THE TEXAS HEART INSTITUTE® JOURNAL

ISEVS 30th Anniversary Interactive Cardiovascular Symposium

Endovascular Strategies for Aortic Arch When US Food and Drug Administration–Approved Devices Are Not Available

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Keywords: Stents; endovascular aneurysm repair; lasers; transplants; endovascular procedures; United States Food and Drug Administration

Background

Open surgical repair is the standard of care for aortic arch aneurysms and dissections. Innovations in endovascular modalities have broadened the treatment regime for patients unable to tolerate open surgery.[1] A hybrid approach as well as designated endovascular devices for aortic arch repair can be used to treat high-risk patients with suitable anatomy. Devices approved by the US Food and Drug Administration, however, are not available in all hospitals primarily because of their high costs; many aortic arch–specific devices are still investigational in the United States, and only a limited number of centers participate in those trials. Off-label use of existing devices or alternative endovascular strategies may therefore be required. A total of 40% of patients undergoing thoracic endovascular aortic repair require coverage of at least 1 supra-aortic trunk.[2] In urgent and emergent cases, coverage of the left subclavian artery without revascularization is possible, though it carries an increased risk of arm ischemia, stroke, and spinal cord injury. The American Heart Association and Society of Vascular Surgery guidelines recommend routine revascularization of the left subclavian artery in elective cases[1,3] because making the choice to land more distally with a short seal zone can lead to thoracic aortic enlargement and endoleak, which is blood flow within the aneurysm sac but outside the endoluminal graft. Few options exist for complete endovascular aortic arch repair without using stent grafts, which have been approved by the Food and Drug Administration. These options include parallel stent grafts, physician-modified endografts, and in situ laser fenestration.

Parallel Stent Grafts

Chimney, or parallel stent, grafts were introduced by Greenberg et al,[4] who used a kidney stent parallel to the aortic stent graft to salvage the renal artery during endovascular treatment of an abdominal aortic aneurysm. Since then, the technique has been expanded to preserve blood flow into other arteries, including aortic arch branches. Results have demonstrated that the technique is safe and efficient in elective and emergent cases. One systematic review that included 18 studies (124 patients and 136 chimneys), with 25 patients having chimneys involving the proximal arch (zone 0) and 99 patients having chimneys involving the distal arch (60 left common carotid arteries, 51 left subclavian arteries), reported a 30-day mortality rate of 5% and a 4% incidence of stroke.[5] Another systematic review that included 12 studies (379 patients) with 28 cases of innominate coverage (zone 0) reported a similar 30-day mortality rate of 4% and a stroke incidence rate of 5%. This review included late-morbidity events, with endoleak

Citation: Sutton G, Afifi, R. Endovascular strategies for aortic arch when US Food and Drug Administration–approved devices are not available. *Tex Heart Inst J.* 2024;51(1):e248391. doi:10.14503/THIJ-24-8391
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occurring in 73 patients (19.3%); the majority of these complications were type I endoleaks.[6]

Physician-Modified Endografts

Physician-modified endografts for the aortic arch involve the deployment of a conventional stent graft device ex vivo, which is then given customized, reinforcing fenestrations or inner branches that fit the patient's anatomy before it is reconstrained into the delivery system. The number and size of fenestrations and branches vary per patient and per the surgeon's preference and level of experience. A comprehensive review of physician-modified endografts by Canonge et al[7] included 20 papers published over the past 20 years in which 711 patients were treated; 36.2% of physician-modified endografts were used to treat aortic arch pathologies, the majority of which were deployed for zone 2 repairs.

Canaud et al[8] published a report of the single-center experience of 100 patients who underwent zone 0 thoracic endovascular aortic repair. The study included a large fenestration for the innominate and left carotid arteries and a distal, smaller fenestration of the left subclavian artery, which was stented. They reported a 30-day mortality rate of 2%, a 4% incidence of minor stroke, a 1% incidence of type IA and type IB endoleaks, and a 2% incidence of type II endoleak from the left subclavian artery. They had a mean (SD) follow-up period of 24 (7.2) months, with an 8% reintervention rate.[8]

In Situ Fenestration

In situ fenestration was first described in 2004 as a treatment approach to maintain left subclavian arterial flow. Later, the technique was adopted for use in traumatic acute aortic injury and aortic dissections. A systematic review of 8 studies and 440 patients presented 299 patients (68%) with a single fenestration, 40 patients (9%) with a double fenestration, and 97 patients (22%) with a triple fenestration; the study demonstrated a 30-day mortality rate of 2%, a 2% rate of stroke, and a 4.8% rate of endoleak.[9] In a similar analysis of 6 retrospective studies with a total of 247 patients, 59 patients (23.9%) presented with aortic arch aneurysms, and 146 patients (59.1%) presented with dissections; the technical success rate was 98%. There were 11 cases of stroke within 30 days; 13 reinterventions (5.3%); and 10 patient deaths (4.2%), of which 1 was related to an aortic complication.[10]

Limitations

The use of these techniques is limited by patient pathology and anatomy as well as by the surgeon's level of expertise and the available technology. With chimney grafts, a type I endoleak represents the biggest challenge. Though physician-modified endografts may be performed without manufacturing delays, the technique requires hours of preparation, often making it unsuitable in the case of emergencies. Another time delay involves the need for detailed imaging as alignment against the supra-aortic branches is crucial. The use of in situ fenestration has several exclusionary criteria, including (1) the extension of the aneurysm or dissection to the supra-aortic trunks, (2) vessel tortuosity, (3) a proximal landing area smaller than 15 to 20 mm, and (4) a proximal diameter of at least 40 mm. Though available data do not demonstrate a stroke rate in relation to the use of physician-modified endografts, there is a pervasive concern for high-energy, laser-induced air bubbles or tissue debris.

Conclusion

Though several studies have demonstrated the safety of chimney grafts, physician-modified endografts, and in situ fenestration, there is considerable heterogeneity in the results and a lack of standardization regarding the techniques that make it challenging to decide on the best individualized care for patients. The patient populations in these studies differed in their comorbidities, age, and presenting pathology, and the surgeons differed in their levels of expertise and access to technology. More comprehensive studies are required to understand the risks and benefits of these techniques—and how they might be improved or adapted—while waiting for off-the-shelf devices specifically designed for the treatment of aortic arch disease to be approved for use in the United States and, eventually, to become more affordable and available for broader use. Several companies are investigating branched endografts for aortic arch aneurysms, and those products should be available for commercial use in the near future.

Article Information

Published: 14 March 2024

Author Contributions: Both authors contributed to the overall concept, design, and approval of manuscript. G.S. was the primary writer.

Conflict of interest Disclosure: None.

Funding/Support: None.

Meeting Presentation: Presented at the International Society of EndoVascular Specialists 30th Anniversary Interactive Cardiovascular Symposium; September 22-23, 2023; Houston, TX.

References

1. Isselbacher EM, Preventza O, Black JH III, et al. 2022 ACC/AHA Guideline for the Diagnosis and Management of Aortic Disease: A Report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines. *Circulation.* 2022;146(24):e334-e482. doi:10.1161/CIR.0000000000001106
2. Kotelis D, Geisbüsch P, Hinz U, et al. Short and midterm results after left subclavian artery coverage during endovascular repair of the thoracic aorta. *J Vasc Surg.* 2009;50(6):1285-1292. doi:10.1016/j.jvs.2009.07.106
3. Matsumura JS, Lee WA, Mitchell RS, et al; Society for Vascular Surgery. The Society for Vascular Surgery Practice Guidelines: management of the left subclavian artery with thoracic endovascular aortic repair. *J Vasc Surg.* 2009;50(5):1155-1158. doi:10.1016/j.jvs.2009.08.090
4. Greenberg RK, Clair D, Srivastava S, et al. Should patients with challenging anatomy be offered endovascular aneurysm repair? *J Vasc Surg.* 2003;38(5):990-996. doi:10.1016/s0741-5214(03)00896-6
5. Moulakakis KG, Mylonas SN, Dalainas I, et al. The chimney-graft technique for preserving supra-aortic branches: a review. *Ann Cardiothorac Surg.* 2013;2(3):339-346. doi:10.3978/j.issn.2225-319X.2013.05.14
6. Li Y, Hu Z, Wang J, Zhang Y, Chen Z, Zhang H. Endovascular chimney technique for aortic arch pathologies treatment: a systematic review and meta-analysis. *Ann Vasc Surg.* 2018;47:305-315. doi:10.1016/j.avsg.2017.09.006
7. Canonge J, Jayet J, Heim F, et al. Comprehensive review of physician modified aortic stent grafts: technical and clinical outcomes. *Eur J Vasc Endovasc Surg.* 2021;61(4):560-569. doi:10.1016/j.ejvs.2021.01.019
8. Canaud L, Chassin-Trubert L, Abouliatim I, et al. Total arch thoracic endovascular aortic repair using double fenestrated physician-modified stent-grafts: 100 patients. *J Endovasc Ther.* 2024;31(1):89-97. doi:10.1177/15266028221116747
9. Tish S, Chase JA, Scoville C, Vogel TR, Cheung S, Bath J. A systematic review of contemporary outcomes from aortic arch in situ laser fenestration during thoracic endovascular aortic repair. *Ann Vasc Surg.* 2023;91:266-274. doi:10.1016/j.avsg.2023.01.009
10. Le Houérou T, Nana P, Pernot M, et al. Systematic review on in situ laser fenestrated repair for the endovascular management of aortic arch pathologies. *J Clin Med.* 2023;12(7):2496. doi:10.3390/jcm12072496