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, 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.

Figure 1. Volume-rendered CT image demonstrating tortuous and calcified iliac arteries.
TABLE 1. EXAMPLES OF EVAR DELIVERY DEVICE DIAMETERS

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Outer Diameter (F)*</th>
<th>CE Mark Approval</th>
<th>FDA Approval</th>
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</thead>
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<tr>
<td>Incraft</td>
<td>Cordis Corporation</td>
<td>14</td>
<td>Yes</td>
<td>No</td>
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<tr>
<td>Ovation</td>
<td>Endologix</td>
<td>14</td>
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<td>Nellix</td>
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<td>17</td>
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<tr>
<td>AFX</td>
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<td>17</td>
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<tr>
<td>Zenith Alpha AAA</td>
<td>Cook Medical</td>
<td>18</td>
<td>Yes</td>
<td>No</td>
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<td>Endurant II</td>
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<tr>
<td>Excluder</td>
<td>Gore &amp; Associates</td>
<td>20.4†</td>
<td>Yes</td>
<td>Yes</td>
</tr>
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</table>

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 tri-modular 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. 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.

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. 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. 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.

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...
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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