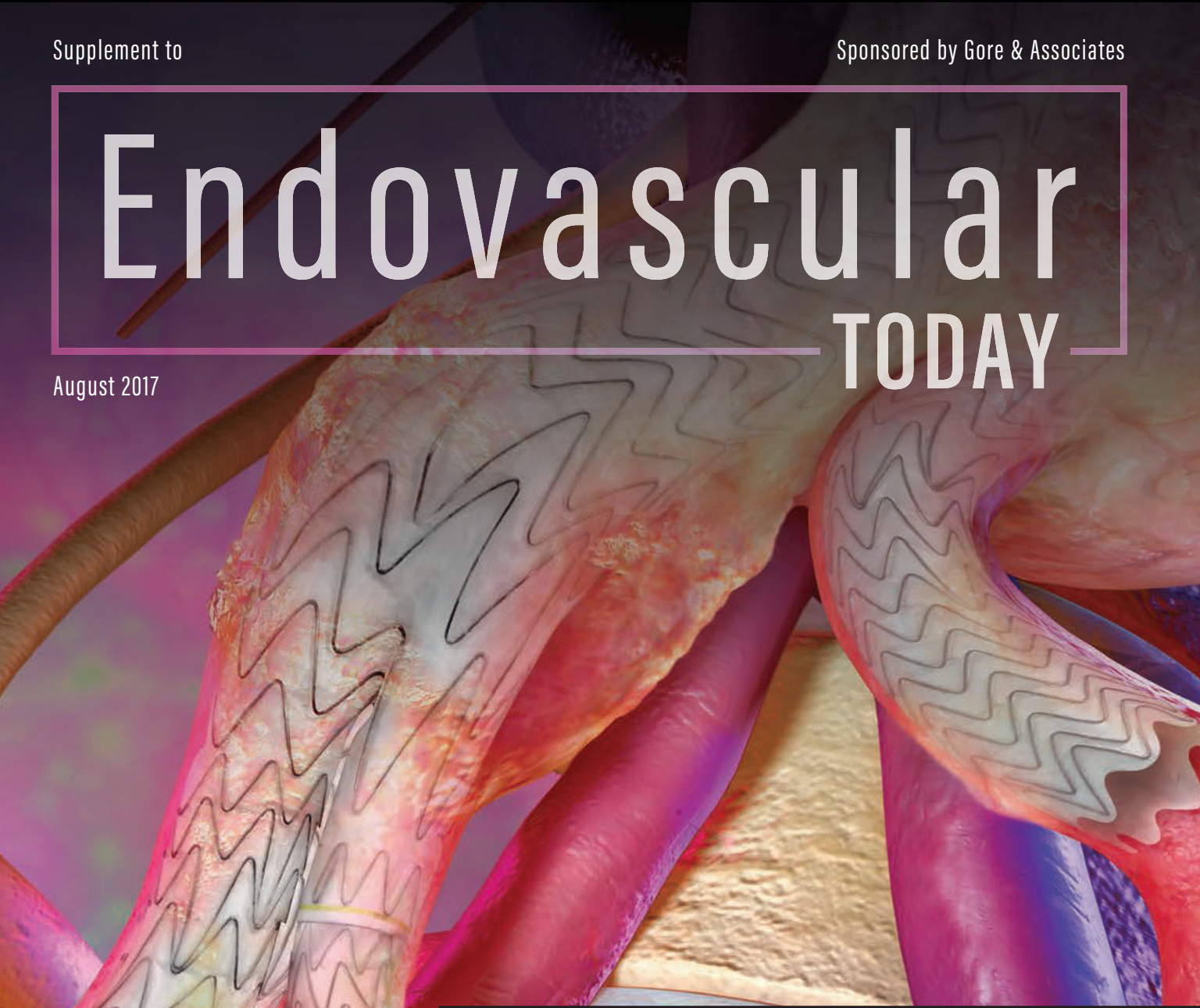
Supplement to

Sponsored by Gore & Associates

Endovascular TODAY

August 2017



PRESERVING THE HYPOGASTRIC ARTERY

Why, **when**, and **how**: an expert consensus.

Sponsored by Gore & Associates

Expert Discussion: When to Preserve the Hypogastric Artery

WITH PROF. ANTOINE MILLON, MD, PHD; ROSS MILNER, MD, FACS; GUSTAVO S. ODERICH, MD; DARREN B. SCHNEIDER, MD; PROF. IAN SPARK, MD, FRACS, FRCS; AND PROF. FABIO VERZINI, MD, PHD, FEBVS

MODERATOR

Ross Milner, MD, FACS
Professor of Surgery
Director, Center for Aortic Diseases
University of Chicago
Chicago, Illinois
rmilner@surgery.bsd.uchicago.edu
Disclosures: Consultant for Gore & Associates, Medtronic, Cook Medical, and Endospan.

PARTICIPANTS

Prof. Antoine Millon, MD, PhD
Professor of Vascular Surgery
Department of Vascular and Endovascular Surgery
University Hospital of Lyon
Lyon, France
antoine.millon@chu-lyon.fr
Disclosures: Consultant for Gore & Associates.

Gustavo S. Oderich, MD
Professor of Surgery
Director of Endovascular Therapy
Advanced Endovascular Aortic Research Program
Division of Vascular and Endovascular Surgery
Mayo Clinic Rochester, Minnesota
oderich.gustavo@mayo.edu
Disclosures: Consultant to and receives research grants from Cook Medical, Gore & Associates, and GE Healthcare (all fees and grants paid to Mayo Clinic).

Darren B. Schneider, MD
Associate Professor of Surgery
Weill Cornell Medical College
Chief, Vascular and Endovascular Surgery
Weill Cornell Medicine
New York-Presbyterian Hospital
New York, New York
dbs9003@med.cornell.edu
Disclosures: Consultant for Gore & Associates and Cook Medical; receives research support from Gore & Associates and Cook Medical; receives honoraria from Gore & Associates.

Prof. Ian Spark, MD, FRACS, FRCS
Department of Vascular and Endovascular Surgery
Flinders Medical Centre and Finders University
Clinical Director, Vascular Surgery
Adelaide, Australia
ian.spark@sa.gov.au
Disclosures: None.

Prof. Fabio Verzini, MD, PhD, FEBVS
Associate Professor of Vascular Surgery
University of Perugia
Vascular Surgery Unit
Hospital S. Maria della Misericordia
Perugia, Italy
fabio.verzini@unipg.it
Disclosures: Consultant for Gore & Associates, Medtronic, and Cook Medical.

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 measure ≥ 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 criteria—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 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.*

(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 Munster, Germany, has developed an endovascular treatment algorithm for common iliac aneurysm 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]

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 sequalae, 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.

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 aneurysmal 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. $R_{x\ Only}$

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 aneurysmal 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. $R_{x\ Only}$

Gore products referenced within are used within their FDA approved / cleared indications or are under investigation for the uses referenced within. Gore does not have knowledge of the indications and FDA approval / clearance status of non-Gore products. Gore makes no representations as to the surgical techniques, medical conditions or other factors that may be described in this article. The reader is advised to contact the manufacturer for current and accurate information.

GORE
Creative Technologies Worldwide

W. L. Gore & Associates, Inc.
Flagstaff, AZ 86004

+65 67332882 (Asia Pacific)
1800 680 424 (Australia / New Zealand)
00800 6334 4673 (Europe)
800 437 8181 (United States)
928 779 2771 (United States)

goremedical.com

Products listed may not be available in all markets.