Case Planning for an Iliac Branch Endoprosthesis Procedure

Essential anatomic and imaging considerations for a successful repair.

BY ROSS MILNER, MD, FACS

ndovascular aneurysm repair (EVAR) precase planning is critical. The success of an EVAR procedure is as dependent on imaging review and device selection as the actual insertion of the endovascular device. In addition, compliance with the instructions for use (IFU) enhances the likelihood of a successful repair and excellent patient outcome. The precase planning and IFU compliance is even more critical when using new technology. Any new device has successfully completed a clinical trial with results that provide insight into the efficacy of a device, but the patients enrolled in a clinical trial have the most appropriate anatomy for any given device. Therefore, the learning curve to succeed with new EVAR technology requires a thorough appreciation of the patient's anatomy and the knowledge of the appropriate precase plan.

Iliac branch devices allow for hypogastric artery preservation in the setting of complex aortoiliac aneurysmal disease. As many as 30% of patients with an aortic aneurysm have associated iliac artery aneurysms. These complex patients are at risk for failed treatment initially and long-term complications, such as endoleaks and iliac limb thrombosis due to the complexity of the disease. Gore & Associates received US Food and Drug Administration (FDA) approval for the GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) in February 2016, and this has provided interventionalists with an option to treat complex aortoiliac aneurysmal disease with the additional benefit of hypogastric artery preservation. The precase planning, however, is more complex than standard EVAR. In addition, there are anatomic requirements that may prevent the use of this device in certain patients. This article will review case planning, imaging, anatomy, and specific considerations related to the IBE that will simplify the process.

CASE PLANNING

Every patient's plan requires a thorough assessment of issues such as landing zones, aorta and iliac artery length measurements, tortuosity, and calcification. These precase planning issues are even more critical for an IBE case. The combination of the standard GORE® EXCLUDER® Device with the IBE requires the insertion of a bridging component that mandates a certain aortic length based on the needed

main body device diameter. Therefore, the first step in successful case planning is understanding the specifics of each component needed to complete the procedure. For example, the IBE has a 5.5 cm main body length (3 cm for AAA limb overlap and 2.5 cm for the internal iliac gate), and the internal iliac branch extends approximately 4.5 cm from the gate of the device into the hypogastric artery. Knowing the specifics of the device design, you can appropriately plan your distal landing site in the hypogastric artery in order to preserve important branches and still achieve successful aneurysm exclusion. The IBE main body device can be deployed in the common iliac artery in order to plan for the 4.5 cm length of the internal iliac component. A narrow proximal common iliac artery can make the device manipulation challenging, and a minimum diameter of 17 mm is required. The device has the feature of being repositionable like the

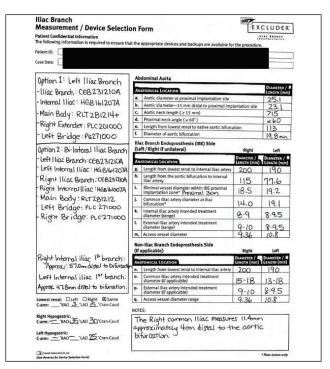


Figure 1. Example sizing sheet for a GORE® EXCLUDER® Iliac Branch Endoprosthesis case.

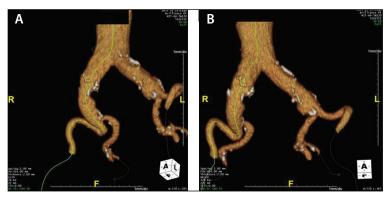


Figure 2. CTA reconstruction demonstrating the origins of each hypogastric artery and the necessary gantry corrections. Right internal iliac angle: left anterior oblique, 35°; CAU, 30° (A). Left internal iliac angle: CAU, 25° (B).

GORE® EXCLUDER® Device featuring C3® Delivery System due to the staged deployment, but is unable to be reconstrained.

A second unique feature for planning of an IBE case is knowing the specifics of the bridging component. The bridging component, which is essentially a flared iliac limb, is available in different distal diameters (23 or 27 mm) and different lengths (10, 12, or 14 cm). The bridging component is selected based on the length between the GORE EXCLUDER Device and the IBE so that maximum overlap between components can be achieved to prevent the development of a type 3 endoleak. The length also needs to be selected so that the bridge component does not compromise or cover the internal iliac component, which can lead to occlusion of the internal iliac artery limb. This aspect of precase planning is unique to an IBE case and is a critical difference from standard EVAR. Figure 1 is an example of a sizing sheet for a bilateral IBE case and demonstrates the additional considerations and measurements needed for the plan and the possible options for a specific case.

IMAGING

Quality imaging remains the most important precase factor. A case plan made with bad imaging is at risk for a poor outcome. The ideal imaging for planning an IBE case is a CTA of the abdomen and pelvis (including the femoral arteries) with 2 mm slices or smaller. Centerline measurements to determine lengths is also recommended. The imaging criterion does not differ from a standard EVAR case. But, what does differ is a critical assessment of the length from the lowest renal artery to each iliac artery bifurcation. It is important to ensure the diameter of the proximal common iliac artery, in addition to the aortic bifurcation measurement, so that the proximal portion of the IBE will not be compromised. The anatomy of the hypogastric artery that will be preserved is critical, with specific attention to the diameter and quality of the distal landing zone.

The distal landing zone should not be too calcified or too tortuous. The minimum diameter of the distal portion of the internal iliac artery branch device is 10 mm and is intended to treat a distal landing zone as small as 6.5 mm in diameter. These anatomic qualities of the distal landing zone can lead to compromise of the distal outflow of the internal iliac artery branch and predispose to branch occlusion. An in-depth analysis of the small number of occlusions that occurred in the clinical trial has highlighted these issues to be a key factor in preventing internal iliac artery branch occlusion. Preprocedural imaging that can adequately visualize the quality of the hypogastric artery outflow is mandatory.

Finally, the origin of the hypogastric artery has a tremendous amount of variability. Precase imaging can be used to assess the appropriate obliquity and cranial-caudal (CAU) correction to visualize the origin of the treated hypogastric artery (Figure 2). This knowledge will facilitate the orientation of the iliac branch component to simplify cannulation of the hypogastric artery. CTA imaging can identify any evidence of stenosis or aneurysmal degeneration of the hypogastric artery that can complicate the placement of the device.

ANATOMY

Several anatomical issues have been discussed thus far, but the necessity to critically review each patient's anatomy with more attention to detail than a standard EVAR cannot be overemphasized. The main issues when assessing a patient for candidacy for an iliac branch repair are lengths, calcification, tortuosity, and diameters (Figures 3–5). Although this is standard operating procedure when planning EVAR, there are some distinctions when planning for an IBE.

The lowest renal artery is always critical to assessing the ability to successfully treat an aneurysm based on the infrarenal neck. But, it is not solely an assessment of neck length. The length to the aortic bifurcation and the length to the iliac bifurcation from the renal arteries must be measured critically. The diameter of the chosen main body device will determine the minimum length of aortic and iliac artery anatomy that can be treated. The minimum recommended length is 165 mm from the renal arteries to the iliac artery bifurcation for the smaller-diameter main body devices, but techniques such as crossing the limbs can be utilized to reduce this necessary overall length.

The hypogastric artery is critical as well. The patency of both hypogastric arteries must be assessed. It is possible to treat both hypogastric arteries if necessary with the IBE technology as long as the length requirements can be met. But, the anatomy of one hypogastric artery may prevent placement of an iliac branch endoprosthesis—for example,

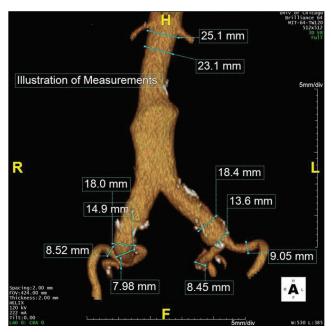


Figure 3. Diameter measurements based on CTA imaging. The reconstructed images are shown.

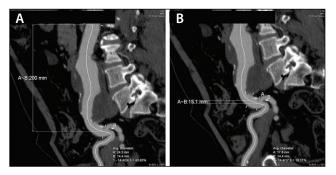


Figure 4. Length measurements from the lowest renal artery to the right iliac bifurcation. Length from the renals to the right internal iliac, 200 mm (A). Approximate right common iliac sealing length if standard EVAR limb is used (B).

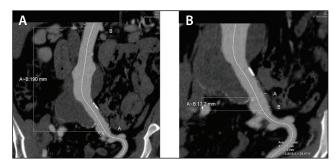


Figure 5. Length measurement from the renal arteries to the left iliac bifurcation. Length from renal arteries to the left internal iliac (A). Approximate left common iliac sealing length if standard EVAR limb is used (B).

when the main trunk of the hypogastric artery is short and the divisions do not have an adequate distal landing zone. If length is an issue, one hypogastric artery may have to be sacrificed in order to successfully preserve the other hypogastric artery. The decision of which artery to preserve is based on all of the previously mentioned factors with a specific focus on tortuosity and the distal landing zone for successful preservation.

Finally, access is always an essential aspect of the anatomy. The minimum diameter necessary is 12 Fr, and the maximum diameter necessary is 16 or 18 Fr (16 Fr for IBE and 16 or 18 Fr for GORE EXCLUDER Device main body). One aspect of access anatomy, a narrow aortic bifurcation, can lead to difficulty with placing the GORE® DrySeal Flex Introducer Sheath (12 Fr x 45 cm) required to insert the Internal Iliac Component from the contralateral side. Tortuous iliac anatomy may also lead to challenges with the up-and-over access. The GORE DrySeal Flex Introducer Sheath allows for a through-and-through wire to be maintained at all times to overcome this issue.

CONCLUSION

There are key differences in an iliac branch case compared to a standard EVAR case. The efficacy of the IBE technology has been clearly proven based on clinical trial data. However, the IFU is constantly challenged when a new device is granted FDA approval. Issues related to pre-case planning, imaging, and anatomy are some of the important aspects that need to be evaluated to have a successful case and excellent patient outcomes. When significantly deviating from these recommendations, especially during early experience with this technology, the patient is potentially at risk for a poor outcome.

I have highlighted the above facets of the IBE planning and insertion based on the experience of having directed several training courses. The feedback from attendees has been invaluable, and I have continued to hone my skills for these cases.

1. Hobo R, Sybrandy JE, Harris PL, Buth J; EUROSTAR Collaborators. Endovascular repair of abdominal aortic aneurysm with concomitant common iliac artery aneurysm: outcome analysis of the EUROSTAR experience. J Endovasc Ther. 2008;15:12-22.

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