Innovation Spotlight: Expanding Indications to Treat More Thoracic Patients

How a branch graft for the left subclavian artery may extend the benefits of endovascular repair.

BY FRANK R. ARKO, III, MD

The Valiant® thoracic stent graft (Medtronic, Inc., Minneapolis, MN) (Figure 1) is a monofilament polyester fabric graft with nitinol springs that is indicated for the endovascular repair of isolated lesions (excluding dissections) of the descending thoracic aorta. The design consists of an eight-peak proximal self-expanding FreeFlo stent design that distributes radial force evenly across the aortic wall. There is no connecting bar between stents, which makes the graft highly conformable. Advantages of the delivery system include its tip capture for enhanced control and simplified operation with back-end design changes for tip-capture release and a hydrophilic coating to allow for improved delivery through difficult access vessels.

Multiple publications have addressed the use of the Valiant® stent graft in the treatment of thoracic aortic pathology, including the TRAVIATA registry, the VIRTUE registry, the Valiant® Captivia® registry, and the pivotal results of the VALOR II trial.[1-4] The VALOR II trial reported the 30-day and 12-month results of the Valiant® stent graft in patients with thoracic aortic aneurysms. This was a prospective nonrandomized pivotal trial at 24 sites in the United States. A total of 160 patients were enrolled in this trial. Technical success was achieved in 96.3% of patients being treated. Perioperative mortality was 3.1%, with a 0.6% paraplegia, 1.9% paraparesis, and 2.5% stroke rate. Aneurysm-related mortality at 1 year was 4%, with no ruptures or conversions to open surgery. These results demonstrate that the Valiant® stent graft is safe and effective in the treatment of descending thoracic aortic aneurysms.[4] This information corresponds to the currently approved version of the Valiant® thoracic stent graft; however, the following discussion pertains to a device that is currently under development and is unavailable globally.

Left subclavian artery (LSA) coverage during thoracic endovascular aortic repair (TEVAR) is often necessary due to anatomic factors and is performed in up to 40% of procedures.[5] Controversy still exists as to the appropriate management of the LSA when it requires coverage. Society for Vascular Surgery practice guidelines recommend that in patients who need elective TEVAR in which proximal seal necessitates coverage of the LSA, preoperative revascularization should be performed. Furthermore, in selected patients who have anatomy that compromises perfusion to critical organs, routine preoperative LSA revascularization is strongly recommended. However, in patients who need urgent TEVAR where LSA coverage is necessary, revascularization should be individualized and addressed expectantly.[6]

Figure 1. The Valiant® Captivia® device.

Data to date are inconclusive as to the appropriate management of the LSA during TEVAR. There is literature that suggests that LSA coverage is associated with an increased risk of arm ischemia, vertebrobasilar ischemia, and possibly spinal cord ischemia and anterior circulation stroke, and that left subclavian revascularization should be performed before coverage based on two different meta-analyses.[7,8] Single-center data have found that the use of selective revascularization is safe and does not appear to increase the risk of neurologic events;[9,10]

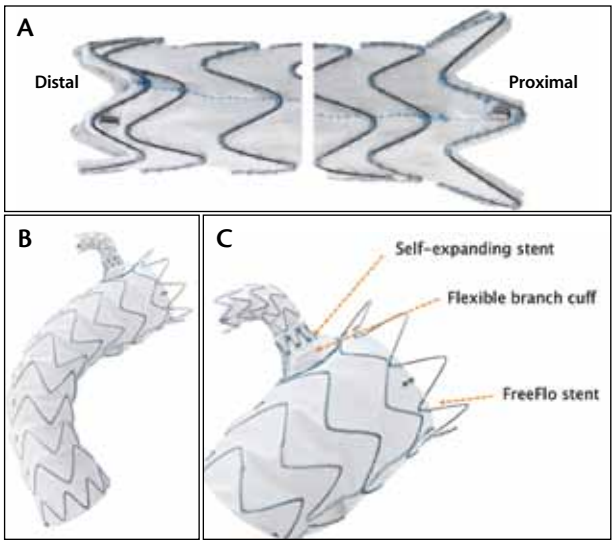

Figure 2. The Valiant® Mona LSA thoracic branch stent graft is currently under development and is unavailable globally. The LSA branch stent graft (A). Main and branch stent graft system (B). Detail of the main stent graft and the cuff component (C).

the data also suggest that LSA revascularization will clearly benefit some patients in the management of thoracic aortic disease that requires endovascular stent grafts. Clearly, if a procedure were simple, safe, and effective, and it avoided the need for surgical bypass for LSA revascularization, most physicians would utilize it.

THE MONA LSA THORACIC BRANCH STENT GRAFT

The Valiant® Mona LSA thoracic branch stent graft currently in development is based on a modified Valiant® thoracic stent graft (Medtronic, Inc.) with a single-branch stent graft designed to perfuse the LSA. It is intended to be an "off-the-shelf" device. It is not yet available anywhere in the world. It will utilize the same stent graft platform as Valiant®, which has proven clinical performance since its first commercial introduction in 2005. The main body of the graft has the same eight-peak self-expanding FreeFlo proximal design as the Valiant® thoracic stent graft. The first two proximal covered stents have been modified to include space to accommodate a flexible cuff, which serves as a conduit between the main stent graft and the LSA branch stent graft. The cuff is radiopaque to aid visualization while positioning at the LSA. It also acts as a guide to ensure adequate overlap of the LSA branch stent graft with the cuff. There is a self-expanding stent at the top of the cuff to ensure fixation and seal of the LSA branch stent graft and the cuff (Figure 2).

The main stent graft delivery system is also modified from the current Captivia® delivery system. It has a dual-wire lumen with the main wire supporting the main stent graft and a second wire for LSA access. It maintains the tip capture feature of Valiant® Captivia® for controlled and accurate deployment (Figure 3). The second lumen is cannulated with a hydrophilic wire. The proximal nosecone has been modified to accommodate passage of two wires.

The left subclavian branch stent graft is composed of a nitinol stent and a polyester graft material with a proximal flare to provide a seal between components. The branch stent graft will come in a range of sizes specifically designed to treat the LSA. It is delivered from a femoral approach through a hydrophilic delivery system.

STENT GRAFT DEPLOYMENT AND DELIVERY

A 5-F sheath is inserted for access, and a pigtail catheter is placed in the contralateral groin. Placement of a stiff wire up over the arch through the ipsilateral femoral artery will be required. After the main delivery system is flushed, a hydrophilic wire is sent up the second lumen to the end of the sheath. Once left brachial access is achieved, a 7-F sheath is placed, and utilizing standard catheter techniques, a large snare is placed just within the aortic arch from the left subclavian orifice. The main stent graft is then advanced over the stiff wire to a location just proximal from the left subclavian orifice. Care is taken to keep the orientation of the cuff toward the greater curvature.

The second wire is then advanced out of its lumen and is snared through the brachial access. Aortography is performed to allow for adjustment and alignment of the cuff with the orifice of the LSA.

The main stent graft is then slowly deployed to the level of the left carotid artery and the cuff engages in the orifice of the LSA. The main stent graft is then deployed with subsequent release of the tip-capture mechanism. The delivery system is resheathed after recapture of the tip and then removed. The proximal stent graft is then

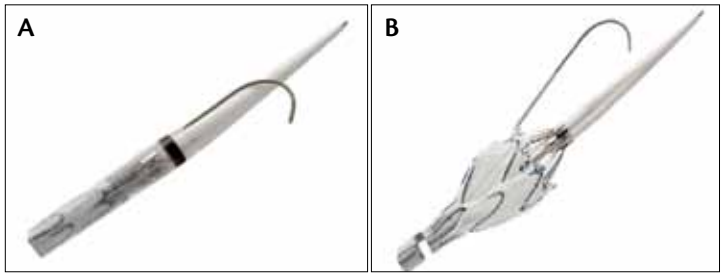

Figure 3. The second lumen allows for rapid cannulation of the LSA. The wire can be advanced easily through this inner lumen in both constrained (A) and semiconstrained (B) form.

modeled with a Reliant® balloon (Medtronic, Inc.). The LSA branch stent graft is advanced over the second wire and deployed with the proximal portion inside of the branch cuff. Standard percutaneous transluminal angioplasty is performed between the components, and completion aortography is used to assess the patency of the arch vessels and the left subclavian branch graft. Assessment for endoleaks is also performed at this time.

DISCUSSION

Conventional repair of aortic arch pathology is associated with significant mortality and stroke rates of 6% to 20% and 2% to 18%, respectively.[11,12] Aneurysms involving the aortic arch have been treated with open surgical techniques that require cardiopulmonary bypass with hypothermic circulatory arrest. The use of endovascular stent grafts has clearly allowed for the application of interventions in the descending aorta as well as the visceral aorta.

The extension of these techniques has been utilized in the aortic arch given the current results of open surgical repair. Techniques have included in situ fenestrations using different tools, branch grafts, and chimney grafts placed parallel to the thoracic graft with varying results in small numbers of patients.[11,12] Utilization of a hybrid approach will typically be performed in stages, with the first surgical stage often being a carotid-carotid bypass and/or a carotid-subclavian revascularization. This is followed by thoracic stent graft repair with placement of the graft to the innominate or left carotid artery, respectively.[11,12]

Chimney grafts parallel to the main thoracic graft, typically in the carotid or subclavian arteries, have been used with varying results in the aortic arch. Concerns regarding this technique are the unknown and untested durability and the continued risk of type I endoleaks between components through the curvature of the arch.[13] The use of in situ techniques to create fenestrations within the graft after deployment across the supra-aortic vessels has been reported. As first reported by Murphy et al, good results have been shown with the use of a laser for in situ techniques.[14,15] As is seen in other series evaluating endovascular repair of aortic arch pathology, the number of patients treated is small with limited follow-up.

There have been case reports utilizing homemade branch grafts with favorable outcomes as well.[16,17] Any method that requires treatment of the arch should be performed with careful preoperative planning (preoperative imaging, ease of device use and durability, and should be devoid of access issues), high endovascular skills, and appropriate imaging equipment, as they are imperative for a successful result.

The Valiant® Mona LSA branch graft developed by Medtronic was selected by the US Food and Drug Administration (FDA) for participation in the FDA's early feasibility pilot program. This program allows for early clinical evaluation to provide proof of principle and initial clinical safety data. The device is one of nine devices selected by the FDA after its draft guidance document to encourage and facilitate early feasibility studies of innovative medical devices in the United States. This follows multiple benchtop testing, computer-simulated flow modeling, fatigue testing, and multiple animal studies evaluating proof of concept. If successful, the Valiant® Mona LSA system could potentially obviate the need for LSA bypass, extend the benefits of endovascular repair without surgery to more patients with thoracic aortic aneurysms, and quell the controversy that is related to whether the LSA needs to be, should be, or can be covered. ■

Frank R. Arko, III, MD, is with the Department of Vascular and Endovascular Surgery, Sanger Heart and Vascular Institute in Charlotte, North Carolina. He has disclosed that he is a paid consultant to Medtronic. Dr. Arko may be reached at farkomd@gmail.com.

1. Torsello GB, Torsello GF, Osada N, et all. Midterm results from the Traviata registry: treatment of thoracic aortic disease with the Valiant stent graft. J Endovasc Ther. 2010;17:137-150.
2. Virtue Registry Investigators. The VIRTUE registry of type B thoracic dissections—study design and early results. Eur J Vasc Endovasc Surg. 2011;41:159-166.
3. Heijmen RH, Thompson MM, Fattori R, et al. Valiant thoracic stent-graft deployed with the new Captivia delivery system: procedural and 30-day results of the Valiant Captivia registry. J Endovasc Ther. 2012;19:213-225.
4. Fairman RM , Tuchek JM, Lee WA, et al. Pivotal results for the Medtronic Valiant Thoracic stent graft system in the Valor II trial. J Vasc Surg. In press.
5. Chung J, Kasirajan K, Veeraswamy RK, et al. Left subclavian artery coverage during thoracic endovascular aortic repair and risk of perioperative stroke or death. J Vasc Surg. 2011;54:979-984.
6. Matsumura JS, Lee WA, Mitchell RS, et al. The Society for Vascular Surgery Practice Guidelines: management of the left subclavian artery with thoracic endovascular aortic repair. J Vasc Surg. 2009;50:1155-1158.
7. Rizvi AZ, Murad MH, Fairman RM, et al. The effect of left subclavian artery coverage on morbidity and mortality in patients undergoing endovascular thoracic aortic interventions: a systematic review and meta-analysis. J Vasc Surg. 2009;50:1159-1169.
8. Weigang E, Parker JA, Czerny M, et al. Should intentional endovascular stent-graft coverage of the left subclavian artery be preceded by prophylactic revascularization? Eur J Cardiothorac Surg. 2011;40:858-868.
9. Lee TC, Anderson ND, Williams JB, et al. Results with a selective revascularization strategy for left subclavian artery coverage during thoracic endovascular aortic repair. Ann Thorac Surg. 2011;92:97-102.
10. Riesenman PJ, Farber MA, Mendes RR, et al. Coverage of the left subclavian artery during thoracic endovascular aortic repair. J Vasc Surg. 2007;45:90-94.
11. Murphy EH, Stanley GA, Ilves M, et al. Thoracic endovascular repair in the management of aortic arch pathology. Ann Vasc Surg. 2012;26:55-66.
12. Moon MC, Morales JP, Greenberg RK. The aortic arch and ascending aorta: are they within the endovascular realm? Semin Vasc Surg. 2007;20:97-107.
13. Gehringhof B, Torsello G, Pitoulias GA, et al. Use of chimney grafts in aortic arch pathologies involving the supra-aortic branches. J Endovasc Ther. 2011;18:650-655.
14. Murphy EH, Dimaio JM, Dean W, et al. Endovascular repair of acute traumatic thoracic aortic transection with laser-assisted in-situ fenestration of a stent-graft covering the left subclavian artery. J Endovasc Ther. 2009;16:457-463.
15. Ahanchi SS, Almaroof B, Stout CL, Panneton JM. In situ laser fenestration for revascularization of the left subclavian artery during emergent thoracic endovascular aortic repair. J Endovasc Ther. 2012;19:226-230.
16. Murphy EH, Dimaio JM, Jessen ME, Arko FR. Technique for branched thoracic stent-graft repair of a chronic type A aortic dissection in a patient with multiple prior sternotomies. J Endovasc Ther. 2011;18:359-364.
17. Chuter TA, Schneider DB. Endovascular repair of the aortic arch. Perspect Vasc Surg Endovasc Ther. 2007;19:188-192.