Perspective:
Utility of a Dedicated Aorto-Uni-Iliac Stent Graft

Michel S. Makaroun, MD, discusses patient candidacy and optimal application of AUI devices.

How does the availability of an aorto-uni-iliac (AUI) stent graft (the Endurant II AUI stent graft system, Medtronic, Inc., Minneapolis, MN) potentially expand the population of aneurysmal patients who are eligible for endovascular treatment?

Certain patients are not good candidates for endovascular repair of their aneurysms because of anatomic features of their aorta and iliac arteries. The most obvious anatomic criterion that precludes the use of an ordinary bifurcated device is when one iliac artery is completely occluded and cannot be accessed to provide an outflow to the contralateral limb of a bifurcated device. That's one example in which the AUI device will immediately provide significant help.

Another example would be patients with severe iliac disease on one side, making it very hard to place a limb in the iliac artery and maintain long-term patency. This can be due to heavy calcification or a very small, stenotic lumen throughout the iliac artery. In other situations, there may be aneurysmal disease or severe tortuosity of the iliac on one or both sides that makes it quite difficult to perform a successful bifurcated case or, on occasion, prevents the operator from saving flow in one internal iliac artery.

The AUI configuration can also be very useful in patients with very small distal aortas. For instance, when an aneurysm ends a couple of centimeters above the aortic bifurcation, and the distal aorta is heavily calcified and very small, it may be disadvantageous to try and force two limbs in that hostile outflow. Although a kissing balloon technique can fracture the distal aorta and prevent the limbs from being compressed externally, many operators may prefer to avoid such situations. Most endograft limbs are typically between 13 and 14 mm, and if the distal aorta is 12 or 14 mm, it is hard to expect two limbs inside it to stay open. The AUI device is a very good option in those patients.

So to answer your question, the availability of the AUI device will definitely expand the population we treat by EVAR, but not by a large number. However, some patients with challenging anatomies will have a much better fit with an AUI option than a bifurcated device.

Before having access to a dedicated AUI device, what were your options for treating these patients?

Previously, the options were either open repair or placing a bifurcated graft and forcing it to accommodate the unwelcoming anatomy. For example, the issue of a narrowed iliac artery or distal aorta would be handled by dilating the iliac aggressively and covering it with covered stents or tearing the distal aorta with a kissing balloon. There was no easy endovascular mean to deal with these cases, and the patients with complete occlusion on one side or severe disease on both sides required an open repair. On occasion, a bifurcated device would be converted into an AUI configuration by covering the contralateral branch. Clearly, the commercial availability of an AUI now provides us with additional options.

In your own practice, do you anticipate using the device mostly as a primary option or more so a bailout or conversion option?

In the majority of situations, we anticipate the use of this device as a primary option, and we have for some time. Before the approval of the Endurant II AUI stent graft, we had the Renu device (Cook Medical, Bloomington, IN) that was designed for a bailout of migrated grafts, but in many cases, we used it primarily where we believed an AUI was advantageous. Of course, we will continue to use the AUI configuration, both the Renu and the new Endurant, as a bailout option.

One recent example of using the Endurant II AUI device as a bailout was a case from last week. I initially

treated the patient with a bifurcated device 12 years ago, and one of the limbs recently pulled out of the iliac artery into the AAA and kinked on one side. It was necessary to use an AUI to cover the origin of the limb to prevent any endoleaks. We also used an endovascular technique to perform an external-to-internal connection and then a fem-fem bypass. So although we still use an AUI configuration as a bailout option, I anticipate the device will be used more often as a primary treatment for the AAA.

Should any specific training be undertaken before a physician implants an AUI graft for the first time?

Actually, there is very little training needed except to understand how to plan the procedure itself, especially if the contralateral side requires management of the internal iliac artery or planned occlusion of the common iliac artery to prevent a retrograde endoleak. The deployment of the device is actually much simpler than a bifurcated device because you don't have to cannulate the contralateral leg. Most operators will not have any issue deploying the device itself, as it is essentially the same device as the bifurcated version, but simpler.

Are there any other distinct aspects of the implantation procedure of an AUI versus a bifurcated device?

Yes. In cases in which both iliacs are open, deciding which side would be more advantageous for introducing the device and methods of preserving some internal iliac artery flow can be quite important. Planning how to occlude a patent contralateral iliac may require familiarity with a variety of embolization products and techniques, including the use of large, dedicated occluders, such as the Talent Occluder system (Medtronic, Inc.) or a similar product from Cook. The actual technical aspects of the deployment are otherwise simple. As with all other endovascular procedures for AAAs, proper attention should be given to a good landing zone proximally to ensure a good seal. Although the AUI solves some difficult problems on the distal end, the operator must be sure not to ignore the appropriate indications for an EVAR on the proximal side.

Do AUI devices have any unique failure modes that should be considered both in determining candidacy and in planning follow-up?

If anything, the AUI device has one fewer failure mode than a bifurcated device because it does not have a second branch. You cannot have a problem in that branch in terms of dislocation, angulation, or crushing injury of any sort. All other failure modes of an EVAR would still apply to an AUI. Unique issues of the AUI, however, relate more to the procedure rather than the device itself, including a successful obliteration of patent iliacs on the contralateral side and a well-functioning fem-fem bypass.

Like all EVAR patients, follow-up is very important and should be essentially identical to that of a bifurcated patient, which, although variable from institution to institution, is usually at least once per year. Special attention should also be given to follow up the patency of the cross-femoral bypass graft. The Endurant II AUI study followed the same routine as all other FDA studies, but most large centers now tend to do less CT scanning and more ultrasound imaging during the follow-up phase.

What are some important lessons learned in the clinical study of the Endurant II AUI device that might be helpful as others apply this technology in a real-world setting?

The key lesson from the United States investigational device exemption trial is that the population for which we typically consider the AUI is very different from the average patient we treat with EVAR. Most of these patients are sicker and have worse underlying morbidity, and that's why the complication rate is slightly higher with an AUI than it is with a bifurcated device. The AUI population has a lot more calcific iliac disease, which is typically associated with more coronary disease and other issues. They're also slightly older, and there are more women than men in the AUI cohort.

Going back a decade or more, when the first AUI device was approved, the Ancure AUI (formerly Guidant Corporation), we knew that the patients in whom we were using the AUI were sicker, so we had to anticipate a little more difficulty and be more careful with them. Although we have seen the same general trend with the Endurant AUI, complication rates were not dramatically higher, because this device is simpler. ■

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