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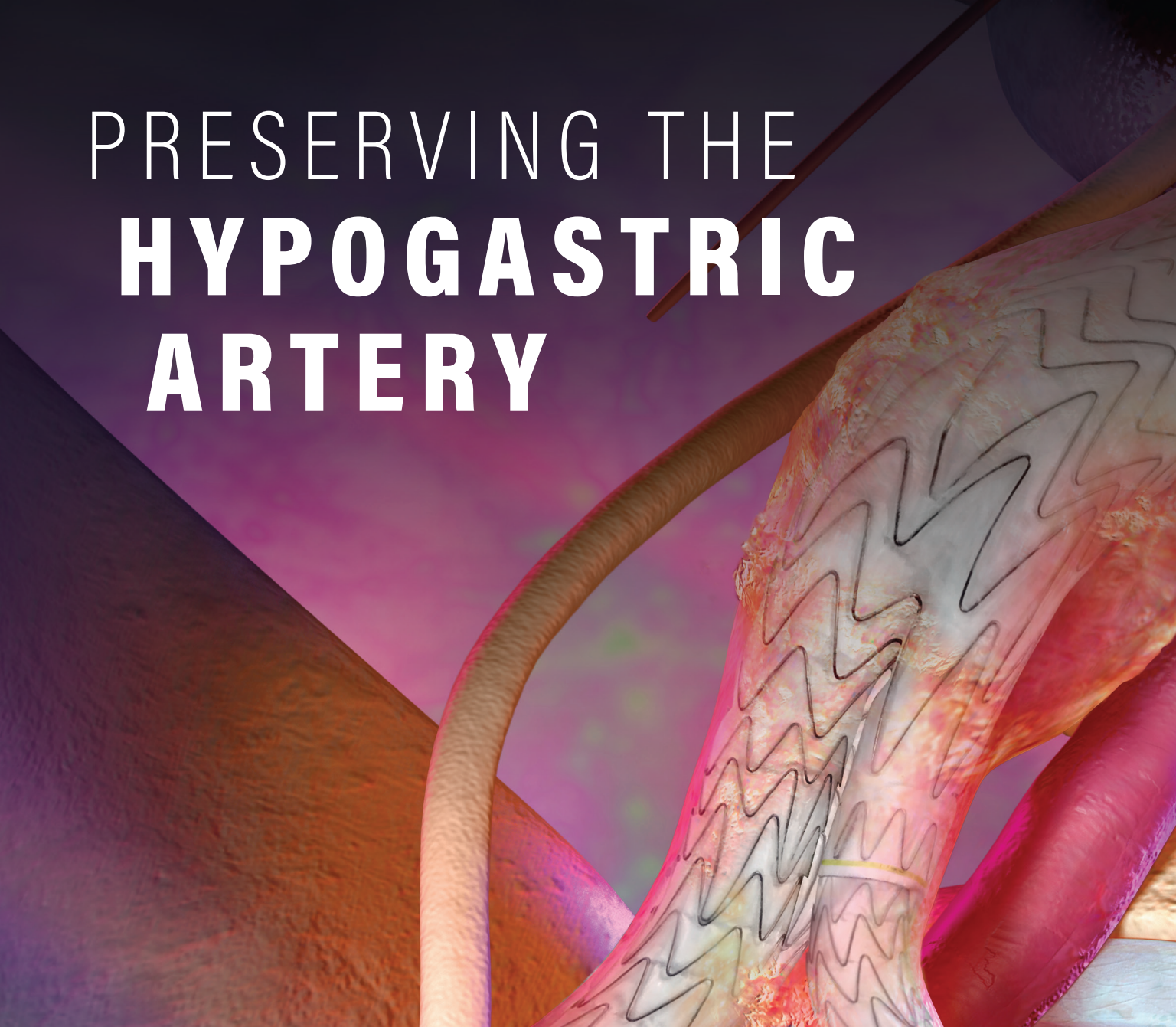
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Endovascular TODAY

August 2017

PRESERVING THE **HYPOGASTRIC ARTERY**

Why, when, and how: an expert consensus.

A 3D medical illustration showing a hypogastric artery. A stent graft, depicted as a series of interconnected diamond-shaped mesh cells, is placed over a section of the artery. The surrounding tissue is rendered in shades of purple, pink, and orange, with a textured, almost fibrous appearance. The overall lighting is dramatic, with strong highlights and shadows that emphasize the three-dimensional nature of the model.

PRESERVING THE **HYPOGASTRIC** **ARTERY**

In April of 2017, Gore & Associates convened a panel of aortic specialists in London, United Kingdom, to develop a treatment algorithm for the use of iliac branch stent grafts to preserve the hypogastric artery in patients with iliac artery aneurysms. The panel examined the subject of which patients to treat and how best to treat them.

The panel found broad consensus that the data and their personal experience support the concept of hypogastric artery preservation whenever possible, but also identified several factors that might influence the decision of whether to use an iliac branch stent graft or to choose an alternative treatment. These issues include general patient condition, such as age and activity level; the extent of aortic disease; anatomic suitability; additional cost; and complexity of the procedure. An overview of their discussion and the details of these considerations are found in this supplement to *Endovascular Today*.

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The Importance of Hypogastric Artery Preservation

BY DARREN B. SCHNEIDER, MD

Elective endovascular aortic aneurysm repair (EVAR) is a prophylactic procedure intended to protect patients from death and disability due to aneurysm rupture. Central to the concept of prophylaxis is that an intervention performed to treat an asymptomatic problem should have an acceptably low risk of adversely impacting the patient's quality of life or exposing the patient to potentially harmful new problems. Although EVAR has lower procedural risks of death and disability compared to open surgical aneurysm repair, EVAR with hypogastric artery sacrifice does expose patients to additional and potentially unnecessary risk of pelvic ischemic complications that may affect quality of life and even cause serious harm or death. Fortunately, with the availability of iliac branch devices, we now have safe and effective options available to treat patients with common iliac artery aneurysms using EVAR without sacrifice of hypogastric artery perfusion (Figure 1).

HYPOGASTRIC ARTERY SACRIFICE IS NOT BENIGN

Common complications of hypogastric artery sacrifice during EVAR include new-onset buttock claudication and sexual dysfunction. Approximately 25% of patients who undergo unilateral hypogastric artery sacrifice will experience buttock claudication and the risk increases if both hypogastric arteries are sacrificed.^{1,2} Although buttock claudication symptoms are not life-threatening and do

improve or resolve in some patients, buttock claudication persists in about 50% of patients and is associated with decreased patient-reported quality of life.² Unfortunately, for patients who develop buttock claudication after EVAR with hypogastric artery sacrifice, there are no effective treatment options.

More devastating ischemic complications may occur because of hypogastric artery sacrifice, including ischemic colitis, spinal cord injury, and buttock necrosis. Fortunately, these potentially life-threatening complications are uncommon, but they expose elective EVAR patients to added risks of serious harm and death. In a recent analysis of EVAR using the American College of Surgeons National Surgical Quality Improvement Program dataset, patients who underwent EVAR with hypogastric artery embolization had an increased 30-day mortality in comparison to EVAR without hypogastric artery embolization (4.1% vs 2.5%; $P = .044$). Moreover, EVAR with hypogastric artery embolization was independently associated with an increased risk of ischemic colitis (odds ratio, 2.98; 95% confidence interval, 1.44–6.14; $P = .003$).³ Eagleton and colleagues found that the incidence of spinal cord injury and failure to recover was more common in patients undergoing endovascular repair of complex aortic aneurysms who had a hypogastric artery sacrificed.⁴ These and other studies clearly demonstrate that hypogastric artery sacrifice during EVAR places patients at significant added risk for harm.

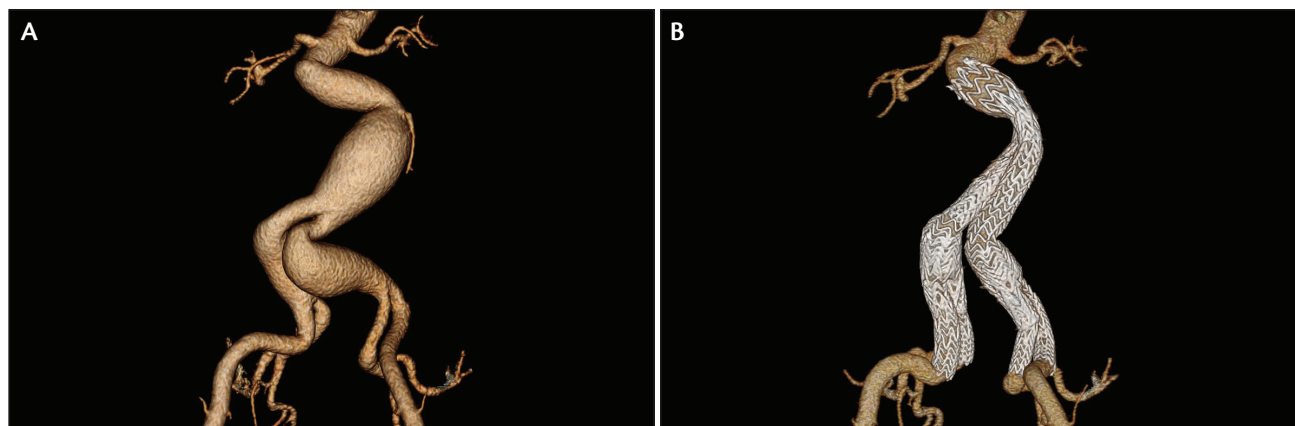


Figure 1. A 48-year-old male competitive triathlete with abdominal and bilateral iliac artery aneurysms. Pre-implant (A) and 1-year follow-up (B). Courtesy of Sharif Ellozy, MD, and Darren Schneider, MD, New York Presbyterian/Weill Cornell Medical Center; New York, New York.

OUTCOMES OF EVAR WITH ILIAC BRANCH DEVICES

Dedicated iliac branch devices have been developed specifically to preserve hypogastric artery perfusion in patients with common iliac artery aneurysms undergoing EVAR. Multiple centers have described excellent outcomes of treatment with iliac branch devices, reporting high rates of technical success, procedural risks that are comparable to standard EVAR, excellent patency, and rates of reintervention that are comparable to standard EVAR.⁵⁻⁸ We recently reported similarly promising outcomes of treatment of iliac and aortoiliac aneurysms using the GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) (Figure 2) in a prospective, multicenter United States clinical trial (the IBE 12-04 study).⁹ At the 6-month primary endpoint, IBE patency was 95.2% with no type 1 or 3 endoleaks and 98.4% freedom from reintervention. Importantly, the IBE prevented pelvic ischemic complications and there was 100% freedom from new-onset buttock claudication on the side treated with the IBE. In contrast, 21 patients with bilateral iliac artery aneurysms in the IBE 12-04 study underwent sacrifice of one hypogastric artery, and in this cohort, there was a 28% incidence of buttock claudication on the side of the sacrificed hypogastric artery (opposite to the IBE side).

HYPOGASTRIC ARTERY PRESERVATION DURING EVAR IS THE NEW STANDARD OF CARE

Iliac artery aneurysms are common, occurring in around 25% of patients undergoing EVAR¹⁰ and treatment with internal iliac artery sacrifice is associated with complications that can affect quality of life or cause serious harm. Multiple studies have demonstrated that hypogastric artery preservation with iliac branch devices during EVAR is safe and effective and has high rates of technical success, low branch occlusion rates, and intervention rates comparable to standard EVAR. Therefore, most patients with iliac aneurysms who are candidates for EVAR with an iliac branch device should no longer undergo hypogastric artery sacrifice and be exposed to likely avoidable pelvic ischemic complications.

Although not all patients with iliac aneurysms undergoing EVAR have suitable anatomy for treatment with the currently available iliac branch devices,^{11,12} EVAR with hypogastric artery preservation should be strongly considered in those with suitable anatomy. Hypogastric artery preservation may have the most beneficial impact in younger and more active patients and in patients with bilateral iliac artery aneurysms who are more likely to be affected by buttock claudication. In patients with multifocal aneurysmal disease or complex aortic aneurysms, hypogastric artery sacrifice increases the risk of spinal cord injury and paraplegia and is a near absolute indication for hypogastric artery preservation. Although the risks of hypogastric artery sacrifice in each individual



Figure 2. The GORE® EXCLUDER® Iliac Branch Endoprosthesis.

patient need to be balanced against the increased case complexity and the added cost associated with use of an iliac branch device, EVAR hypogastric artery preservation should become the default treatment strategy for patients with iliac aneurysms. ■

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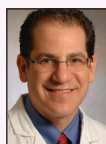
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Expert Discussion: When to Preserve the Hypogastric Artery

WITH PROF. ANTOINE MILLON, MD, PhD; ROSS MILNER, MD, FACS;
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PATIENT CONDITION

AGE AND ACTIVITY LEVEL

The panel agreed that age was not considered to be a single determinant of whether a patient would be included or excluded from receiving an iliac branch stent graft. Only advanced age with very limited activity and favorable anatomy to mitigate complications of embolization would be considered a deterrent for iliac branch graft implantation.

Dr. Schneider: There are some relative indications when it is important, particularly in the younger, more active patient in whom you want to prevent the onset of claudication, be able to maintain their activity level, and to avoid complications of sexual dysfunction.

Prof. Verzini: Age, to me, is not a major determinant by itself. Older patients may appreciate the benefits of maintaining an activity level like that of younger patients, especially to preserve their cardiac function and to sustain other activities of daily life.

Prof. Spark: Age itself is not a contraindication, but rather activity levels and overall fitness. For those with bilateral iliac disease but limited activity, I would always try and preserve one hypogastric to reduce the small, but catastrophic risk of bowel ischemia.

Dr. Oderich: I would agree that the default should be to preserve the hypogastric artery, and you almost have to look at which patient not to preserve. There is that occasional patient, although rare, who has very advanced age and is limited in activities, but has a very large aneurysm and needs unilateral embolization with a very good contralateral collateral system. Perhaps this is the case in which you would not preserve the hypogastric artery, with the idea of minimizing the extent and cost of the procedure.

EXTENT OF AORTIC DISEASE

In patients with extensive aneurysmal disease involving both the abdominal and the thoracic aorta, the panelists agreed that preserving hypogastric flow may be particularly important to mitigate the risks of spinal cord ischemia.¹

Dr. Schneider: I think there may be some absolute indications for preserving the hypogastric artery. In the patient with complex or multifocal aneurysm disease who may have extensive aortic coverage and who has an iliac aneurysm, the hypogastric artery probably needs to be preserved to reduce the risk of devastating complications like spinal cord ischemia. This is a benefit to patients who are at risk for future endovascular aortic repair as well. For example, an EVAR patient who also has a small thoracic aortic aneurysm and may need TEVAR in the future should have their hypogastric artery preserved.

Prof. Spark: I agree, always preserve the hypogastric with thoracoabdominal aneurysms.

KISSING BALLOON TECHNIQUE

The GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) indications for use have anatomic requirements including a common iliac diameter of ≥ 17 mm at the proximal implantation zone. Additionally, it is recommended that the diameter at the iliac bifurcation measures ≥ 14 mm. These requirements can exclude patients from receiving the benefits of an iliac branch device if the diameter of the iliac artery is narrow; for these patients, the kissing balloon technique may be an option.

The kissing balloon technique is commonly used when arterial bifurcations are narrow and where intervention on one side may compromise the diameter of the adjacent branch vessel. The technique of placing protective “kissing balloons” in each vessel may mitigate the occurrence of side-branch occlusion compared to sequential stent branch placement.

Dr. Milner: There is one anatomic criterion—the narrow common iliac close to the hypogastric—where the kissing balloon technique is very critical to proper deployment.

Dr. Schneider: It becomes challenging when a segment of the artery is calcified and narrower proximally with insufficient room for the device. I use kissing balloons to make sure I have both limbs open. If there is competition for space through the bifurcation, both the internal and external arteries are then accommodated, and one limb isn't compressing the other. When I complete the internal branch deployment, I still have my balloon in place. Sometimes I even remove the wire from the balloon and shoot the completion angiogram through the balloon to see the end of the internal stent. I then put the wire back into the internal iliac artery, complete the deployment of the branch in the external iliac artery, and then I reinflate my balloon in the internal as I dilate the external artery.

Prof. Verzini: I don't mind if the bifurcation of the common iliac artery is tight because you can almost always accommodate the two branches inside the distal common iliac artery. I agree that if you don't have enough room for the opening of the short gate of the device, it's a major problem. That is why I routinely do the kissing balloon technique when the common iliac is narrow. After I deploy the internal iliac stent, I usually perform kissing balloon dilatation of the external and internal iliac limbs, followed by a completion angiogram to confirm both internal and external iliac branches are open. I do think you must be very careful to make sure you don't over-dilate the distal vessel, so you don't dissect your healthy internal iliac artery.

PATIENT CONDITION

DIAMETER

Longevity and the durability of the endovascular procedure weighed more heavily on the discussion of whether to treat smaller common iliac diameters and the current standard of practice. The consensus of the group suggested treatment of iliac diameters in the 20 to 21 mm range with an iliac branch stent graft, especially in younger patients considering the risk of dilation over time. This opinion is consistent with data that shows adverse outcomes related to standard endovascular aneurysm repair (EVAR) in iliac limbs where the diameter is > 20 mm.²

Prof. Spark: Ideally, I would try to seal in the normal vessel. A 2 cm diameter common iliac is abnormal; in an elderly patient a flared limb may be durable, but still at high risk of developing a leak with time. The other consideration is the size of the patient's native vessels—a 2 cm diameter common iliac in a patient whose contralateral common iliac diameter is 9 mm or 10 mm may be considered large. The shape of the common iliac may also be an issue if the flaring occurs at the iliac bifurcation rather than at the origin of the common iliac—the former being more difficult to seal with a flared limb.

Dr. Milner: At a meeting I attended earlier this year, experienced physicians said they've changed their criteria when a common iliac artery diameter is 2 cm. In a younger patient, they put in an iliac branch device, knowing that the risk of dilation of the common iliac over time is high in the younger patient who already has obvious aneurysmal disease. In a younger patient who has a reasonable life expectancy, what is the diameter that we should transition from just doing standard EVAR to doing an iliac branch stent graft?

Dr. Oderich: I like the statement where it says 'provided it is within the instructions for use for the flared limb.' A diameter of, say, 24 or 25 mm. That's where I think we should draw the line.

Prof. Verzini: I'd go lower than that, 21 mm is the largest diameter for me because I believe the growth rate of a 25 mm common iliac artery is much faster than a smaller one. I can't trust a big common iliac in this diameter range.

Dr. Schneider: I would say definitely 2.5 cm, and that was what was in the GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) clinical trial as the threshold to qualify for treatment. We have data on that population and know that the device works well, and that hopefully we're going to get what will be a durable result in that population. But, to Prof. Verzini's point, an iliac that's larger than 2 cm in somebody who has reasonable longevity is not a normal iliac and the natural history may not be one that's safe in the long-term. It's like the concept of using a fenestrated or branched stent graft to get proximal fixation and seal in normal aorta. We now can similarly use an iliac branch device to go distally and achieve fixation and seal in the internal and external iliac arteries.

LENGTH

The length of the landing zone in the common iliac artery was considered by the panelists to be a deciding factor in choosing an iliac branch stent graft. The consensus was to

FLARED LIMB (BELL-BOTTOM TECHNIQUE) VERSUS ILIAC BRANCH STENT GRAFT

The panel discussed alternative endovascular techniques for the treatment of patients with iliac artery aneurysms who are candidates to preserve hypogastric flow, such as deploying a flared iliac limb (known as the bell-bottom technique) in order to achieve a distal seal. These patients can be candidates for either iliac branch stent grafts or flared limbs to preserve hypogastric flow, and the treatment options must be evaluated to determine which may provide the most benefit to the patient.

Factors that influence the decision included the diameter of the common iliac artery, proximal and distal landing zone, the length of the common iliac artery, the presence of thrombus, vessel taper, and the general condition of the patient (e.g., age and/or life expectancy).

The panelists agreed that for younger patients with a common iliac artery diameter of > 20 mm, an iliac branch stent graft would be the preferred treatment. For older patients, a bell-bottom technique with a flared limb to treat a common iliac diameter of < 25 mm would be acceptable. The additional caveats regarding anatomic considerations to achieve best results for the bell-bottom technique with a flared limb are a long common iliac artery with a proximal and distal landing zone of 2 cm, minimal thrombus, and degree of taper.

Dr. Schneider: We have limbs that can treat common iliac arteries up to diameters of 26 mm, but the question is, should we? Probably yes for elderly patients with predicted poor longevity. However, the younger patient who has a risk of developing further iliac dilation and a type IB endoleak should be considered for treatment with an iliac branch device.

Dr. Oderich: I think there are factors that we should take into consideration that should make us shy away from using flared limbs. In patients in whom the quality of the common iliac arteries is questionable even though the diameter is suitable

extend the landing zone to a length of 2 cm to achieve durable distal seal for standard EVAR or flared limb. Otherwise, if the landing zone was shorter, the preferred treatment option would be an iliac branch stent graft.

Dr. Oderich: *The length of the landing zone of the common iliac artery is often underestimated at 1.5 cm. I like to have at least 2 cm of normal landing zone length in the common iliac artery, and I think that is something that I factor in when selecting whether I do a flared limb versus an iliac branch device.*

Dr. Schneider: *That's a very good point that speaks to the overall health of, and how normal, the iliac is. Because these vessels you're describing that are short, conical, and thrombus-laden aren't going to provide a durable distal implantation site.*

The short common iliac artery may present a challenge for contralateral cannulation of the target hypogastric artery, as well as for proper opening of the branch stent graft. One technique to circumvent this issue includes the creation of additional length for easier cannulation by placing the iliac branch component above the bifurcation.

Dr. Schneider: *I was always afraid to go more than a couple of centimeters above the bifurcation with the IBE, but then I saw cases where the device was approximately 5 cm above the aortic bifurcation and it was possible to accomplish the procedure*

(e.g., it is thrombus-laden, relatively short, kind of conical), those patients will tend not to do well with the bell-bottom technique. I think it might be possible, if there is bilateral disease, to do an iliac branch on one side (the worse side) and try to use the bell-bottom technique on the other side.

Prof. Verzini: *Still, in patients with a limited life expectancy, let's say 3 to 5 years, who may be treated by bell-bottom technique to ensure hypogastric flow, the risk of iliac dilation to cause an adverse event in 3 years is a measured risk.*

Prof. Millon: *If I see a large common iliac artery but the proximal common iliac artery is healthy and there is no dilation, I place the flared iliac limb to seal the aortic aneurysm—that is the ultimate goal. Especially for elderly and patients with limited life expectancy, I think when you have a sealing zone at the proximal part of the common iliac artery and when the distal common iliac artery is < 25 mm, the bell-bottom technique is associated with a low risk of type IB endoleak, and the risk of rupture of the common iliac artery is also very low.*

The group from St. Franziskus Hospital in Münster, Germany, has developed an endovascular treatment algorithm for common iliac aneurysms that is in accord with the panelists' recommendations for the use of a flared limb or bell-bottom technique in older patients with aortoiliac aneurysms and common iliac diameters of < 25 mm. For younger patients, the preferred treatment is to preserve the hypogastric artery with an iliac branch stent graft. The St. Franziskus group published long-term results of 89 patients who were treated with the bell-bottom technique and the reported technical success was 97.8%. During 4-year follow-up, three patients developed type I endoleaks, requiring secondary procedures. Due to the risk of endoleak, the use of iliac branch stent grafts, which allow better fixation and durable results, reflects their preferable use in younger patients.³

without too much difficulty. But I think it really depends on the aorta. Basically, you should have room to maneuver if you are going to land the device that far above the aortic bifurcation. So, you've got to have overall length requirements from the renal arteries to the internal iliac, and then you've also got to have space to come from a contralateral femoral approach and be able to catheterize from the top. I think if you have a normal narrow aorta, it may be very difficult, but if you have an aneurysmal aorta, it may be much easier to position the top of the device above the aortic bifurcation.

Dr. Oderich: *I agree. In general, the IBE is very forgiving and can be placed above the aortic bifurcation with the ability to cannulate and deliver the hypogastric branch graft from the contralateral side. The one patient group in which you might be more concerned is the group with relatively focal common iliac disease with a normal aorta.*

TORTUOSITY

Internal iliac artery diameters of < 6.5 mm combined with tortuosity are risk factors for failure modes of iliac branch stent grafts. The practice of making the stent graft conformable to the anatomy of the patient could decrease the risk of thrombosis related to adverse anatomy.

Dr. Milner: *My sense from the analysis of the US IBE clinical trial is that the failures were in small outflow, tortuous vessels.*

Dr. Schneider: *It's not okay to just get the covered stent in the internal iliac, you actually want to get it to the right spot in the internal iliac. The end of the internal iliac branch should not land at a bend in the artery.*

Prof. Spark: *Small and/or tortuous outflow vessels were associated with poor outcomes with the COOK® ZENITH® Branch Endovascular Graft-Iliac Bifurcation.⁴ This applies to both the external and internal iliac. Improved vessel apposition and conformability may improve this.*

THROMBUS

The presence of thrombus and large-diameter common iliac arteries was considered by all to be a risk factor for poor outcomes. Eccentric and diameter-limiting thrombus was thought to be an especially high-risk factor of occlusion for an iliac branch stent graft.

Dr. Milner: When do you look at thrombus and say it's even more of a predictor of poor outcomes than just diameter? Or, is it diameter and thrombus combined? When does the presence of thrombus affect the ability to safely do the wire and catheter manipulations that you need to do in an iliac branch procedure?

Dr. Oderich: Diameter and thrombus combined is very important. A patient with borderline common iliac diameter (20 to 25 mm) that is thrombus-laden will be more likely to fail a repair with a flared limb and should ideally be offered an iliac branch device based on healthier sealing zones. If there is any measurable thrombus within the wall, I tend to go to an iliac branch stent graft.

Prof. Spark: Large-volume thrombus in the common or internal iliac represents a greater challenge for all forms of intervention, whether it is an IBE, iliac branch device, flared limb, or even open surgery and is something to consider when consenting the patient.

Prof. Verzini: On the other hand, too much thrombus, like a shaggy iliac artery, is also dangerous for your branch—when it's that finger length-type of thrombus that is very irregular with protrusion into the lumen rather than that smooth lining of the iliac. In this case, I usually avoid using an iliac branch device and instead over-stent the hypogastric artery, minimizing the risk of embolization.

Dr. Schneider: I agree regarding shaggy irregular thrombus. When you start talking about lots of thrombus, it can limit the space to have adequate room for the device, so that's an issue. In this case, I would consider other options besides an iliac branch device.

HYPOGASTRIC ARTERIAL CIRCULATION (POSTERIOR/ANTERIOR BRANCH)

There was a uniform opinion among the panelists to preserve the posterior branch of the hypogastric artery if there was only one branch to preserve.

Dr. Milner: Should the hypogastric be preserved if you can only preserve the posterior division or the anterior division? Is it still worth preserving?

Dr. Oderich: Yes, whenever possible. This was a question that was not addressed in the trial, as extension of the branch device into divisional branches was an exclusion criteria. I believe these patients benefit from iliac branches because occlusion of the divisional branches by coil embolization is associated with very high rates of hip claudication. Moreover, these patients have few to no options to improve their disabling symptoms.

Dr. Schneider: My experience has actually been very satisfying and I don't recall any patients in whom I preserved the posterior branch having buttock claudication on that side. So, I think that it was effective.

Dr. Oderich: Again, I don't think you should have a fixed rule because it may be practically impossible to get to those posterior branches if it's super tortuous. But in general, that branch will be larger. That's the branch that would perfuse the buttock muscles, so if you want to prevent buttock claudication, that would be the one to save.

EXPERTS' ANTIPLATELET THERAPY PROTOCOLS

Prof. Millon	Dual antiplatelet therapy for 3 months, then ASPIRIN® alone
Dr. Milner	ASPIRIN® alone in most cases. In complex cases, dual antiplatelet therapy for 1 month, then switch to ASPIRIN® alone
Dr. Oderich	ASPIRIN® alone in most cases. If there are concerns about patency, 1 year of dual antiplatelet therapy, then switch to ASPIRIN® alone if patency is confirmed
Dr. Schneider	ASPIRIN® alone in most cases; dual antiplatelet therapy in select cases
Prof. Spark	ASPIRIN® alone in most cases. In cases with outflow concerns, dual antiplatelet therapy for 1 month
Prof. Verzini	ASPIRIN® alone in most cases. In complex cases, 1 month of dual antiplatelet therapy

COST

The cost of Iliac branch stent grafts impacts the overall costs of the EVAR procedure for the implanting hospital. In the United States, facilities using the GORE EXCLUDER Iliac Branch Endoprosthesis are eligible for a new technology add-on payment (NTAP) of up to \$5,250 per case, in addition to the applicable base payment for the Medicare Severity Diagnosis-Related Group (MS-DRG). This should improve hospital payments and align better with costs of using this new technology. The panelists also suggested that the cost of embolization may not be less expensive and, in some cases, could be more expensive with additional procedures and the cost of multiple coils. The cost of complications related to hypogastric occlusion, such as claudication and other sequelae, must also be considered. It may be suggested that long-term costs related to negative clinical outcomes (e.g., readmissions or additional treatments or appointments to monitor complications) with embolization or other alternate techniques may ultimately make the IBE a more cost-efficient option. The panelists suggested that a study to look at the cost effectiveness of hypogastric occlusion versus preservation may be important to support the benefits of iliac branch stent grafts.

EXPERTS' POSTOPERATIVE SURVEILLANCE PROTOCOLS

Prof. Millon	CT within the first month, then every year
Dr. Milner	CT at 1 month, then duplex ultrasound thereafter; renal ultrasound annually in complex patients
Dr. Oderich	CT angiography at 4 months, then duplex ultrasound thereafter
Dr. Schneider	CT at 1 month and 1 year, then duplex ultrasound thereafter
Prof. Spark	CT and duplex ultrasound at 1 month
Prof. Verzini	CT at 1 month and 1 year, then one duplex ultrasound or CT thereafter depending on results of the CT at 1 year

Dr. Milner: *It is difficult to calculate the value of hypogastric artery preservation for an individual patient. Although the endovascular device is more expensive than standard EVAR, the quality of life limitations of buttock claudication or sexual dysfunction are very difficult to calculate and may be worth the cost difference.*

Dr. Oderich: *In the United States, reimbursement does not entirely cover the cost of a standard EVAR. So, the financial loss is even greater with more complex repairs, such as an iliac branch device plus a standard EVAR. On the other hand, you could argue that the cost of embolization may be the same, depending on how many coils you're going to use, etc.*

Prof. Verzini: *Plus, we don't consider the additional embolization procedure and recovery if it is staged prior to EVAR. Plus, there is the rehab necessary for treating claudication. I don't think the costs are lower in case of embolization. The risk of chronic ischemia is also much higher after embolizing the hypogastric artery compared to EVAR, so there are costs associated to that.*

Prof. Spark: *As well as looking at the cost of the procedures (embolization vs preservation), there are the hidden costs to the community. For example, a younger patient who suffers buttock claudication may not return to work, or an older patient may require relatives to take time off work to care for them.*

Dr. Schneider: *I think we should make a point that a cost-effectiveness analysis is sorely needed. We need to do a good cost analysis of embolization versus preservation, looking at quality of life years and other factors.*

CONCLUSION

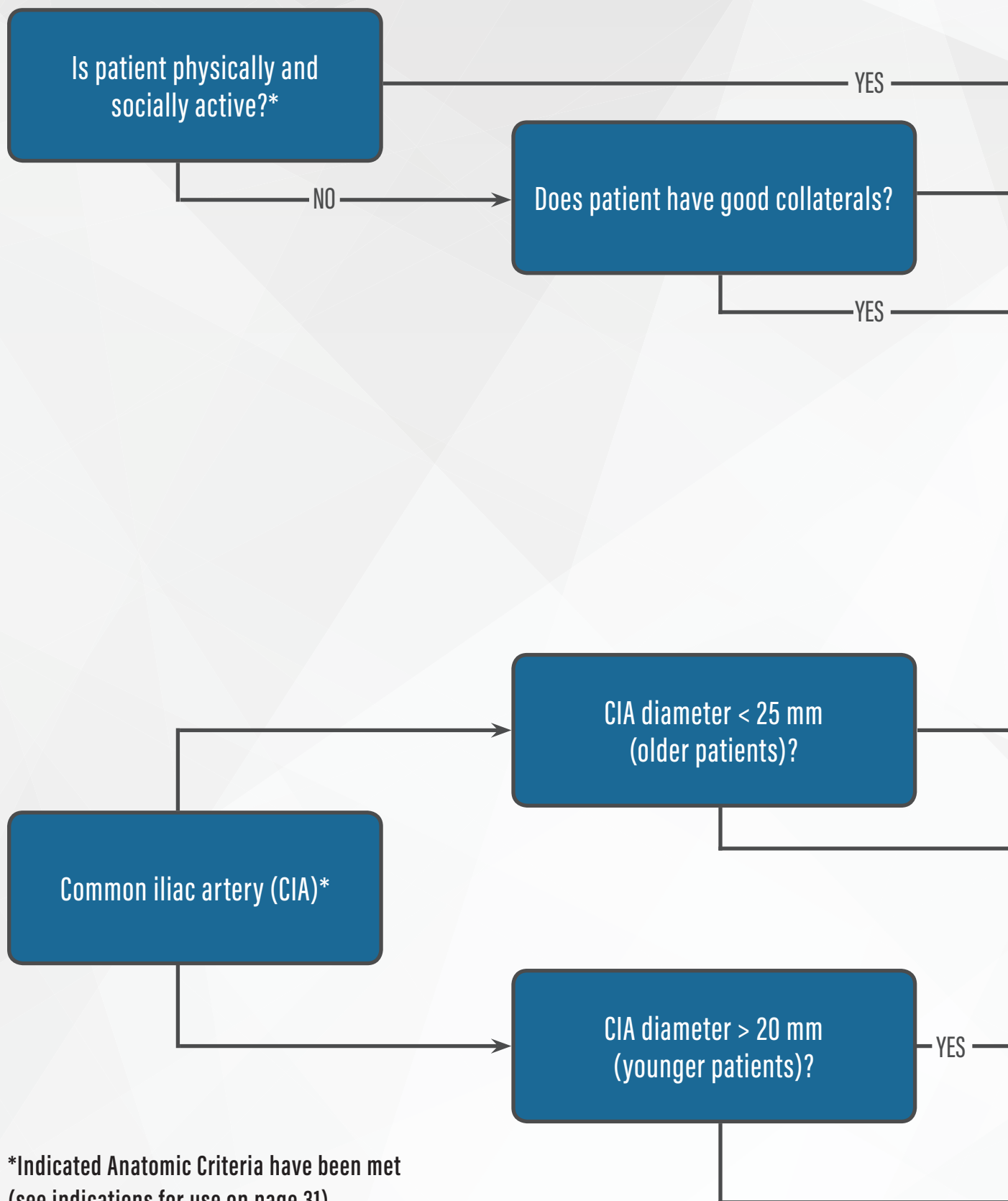
Based on the variety of factors, the panel agreed that preservation of the hypogastric artery via use of iliac branch stent grafts in AAA patients with concomitant common iliac artery aneurysms should be the default position of aortic specialists, with limited exceptions based on the comorbidities and anatomical anomalies of particular patients. ■

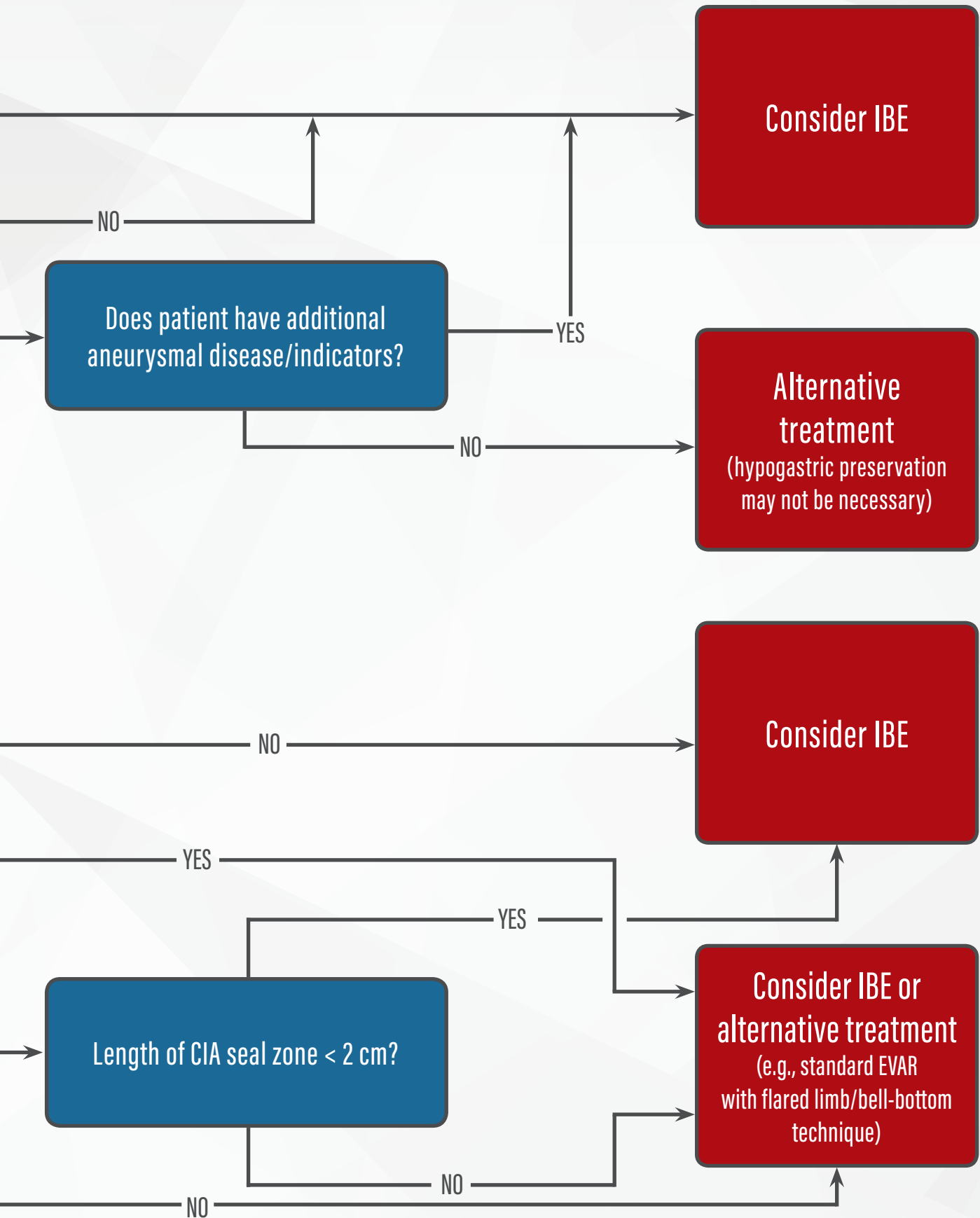
1. Eagleton MJ, Shah S, Petkosevek D, et al. Hypogastric and subclavian artery patency affects onset and recovery of spinal cord ischemia associated with aortic endografting. *J Vasc Surg.* 2014;59:89-95.

2. Schanzer A, Greenberg RK, Hevelone N, et al. Predictors of abdominal aortic aneurysm sac enlargement after endovascular repair. *Circulation.* 2011;123:2848-2855.

3. Panuccio G, Torsello GF, Torsello GB, Donas KP. Therapeutic algorithm to treat common iliac artery aneurysms by endovascular means. *J Cardiovasc Surg.* 2016;57:712-715.

4. Parlani G, Verzini F, De Rango P, et al. Long-term results of iliac aneurysm repair with iliac branched endograft: a 5-year experience on 100 consecutive cases. *Eur J Vasc Endovasc Surg.* 2012;43:287-292.





Case Planning for an Iliac Branch Endoprosthesis Procedure

Essential anatomic and imaging considerations for a successful repair.

BY ROSS MILNER, MD, FACS

Endovascular 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.¹ 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

Iliac Branch Measurement / Device Selection Form

Patient Confidential Information
The following information is required to ensure that the appropriate devices and backups are available for the procedure.

Patient ID:

Case Date:

Option 1: Left Iliac Branch
 - Iliac Branch: CEB231210A
 - Internal Iliac: HGB161207A
 - Main Body: RLT281214+
 - Right Extender: PLC201000
 - Left Bridge: Pz271000

Option 2: Bi-lateral Iliac Branch
 - Left Iliac Branch: CEB231210A
 - Left Internal Iliac: HGB161207A
 - Right Iliac Branch: CEB231210A
 - Right Internal Iliac: HGB161207A
 - Main Body: RLT281212
 - Left Bridge: PLC271000
 - Right Bridge: PLC271000

Right Internal Iliac 1st branch:
 Approx. 57.0mm distal to bifurcation

Left Internal Iliac 1st branch:
 Approx. 47.8mm distal to bifurcation

Lowest renal: ☐ Left ☐ Right ☐ Same
 C-arm: ☐ RAO ☐ LAO ☐ 30° Cran-Caud

Right Hypogastric:
 C-arm: ☐ RAO ☐ LAO ☐ 30° Cran-Caud

Left Hypogastric:
 C-arm: ☐ RAO ☐ LAO ☐ 25° Cran-Caud

Abdominal Aorta

ANATOMICAL LOCATION	DIAMETER / LENGTH (mm)
a. Aortic diameter at proximal implantation site	25.1
b. Aortic diameter—15 mm distal to proximal implantation site	23.1
c. Aortic neck length (> 15 mm)	7.5
d. Proximal neck angle (< 60°)	< 60
e. Length from lowest renal to native aortic bifurcation	113
f. Diameter of aortic bifurcation	19.8 mm

Iliac Branch Endoprosthesis (IBE) Side

Left / Right if unilateral	Right DIAMETER / LENGTH (mm)	Left DIAMETER / LENGTH (mm)
g. Length from lowest renal to internal iliac artery	200	190
h. Length from the aortic bifurcation to internal iliac artery	115	77.6
i. Minimal vessel diameter within IBE proximal implantation zone* Proximal 3cm	18.5	19.2
j. Common iliac artery diameter at iliac bifurcation	14.0	19.1
k. Internal iliac artery intended treatment diameter (range)	8-9	8-9.5
l. External iliac artery intended treatment diameter (range)	9-10	8-9.5
m. Access vessel diameter	9.36	10.8

Non-Iliac Branch Endoprosthesis Side (if applicable)

Right DIAMETER / LENGTH (mm)	Left DIAMETER / LENGTH (mm)	
n. Length from lowest renal to internal iliac artery	200	190
o. Common iliac artery intended treatment diameter (if applicable)	15-18	13-18
p. External iliac artery intended treatment diameter (if applicable)	9-10	8-9.5
q. Access vessel diameter range	9.36	10.8

NOTES:
 The Right common iliac measures 11.4mm approximately 4cm distal to the aortic bifurcation.

(*) Lowest measured for proximal (See Operator for Device Selection Form) * Please Sumner only

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

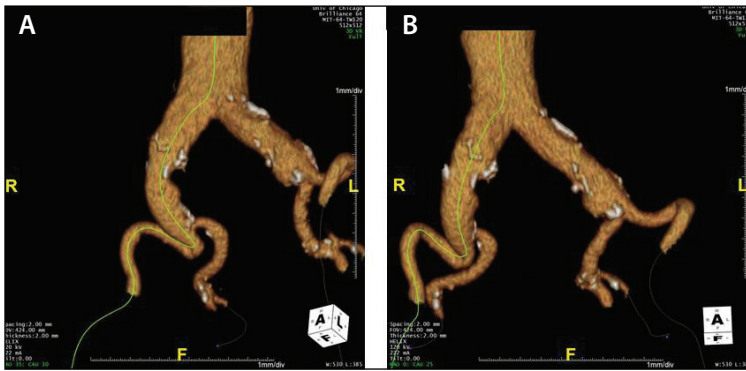


Figure 2. CTA reconstruction demonstrating the origins of each hypogastric artery and the necessary gantry corrections. Right internal iliac angle: left anterior oblique, 35°; CAU, 30° (A). Left internal iliac angle: CAU, 25° (B).

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,

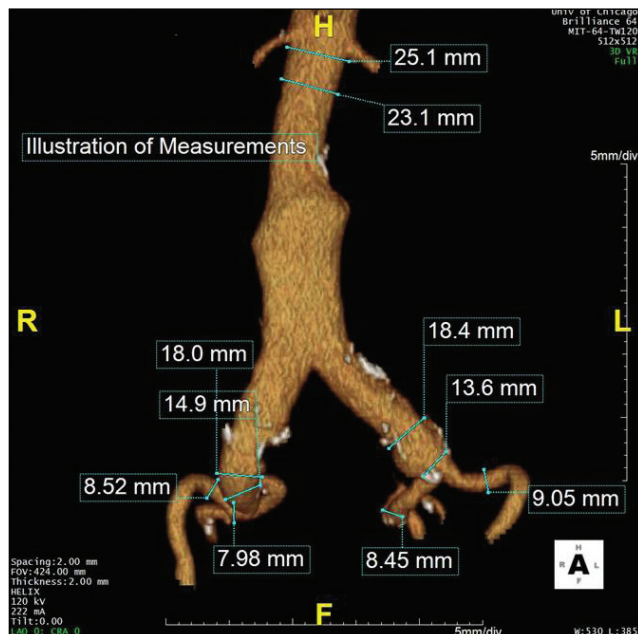


Figure 3. Diameter measurements based on CTA imaging. The reconstructed images are shown.

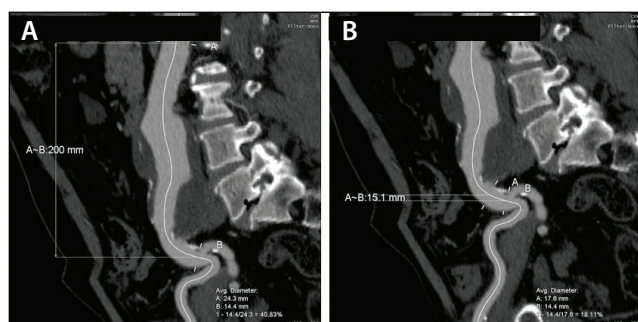


Figure 4. Length measurements from the lowest renal artery to the right iliac bifurcation. Length from the renals to the right internal iliac, 200 mm (A). Approximate right common iliac sealing length if standard EVAR limb is used (B).

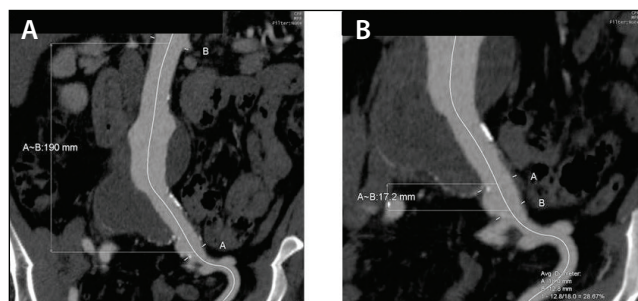


Figure 5. Length measurement from the renal arteries to the left iliac bifurcation. Length from renal arteries to the left internal iliac (A). Approximate left common iliac sealing length if standard EVAR limb is used (B).

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, Sybrandt JE, Harris PL, Butz 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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Disclosures: Consultant for Gore & Associates, Medtronic, Cook Medical, and Endospan.

Techniques of Endovascular Aortoiliac Repair Using an Iliac Branch Endoprosthesis

BY GUSTAVO S. ODERICH, MD; GIULIANO DE ALMEIDA SANDRI, MD;
AND EMANUEL TENORIO, MD, PhD

Endovascular aneurysm repair (EVAR) has revolutionized treatment of abdominal aortic aneurysms. However, the applicability of EVAR continues to be challenged in patients with unfavorable anatomy because of inadequate proximal or distal landing zones or involvement of the renal, mesenteric, and iliac arteries.¹ In these patients, exclusion of one or both internal iliac arteries and extension of the stent graft to the external iliac artery has been applied frequently to extend the indications of EVAR, accepting the risks of buttock or thigh claudication, erectile dysfunction, ischemic colitis, gluteal or perineal necrosis, spinal cord injury, and acute limb ischemia.

The development of iliac branch devices has allowed incorporation of one or both internal iliac arteries using a total endovascular approach with modular stent grafts.²⁻⁶ There are currently five iliac branch device designs by three manufacturers. The GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) is the first and only commercially available iliac branch device in the United States. The early and midterm outcomes have shown excellent technical success and patency rates, without increase in mortality or stent graft–related complications.⁷

ANATOMICAL CONSIDERATIONS

The challenges imposed with placement of a stent in the internal iliac artery are the same for any specific iliac branch device and also for parallel stent grafts. The most common limitation is inadequacy of the internal iliac artery because of aneurysms involving branches without a suitable landing zone. Although this represents a violation of the recommendations for use of these devices, it is not an absolute contraindication. Repair can still be done to one of the internal iliac branches, usually the posterior divisional branch. Another limitation is an excessively short distance between the aortic and iliac bifurcation. Although this limitation may be less important for parallel grafts, it can also be overcome with branch designs. In the IBE pivotal

trial, one-third of the patients had extension of the IBE up and above the aortic bifurcation. A very narrow common iliac artery at the origin of the internal iliac artery may be a relative contraindication with any approach. Finally, severe tortuosity and presence of narrow or excessively diseased iliac arteries pose anatomical challenges for these procedures.

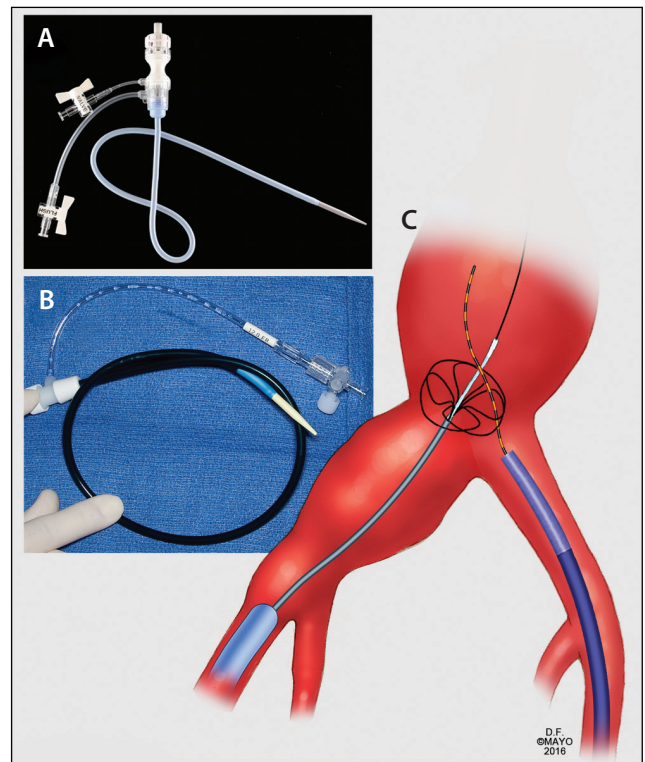


Figure 1. Ancillary tools that are used for iliac branch procedures include use of flexible 12 Fr sheaths such as the GORE® DrySeal Flex Introducer Sheath (A) or the COOK® FLEXOR® Ansel Guiding Sheath (B). Typically, the COOK® INDY OTW Vascular Retriever, which is advanced over the wire, is most useful to snare the 480 cm COOK® METRO® Wire (C). Used with permission of Mayo Foundation for Medical Education. All rights reserved.

The IBE can be used for unilateral or bilateral aortoiliac aneurysms and also for isolated iliac aneurysms. Anatomic criteria and sizing guidelines proposed in the instructions for use (IFU) are summarized as follows:

1. Adequate iliac and femoral access compatible with the 16 Fr introduction system, without excessive tortuosity or calcifications
2. Minimum proximal common iliac artery diameter of 17 mm
3. External iliac artery with diameter range between 6.5 mm and 25 mm and ≥ 30 mm in length (recommended) with a nonaneurysmal seal zone of ≥ 10 mm
4. Internal iliac artery with diameter range between 6.5 mm to 13.5 mm and ≥ 30 mm in length (recommended) with a nonaneurysmal seal zone of ≥ 10 mm

ANCILLARY TOOLS

Techniques of iliac branch device placement require more advanced endovascular skills and a comprehensive inventory with a wide variety of balloons, stents, stent grafts, catheters, guidewires, and sheaths. Although many of the tools are variable depending on physician preference, a few are essential to the success of the technique. Our preference is to use a 45 cm 12 Fr GORE® DrySeal Flex Introducer Sheath

(Figure 1), which has a flexible dilator and was designed especially for the IBE procedure. Although the IFU suggests a 0.035 inch guidewire for through-and-through femoral access, we use the 0.25 inch COOK® TRACER METRO® Wire Guide, which is 480 cm long and has enough length for exchanges while allowing continuous traction from the foot of the table. In addition, the COOK® INDY OTW Vascular Retriever is optimal for advanced aortic procedures.

TECHNIQUE

The procedure is performed in a hybrid room with a fixed imaging unit. Our preference is to use a percutaneous approach, unless the common femoral arteries are calcified or if there is a high bifurcation. After achieving access, the patient is systematically heparinized, and an activated clotting time (ACT) > 225 seconds is maintained throughout the case. Onlay fusion technology is used to locate the ostia of the internal iliac arteries. Most of the guidewire and catheter manipulations are done using a COOK® KUMPE Access Catheter and a floppy 0.035 inch hydrophilic guidewire. A 16 Fr GORE® DrySeal Flex Introducer Sheath is advanced over a COOK® LUNDERQUIST® Wire Guide in the ipsilateral side, and a 12 Fr GORE® DrySeal Flex Introducer Sheath is advanced over a COOK® LUNDERQUIST® Extra Stiff Wire

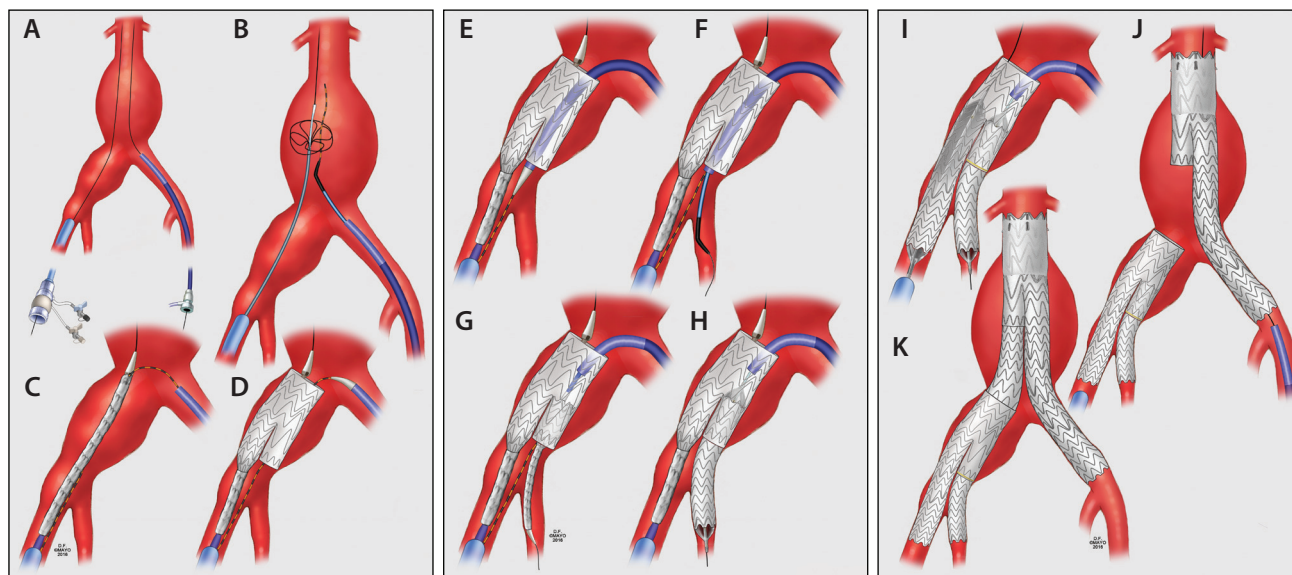


Figure 2. Technique of endovascular repair using the GORE® EXCLUDER® Iliac Branch Endoprosthesis. Bilateral femoral access is established (A), and a guidewire is snared to establish femoral-femoral access (B). The device is loaded into the aortic wire, and the preloaded wire and advanced into position (C). It is important to document that there is no wire wrapping. The device is deployed releasing the iliac branch (D). A 12 Fr sheath is advanced up and over the aortic bifurcation into the iliac branch (E). A buddy catheter is used to selectively catheterize the internal iliac artery (F). The internal iliac component stent is advanced into the internal iliac artery (G) and deployed (H). The stent is ballooned, and the remaining external iliac limb is deployed. The delivery system is removed. Kissing-balloon angioplasty is performed in the transition of the iliac branch (I). The remainder of the repair includes deployment of a GORE® EXCLUDER® Device via the contralateral femoral approach (J), followed by a 23 or 27 mm iliac extension from the contralateral gate to the IBE (K). Used with permission of Mayo Foundation for Medical Education. All rights reserved.

Guide in the contralateral side (Figure 2A and 2B). A buddy catheter is introduced via the 16 Fr sheath, and an Indy snare is introduced in the contralateral 12 Fr sheath. The COOK TRACER METRO Wire Guide is snared, establishing the through-and-through femoral access. The IBE is prepped with normal saline flushes. It has a removable guidewire tube, which is included to allow preloading of the up-and-over through wire. This tube should not be removed at this point. Instead, the through-and-through guidewire is loaded through the green cannula tube, while the IBE is loaded into the COOK LUNDERQUIST Extra Stiff Wire Guidewire. The green cannula is then removed, and the IBE is advanced into position over both wires. Limited contrast angiography can be obtained through the 16 Fr ipsilateral sheath to demonstrate the level of the iliac bifurcation, before IBE deployment.

One of the first and most important steps is to determine that there is no wire wrapping involving the preloaded guidewire and the device cannula. If wire wrapping is noted, the device should be rotated to unwrap the wire. The first step of deployment is done, releasing the iliac branch portal, which should be deployed 1 to 1.5 cm above the iliac bifurcation (Figures 2C and 2D) to aid in internal iliac artery cannulation. The 12 Fr sheath is advanced up and over the aortic bifurcation using a push-and-pull movement. The sheath is positioned at the distal end of the iliac branch portal (Figure 2E). A buddy catheter and guidewire are used to catheterize the internal iliac artery and posterior branch (Figure 2F). While advancing the buddy catheter into the 12 Fr sheath, it is important to place continuous traction in the through-and-through COOK TRACER METRO Wire Guide. This helps prevent wrapping of the catheter and the COOK TRACER METRO Wire Guide, which could create difficulty in advancing the bridging stent. Once the COOK® AMPLATZ Support Wire Guide, extra stiff, is positioned in the posterior divisional branch, we recommend exchanging the guidewire for a 1 cm short-tip COOK® AMPLATZ Fixed Core Wire Guide.

Next, contrast angiography is obtained via sheath injection for measurements and to determine the distal landing zone within the internal iliac artery. The IBE is introduced over the COOK AMPLATZ Support Wire Guide, extra stiff, and deployed into the internal iliac artery (Figures 2G and 2H). The iliac branch portal is dilated using a 14 mm angioplasty balloon, while the external iliac stent portion of the device is deployed and the delivery catheter is removed. Kissing-balloon angioplasty is performed using a COOK® CODA® Balloon Catheter for the external iliac artery (Figure 2I). Completion angiography of the iliac branch is performed with injection via the 12 Fr sheath, while the 16 Fr sheath is aspirated. The remainder of the procedure is a standard EVAR, with introduction of the GORE® EXCLUDER® Device using the contralateral femoral approach (Figure 2J). The device main body is deployed below the lowest renal artery, while the

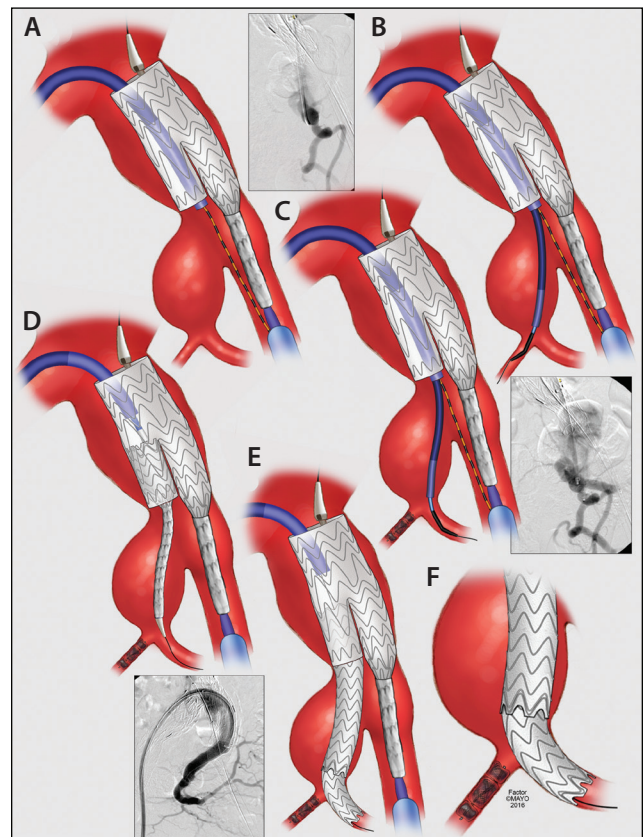


Figure 3. A patient with large internal iliac artery aneurysms needs a modification of the technique. After deployment of the iliac branch device (A), the 12 Fr sheath is advanced, and the anterior division branches are catheterized (B) and excluded using ST. JUDE AMPLATZER® Vascular Plug or coils (C). The posterior division branch is then catheterized. The safest maneuver is to place first the proximal stent into the aneurysm sac (D) and then extend the repair into the posterior branch by placement of an additional component (E, F). Used with permission of Mayo Foundation for Medical Education. All rights reserved.

ipsilateral iliac limb remains constrained. The contralateral gate is cannulated via the side of the IBE. The repair is extended from the contralateral gate to the main body of the IBE using a flared 23 or 27 mm iliac limb extension (Figure 2K). At this point, the ipsilateral limb of the GORE EXCLUDER Device is deployed, and overlaps are dilated with the COOK CODA Balloon Catheter.

BILATERAL ILIAC ANEURYSMS

The indications of iliac branch devices have been expanded to patients with bilateral iliac aneurysms with high rates of technical success and low morbidity and mortality. Special considerations are selection of side for the aortic device, which is usually placed in the straightest side or longer distance between the renal-iliac bifurcation. Upon advancement of

the aortic stent graft delivery system, it is critical to avoid dislodgement of the iliac branch component. This can be done by maintaining the balloon inflated in the iliac branch while the larger sheath is advanced across the first IBE.

INTERNAL ILIAC ANEURYSMS

The presence of aneurysmal internal iliac arteries with inadequate landing zone for placement of the bridging stent represents the main reason for anatomical unsuitability of iliac branch devices according to their IFU. Increasing clinical experience has been reported with extension of the repair to the posterior division branch of the internal iliac artery while using coils or plugs to exclude the anterior branch or other smaller side branches. In these cases, the IBE is deployed using the techniques already described. The internal iliac artery is catheterized, and a 7 or 8 Fr COOK® FLEXOR® Raabe Guiding Sheath is advanced into the aneurysmal iliac artery (Figure 3). The anterior division branch is excluded using ST. JUDE AMPLATZER® Vascular Plug or coils, although plugs are ideal because of the lack of metallic artifact on surveillance CT studies. If the branch is excluded, it is useful to leave the plug connected and to use a buddy catheter to go the next branch or the posterior branch. This maneuver keeps the sheath in close proximity to the next branch, minimizing manipulations.

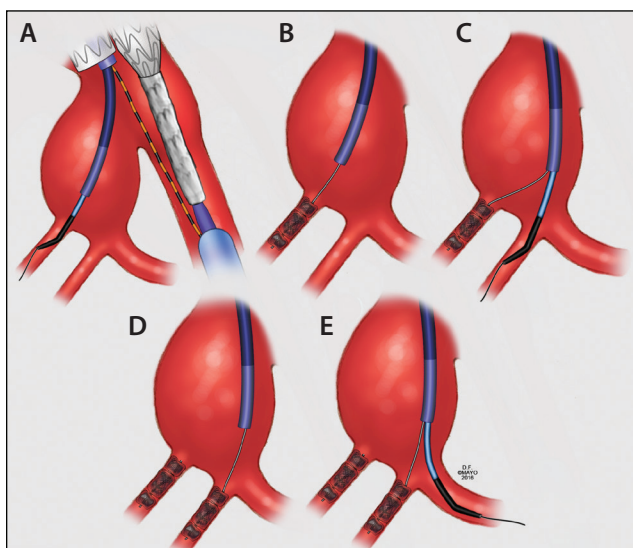


Figure 4. When multiple branches need to be excluded, this is done by selective catheterization of each branch (A) and placement of ST. JUDE AMPLATZER® Vascular Plug or coils (B). It is most useful to keep the plug connected to secure the sheath either with the connecting plug wire or a separate buddy wire, while a catheter is used to catheterize the next adjacent branch (C). This maneuver is repeated (D), and the posterior branch is used as a target for the iliac branch device (E). Used with permission of Mayo Foundation for Medical Education. All rights reserved.

The posterior branch is catheterized, and a COOK AMPLATZ Support Wire Guide, extra stiff, is positioned. The repair is extended into the posterior branch by placing the first branch component into the internal iliac artery using the iliac bridging stent and then to further extend to the divisional branches. Finally, the internal iliac aneurysm may be large and have numerous side branches. It is important to exclude all side branches to avoid retrograde type II endoleak (Figure 4). The technique of going from one side branch to the other using a buddy catheter is very useful to help minimize catheter manipulations.

CONCOMITANT FENESTRATED AND BRANCHED STENT GRAFT REPAIR

Preservation of internal iliac artery perfusion is important to minimize risk of spinal cord injury. Among patients who have extensive aortic coverage during repair of thoracoabdominal aortic aneurysms, occlusion of a collateral network has been associated with higher rates of immediate paraplegia and lack of recovery. Therefore, every attempt should be done to preserve the internal iliac artery using iliac branch devices or alternative techniques. In these cases, it is important to minimize lower extremity ischemia, which can be done by expeditious technique, use of femoral conduits, or preferential use of branches for the visceral arteries, which can be performed via the brachial approach.

COMMON PROBLEMS AND BAILOUT MANEUVERS

Iliac branch devices require familiarity with endovascular techniques and the availability of a comprehensive inventory with wide range of guidewires, balloons, catheters, sheaths, and stents. Some of the most common intraoperative problems are described here.

Pseudo-occlusion of the Internal Iliac Artery

Patients with exceedingly tortuous and noncalcified iliac arteries may have the uncommon occurrence of a pseudo-obstruction of the origin of the internal iliac artery after placement of a stiff guidewire system. Before introduction of the iliac branch device and its deployment, it is prudent to document patency of the internal iliac artery. If occlusion is documented, the delivery system should be removed and repeat angiography would reveal a widely patent origin of the internal iliac artery. Some of the techniques to solve the problem include placement of a short balloon-expandable stent at the origin of the vessel with careful attention to avoid stenting into the common iliac artery, or a double contralateral puncture to introduce a separate sheath, with stenting only if absolutely needed because of inability to catheterize the vessel via the 12 Fr contralateral sheath.

Difficult Catheterization of the Internal Iliac Artery

Catheterization of the internal iliac artery may be difficult or impossible because of misalignment of the branch, presence of a shelf precluding enough space for the delivery system causing occlusion of the origin of the internal iliac artery, or ostial occlusive disease. With deployment of the iliac branch that is not well aligned, the device can be gently rotated so that catheterization is easier. The presence of occlusive ostial disease can be dealt with by preemptive angioplasty. However, the most difficult scenario is when there is not enough space for the delivery system. Current recommendation is a minimum diameter of 14 mm in the iliac bifurcation, but this can be decreased to 12 mm in experienced hands with high technical success.

Kinks

One of the most frequent failure mechanisms are kinks, which can occur in almost any of the joints involving the iliac branch, the bridging stent, or the iliac limb extension. Kinks have occurred less frequently with the IBE compared to historical results of other iliac branch devices. In particular, a kink at the distal external iliac limb stent can result in occlusion of the stent, but this has not been observed with the IBE components in the pivotal trial. Presence of a kink needs to be immediately recognized intraoperatively and treated by placement of an additional stent.*

Branch Occlusion

Branch occlusion is rare intraoperatively and uncommon in the first 30 days. However, early occlusion of an iliac branch is usually technical or patient selection-related and typically has a culprit lesion or cause. Some of the most common causes are kinks in the internal iliac component, placement of long stents into divisional branches, history of prior branch occlusions, disease outflow branches of the internal iliac artery, and vessel dissection with flow compromise. In patients with these complications or predisposing factors, all measures to improve flow should be done, and long-term dual antiplatelet therapy with or without anticoagulation is recommended.

Perforations and Dissections

Branch stenting requires advancement of stiff guidewires and delivery sheaths. Preferentially, the guidewire should be positioned in the larger segment of the posterior division branch, avoiding positioning the tip within a small branch, which is more prone to perforation. In addition, any manipulation should be done with a floppy guidewire with careful attention to avoid inducing a dissection of the branch.

CONCLUSION

Iliac branch technology represents one of the methods by which complex anatomy can be treated with an

endovascular approach in a manner analogous to open repair. The principles of antegrade pelvic blood flow are maintained, and patients are encouraged to exercise following their repair. The technique with the IBE has been reproduced with satisfactory results in many centers, achieving high technical success and low morbidity and mortality. The iliac bed is an appealing region to perfect such techniques, as a technical failure in the setting of an iliac aneurysm most frequently results in an occluded internal iliac artery, which is how most aneurysms were managed until recent approval of the GORE® EXCLUDER® Iliac Branch Endoprosthesis. ■

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* The IBE has been designed, tested, and studied for modular use only with other GORE EXCLUDER Device components and is not approved for use with other stents or stent grafts.

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Imaging Considerations for the GORE® EXCLUDER® Iliac Branch Endoprosthesis Procedure

BY PROF. ANTOINE MILLON, MD, PhD

Imaging considerations for GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) placement are quite similar to standard endovascular aneurysm repair. Precise preoperative planning is fundamental, especially the calculation of the C-arm projections for the iliac bifurcation and the internal iliac division. The internal iliac gate of the IBE should be deployed at least 10 mm above the iliac bifurcation and in good anterior-posterior position to aid in cannulation of the internal iliac artery. The better the image of the iliac bifurcation, the more precise the positioning of the device will be. The anterior and caudal obliquity of the C-arm must be determined to get the perpendicular view of the internal iliac artery origin (Figure 1). The angulation of the C-arm must also be positioned to get the better view of the internal iliac artery division (anterior and posterior trunk) in order to precisely deploy the internal

iliac component (Figure 2). All these angulations have to be preoperatively calculated with a dedicated 3D workstation.

The procedure can be performed in a hybrid room or with a mobile C-arm. However, for obese patients and those requiring strong angulations of the C-arm, a high-power C-arm system is needed to get good imaging quality. Fusion imaging for this procedure is not yet fully reliable. A stiff guidewire in tortuous iliac arteries considerably changes the arterial morphology.

At the beginning of the procedure, angiography is performed with the appropriate angulation of the C-arm to determine the origin of the internal iliac artery (Figure 3). The IBE is then deployed with the internal iliac gate 10 mm above the internal iliac artery to have enough room for the catheterization. Before deployment, the lateral marker of the internal gate has

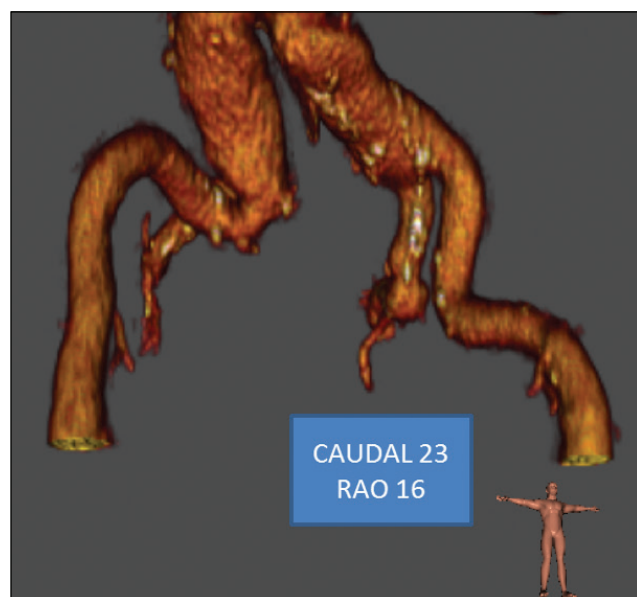


Figure 1. Preoperative projection of the C-arm to visualize the origin of the left internal iliac artery using a THERANVA ENDOSIZE® 3D workstation.

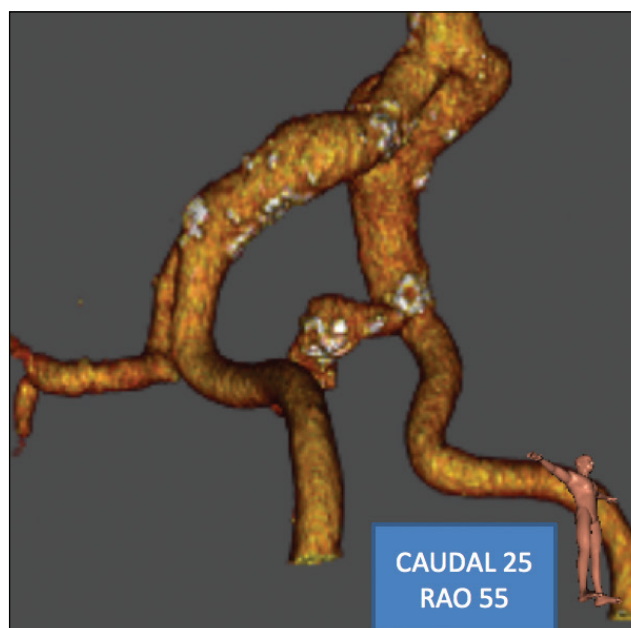


Figure 2. Preoperative projection of the C-arm to visualize the division of the right internal iliac artery using 3D workstation.

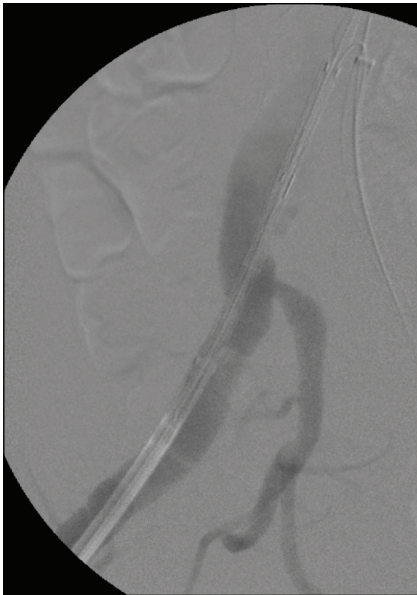


Figure 3. Initial angiography in the proper projection for the origin of the internal iliac artery before deployment of the Iliac Branch Component. Markers of the internal gate are positioned on the good position.



Figure 4. Angiography in the proper projection for the internal iliac division before deployment of the internal iliac component.

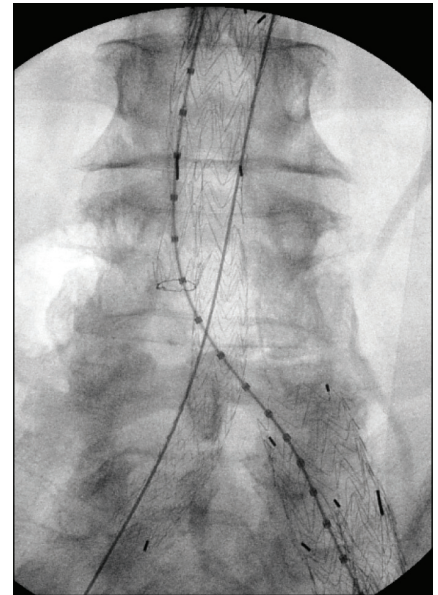


Figure 5. High-power fluoroscopy image before deployment of the bridging component in order to visualize the markers of the proximal end of the IBE.

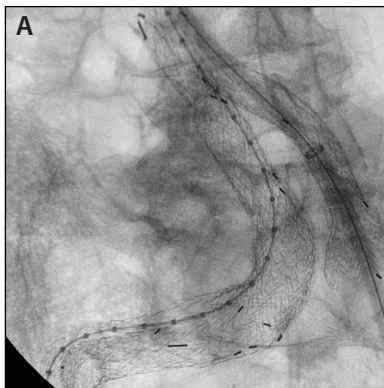


Figure 6. Insufficient overlap between the IBE and the bridging component, leading to an endoleak.

Trunk-Ipsilateral Leg Endoprosthesis and the Iliac Branch Component (IBE main trunk). Markers of the GORE EXCLUDER Device contralateral gate and markers of the IBE must be on the same image. The marker of the proximal end of the IBE must be aligned in order to eliminate the parallax and to obtain the optimal overlap. High-power fluoroscopy is sometimes needed to get a better visualization of the markers (Figures 5 and 6). ■

to be positioned on the proper lateral side. Once the IBE is deployed and the internal iliac artery is catheterized, angiography is performed with the appropriate angulation to determine the internal iliac artery division before deployment of the internal iliac component (Figure 4).

Another key point is the imaging during the deployment of the bridging component between the contralateral gate of the GORE® EXCLUDER® Device

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Which Anatomy Presents the Greatest Technical Challenges for Iliac Branch Endografts?

BY PROF. FABIO VERZINI, MD, PhD, FEBVS

With currently available iliac branch devices, almost 40% of patients with extensive aortoiliac aneurysms may be suitable for endovascular repair, according to the manufacturers' indication for use and recently published literature.^{1,2} With increasing operator experience and new material availability, these indications are often broadened today to allow treatment of most patients' anatomies.

One of the most common adverse features in extensive aneurysmal disease is the tortuosity of the iliac vessels secondary to the increasing diameter and length of the growing aortoiliac aneurysm. Common iliac aneurysms tend to grow deepening down into the small pelvis, rotating anteromedially due to the fixed point of the hypogastric bifurcation with elongation and tortuosity of the common and external iliac arteries.

In some patients, this tortuosity is associated with atherosclerotic changes of the arterial wall and extensive calcification that may limit endograft access, correct deployment, and expansion. External iliac tortuosity and calcification may necessitate the use of multiple introducers of increasing size to allow the advancement of the iliac branch device. In such settings, having smaller devices available that can be introduced in 16 Fr sheaths, such as the GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE), could be helpful to enable axial rotation for proper device orientation.

Another challenge is the risk of kinking the external iliac limb of the graft into the first segment of the external iliac artery, where its take-off angulation may increase after deployment. It is therefore of paramount importance to remove the stiff guidewire, taking multiple projections during the postdeployment angiographic control to avoid leaving sharp angulations. Early graft occlusion may be prevented by reinforcing the external iliac graft segment with a bare stent.

Excessive tortuosity in the common iliac arteries is usually a less critical challenge that can be dealt with by stiff guidewires. After deployment, the reinforcement of the proximal tubular segment of the iliac branch device with the mating iliac limb of the bifurcated abdominal graft will decrease the tortuosity of the resulting iliac axis.

Tortuosity of the hypogastric artery is less problematic, because the wire used for hypogastric stent grafting may be well advanced in one of the distal branches to support navigation through the proximal trunk; we use a stiff wire with a long, soft tip, 0.035 inch ABBOTT® SUPRA CORE Guidewire with success in such cases.

With the stiff guidewire in place in the external common iliac aneurysm, another challenge may be the increasing angulation at the level of the ostium of the hypogastric artery, with its functional occlusion that sometimes may impede access to the vessel for hypogastric component deployment. In such cases, after retraction of the wire and verification of the patency, a buddy hypogastric guidewire may be inserted from the contralateral access before advancement of the homolateral stiff wire to maintain the ostium patency.

The most challenging anatomical feature for an iliac branch device is the presence of a tight iliac bifurcation to accommodate both iliac limbs of the graft.

When the lumen is < 14 mm, all the available room may be occupied by the external iliac limb of the graft, leaving not enough space to cannulate the hypogastric ostium. This difficulty may even increase in the presence of a saccular aneurysm of the common iliac artery, where the hypogastric short segment of the graft may open during deployment. The best option here is to deploy the iliac branch device with the hypogastric branch opening opposite from the saccular expansion, leaving more room for the guidewire to navigate into the hypogastric ostium.

Lastly, a diseased, stenotic, proximal hypogastric artery may render difficult cannulation once the iliac branch device is in place. Careful evaluation should consider alternative options, most of the time occluding the diseased internal iliac artery. In selected cases, precannulation and gentle dilation of the hypogastric artery (avoiding dissection) before iliac branch device deployment may allow further access through the graft. ■

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CASE REPORT

The GORE® EXCLUDER® Iliac Branch Endoprosthesis in a Tortuous Aortoiliac Aneurysm

BY PROF. FABIO VERZINI, MD, PhD, FEBVS, AND ELEONORA CENTONZA, MD

Ensuring an adequate proximal and distal landing zone is crucial for a successful and durable endovascular aneurysm repair (EVAR). Abdominal aortic aneurysms (AAAs) associated with common iliac artery (CIA) aneurysm (CIAA) are not uncommon. CIAA is defined by a transverse diameter > 18.5 mm for men and ≥ 15 mm for women and are found in up to 20% of patients diagnosed with an AAA.¹ Current suggestions for elective CIAA repair recommend a transverse diameter > 30 mm.² Standard endografts are not designed to guarantee an adequate distal landing zone in the presence of extensive CIAA, therefore, different endovascular solutions have been proposed to achieve distal sealing with either internal iliac artery (IIA) occlusion or preservation. IIA embolization is associated with erectile dysfunction, buttock or thigh claudication, paraplegia, and sphincter dysfunction in nearly 30% of patients.³ Preservation of at least one hypogastric artery is advisable to reduce the incidence of such complications.⁴ Initially to maintain endovascular perfusion of the IIA during EVAR, many different techniques have been described using off-the-shelf devices such as the bell-bottom, chimney, sandwich, and double-barrel techniques.⁵⁻⁷ Currently, dedicated iliac branch devices are available* to preserve antegrade perfusion of the hypogastric artery.

CASE PRESENTATION

A 72-year-old man with a history of smoking, obesity (BMI, 38 kg/m²), hypertension, type II diabetes, and severe chronic obstructive pulmonary disease was diagnosed with an asymptomatic aortoiliac aneurysm (55 mm maximum diameter) and a concomitant CIAA of 37 mm with highly tortuous iliac vessels (Figure 1). In consideration of his comorbidities and anatomical features, a total endovascular repair was suggested, discussed, and chosen with the patient.

Preoperative CTA was analyzed with a dedicated workstation, and planning and sizing was based on centerline flow measurements (Figure 1). A GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) was selected

to accommodate and navigate the patient's tortuous iliac anatomy and achieve complete exclusion of the right CIAA. Due to the patient's obesity, ultrasound-guided bilateral percutaneous femoral access was achieved, and two ABBOTT® PERCLOSE® PROGLIDE Closure Systems for each side were preimplanted for the percutaneous perclose technique. A hydrophilic guidewire with parallel puncture of a 16 Fr introducer sheath was snared from the right to the left femoral access in a through-and-through fashion and then loaded on the precannulated internal iliac artery gate. A 23 x 14 x 100 mm IBE was then deployed into the iliac aneurysm, with the bifurcated component just proximal to the right iliac bifurcation over a Lunderquist guidewire. A 12 Fr COOK® FLEXOR® Introducer Sheath was then advanced from the left femoral access over the through-and-through guidewire in the internal iliac artery gate of the IBE.

After selective cannulation of the superior gluteal artery with a Cobra-shaped 5 Fr CORDIS® Diagnostic



Figure 1. Preoperative CTA demonstrating the right aortoiliac aneurysm with highly tortuous iliac access.

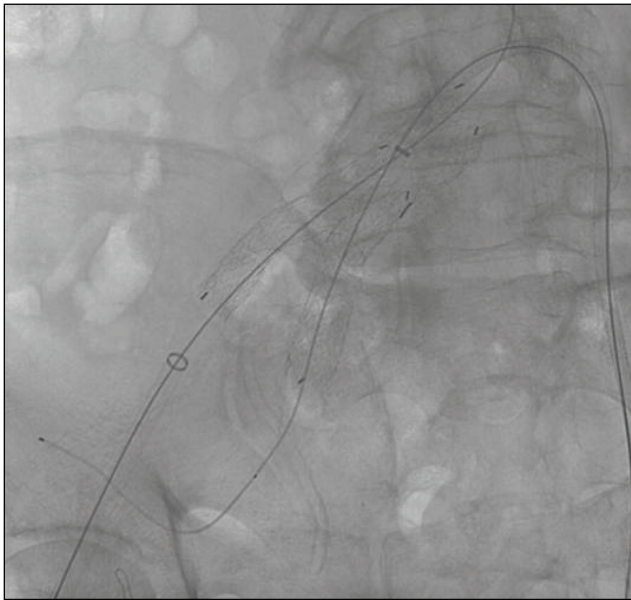


Figure 2. Deployment of the dedicated internal iliac component in the IBE gate.

Catheter and positioning of an ABBOTT® SUPRA CORE 0.035 inch Guidewire, a Gore 16 x 14.5 x 70 mm Internal Iliac Component was deployed in the IIA (Figure 2). In a standard fashion, a 31 x 14.5 x 160 mm GORE® EXCLUDER® Device Trunk-Ipsilateral Leg Component was deployed in the infrarenal aorta just distal to the renal artery ostia, with a 23 x 100 mm right bridging component to the IBE in the

right iliac artery. Lastly, a 20 x 100 mm iliac extender graft was deployed from the left femoral access in overlap with the GORE EXCLUDER Device Ipsilateral Leg.

Postprocedural angiography documented complete exclusion of the aortoiliac aneurysm with no signs of endoleaks, patency of the right iliac branch, and both IIAs (Figure 3) demonstrated good conformability of the IBE to the patient's tortuous anatomy. The postoperative course was uneventful, and the patient was promptly discharged on postoperative day 2.

Follow-up protocol consisted of a postoperative CTA at 1 month, duplex scan at 6 months, and CTA yearly thereafter. A type II endoleak sustained by lumbar arteries was detected at the first-year CTA with no aortic sac increase, and it is currently under surveillance. The right iliac aneurysm is still completely excluded after 2 years of follow-up with good patency of the IIA (Figure 4).

DISCUSSION

Iliac branch devices have contributed to the expansion of total endovascular repair of extensive aortoiliac aneurysmal disease. Preservation of the antegrade perfusion of the hypogastric arteries is effective in reducing the risk of buttock claudication occurring in about 30% of patients after endovascular repair of CIA with embolization/coverage of the IIA.⁸⁻¹⁰ Safety and efficacy of iliac branch devices have been investigated with patency rates reported to be over 80% in most of the recent series¹¹⁻¹³ in a midterm setting. Long-term

durability has been further investigated in a recent series, with freedom from iliac branch-related reintervention of 97.4%, 95.6%, 94.0%, and 91.8% at 1, 3, 5, and 9 years, respectively. Hypogastric artery patency was 94.7%, 92.6%, and 90.4% at 1, 3, and 10 years, respectively.^{14,15} The IBE is a 16 Fr nitinol and expanded polytetrafluoroethylene new-generation device with a precannulated internal iliac limb and a dedicated iliac internal component designed to improve kink resistance and accommodate a wide range of both external and internal iliac diameters



Figure 3. Postoperative angiogram documenting complete aneurysm exclusion with no signs of endoleak, patency of the hypogastric arteries, and good conformability of the device to the patient's anatomy.



Figure 4. Postoperative CTA at 2 years.

(6.5 to 25 mm and 6.5 to 13.5 mm, respectively) with proven results in iliac patency preservation.¹⁶⁻¹⁹

The IBE has to be considered as a first-choice option for total endovascular aortic aneurysm repair in aortoiliac extensive aneurysmal disease, especially in patients with iliac tortuosity, thanks to its high conformability to patient anatomy and the ability to preserve pelvic circulation.²⁰ A tailored approach with accurate preoperative planning and patient selection is strongly recommended for successful and durable endovascular repair. Life-long surveillance is still necessary after graft implantation, as long-term device-specific data are lacking. ■

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CASE REPORT

Managing an Infrarenal AAA With Significant Iliac Tortuosity

BY PROF. IAN SPARK, MD, FRACS, FRCS

A 79-year-old man originally from Burma presented to the outpatient clinic with a tender abdominal aortic aneurysm. A CT scan showed a 4.3 cm infrarenal aortic aneurysm with dilated common iliac arteries (left, 2.3 cm; right, 2.3 cm; Figure 1). There was significant iliac tortuosity, with the external iliac arteries measuring only 8 mm (Figures 2 and 3).

As he was an active man and sole caretaker for his wife, who was wheelchair bound, an endovascular option with preservation of both hypogastric arteries was considered.

Due to the iliac tortuosity, the GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) with a standard GORE® EXCLUDER® Device was selected due to the high conformability of the iliac limbs, which allow good adaptation and avoidance of flow-limiting kinking.

The procedure was performed with a percutaneous approach. The bifemoral up-and-over through wire was introduced via the right groin and captured with a snare from the contralateral groin. The right IBE was deployed first followed by the left. The first IBE was implanted on the right side for no particular reason in this case. However, factors to consider when determining which side to treat first

when placing devices bilaterally can include anatomy and case complexity. If the IBE will land above the aortic bifurcation, it can be easier to implant that device second to avoid potential challenges associated with working through the first implanted IBE. Additionally, case complexity due to tortuosity, vessel

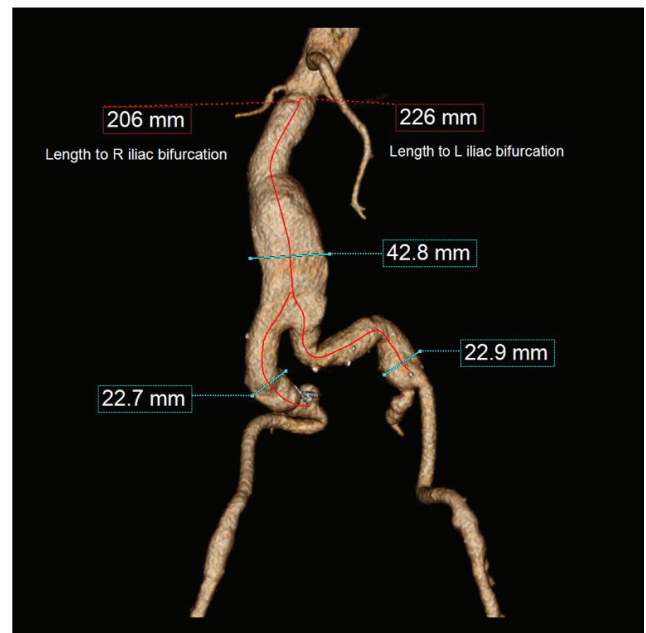


Figure 1. Pre-operative image showing key anatomic measurements.



Figure 2. Pre-operative image showing the tortuosity of the left iliac arteries.

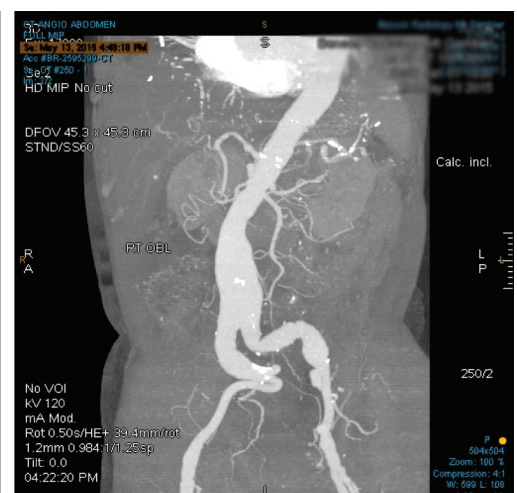


Figure 3. Pre-operative image showing the vessel tortuosity, as well as the narrow and calcified iliac bifurcation of the right iliac arteries.

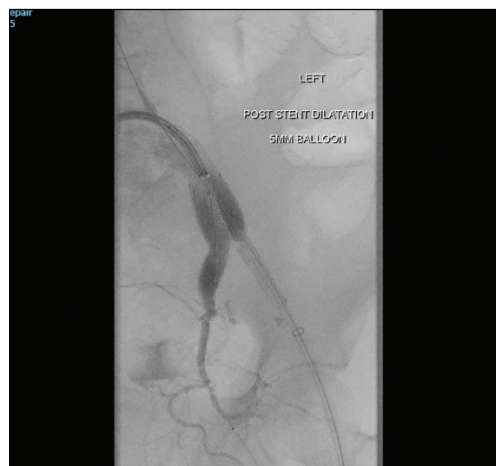


Figure 4. Deployment of the left GORE® EXCLUDER® Iliac Branch Endoprosthesis.

diameter, or hypogastric cannulation may impact this decision because deployment of the second IBE can be impacted by the first IBE.

Briefly, the right Gore Iliac Branch Component was implanted first, followed by deployment of the right Internal Iliac Component. Deployment and ballooning of the Iliac Branch Component and Internal Iliac Component overlap was completed before moving on to the next IBE. Next, the left Iliac Branch Component was deployed, followed by deployment of the left Internal Iliac Component. Ballooning was performed on the left Iliac Branch Component and Internal Iliac

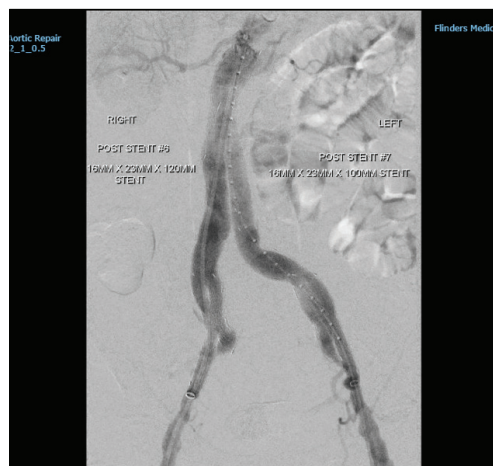


Figure 5. Completion angiogram of the bilateral GORE® EXCLUDER® Iliac Branch Endoprosthesis implants.

Component overlap. After completion of all IBE components on both sides, the GORE EXCLUDER Device trunk was introduced and deployed (Figure 4). Last, a bridge component was introduced on each side to bridge the IBE components to the GORE EXCLUDER Device trunk via the contralateral and ipsilateral legs to complete the repair (Figure 5).

He was discharged home 2 days later without complications. At 2-year follow-up, he had no endoleaks or claudication and all vessels remained patent on ultrasound. ■

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Disclosures: None.

GORE® EXCLUDER® Iliac Branch Endoprosthesis

INDICATIONS FOR USE IN THE US: The GORE® EXCLUDER® Iliac Branch Endoprosthesis is indicated for use with the GORE® EXCLUDER® AAA Endoprosthesis to isolate the common iliac artery from systemic blood flow and preserve blood flow in the external iliac and internal iliac arteries in patients with a common iliac or aortoiliac aneurysm, who have appropriate anatomy, including: adequate iliac / femoral access; minimum common iliac diameter of 17 mm at the proximal implantation zone of the IBE; external iliac artery treatment diameter range of 6.5 – 25 mm and seal zone length of at least 10 mm; internal iliac artery treatment diameter range of 6.5 – 13.5 mm and seal zone length of at least 10 mm; adequate length from the lowest major renal artery to the internal iliac artery to accommodate the total endoprosthesis length, calculated by adding the minimum lengths of required components, taking into account appropriate overlaps between components. **Trunk-Ipsilateral Leg Endoprosthesis Components:** The Trunk-Ipsilateral Leg Endoprosthesis is intended to provide proximal seal and fixation for the endovascular repair of the aneurysm. For more information on the Trunk-Ipsilateral Leg Component indications for use and deployment, see the GORE® EXCLUDER® AAA Endoprosthesis Instructions For Use. **Contralateral Leg Endoprosthesis Components:** The Contralateral Leg Endoprosthesis is intended to bridge the GORE® EXCLUDER® Trunk-Ipsilateral Leg Component to the GORE® EXCLUDER® Iliac Branch Endoprosthesis. Additionally, the Contralateral Leg Endoprosthesis is intended to be used for distal extension of the Iliac Branch Component in the external iliac artery. The Iliac Branch Component can treat external iliac artery diameters up to 13.5 mm. This ability to extend the Iliac Branch Component distally with any Contralateral Leg Endoprosthesis expands the external iliac artery treatment range up to 25 mm. For more information on the Trunk-Ipsilateral Leg and Contralateral Leg Endoprosthesis Component indications for use and deployment, see the GORE® EXCLUDER® AAA Endoprosthesis Instructions For Use. **Aortic Extender Endoprosthesis and Iliac Extender Endoprosthesis Components:** The Aortic and Iliac Extender Endoprostheses can be used after deployment of the GORE® EXCLUDER® Iliac Branch and AAA Endoprostheses. These extensions are used when additional length and / or sealing for aneurysm exclusion is desired. For more information on Aortic Extender and Iliac Extender indications for use and deployment, see the GORE® EXCLUDER® AAA Endoprosthesis *Instructions for Use*. **CONTRAINDICATIONS:** The GORE® EXCLUDER® Iliac Branch Endoprosthesis is contraindicated in: Patients with known sensitivities or allergies to the device materials. All components of the GORE® EXCLUDER® Iliac Branch Endoprosthesis and the GORE® EXCLUDER® AAA Endoprosthesis contain ePTFE, FEP, nitinol (nickel-titanium alloy), and gold. Patients with a systemic infection who may be at increased risk of endovascular graft infection. **Rx Only**

INDICATIONS FOR USE UNDER CE MARK: Iliac Branch and Internal Iliac Components. The GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) is intended to isolate the common iliac artery from systemic blood flow and preserve blood flow in the external iliac and internal iliac arteries in patients with a common iliac or aortoiliac aneurysm, who have appropriate anatomy, including: Adequate iliac / femoral access; Minimum common iliac diameter of 17 mm at the proximal implantation zone of the IBE; External Iliac artery treatment diameter range of 6.5 – 25 mm and seal zone length of at least 10 mm; Internal iliac artery treatment diameter range of 6.5 – 13.5 mm and seal zone length of at least 10 mm. **Trunk-Ipsilateral Leg and Contralateral Leg Endoprosthesis Components.** The Trunk-Ipsilateral Leg and Contralateral Leg Endoprostheses are intended to provide proximal seal and fixation to the GORE® EXCLUDER® Iliac Branch Endoprosthesis following deployment of the GORE® EXCLUDER® Iliac Branch Endoprosthesis. For more information on the Trunk-Ipsilateral Leg and Contralateral Leg Endoprosthesis Component indications for use and deployment, see the GORE® EXCLUDER® AAA Endoprosthesis Instructions For Use. **Aortic Extender Endoprosthesis and Iliac Extender Endoprosthesis Components.** The Aortic and Iliac Extender Endoprostheses can be used after deployment of the GORE® EXCLUDER® Iliac Branch and AAA Endoprostheses. These extensions are used when additional length and / or sealing for aneurysm exclusion is desired. For more information on Aortic Extender and Iliac Extender indications for use and deployment, see the GORE® EXCLUDER® AAA Endoprosthesis *Instructions for Use*. **CONTRAINDICATIONS:** The GORE® EXCLUDER® Iliac Branch Endoprosthesis is contraindicated in: Patients with known sensitivities or allergies to the device materials, and patients with a systemic infection who may be at increased risk of endovascular graft infection. Refer to Instructions for Use at goremedical.com for a complete description of all warnings, precautions, and adverse events. **Rx Only**

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- **Advances Repair:** All-In-One System with proven outcomes
- **Performs as Promised:** High patency³, conformability, and durability
- **Complete Confidence:** More than 20 years of aortic device experience

1,2,3 For the complete list of references, visit goremedical.com/IBE

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