Low-Profile EVAR

Have low-profile endografts modified our practice and outcomes?

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The anatomy of the aortoiliac arterial segment is important because it determines the suitability for, and the durability of, endovascular abdominal aortic aneurysm repair (EVAR). Patients have been shown to derive the greatest limb patency and long-term benefit after EVAR if the incidence of perioperative complications and secondary interventions are minimized.[1]

Several morphologic criteria must be assessed preoperatively to determine anatomic suitability. Reports on anatomic suitability for EVAR are inconsistent, varying between 25% and 66%, and most often refer to the most liberal anatomic restrictions for each device.[2-8] One of the reasons for this variation is that many subjective features determine suitability, such as wall calcification and luminal thrombus, which are not always carefully defined. Adherence to each manufacturer's instructions for use can minimize the incidence of perioperative complications and secondary interventions, and preserve the long-term durability of the endovascular repair.[9-11]

ACCESS-RELATED COMPLICATIONS

Significant access-related complications occur in 5% to 17% of cases. Poor access has been reported as the most common exclusion criteria for EVAR and the leading cause of conversion to open repair.[12] It is expected that patients with challenging access, often defined as narrow, calcified, and tortuous iliac arteries, will have a higher rate of iliac artery complications compared to patients without these features (Figure 1); these complications tend to be limb occlusion, limb stenosis, and limb kinking. In the EUROSTAR experience, 28.6% of the 49 conversions to open repair occurred because of injury during the introduction of the device.[13]

The EVAR delivery systems used were, however, of a larger diameter than the current devices available. This tended to limit EVAR to patients with large access vessels or required the use of vascular conduits and/or a retroperitoneal approach.

CHANGES IN DEVICES

Devices have undergone changes in terms of the design and the materials used in order to achieve a lower profile,

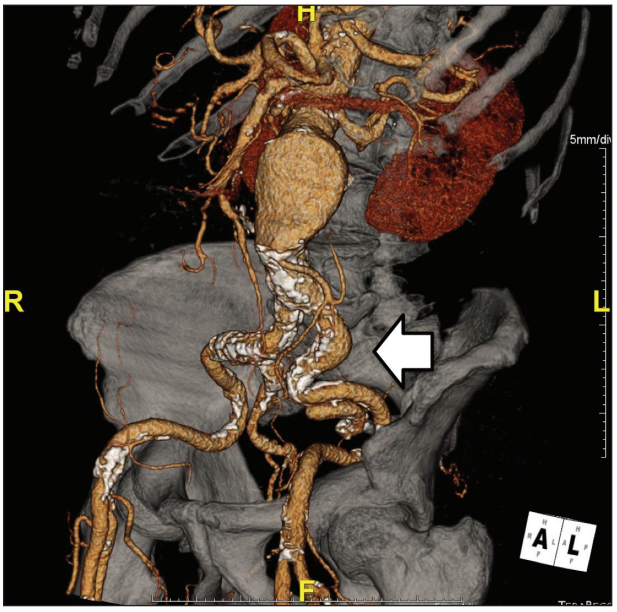

Figure 1. Volume-rendered CT image demonstrating tortuous and calcified iliac arteries.

and to therefore increase the number of patients that are suitable for EVAR.[14] An initial reduction in profile was achieved by making devices modular. There were also changes in the fabric used for the graft and the types of metal used for the stents. A number of devices are currently available for EVAR with profiles that range from 14- to 20.4-F outer diameters (ODs) (Table 1). The safety and effectiveness of these devices have been assessed in a number of studies.[15-21] Kristmundsson et al determined that lower-profile aortic stent grafts could increase the proportion of patients that are suitable for EVAR by up to 60%.[22]

The Cordis Incraft (Cordis/Cardinal Health) and Ovation (Endologix) systems are the two stent grafts currently available with the lowest profiles (14-F OD). The 14-F profile of the Incraft system is accomplished by keeping the number of crowns in the suprarenal stent to a minimum, with the addition of hooks to aid fixation and redesign the way the individual stent rings are attached to the fabric. The Ovation system has a network of inflatable channels and sealing rings in the aortic body that are filled during deployment

TABLE 1. EXAMPLES OF EVAR DELIVERY DEVICE DIAMETERS

Device	Manufacturer	Outer Diameter (F)*	CE Mark Approval	FDA Approval
Incraft	Cordis Corporation	14	Yes	No
Ovation	Endologix	14	Yes	Yes
Nellix	Endologix	17	Yes	No
AFX	Endologix	17	Yes	Yes
Zenith Alpha AAA	Cook Medical	18	Yes	No
Endurant II	Medtronic	18	Yes	Yes
Excluder	Gore & Associates	20.4†	Yes	Yes

Abbreviations: CE, Conformité Européenne; EVAR, endovascular aneurysm repair; FDA, US Food and Drug Administration.
*Size represents the majority of the main body devices in the product range.
†Outer diameter of 18-F introducer sheath.

to create the seal. This feature, in conjunction with the trimodular design, promotes a low profile for the device.

The safety and effectiveness of the Cordis Incraft system was tested in the INNOVATION prospective multicenter trial.[15,23,24] This trial involved six centers across Europe and enrolled and treated 60 asymptomatic patients; a percutaneous approach was used in 60% of the patients. Technical success was achieved in 90% of the patients. Six of the patients had endoleak; one patient had type I, four patients had type IV, and one patient had an endoleak of indeterminate type. At 2 years, three patients required reintervention, two for type I endoleak and one for limb occlusion; there was no incidence of sac enlargement or stent fracture.

The Ovation international, multicenter trial enrolled 161 patients, 50 of whom had an access vessel diameter < 6 mm. Forty-three percent of cases were performed using percutaneous access. All-cause mortality at 1 year was 3%, and there were no conversions to open repair. Three patients had iliac limb stenosis or occlusion, and there were four cases of stent graft fracture identified at 1 year.[16]

Cook Medical has recently developed a low-profile stent graft for the abdominal aorta called the Zenith Alpha, which has an 18-F OD. The Zenith Alpha is a three-piece device that is made from nitinol rather than stainless steel, which was used in earlier versions of the Zenith device. The design of the suprarenal stent and fixation hooks was also changed, and the top cap was eliminated from the delivery system, which allowed a further reduction in overall profile.

The Zenith Alpha low-profile system was evaluated in 101 patients, and the results were comparable to those achieved in 107 patients treated using the standard-profile Zenith device.[17] Twenty-two percent of the patients in the low-profile group had bilateral external iliac artery diameters < 7 mm, and 34% had a combination of the external iliac diameter of < 7 mm and an iliac artery tortuosity index (distance along the central lumen line between the common femoral artery and the aortic bifurcation/straight-line distance from the common femoral artery and the aortic bifurcation) of > 1.5 mm. Despite the more complex anatomy in the low-profile group, this group did not demonstrate a higher incidence of limb occlusion (1.3% vs 3.6%) or endoleak (5% vs 8%) during follow-up. There was no incidence of sac expansion.

Another important design feature of these low-profile devices is the delivery systems. The majority of devices now include an introducer sheath integrated into the delivery system. This has been an important step in lowering the profile of the devices for EVAR. The mechanical properties of the delivery system, such as the flexibility and the presence of a hydrophilic coating are also important. These affect not only how easy it is to advance the device into the aorta, but also the rotational movement needed for accurate deployment of the stent graft.

The low-profile systems currently available lend themselves to performing the procedure using a percutaneous approach. Use of a percutaneous approach may be particularly attractive in cases of ruptured aneurysms due to the ability to perform the endovascular repair under local anaesthesia, which can be beneficial in unstable patients. In a systematic review of 1,087 patients, the overall success rate of percutaneous arterial closure was 92%, and the rate of access-related complications was 4.4%. Selecting the right patients for this approach is key and vessel calcification, obesity, and scar tissue in the groin have been considered as factors that have contributed to failure in several series.[25] In our practice, we prefer to perform an open groin approach in the setting of challenging iliofemoral anatomy, although some groups report extensive use of the percutaneous approach.[26]

There are many EVAR devices becoming available or currently in the pipeline that promise to improve on the available, low-profile devices by refining the delivery system and further reducing the profile. Lombard has developed the Altura system, which has a unique, bilateral D-stent

design that simplifies the procedure and is made of braided nitinol, which provides flexibility and conformity to the vessel geometry. The device has a 14-F OD delivery system and received CE Mark approval in 2015. The Treovance abdominal stent graft system has been developed by Bolton Medical and incorporates a Navitel delivery system, which has proximal and distal fixation and is designed to allow repositioning and accurate placement of the device. The delivery system has an 18-F OD, and the device has received CE Mark approval; US Food and Drug Administration approval is pending. Medtronic, Inc. and Gore & Associates also have new devices in the pipeline to further reduce the profile of the currently available Endurant and Excluder platforms, respectively. Medtronic, Inc.'s Endurant Evo is currently in early clinical studies in Europe and the United States; both CE Mark and FDA approval are awaited. Further details of both devices should be available soon.

Low-profile devices may be particularly beneficial in Asian patients and women, who typically have more challenging aortoiliac anatomy, with narrower femoral and iliac arteries. Studies from Asia have shown that up to half of the stent grafts implanted in women require construction of an iliac conduit.[27] Sweet et al showed that 19% of men and 51% of women have bilateral iliac artery diameters of < 6 mm, therefore, this represents a cohort who would benefit from treatment with a low-profile device.[28] Large-scale studies of women with abdominal aortic aneurysms have demonstrated poorer outcomes than those experienced by men.[1] The minimum diameter of the external iliac arteries has been shown using multivariate modeling to be an important predictor of postoperative complications and secondary interventions.[17]

Complex aortoiliac anatomy with narrow iliac arteries may also make the procedure more complex. Iliac angioplasty may be needed prior to the intervention to allow introduction of the delivery system or additional iliac stenting (kissing) after stent graft deployment may be required. Quality intraoperative imaging is crucial to ensure that the iliac limbs are correctly positioned after deployment and that no conflict has occurred due to the limited space available in the aortoiliac segment. Inadequate assessment could lead to limb occlusion and postoperative secondary intervention. Intraoperative three-dimensional imaging has an important role in this type of assessment and can provide a more comprehensive evaluation of stent graft positioning compared to two-dimensional anterior/posterior angiography, as well as two X-ray images taken in perpendicular planes.[29] The latest technology has significantly reduced the radiation dose associated with three-dimensional cone-beam CT, and this type of imaging is now the method of choice in our center for evaluation of low-profile endografts after deployment.[30]

CONCLUSION

Low-profile devices have the potential to change the way we plan and implement endovascular repair of abdominal aortic aneurysms. The early results of the devices currently available on the market with the lowest profile are encouraging and demonstrate that favorable midterm outcomes can be achieved using low-profile technology in patients with unfavorable iliac anatomy. These devices may have a particular role in the treatment of patients who tend to have smaller access vessels, such as Asian and female patients. Further studies are required to substantiate these early results and to assess longer-term outcomes. ■

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