Fenestrated Options for Treating Compromised AAA Necks

An overview of today's available devices to overcome a hostile neck.

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An adequate proximal and distal landing zone is one of the absolute requirements for successful endovascular exclusion of an aortic aneurysm. One difficulty to overcome is the anatomic limitation of a hostile neck. An infrarenal neck is considered compromised when it does not meet the anatomic criteria of a device's instructions for use. As interventionalists strive to seal in a "healthy" aorta, they have become more resourceful in finding solutions to overcome these anatomic limitations.

One of the most established techniques for managing a compromised neck is the use of a fenestrated endograft. The unique feature of this endograft is that it can cover the visceral segment (ie, the sealing zone can be selected independent of visceral vessels). The use of these devices to treat juxtarenal abdominal aortic aneurysms (JAAAs) began in 1999.[1] Over time, the number of fenestrations incorporated in juxtarenal repair has increased in many high-volume centers, recognizing the inherent issues with durability that come with sealing in the middle of the visceral segment.[2] High-volume operators now agree that device failure as a result of aortic disease progression can be mitigated by extending longer landing zones into a healthy part of the aorta.[3]

CUSTOM-MADE FENESTRATED DEVICES

The largest experience of fenestrated devices has been reported using the Zenith platform (Cook Medical). There is a significant learning curve, but when complex aortic care is undertaken at high-volume centers, technical success is high, estimated perioperative mortality is low (2.3%), and spinal cord ischemia is rarely reported.[4-7] Reports on long-term follow-up are limited. The Cleveland group reported 2% aortic-related mortality over an 8-year mean follow-up in their 12-year experience.[7] Outcomes of fenestrated devices have shown that they are safe in the long term, as well as durable, with a 37% rate of lifetime reintervention.[8]

Other platforms have been used to develop custom-made fenestrated stent grafts. The Fenestrated Anaconda stent graft (Vascutek Ltd.) has the advantage of being able to be repositioned. Although one to four fenestration designs are possible, the valleys of the ring stent are positioned on an anterior-to-posterior axis to be used as a scallop for the superior mesenteric artery (SMA) or the celiac trunk. Furthermore, target vessel cannulation can be facilitated with the fenestration's position on the unsupported upper part of the body graft, which is more flexible. Fenestrations are reinforced with a nitinol ring, and cannulations can be performed through brachial or femoral access. Midterm results showed 95% target vessel patency and 86.3% overall survival after 3 years,[9] with no aneurysm-related deaths; however, a relatively high number of limb occlusions (7%) was reported.[10] Early type Ia endoleak occurred in 11.7% but spontaneously resolved.[9]

Jotec GmbH launched the E-xtra Design Engineering stent graft, which can be a fenestrated and/or branched custom-made device. Fenestrations are proposed for aortic lumen diameters ranging from 18 to 30 mm and are systematically placed below three proximal sealing stents. Target vessel cannulation requires brachial or axil-

lary access. In a retrospective multicenter experience, a major early complications rate of 37% has been reported, including 5.5% spinal cord ischemia (permanent in 1.8%),[11] suggesting that further development of the graft and the technique should improve these results.

OFF-THE-SHELF DEVICES

Other off-the-shelf devices offer a solution for emergency cases. The Zenith t-Branch device (Cook Medical) is designed for proximal sealing in the descending aorta and incorporates four branches, which fit 70% of all anatomies. In addition to classic anatomic requirements for standard endovascular aneurysm repair, the lumen diameter at the level of visceral arteries must be > 18 mm to have enough space for correct deployment of the branches. With brachial access, a catheter is placed in the main device to canalize the branches and connect them to the visceral arteries with bridging stents. It has a more extensive coverage than the Zenith p-Branch device (Cook Medical) that was developed to treat JAAAs. The Zenith p-Branch device has one scallop for the celiac trunk and three fenestrations for the SMA and renal arteries. Two configurations are available according to the side of the lowest renal artery. Unfortunately, this off-the-shelf fenestrated device is only anatomically suitable for 30% to 40% of all patients. Nevertheless, according to a recent review, clinical outcomes for the aforementioned off-the-shelf devices are promising, with no 30-day mortality, a 1.7% rate of paraplegia, a 97.6% 30-day target vessel patency rate, and a 3.3% rate of type I endoleak. No long-term results are currently available.[12]

The Ventana fenestrated stent graft system (Endologix) is an off-the-shelf proximal extension with a 4-cm-long scallop for the SMA and the celiac trunk. Preloaded fenestrations for the renal arteries are movable longitudinally (± 3 cm) and circumferentially (90°–210°). The first results published in 2013 on 31 patients with JAAAs reported no type I endoleak and no aneurysm-related death after 23 months of follow-up.[13] However, the Ventana device study has been placed on hold by Endologix, and the US Food and Drug Administration has suggested difficulties with the durability and patency of the renal artery stent graft components.

OFF-LABEL DEVICES

To overcome the manufacturing delay and additional costs of custom-made devices while maintaining anatomic suitability as a primary concern, off-label techniques were developed. Standard, straight, off-the-shelf aortic stent grafts are fenestrated by the surgeon (ie, physician-modified endovascular grafts [PMEGs]) before insertion in the aorta or after deployment in the aorta (in situ fenestration). PMEGs were initially described to treat patients with symptomatic or rapidly growing JAAAs and are now considered an option for elective cases in some institutions.

The preoperative sizing plan requires three-dimensional reconstruction software to precisely assess the position of the fenestrations on the stent graft. Usually, the SMA is used as the reference to localize the position of the two or three other vessels. The anatomic requirements mostly relate to the proximal aortic diameter (< 40 mm) and juxtarenal aortic angulation (> 45°). According to patient's anatomy, the SMA can be left unstented. It will stay perfused through a wide fenestration.

Regarding the operative technique, a straight or bifurcated device is modified on-site by the surgeon on a back table. The device is totally unsheathed. Fenestration positions are marked according to the preoperative plan and can be adjusted to avoid struts. The fabric is perforated with an ophthalmologic cautery pen to create a controlled fenestration. Each fenestration is reinforced with a radiopaque wire (tip of a 0.014-inch wire or loop of a snare) and fixed with a few 5-0 Prolene sutures and a polytetrafluoroethylene CV-5 running locking suture. Reducing ties are placed posteriorly on the device using two loops of 4-0 Prolene on both sides of one of the trigger wires, which has been repositioned between Dacron and stents all along the device. Finally, the stent graft is resheathed and proximal barbs can be removed to facilitate this last step. Device implantation is performed according to the same general recommendations for custom-made fenestrated devices.

Outcomes of PMEGs for JAAAs are favorable, with a 30-day mortality rate of 5.1% and no type Ia endoleak after 50 months of follow-up.[14] Improvements of the technique, such as reinforced cuffs or reducing ties, were reported by high-volume centers.[15,16] Nevertheless, it is important to highlight that, in addition to the experience and endovascular skills needed to manage complex aortic aneurysms,[17] specific training is required and a learning curve must be overcome to master the technique and achieve good results.

In situ fenestration was first reported to treat aortic arch aneurysm, with preservation of the left subclavian artery anterograde flow. Adaptation of this approach to the juxtarenal level by anterograde fenestrations presented the technical issue of how to track the ostia of the visceral and renal arteries. Physical and radiopaque landmarks in the form of wires, catheters, or stents have been used. In 2007 in a canine model, Tse et al first described an anterograde technique using intravascular ultrasound guidance in the vena cava to localize the ostia before perforating the fabric.[18] Intraoperative three-dimensional

fusion imaging integrating the deformation induced by the stent graft itself and its deployment might be the best way to improve safety and technical feasibility of in situ fenestration. The other technical issue concerning in situ fenestration is the perforating device and the integrity of the perforated graft. Among the reported experience, perforation was mechanically achieved with a needle or wire or by physical means with a radiofrequency or laser probe.

Although anterograde in situ fenestration appears to be a high-risk procedure in the juxtarenal aorta, the early results of Fabre et al presented this past January at the Controversies & Updates in Vascular Surgery meeting are promising (D. Fabre, personal communication, January 2018).

Chimneys have been presented as an off-the-shelf alternative to fenestrations, but the main issue remains the gutters between parallel grafts, with a higher risk of type I endoleak along the gutters and a reported 7.9% rate of type Ia endoleak in the PERICLES registry.[19]

CONCLUSION

Over the years, interventionalists have learned to safely overcome the limitations of the hostile neck anatomy with multiple devices that cover the visceral part of the aorta. Lack of availability and financial shortcomings led to more alternative approaches. Individual operator preference and expertise in high-volume complex aortic centers will lead us into a new endovascular era, and we are awaiting long-term results on durability. ■

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