INVITED COMMENTARY

The GORE iliac branch device: a new kid on the block

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Preservation of at least one hypogastric artery is a common practice in the endovascular repair of aorto-iliac aneurysmal (AIA) disease, as this has been recommended from both the European and the Society of Vascular Surgery guidelines.[1,2] At present, there are several devices in the market, which are dedicated to treat solely by endovascular means aneurysms involving the common iliac artery. The main concept behind all these devices is the delivery of a bridging stent-graft through a contralateral or a trans-brachial approach and through a small iliac side branch in the hypogastric artery.

Until the introduction of the new GORE® Excluder® Iliac Branch Endoprosthesis (IBE, W.L. Gore & Associates, Flagstaff, AZ, USA), the most frequently used CE-certified off-the-shelf iliac-branch devices were the Zenith® Branch Endovascular Graft- Iliac Bifurcation (ZBIS, COOK Medical, Limerick, Ireland) and the E-iliac stent-graft (Jotec, Hechingen, Germany). The effectiveness of both endografts has been confirmed in several studies.[3-5] Thus, the added value of an additional iliac-side branch device remains questionable.

Considering the features of each device in details, we can recognize that all three have their pros and cons. The ZBIS device has been implanted in the largest number of patients worldwide.[3] Currently, the PeLVIS investigators from 9 European centers showed favorable outcomes, with a low rate of late graft occlusion and aneurysm-related death in a real world setting.[4] Of note, no significant differences in clinical outcomes were observed in patients receiving hypogastric balloon-expandable vs self-expandable stent-graft or endovascular relining.[4] However, the main limitations of the ZBIS device are: (1) the single proximal of 12mm which is disadvantageous for isolated common iliac artery aneurysms, (2) the distal diameter which varies between 10 and 12 mm, which is problematic for larger external iliac artery and (3) finally, the stiffness of the device, which may lead to kinking in angulated iliac arteries. Of note, the ZBIS device is not indicated for aneurysms of the hypogastric artery.

The self-expanding E-liac® stent-graft system consists also of a bifurcated graft including a main iliac limb with an additional reinforced stump for the internal iliac artery side branch.[5] Its tip-to-tip design with asymmetric stents provides flexibility and clear visibility during implantation whereas compression springs ensure the connection of the bridging stent at the side branch. The E-iliac registry enrolled 45 patients at 11 European sites and confirmed high clinical success rate, low rates of device-related re-interventions and excellent patency rate.[5] Compared to the ZBIS device, the E-liac® is available in more configurations with the proximal diameter ranging between 14 and 18mm and the distal diameter 10-14mm.[5] This is advantageous in cases of larger diameters of common iliac artery (CIA) in isolated CIA aneurysms or large external iliac artery (EIA). The CIA segment length can be 41, 53 or 65 mm and can be simplify the endovascular repair of aneurysmal distal seal post endovascular aortic aneurysm repair (EVAR) considering that the majority of EVAR limbs are up to 14mm in diameter. Again, this device is not indicated for aneurysms of the hypogastric artery.

The GORE Excluder IBE consists of two modular components: the iliac branch component (IBC) and the internal iliac component (IIC). *Schneider et al.*[6] showed in the framework of the IBE 12-04 study that the IBE device is effective at treating CIAs and AIAs, maintaining blood flow into the hypogastric artery with excellent patency rates. The device has unique characteristics, which expands the indications of IBE in more demanding anatomies. The proximal diameter of 23 mm allows endovascular repair of isolated CIA aneurysms with minimum iliac diameter of 17 mm at the proximal implantation zone. Moreover, the unique flexibility of the PTFE-covered endoskeleton of the GORE devices makes it unique for severely elongated distal landing zones, whereas the distal diameter allows external iliac artery treatment diameter range of 6.5 - 25 mm. Finally, the device is the only one which is indicated also for aneurysms of the internal iliac artery (IIA) with treatment diameter range of 6.5 - 13.5 mm. In this context, the combined use of Viabahn stent-grafts with the dedicated internal iliac component allows treatment of aneurysms involving even the first branches of the hypogastric artery.

In this context, *Batzalexis et al.*[7] reported on the mid-term outcomes of the GORE Excluder IBE device regarding the endovascular repair of aorto-iliac aneurysmal disease and they have to be congratulated for their encouraging outcomes. This is single center experience in a real-world setting with demanding anatomies; thus, this explains the patency rate of 89%, which were lower than the IBE 12-04 study. Moreover,

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once the device was successfully implanted without any 30-day events, no further events during the follow-up occurred. The freedom from type I/III endoleak was 100%.

In summary, the GORE Excluder IBE device is a new kid on the block, which seems to be a necessary tool expanding even more our ability to treat challenging aortoiliac anatomies. The first studies showed excellent short and mid-term performance, whereas data about the long-term performance (> 5 years) still remain mandatory.

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