Unmet Needs in…
Iliac Branch Disease

The wish list for future devices for iliac branch disease includes a reduced delivery system to allow navigation in highly tortuous iliac arteries and a broader range of diameter and length options to avoid hybrid or open repair and off-label use for patients who are unfit for surgery.

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Nowadays, hypogastric preservation with iliac branch devices (IBDs) is the standard of care to preserve antegrade flow to the internal iliac artery (IIA) during endovascular aneurysm repair (EVAR) involving the iliac bifurcation whenever anatomically feasible to reduce ischemic complications, as recognized by the most recent guidelines.[1] Since its introduction 15 years ago, iliac branch technology has now reached a state of maturity thanks to the learning curve, patient selection, procedure standardization, and evolution of dedicated devices, which have been validated by high technical success, a low rate of graft-related reintervention, and improved outcomes regarding the quality of life of our patients.

Our early experience with the first 85 IBDs implanted demonstrated the effectiveness of this procedure, with low complication and reintervention rates at midterm follow-up.[2] These promising results led to the creation of the pELVIS registry, including nine high-volume European vascular centers that enrolled 804 patients treated with 910 IBDs (95% Zenith branch [Cook Medical], 5% Gore Excluder iliac branch endoprosthesis [Gore & Associates]) between January 2005 and

April 2017. This large experience with placement of IBDs showed a low incidence of secondary procedures due to type I endoleaks and occlusions.[3] These important results were accepted by the scientific community and led to the implementation in the guidelines of IBD technology for iliac aneurysm treatment as a first-line option.[4,5]

Thanks to the large amount of data coming from the pELVIS registry, all the main anatomic and clinical challenges were analyzed. In case of an aneurysmatic hypogastric artery, it is routine practice to lengthen the distal landing zone with more than one bridging stent graft in order to land into a distal healthy hypogastric artery or one of its main branches.[6] Regarding hypogastric sealing, there were no differences in the registry for hypogastric artery bridging stent graft in terms of patency and late failure between self-expanding and balloon-expandable stent grafts, even when relined with a bare-metal stent.[7] Moreover, bilateral IBD implantation in suitable anatomy, despite increased technical complexity, has shown effectiveness of the repair and satisfactory results, with low rates of IBD-related adverse events at midterm follow-up.[8] The results of the subgroup analysis of pELVIS registry patients treated for isolated common iliac artery (CIA) aneurysms pointed out no significant differences in short- and long-term outcomes between off-label use of isolated IBDs and those implanted in association with a concomitant/previous bifurcated aortic stent graft.[9] Furthermore, with the growth of EVAR techniques, the need to treat complex and extensive aortoiliac aneurysms posed a challenge in terms of spinal cord ischemia prevention. Our analysis concluded that the combination of fenestrated/branched EVAR (F/BEVAR) and IBDs has early and midterm outcomes equivalent to patients treated with EVAR and IBDs, despite a higher reintervention rate in F/BEVAR patients.[10] Regarding the clinical challenges, the pELVIS registry results demonstrated that IBDs can be considered a feasible repair option for aneurysms involving the iliac bifurcation in selected elderly and female patients with suitable aortoiliac anatomy.[11,12]

The introduction and evolution of IBDs provide favorable results in terms of sealing, freedom from device-related complications, reduction of buttock claudication and impotency rate, and patency of the iliac branches, allowing endovascular repair of extensive aortoiliac aneurysmal disease. In the future, improvements of IBD technology should address two main unmet needs: (1) reduce the delivery system external profile to allow navigation in highly tortuous iliac arteries and (2) broaden the graft's diameter and length options (with both off-the-shelf and custom-made devices) to fit even more anatomies, guaranteeing a tailored approach. These improvements will further expand the applicability of IBDs, which already have excellent clinical results and patency outcomes.

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Aneurysms involving the iliac artery, especially around the bifurcation, present a unique treatment challenge. Although open repair of aneurysms in this area is not limited by anatomic constraints, this can be a difficult area in which to work, as aneurysms of the IIA can extend deep into the pelvis. Additionally, many patients are not candidates for open repair, making clear the need for total endovascular solutions to this complex problem.

Currently, the Gore Excluder iliac branch endoprosthesis is the only FDA-approved device for the treatment of CIA aneurysms or aortoiliac aneurysms. Although this device has certainly advanced the number of patients who can be treated by total endovascular means, there

are limitations. At the proximal implantation zone, the CIA diameter has to be at least 17 mm. External iliac artery (EIA) treatment diameters range from 6.5 to 25 mm, while IIA treatment diameters range from 6.5 to 13.5 mm. Additionally, this device requires an adequate length from the lowest renal artery to the IIA to accommodate the total length of the endoprosthesis, which includes a standard infrarenal bifurcated device.

There are many cases of iliac artery aneurysms extending to the bifurcation that are treated with coil embolization of the IIA and placement of a covered stent graft or iliac limb from the CIA into the EIA. This, of course, requires an adequate proximal landing zone in the CIA or a proximal EVAR device. Coil embolization of one IIA is generally well tolerated; however, it can lead to disabling buttock claudication in up to 40% of cases. This makes preservation of the hypogastric artery desirable during endovascular iliac aneurysm repair. Certainly, in cases of bilateral iliac artery aneurysms, it is highly recommended to preserve at least one hypogastric artery.

Many techniques to preserve flow to the IIA during repair of iliac aneurysms involve a combination of open and endovascular procedures. A common technique is an EIA-to-IIA bypass, ligation of the proximal IIA, and extension of a stent graft into the EIA. Although this is generally more well tolerated than a total open repair, it still requires general anesthesia, a retroperitoneal incision, and operating deep in the pelvis. Another hybrid approach includes placement of an aorto-uni-iliac device (placed contralateral to the side of the iliac aneurysm), a femorofemoral bypass, and then placement of a stent graft from the EIA into the IIA on the side of the iliac aneurysm. Again, this still requires open surgery, and the repair is subject to the lifespan and complications associated with a femorofemoral bypass.

Many surgeons seeking a total endovascular approach to the repair of iliac aneurysms extending to the bifurcation have sought out off-label use of FDA-approved devices. Before FDA approval of the Gore Excluder, some surgeons did back-table modifications of iliac stent graft limbs.[1] There are some surgeons who employ parallel grafting techniques[2]; however, these come with the complication of gutter leaks, which can be difficult to fix.

The biggest current unmet need for iliac aneurysm disease is a branch device that can treat iliac aneurysms in the presence of a proximal CIA diameter < 17 mm. This would save many patients the need for open or hybrid repairs and offer a better solution for off-label device use that is currently employed when a patient is at prohibitive risk for open surgery. As always, endovascular devices, which are low profile and track easily through oftentimes-tortuous iliac vessels, are desirable. I am amazed at the advances in endovascular technologies for the treatment of complex aortic and iliac aneurysms and look forward to the new devices that will emerge as the field advances. ■

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