny Lu, MD, Priya B. Patel, MD, Joost A. van Herwaarden, MD, Douglas W. Jones, MD, Philip P. Goodney, MD, MS, and Marc L. Schermerhorn, MD, *Boston and Worcester, Mass; Utrecht, The Netherlands; and Lebanon, NH*

**ABSTRACT**

**Objective:** The risk of aortic abdominal aneurysm (AAA) rupture increases with an increasing aneurysm diameter. However, the effect of the AAA diameter on late outcomes after aneurysm repair is unclear. Therefore, we assessed the association of a large AAA diameter with late outcomes for patients undergoing open and endovascular AAA repair.

**Methods:** We identified all patients who had undergone elective open or endovascular infrarenal aneurysm repair from 2003 to 2016 in the Vascular Quality Initiative linked to Medicare claims for long-term outcomes. A large AAA diameter was defined as a diameter >65 mm. We assessed the 5-year reintervention, rupture, mortality, and follow-up rates. We constructed propensity scores and used inverse probability-weighted Kaplan-Meier estimations and Cox proportional hazard models to identify independent associations between large AAA repair and our outcomes.

**Results:** Of the 21,119 aneurysm repairs identified, 15.2% were for large AAAs. Of the 21,119 repairs, 19,017 were endovascular and 2102 were open. The large AAA cohort was less likely to have undergone endovascular aneurysm repair (EVAR; 84.9% cancelled) for the poster competition. Presented at the 2020 Society for Vascular Surgery ONLINE, June 20-July 31, 2020 (selected as the virtual competition winner).

Correspondence: Marc L. Schermerhorn, MD, Division of Vascular Surgery, Beth Israel Deaconess Medical Center, 110 Francis St, Ste 5B, Boston, MA 02215 (e-mail: mscherm@bidmc.harvard.edu).

The editors and reviewers of this article have no relevant financial relationships to disclose per the JV S policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.
The Society for Vascular Surgery, in their guidelines, have recommended elective aortic abdominal aneurysm (AAA) repair at a maximum AAA diameter of 55 mm in men and 50 mm in women. In addition, previous studies have shown an increasing rupture risk and intact repair mortality risk in patients with a larger aortic diameter. However, large variations have been reported in the AAA diameter at repair, and a large proportion of patients have undergone surgery at a threshold >50 mm and >55 mm.

The perioperative benefit and improvement over time of endovascular aneurysm repair (EVAR) has led to an increasing majority of AAAs undergoing EVAR. However, long-term survival data have shown that the perioperative benefit after EVAR persists for only ≤3 years after the index procedure, after which, survival was similar in the open and EVAR cohorts. Also, EVAR has been associated with higher rupture and reintervention rates and procedural costs. Therefore, the true benefit and appropriate selection of patients for EVAR must be carefully considered, especially in specific higher risk cohorts such as patients with large AAA diameters.

Therefore, our aim was to investigate the association of a large AAA diameter with the late outcomes and to compare EVAR and open repair for patients with large AAAs.

METHODS

Data source. We performed a retrospective cohort study using Vascular Quality Initiative (VQI) registry data linked with Medicare claims. Patients identified from the VQI were linked to the Medicare claims files using a previously described method. The method combines the advantages of a prospectively collected vascular quality improvement registry and administrative data. The VQI has granular clinical, technical, and in-hospital outcome data available that were specifically designed per procedure and by vascular surgeons (more information can be found at www.vqi.org). However, long-term data are limited. The Medicare linkage provided long-term follow-up data, enabling us to study late reinterventions, ruptures, follow-up imaging, and mortality. The present report adhered to the applicable STROBE (strengthening the reporting of observational studies in epidemiology) standards for observational studies. The Beth Israel Deaconess Medical Center institutional review board approved the present study and waived the need for written informed consent owing to the retrospective and de-identified nature of the study.

Patient cohort. We identified all patients who had undergone EVAR or open repair of an infrarenal AAA from 2003 to 2016 with linked records (89% matched). We excluded patients if they had presented with a symptomatic AAA (n = 2423), ruptured AAA (n = 2163), or unknown urgency status (n = 102). Also, to improve the comparability with infrarenal EVAR, we excluded patients who had undergone open repair with a clamp location above the infrarenal level (n = 1877). To ensure that we had only captured true elective repairs, we only included the first entry of a patient with multiple entries (n = 30). We also excluded repairs performed on the weekend (n = 106), patients with small AAAs (<50 mm) for whom the indication for repair was an iliac aneurysm (n = 274), and those with a previous AAA repair noted at their first VQI entry (n = 649). Finally, we excluded patients with missing aortic diameter data (n = 283).

Definitions and variables. We defined a large AAA as an aneurysm with a maximum diameter >65 mm, because previous research has shown that this was a clinically relevant threshold. A medium AAA diameter was defined as a diameter greater than the SVS recommended thresholds of 5.5 cm for men and 5.0 cm for women but <6.5 cm. We defined small AAAs as those with a diameter less than the SVS recommended thresholds. The aortic size index (ASI) was defined as the aneurysm diameter divided by the body surface area.
The body surface area was calculated using the Dubois and Dubois formula \((0.20247 \times \text{height (m)}^{0.725} \times \text{weight (kg)}^{0.425})\). Age \(>90\) years was coded as 90 years old in the VQI. Race was stratified as white, black, and other (including Asian, Native American or Alaskan Native, Native Hawaiian, other Pacific Islander, or more than one race). We included race in our analyses, despite its limited biologic significance, because we believe describing racial differences is essential to identifying potential areas for quality improvement. We used the standard formula for computing the body mass index (BMI; weight in kilograms divided by the height in square meters) and considered a BMI \(<18.5 \text{ kg/m}^2\) as underweight and a BMI of \(\geq 30 \text{ kg/m}^2\) as obese. The most recent preoperative creatinine value was used to estimate the glomerular filtration rate for each patient using the Chronic Kidney Disease Epidemiology Collaboration equation.\(^{16}\) Chronic kidney disease was defined as a preoperative estimated glomerular filtration rate \(<30 \text{ mL/min/1.73 m}^2\) or a requirement for dialysis. The definition of congestive heart failure (CHF) included asymptomatic and mild, moderate, and severe CHF presentations. Insulin-dependent diabetes mellitus, any preoperative history of hypertension, and any severity of chronic obstructive pulmonary disease (COPD) were included. Current smoking was defined as smoking in the month before surgery. A positive family history of AAA was defined as a first-degree relative with a diagnosis of an AAA. Preoperative medication use was included if the medication had been used within 36 hours of the procedure. Neck characteristics were only available for patients who had undergone EVAR after 2014, and a hostile neck was defined as the presence of at least one of the following and determined according to the common device instructions for use cutoffs: neck angulation \(>60^\circ\), neck length \(<15 \text{ mm}\), and/or neck diameter \(<30 \text{ mm}\). Our prespecified primary outcomes were the 5-year mortality, reinterventions, loss to imaging follow-up, and ruptures.

**Statistical analysis.** We compared the baseline and operative characteristics between patients with a larger and smaller AAA diameter on univariate analysis. Categorical variables are presented as frequencies and percentages and continuous variables as the median and interquartile range. We calculated the propensity scores using separate logistic regression models for the smaller vs large AAA diameter comparison, stratified by EVAR and open repair and for the EVAR vs open repair comparison, stratified by the small and large AAA diameter. Our logistic model constrained the following a priori-selected covariates: age, sex, race (ie, white, black, other), BMI (ie, underweight, obese), smoking status, renal disease, insulin-dependent diabetes mellitus, hypertension, CHF, COPD, family history, coronary artery disease, statin use, aspirin use, and P2Y12 use. The propensity scores were tested for the adequacy of overlap by plotting the distribution of propensity scores between the study groups. After weighting, minimal imbalance was present, with all standardized differences \(<10\%\). We used these propensity scores to create inverse probability weights, and reweighted the data to ensure that the distribution of confounders was the same between our comparison groups. Using this method, rather than propensity matching, we could adjust for all relevant confounders and retain the entire sample size, making the study findings more generalizable. We used inverse probability-weighted Kaplan-Meier estimations and Cox proportional hazard models to compare the 5-year reintervention, rupture, follow-up, and survival data. The standard errors were \(<0.1\) at 5 years for all outcomes. For the 5-year reintervention, rupture, and follow-up assessments, the patients who had died were censored at the date of death and the patients who had left the Medicare fee-for-service for an alternative program were censored at the date of the switch. Because neck anatomy data were only introduced in 2014 in the EVAR database, we performed a post hoc subanalysis of the patients with available neck anatomy data to compare the large AAA EVAR cohort without hostile neck characteristics with the smaller AAA EVAR cohort without hostile neck characteristics and with the large AAA open repair cohort. We also compared patients who had undergone large AAA EVAR with and without hostile neck characteristics. Previous studies have shown that female patients will generally have a smaller body habitus; therefore, a specific aneurysm diameter might represent a greater relative increase in the aortic diameter for women compared with men.\(^{14,15}\) Therefore we analyzed the mean ASI for male patients at a diameter of 65 mm and used this threshold to define large AAAs in the
female patients. A post hoc subgroup analysis comparing large and small AAA repair using this ASI threshold was performed for the female patients. Also, we performed a post hoc sensitivity analysis of patients who had undergone repair after 2010 and compared the patients with a large AAA with the patients with an AAA diameter <65 mm but greater than the SVS guideline threshold of 55 mm for male patients and 50 mm for female patients.1

To evaluate the predicted open perioperative mortality, we used the VQI risk score to evaluate patients with large AAAs undergoing EVAR.17 This risk score includes open aortic surgery, age >75 years, female sex, history of myocardial disease, history of cerebrovascular disease, history of COPD, creatinine, and an AAA diameter in its model. With this analysis, we aimed to risk stratify these patients to evaluate whether the larger AAA diameter resulted in the risk score exceeding the accepted open repair perioperative mortality of 5%.1

All variables had <2% missing data. All statistical analyses were performed using Stata, version 16, software (StataCorp LLC, College Station, Tex).

RESULTS

Patient cohort. Of the 21,119 patients identified, 19,017 had undergone EVAR (2729 [14.4%] with large AAAs) and 2102 had undergone open repair (484 [23%] with large AAAs). Overall, 15.2% had undergone repair for a large AAA. The proportion of repairs for large AAAs compared with smaller AAAs had decreased over time, with 22.5% large AAA repairs in 2003 and 13.5% large AAA repairs in 2016. Also, EVAR usage for large AAA repairs had increased over time, with 34.9% endovascular repairs in 2003 and 90.6% in 2016.

Baseline and anatomic characteristics. The large AAA cohort compared with the small AAA cohort was older (median age, 76 vs 75 years; P < .001), and were less likely to be women (16.2% vs 21.7%; P < .001), to have a positive family history (8.2% vs 9.4%; P = .030), to have hypertension (82.6% vs 84.1%; P = .037), or to have a history of coronary artery disease (41.4% vs 43.8%; P = .011). Also, patients undergoing large AAA repair were more likely to be underweight (3% vs 2.4%; P = .027), to have renal disease (4.6% vs 3.4%);
P < .001), and to have CHF (13.7% vs 11.4%; P < .001). Finally, patients who had undergone large AAA repair were less likely to use preoperative statin (65.3% vs 71.7%; P < .001), aspirin (63.0% vs 67.5%; P < .001), or P2Y12 (9.3% vs 12.1%; P < .001; Table).

**Large vs small EVAR and open repair.** The adjusted 5-year freedom from reintervention after EVAR was lower after large AAA EVAR (73.9% vs 84.6% for smaller AAA EVAR; hazard ratio [HR], 1.70; 95% confidence interval [CI], 1.46-1.98; P < .001; Fig 1, A). However, after open repair, the reintervention rates were similar between the larger and smaller aneurysms (95.8% vs 93.3%; HR, 0.63; 95% CI, 0.32-1.21; P = 17; Fig 1, B). The adjusted freedom from late rupture after EVAR was lower after large AAA EVAR than after smaller AAA EVAR (88.5% vs 93.6%; HR, 1.53; 95% CI, 1.22-1.93; P < .001; Fig 2, A). However, after open repair, the freedom from late rupture was similar between aneurysm sizes (97.5% vs 97.8%; HR, 1.52; 95% CI, 0.63-3.64; P = .35; Fig 2, B). Also, the adjusted 5-year survival after EVAR was lower after large AAA repair than after smaller AAA EVAR (58.0% vs 66.4%; HR, 1.52; 95% CI, 1.40-1.67; P < .001; Fig 3, A). However, after open repair, no significant difference was found in the 5-year survival between large and smaller AAA repair (70.4% vs 74.1%; HR, 1.22; 95% CI, 0.95-1.56; P = .12; Fig 3, B). After EVAR, the patients with large AAAs had had lower adjusted freedom from loss to imaging follow-up (77.7% vs 83.3%; P < .001). Also, after open repair, no significant difference was found in the loss to imaging follow-up (60.5% vs 62.8%; P = .86).

**EVAR vs open large and smaller AAA repair.** The patients who had undergone large AAA repair had a perioperative adjusted survival benefit after EVAR that lasted <1 year, and, after 5 years, adjusted survival was lower after EVAR at 55.3% compared with 63.7% after open repair (Fig 4, A). Also, freedom from reintervention was lower after EVAR than after open repair (74.0% vs 93.6%; HR, 4.54; 95% CI, 2.20-9.37; P < .001) and the freedom from rupture was similar (89.2% vs 96.5%; HR, 2.04; 95% CI, 0.79-5.26; P = .14). Patients undergoing EVAR of smaller AAAs experienced a longer survival benefit compared with that after open repair, and the adjusted 5-year survival was similar (67.3% vs 70.6%; Fig 4, B). The freedom from reintervention (84.6% vs 93.7%; HR, 2.30; 95% CI, 1.72-3.09; P < .001) and freedom from rupture (93.7% vs 98.2%; HR, 3.95; 95% CI, 2.32-6.73; P < .001) were lower after EVAR than after open repair.
Predicted mortality risk. When applying the VSGNE (Vascular Study Group of New England) risk score to calculate the predicted open mortality for patients with large AAA who had undergone EVAR, 73.6% had had a predicted open repair mortality of <5% (median, 3.2%; interquartile range, 1.8%-6.3%; Fig 5).

Hostile neck anatomy. A subanalysis of patients with available neck anatomy variables (EVAR patients from December 2014 onward; n = 4544) showed that patients with large AAAs who had undergone EVAR were more likely to have hostile neck characteristics (47.4% vs 35.0%; P = .007). Also, in the subgroup of patients with no hostile neck characteristics who had undergone EVAR, a large AAA diameter was associated with lower 2-year adjusted survival rates (84.6% vs 88.9%; P = .007) compared with patients with smaller AAAs. In this same subgroup, although the 2-year freedom from reintervention and rupture was lower in those with large AAAs compared with patients with smaller AAAs, the difference was not statistically significant (90.3% vs 94.6%; P = .17; and 94.0% vs 96.7%; P = .20). Also, patients with a large AAA and without hostile neck anatomy who had undergone EVAR compared with patients who had undergone large AAA open repair had had lower 2-year freedom from reintervention (89.9% vs 97.4%; HR, 3.80; 95% CI, 1.01-14.3; P = .049) and similar freedom from rupture (93.1% vs 96.6%; HR, 1.38; 95% CI, 0.29-6.63; P = .68). The survival benefit from EVAR lasted <1 year. At 2 years, survival was similar (83.7% vs 85.9%; HR, 1.04; 95% CI, 0.51-2.14; P = .91). After repair of smaller AAAs, patients without hostile neck characteristics who had undergone EVAR and patients who had undergone open repair had had similar freedom from 2-year reintervention (94.5% vs 96.2%; HR, 1.53; 95% CI, 0.80-2.93; P = .20) and freedom from 2-year rupture (96.8% vs 97.5%; HR, 2.32; 95% CI, 0.99-5.40; P = .052). Of the patients who had undergone repair of smaller AAAs, those without hostile neck characteristics who had undergone EVAR had had higher 2-year survival rates compared with the patients who had undergone open repair (89.6% vs 87.8%; HR, 0.65; 95% CI, 0.45-0.94; P = .021). Finally, no significant differences were found when comparing patients with a large AAA with and without hostile neck characteristics (n = 567) in the 2-year freedom from reintervention (92.8% vs 90.7%; HR, 0.76; 95% CI, 0.28-2.06; P = .59), freedom from rupture (94.0% vs 92.9%; HR, 1.20; 95% CI, 0.41-3.50; P = .74), and survival (84.3% vs 83.2%; HR, 1.13; 95% CI, 0.67-1.90; P = .64).

Female sex. In the male patients, the mean ASI for patients with an AAA diameter of 65 mm was 3.25 cm/m². When using 3.25 cm/m² as the threshold for large AAAs
in the female patients, the female patients who had undergone EVAR (n = 7188) for large AAAs compared with smaller AAAs were less likely to have an adjusted 5-year freedom from reintervention (75.5% vs 86.3%; HR, 1.66; 95% CI, 1.23-2.23; P < .001). In contrast, in the subgroup of female patients who had undergone open repair (n = 617), those who had undergone large AAA repair had had a similar adjusted 5-year freedom from reintervention (95.6% vs 93.6%; HR, 0.58; 95% CI, 0.20-1.74; P = .33) compared with patients who had undergone smaller AAA repair. Also, female patients who had undergone large AAA EVAR were less likely to have an adjusted 5-year freedom from rupture (87.4% vs 94.4%; HR, 1.78; 95% CI, 1.20-2.66; P = .005) compared with those who had undergone smaller AAA EVAR. However, after open repair, the adjusted 5-year freedom from rupture (97.0% vs 95.0%; HR, 0.67; 95% CI, 0.19-2.36; P = .53) was similar for female patients who had undergone large AAA open repair compared with those who had undergone smaller AAA open repair. Finally, after EVAR, female patients who had undergone large AAA repair were likely to have lower adjusted 5-year survival (53.1% vs 64.3%; HR, 1.49; 95% CI, 1.26-1.77; P < .001) compared with patients undergoing smaller AAA repair. Also, after open repair, the adjusted 5-year survival was lower for patients who had undergone large AAA repair compared with those who had undergone smaller AAA repair (63.7% vs 73.2%; HR, 1.55; 95% CI, 1.02-2.35; P = .040).

**Sensitivity analysis.** A sensitivity analysis comparing patients with large AAAs with those with AAAs of a diameter <65 mm but greater than the SVS guideline threshold gave the same results as our primary analysis. Large AAA repair compared with medium AAA repair showed significantly lower freedom from reintervention (73.6% vs 83.3%; P < .001), rupture (88.1% vs 93.2%; P = .002), survival (54.9% vs 62.5%; P < .001), and lower adherence to imaging follow-up (77.5% vs 83.1%; P < .001) in the EVAR group but not in the open repair group (reintervention, 95.9% vs 94.2% [P = .42]; rupture, 97.4% vs 97.6% [P = .59]; survival, 68.4% vs 71.5% [P = .34]; imaging follow-up, 58.2% vs 62.9% [P = .93]).

Also, in the subgroup of patients who had undergone repair after 2010, patients with large AAAs had a perioperative adjusted survival benefit after EVAR compared with after open repair that lasted <1 year. After 5 years, the adjusted survival was lower after EVAR at 55.2% compared with 61.0% after open repair. The patients who had undergone smaller AAA repair with EVAR experienced a longer survival benefit compared with that after open repair, and the adjusted 5-year survival was similar (66.8% vs 71.3%).

**DISCUSSION**

Patients with a large AAA diameter (≥65 mm) compared with a smaller AAA diameter (<65 mm) who had undergone EVAR had greater mortality, reintervention, rupture, and loss to imaging follow-up rate. However, after open repair, these outcomes were similar. Also, EVAR for large AAAs was associated with greater adjusted 5-year mortality compared with open repair, which was not observed in patients with smaller AAAs.

Previous research has shown that for an AAA diameter >55 mm, the untreated aneurysm-related rupture risk outweighs the operative risk for most patients. However, in our study, 15.2% of elective repairs were performed in patients with a AAA that was >65 mm. Although it is possible that patients with an identified AAA will have surgery deferred until the AAA has reached a larger diameter because of high comorbidity rates, we believe this was unlikely in practice. Our analysis showing a low predicted open operative mortality for patients undergoing large AAA repair supports this assumption. It is more likely that patients will remain undiagnosed until an initial presentation with an incidental large AAA.

It is also possible that delays in care delivery can result in repair at a larger diameter, emphasizing the need for screening and early vascular referral. The United States implemented a Medicare screening program in 2007 for male patients aged 65 to 75 years with a smoking history and patients with a positive family history of AAA. The decrease over time in large AAA repair could reflect the effects of screening and improved access to healthcare. Although the patients who had undergone large AAA repair were less likely to have a positive family history of AAA, the smoking rates were similar, and patients were more likely to be male. Therefore, expansion of the screening guidelines and/or the use of separate strategies to improve access to vascular care are warranted. Also, the indicators for optimal medical management with statins and aspirin or P2Y12 inhibitors for patients undergoing large AAA repair were lower and could, therefore, suggest that this group had had less exposure to guideline-based medical care before detection or had
had a recent diagnosis. This potentially diminished access to preoperative care vascular care for patients with large AAAs could also influence the adherence to follow-up, because we found lower imaging follow-up rates for patients with large AAAs who had undergone EVAR. The high reintervention rates and rupture rates, combined with the lower imaging follow-up rates and potentially diminished access to vascular care in patients with large AAAs, highlight the need for improved follow-up, especially in this high-risk patient group.

The worse adjusted outcomes for the patients undergoing large AAA EVAR compared with smaller AAA EVAR and large AAA open repair raise serious concerns regarding the durability of EVAR for large AAAs. A large AAA diameter was associated with more complex anatomy, which would likely predispose to a less advantageous seal, limiting the suitability of EVAR. Because the neck characteristic variables were only introduced after 2014, our subanalyses regarding hostile neck characteristics had limited follow-up data available and a smaller study population. However, in the subgroup analyses, patients without hostile neck characteristics who had undergone EVAR for a large AAA compared with both smaller AAA EVAR and large AAA open repair showed similar effect sizes and directions compared with the primary analysis. Therefore, we expect our conclusions will remain applicable to patients without hostile neck characteristics. The mechanisms causing worse outcomes for patients with a large AAA remain unclear and warrant further exploration but are likely to include factors not associated with the neck anatomy. Furthermore, when considering the value of EVAR, the higher procedural costs and lifelong surveillance requirement need to be taken into account, especially in patients with an acceptable operative risk and suboptimal access to vascular care.19,20

The SVS has suggested that elective open repair for AAAs should be performed at centers with a documented perioperative mortality of ≤5%.1 Our application of a validated predictive model showed that most patients undergoing large AAA EVAR will have an acceptable operative risk for open repair. This would indicate that patients who undergo EVAR because they are unfit for open surgery are likely to be a minority of the patients with a large AAA and shows the room for quality improvement in the optimal treatment selection in this cohort.

When interpreting the results of the present study, the potential selection bias of the VQI and Medicare data should be considered. Hospitals elect to participate in the VQI and, therefore, are likely to have a dedicated quality improvement focus.21 Furthermore, Medicare only includes individuals aged ≥65 years and select individuals aged <65 years. Also, we excluded patients who had undergone repair of symptomatic or ruptured AAAs. Therefore, the generalizability to younger patient populations or patients undergoing nonelective repair might not be warranted. Finally, the aneurysm neck characteristics were not available from the open repair database and were only available after 2014 from the EVAR database. Therefore, when longer follow-up data are available, further study of the long-term effects of hostile neck characteristics will be warranted.

CONCLUSIONS

Large AAA repair was associated with higher adjusted 5-year mortality reintervention and rupture after EVAR but not after open repair. Despite the greater adjusted 5-year mortality for patients with large AAAs who had undergone EVAR compared with open repair, an increasing majority of patients with large AAAs have undergone EVAR. Therefore, for patients with large AAAs who are medically fit, open repair should be strongly considered, even for those patients with anatomy suitable for EVAR. Furthermore, the high reintervention rates and late ruptures highlight the necessity for rigorous long-term follow-up after EVAR.

AUTHOR CONTRIBUTIONS

Conception and design: LdD, KD, CL, JL, PP, JvH, DJ, PC, MS
Analysis and interpretation: LdD, KD, CL, JL, PP, MS
Data collection: LdD
Writing the article: LdD
Critical revision of the article: LdD, KD, CL, JL, PP, JvH, DJ, PC, MS
Final approval of the article: LdD, KD, CL, JL, PP, JvH, DJ, PC, MS
Statistical analysis: LdD
Obtained funding: Not applicable
Overall responsibility: MS

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Submitted Oct 6, 2020; accepted Feb 9, 2021.

The CME exam for this article can be accessed at http://www.jvascsurg.org/cme/home.