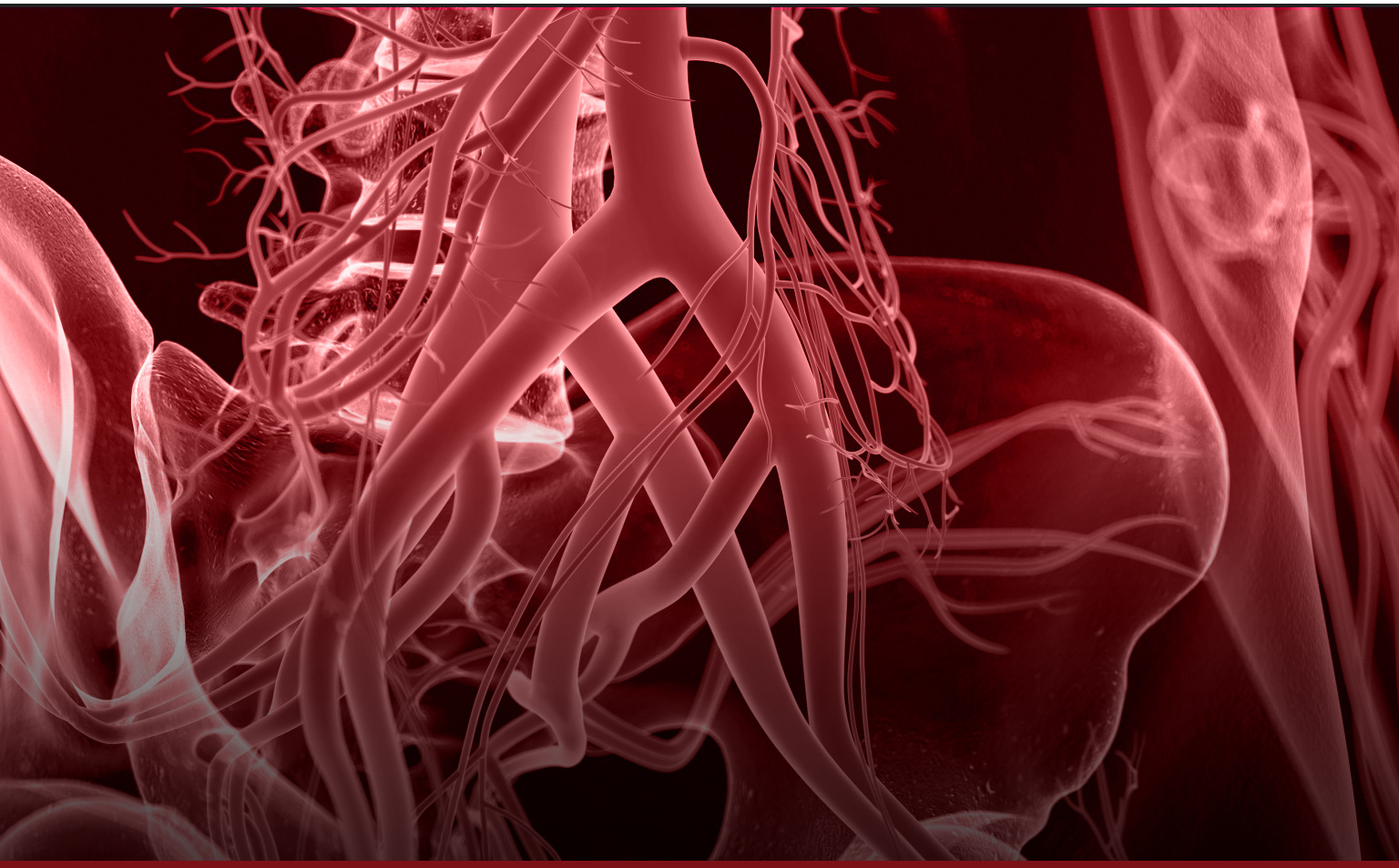
Supplement to

Sponsored by Gore & Associates

Endovascular TODAY

March 2016

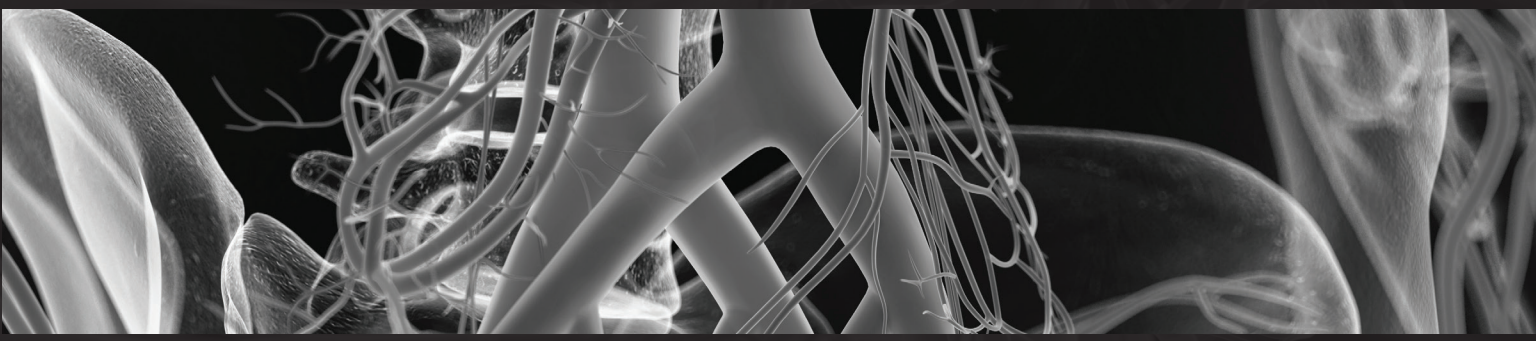


ADVANCING CARE

FROM THE ARCH TO THE ILIACS

A look at innovation and clinical studies advancing endovascular aortic repair.

TABLE OF CONTENTS



Evolution of Endovascular Management of Common Iliac Artery Aneurysms

With newer-generation devices and increasing operator experience, there is potential to broaden the scope of EVAR for iliac artery aneurysms.

BY TIFFANY WU, MD, AND JASON T. LEE, MD

Endovascular aneurysm repair (EVAR) has evolved to become the first choice in the treatment for patients with thoracic and abdominal aortic aneurysms (AAAs). Despite the success of endovascular techniques for abdominal and thoracic pathology, management of aortoiliac aneurysms (AIAs) remains challenging, with up to 30% of AAAs having concomitant common iliac artery aneurysms (IAAs). Typical strategies utilized during standard endovascular repair of AIA involve sacrifice via embolization of unilateral or bilateral hypogastric arteries (HAs). This can lead to complications including buttock claudication, erectile dysfunction, and colon ischemia.

Several novel endovascular techniques have been proposed to preserve the HAs, including "bell-bottom" iliac limbs, the sandwich or double-barrel technique, the cross-chimney technique, and, more recently, the development of iliac branch devices (IBDs). IBDs have been designed as a purpose-specific treatment and have reported high technical success rates. The main concern with IBDs has been their relatively strict anatomic inclusion criteria and the fact that no devices have been approved for this indication by the US Food and Drug Administration as of February 2016. Newer-generation designs and increasing experience may broaden its application scope.

EPIDEMIOLOGY AND CLINICAL PRESENTATION

It is common that AAAs extend to the iliac artery, with the incidence estimated at 20% to 30%.[1,2] Hence, nearly one-third of all patients being considered for standard EVAR might not fit within the instructions for use (IFU) without adjunctive measures due to a lack of seal at the enlarged iliac landing zone. Fortunately, isolated IAAs without AAA are uncommon. Autopsy estimates document rates of 0.03% for IAA, and in clinical series, the prevalence ranges from 2.2% to 7.8%.[3,4]

Most patients with IAA and concomitant AAA or isolated IAA are asymptomatic and are incidentally detected on imaging studies. Owing to the deep pelvic location, symptoms including local visceral or venous compression, neuropraxia, or rupture may not occur until the aneurysms reach a considerable size.[5] IAAs tend to be more symptomatic at larger maximum diameters, and the risk of rupture with isolated IAAs is high (up to 29%).[6] The natural history of isolated IAAs is progressive expansion at a rate dependent on the size of the aneurysm: IAAs smaller than 3 cm expand at an average rate of 0.05 to 0.15 cm/year, whereas aneurysms larger than 3 cm increase at up to 0.28 cm/year. IAA rupture is usually a life-threatening emergency that can lead to hemorrhagic shock and death without intervention. The current consensus is that elective repair should be considered in good-risk patients for isolated IAAs > 3 cm in maximum transverse diameter due to an increasing risk of developing symptoms, including rupture.[7]

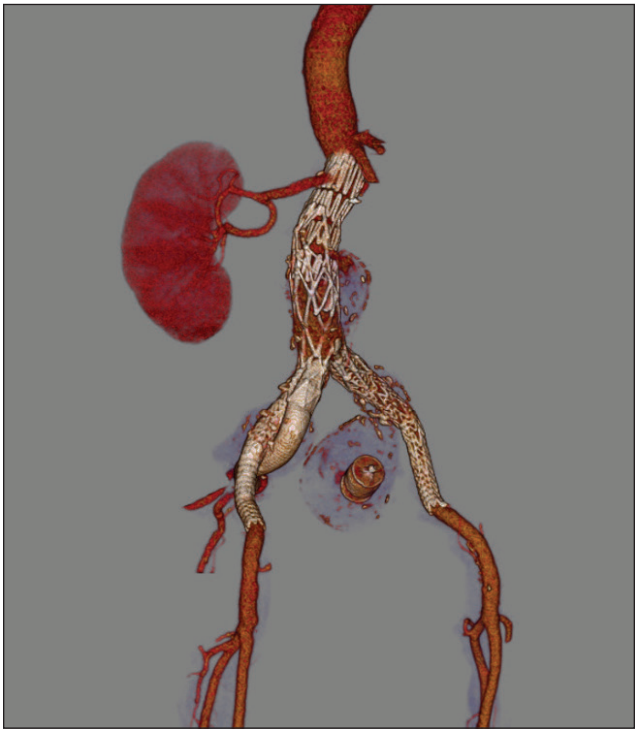


Figure 1. EVAR with embolization.

EVAR WITH EMBOLIZATION

Historically, interventional occlusion of the HA has commonly been applied in patients undergoing EVAR, especially when the aneurysmal process extends to one or both of the iliac artery bifurcations.[8] Figure 1 illustrates an example of coil embolization during EVAR. Several reports have focused on the feasibility and safety of HA embolization. According to these studies, patient age and functional status, unilateral or bilateral status, and the embolization position (main trunk or branch) are the three primary influencing factors affecting clinical outcomes. Coils and ST. JUDE AMPLATZER Vascular Plugs to facilitate otherwise routine EVAR have been described and utilized, and although there is no doubt that HA embolization prior to EVAR has increased the number of patients suitable for EVAR, it is associated with significant risk of pelvic ischemia and other side effects, as noted in the following section. To decrease such side effects, it is reasonable to preserve flow in at least one HA, as per Society for Vascular Surgery guidelines,[9] select patients in whom symptoms are less bothersome, or to employ strategies to preserve both HAs whenever possible, especially in young patients.

INTERNAL ILIAC PRESERVATION

The internal iliac artery (IIA) or HA is the dominant artery in the pelvic region, supplying blood flow to the hips, thighs, left colon, and the reproductive organs. Sacrifice of either the unilateral or bilateral HA can lead to several complications, the most common of which is buttock claudication, with incidences ranging from 1.6% to 56%.[10] Colonic ischemia is another feared pelvic ischemic complication of HA occlusion, with associated mortality and an incidence as high as 9%.[11,12] Because the inferior mesenteric artery is routinely sacrificed during EVAR, loss of collateral circulation from embolization of one or both HAs can have detrimental effects on the blood supply of the distal and sigmoid colon. New-onset erectile dysfunction has also been found to occur in up to 33% of patients undergoing HA occlusion.[13] Although not life-threatening, this complication of HA occlusion is considered by some patients to be quite compromising to their overall quality of life, especially in the 15% of patients who suffer from persistent symptoms.[14] Other rare but devastating complications following HA occlusion include spinal cord ischemia, buttock necrosis, scrotal skin ulceration, and sciatic nerve ischemia.[15,16] These factors should be taken into consideration when planning for EVAR, and early efforts to address these complications came in the form of bell-bottom limbs.

BELL-BOTTOM TECHNIQUE

The bell-bottom technique, also known as the *flared limb technique,* may currently be the most commonly used technique to preserve flow into the IIA during EVAR, particularly now with the increased availability of larger-diameter iliac limbs. One can also use an aortic cuff, which has a maximum diameter of 36 mm. This technique assumes the dilated common iliac artery (CIA) as the healthy vessel and entails the use of a large-diameter iliac extension limb to seal the distal CIA in order to preserve the IIA. The advantages of this technique include its relative ease of use, accessibility, high technical success rates (described as high as 97%), and low type Ib endoleak rate (reported as low as 2%– 4%).[17,18] Most manufacturers provide iliac limbs of 27 to 28 mm, which can only seal in CIA diameters of up to 25 mm. As previously noted, aortic cuffs have also been used by physicians as iliac extensions for the treatment of slightly larger-diameter common IAAs (up to 30 mm). However, the long-term durability of the bell-bottom technique is unclear, as some have raised concerns over further aneurysmal dilation of the iliac artery with resultant stent-graft migration and type Ib endoleak.[19] In seeking more durable repair, physicians began employing various "sandwich" or "snorkel" techniques to gain more distal sealing in nonaneurysmal tissue.

Figure 2. The sandwich/double-barrel/internal iliac snorkel technique.

SANDWICH/DOUBLE-BARREL/INTERNAL ILIAC SNORKEL TECHNIQUE

The sandwich technique, also called the *double-barrel technique,* has been proposed as an alternative endovascular method to preserve the ipsilateral HA when treating CIAAs extending to or involving the iliac bifurcation (Figure 2).[20] As originally described by Lobato, the sandwich technique preserves either unilateral or bilateral

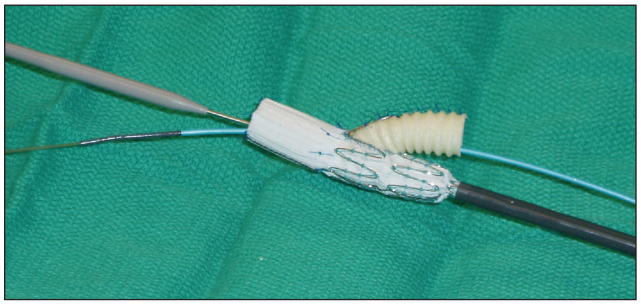


Figure 3. A physician-modified device.

IIAs. Several modifications to the technique have since been described, including avoiding arm access, use of unibody devices, and mixing of peripheral stent-grafts and EVAR limbs. DeRubertis et al[21] reported a technical success rate of 88% in 22 patients, with 9% early type III endoleaks between parallel stent-graft components. Early limb occlusion occurred in 9% (one in the external iliac artery [EIA], two in the HA), with primary patency for EIA and HA limbs at 6 months of 95% and 88%, respectively. Lobato et al reported better midterm outcomes in a more recent cohort of 40 patients, with a technical success rate of 100% and a primary patency rate of 93.8% (three HA occlusions).[22] The main advantages of the sandwich technique include the lack of size restrictions (ie, CIA diameter, HA length or diameter), lower potential cost, relative ease of the procedure, and the immediate availability of stent-grafts. However, potential concerns include gutter-related endoleaks and long-term limb patency.

SURGEON-MODIFIED/HOMEMADE GRAFTS

All of the aforementioned techniques are not purpose-specific solutions for the treatment of iliac aneurysms. Thus, it was obvious that industry would create IBDs to treat down to and include the EIA and HA. Although patients in many other countries have benefited from this technology for more than a decade, IBDs are still (as of February 2016) not commercially available in the United States. Like many of the previously described endovascular innovations, there were creative solutions sought in the United States, including several reports of homemade devices, with Oderich and Ricotta first describing the method of surgeon-modified IBDs for IAA treatment. Polyester or PTFE vascular grafts of 7 to 8 mm were sewn onto limbs, and either a self-expanding covered stent-graft or balloon-expandable covered stent-graft (ATRIUM® iCAST® Covered Stent) could be chosen as the bridging stents (Figure 3).[23] There has been a high technical success rate reported, and the short-term follow-up has been without issue, although it is limited to a small number of case reports. The basic limitation of this technique involves the regulatory issues involved in modification of a device and performing this electively without an investigational device exemption.

TRIFURCATION TECHNIQUE

The trifurcation technique, first described by Minion et al, employs the use of multiple main body bifurcated endografts.[24] Conceptually, the modular graft is built down from the renal arteries rather than up from the iliac arteries. This method, originally requiring bilateral femoral access in addition to brachial access, uses a "top-down" approach to facilitate cannulation of the HA, although later modifications allowed all femoral access. As described in the literature, after securing the infrarenal neck and placing a flared 20-mm-diameter limb into the proximal common iliac, a second 23-mm main body diameter GORE® EXCLUDER® AAA Endoprosthesis creates another bifurcation at the distal common iliac aneurysm, allowing a GORE® VIABAHN® Endoprosthesis to then be deployed to seal into the HA (Figure 4). The anatomic limitations of the trifurcated configuration are that it requires a large enough distal aortic diameter to fit the three limbs and a minimum of 16.5 cm in length from the lowest renal artery to the HA origin. Other possible disadvantages include higher procedural cost due to the use of multiple main bodies, increased length and complexity of procedure, and increased amount of contrast used.

ILIAC BRANCH DEVICES

The GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) is based upon the GORE® EXCLUDER® Device platform and has a modular concept of an iliac branch component mated to a bridging stent into the HA. The device is composed of two components: the Iliac Branch Component and the Internal Iliac Component. The Iliac Branch Component can be repositioned during deployment (via a two-stage deployment) to aid in internal iliac artery cannulation and to ensure accurate device placement. Additionally, the Iliac

Figure 4. A trifurcation.

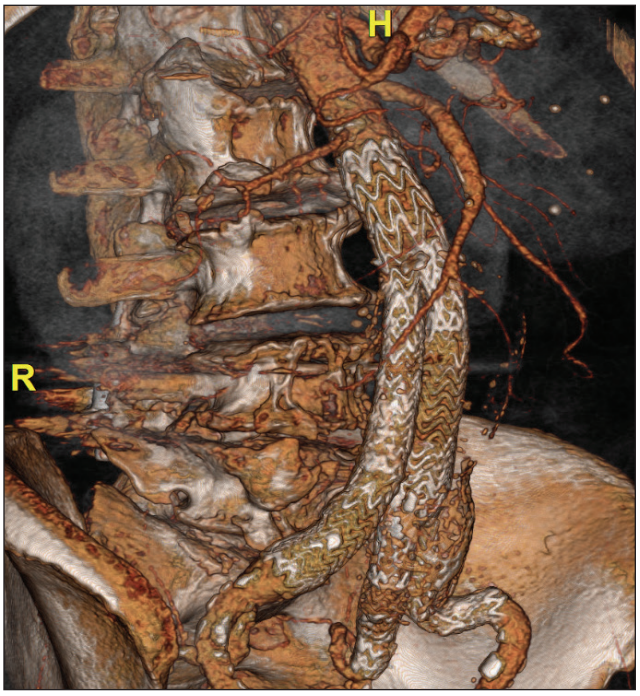


Figure 5. The GORE® EXCLUDER® Iliac Branch Endoprosthesis.

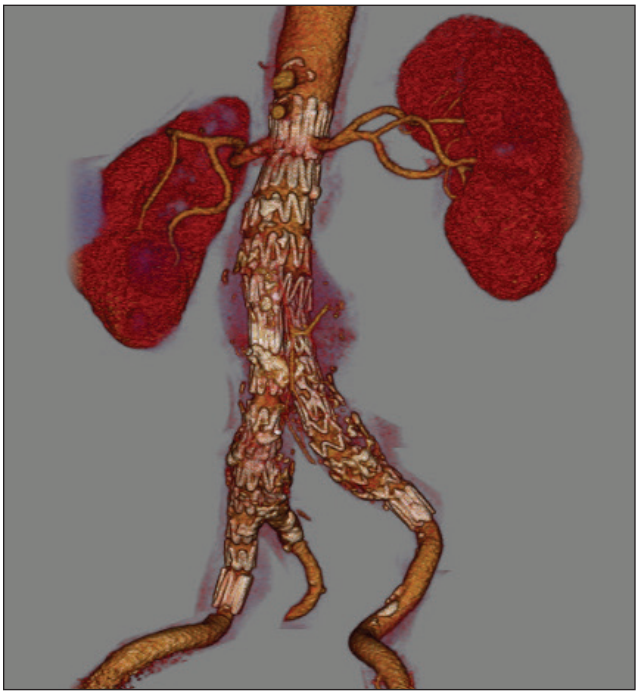


Figure 6. The COOK® ZENITH® Iliac Branch Endoprosthesis.

Branch Component features pre-cannulation of the IIA gate, which aids in ease of use. The devices also offer a broad treatment range, including an EIA treatment range of 6.5 to 25 mm and an IIA treatment range of 6.5 to 13.5 mm. The IBE is designed to be used with the GORE EXCLUDER Device, a AAA endograft with extensive commercial worldwide experience. Overall, the features and design of the IBE offer an all-in-one, user-friendly system that can preserve blood flow to the IIA while providing a durable solution for aneurysm exclusion.

Through 6 months, the results from the United States clinical trial demonstrate that the device offers an effective treatment for these patients with common iliac or aortoiliac aneurysms. Based on site-reported data for 62 patients enrolled during the primary enrollment, the United States clinical trial has shown an overall technical success rate of 95.2%, with an average procedure time of 151.8 minutes for implantation of both the IBE and GORE EXCLUDER Device (Figure 5). There have been no AAA enlargements (0%) reported through 6 months, with 100% patency of the EIA and 95% patency of the HA at 6 months. Additionally, there have been no reports of buttock claudication (0%) on the IBE treatment side and no reports of new-onset sexual dysfunction (0%). There was one reintervention through 6 months to address an EIA dissection distal to a bare-metal stent that was placed as a distal extension to the IBE during the index procedure. These data points are supported by commercial European experience, with reports demonstrating high technical success and positive clinical outcomes while avoiding complications related to sacrificing blood flow to the HA.[25,26]

The COOK® ZENITH® Iliac Branch Endoprosthesis consists of a side branch mounted on the medial side of an iliac limb stent-graft. An indwelling wire passing through the IIA branch can be snared from the contralateral femoral artery to create a through-and-through wire to allow for catheterization of the HA and stable positioning of a sheath to deliver the bridging component. The straight side arm has a relatively short (~14 mm) overlap zone that is intended for use with the balloon-expandable ATRIUM iCAST Covered Stent (Figure 6).

Since its initial conception, results associated with IBDs gradually improved with newer-generation devices and improved experience. In a literature review by Karthikesalingam et al,[27] nine series utilizing IBD (all being the Cook Medical IBD platform, including the COOK ZENITH Iliac Branch Endoprosthesis) were included, and early technical success was between 85% and 100% in these series. The review also revealed a collective 12% IBD limb occlusion rate, of which, 50% developed buttock claudication. In this review, the reported type I and III endoleaks were only 1.6%.

ANATOMIC SUITABILITY

As of February 2016, there are two iliac branch pivotal trials enrolling in the United States: the COOK PRESERVE-ZENITH® Iliac Branch System Clinical Study and the GORE EXCLUDER Iliac Branch Device Clinical Study. Based on the favorable experience noted in the previously mentioned clinical trials, as well as the author's personal experience and participation in both trials, US Food and Drug Administration approval for this important technology is on the horizon. As with any new

endovascular technology, however, careful patient selection is essential to technical success and durable outcomes, as not all the patients are anatomically suitable for these devices. Severe iliac tortuosity and aneurysmal involvement of the IIA can lead to increased procedural challenges and higher rates of type I and III endoleaks, as can issues with length, iliac stenosis, and angulation at the distal aorta.[28]

Studying the IFU for both devices that are currently in trial, there are some differences. The basic anatomic criterion of the COOK ZENITH Iliac Branch Endoprosthesis IFU include: EIA length > 20 mm, EIA diameter between 8 and 11 mm, HA length > 10 mm, HA diameter of 6 to 9 mm, and CIA length > 50 mm. The anatomic criterion of the GORE EXCLUDER Iliac Branch Endoprosthesis are mainly: CIA diameter > 17 mm, distance between the lowest renal artery and the iliac bifurcation > 165 mm, iliac bifurcation diameter > 14 mm, and HA diameter of 6 to 14 mm. Both devices are delivered using reasonably low-profile sheaths that are associated with high conformability in order to offer good adaptation, even in tortuous iliac arteries.

In a study conducted out of the University of Alabama Birmingham and Stanford,[29] Pearce et al found that if one strictly complies with the manufacturer's IFU, only about one-third of patients with IAAs treated over the past decade at those institutions would have been suitable for treatment with an IBD. The primary reasons for exclusion included dilated HA diameters, inadequate HA landing zones, and stenotic proximal CIAs. Although this was only a hypothetical study looking at inclusion/exclusion criteria, the anatomic fit was similar for the IBE and the COOK ZENITH Iliac Branch Endoprosthesis (25% vs 18%, respectively), while the anatomic fit was approximately 35% when assessed using combined criteria for both devices.

CONCLUSION

Up to 40% of AAAs have concomitant IAA disease, compromising the distal seal during standard EVAR. Although initially thought to be somewhat innocuous, the loss of HA patency has some ramifications, and EVAR technology has now evolved to be able to preserve hypogastric flow. Off-the-shelf creative solutions with standard EVAR devices, limbs, and peripheral stent-grafts in parallel configurations or with multiple main bodies all demonstrate good technical success and durability. However, the advent and inevitable approval of purpose-specific devices for iliac aneurysms should make these devices part of the armamentarium of the endovascular specialist. The main challenge of the current IBDs is their applicability to difficult anatomy. Future-generation design modifications, improved branch and bridging stents, and increasing experience may broaden its indication and likely improve results in the future. ■

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Global Perspectives on the Value of Internal Iliac Artery Preservation

Expert vascular surgeons share international experiences with iliac branch devices and the value of preservation.

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Literature has shown an increased risk of complications when internal iliac flow is not preserved during common iliac artery aneurysm repair. What impact do these complications have on patient quality of life (QOL) when they occur?

Prof. Schneider: Although life-threatening complications (such as colonic ischemia and spinal cord ischemia) rarely occur after coil embolization of the hypogastric artery during endovascular aneurysm repair (EVAR), buttock claudication and erectile dysfunction are quite common. Multiple studies have reported rates of buttock claudication of up to 50% and rates of erectile dysfunction up to 25% after EVAR using hypogastric artery "coil-and-cover" techniques. The incidence of these complications is even higher when both hypogastric arteries are sacrificed. Although not life-threatening complications, buttock claudication and erectile dysfunction can have a major impact on patient QOL that should neither be minimized nor ignored.

Dr. Neale: The complications of buttock claudication, erectile dysfunction, and colonic ischemia will affect different patient groups differently. It is, of course, desirable to avoid colonic ischemia in all patients, as development of this complication (depending on severity) will increase risk of bacterial translocation, early stent-graft infection, or need for urgent surgery with the possibility of major morbidity (particularly in a high-risk, elderly patient cohort), the QOL impact of a possible stoma, and potential for further surgery for stoma reversal if required/possible. Risk for colonic ischemia is partly determined by the anatomical situation prior to stent-graft implantation (ie, patency of the internal mammary artery and number of patent internal iliac arteries [IIAs]), and this may affect both risk to the patient and QOL outcomes.

Erectile dysfunction and buttock claudication are perhaps of less concern, depending on the patient's preoperative state. Elderly patients with pre-existing impotence and limited mobility are less likely to suffer any significant effect on QOL because they are unlikely to be functionally/symptomatically different postoperatively (again, particularly if contralateral IIA patency is maintained). Younger patients, however, who are potent and active preoperatively will find a significantly greater decrease in QOL if either impotence or buttock claudication were to develop postoperatively.

Dr. Fernández Noya: We know that when we perform unilateral occlusion of the IIA to deal with ectatic iliac arteries, the risk of complications (buttock claudication, sexual dysfunction, or more nefarious complications such as spinal or bowel ischemia) increases from 12% up to 37%, so it seems that the preservation of the IIA is reasonable. Occlusion of both IIAs can be even worse, however, because in these cases, the risk of colonic and spinal ischemia is increased, with a significant increase in

morbidity and mortality. Therefore, it seems mandatory to preserve at least one IIA.

Buttock claudication and erectile impotence obviously make the QOL worse for these patients. These complications are usually poorly tolerated, mainly in the younger patients, due to the limitations in daily lifestyle, sometimes for their entire lives, and this should be explained to the patients before the procedures.

Before iliac branch devices were available in your region, what steps were taken to mitigate these risks? What were the pros/cons of these methods of iliac preservation?

Prof. Schneider: As of February 2016, iliac branch devices were not yet commercially available in the United States, but hopefully, they will be very soon. Consequently, a variety of endovascular methods have been used (and still are) to preserve hypogastric artery perfusion. Although these methods can be effective in mitigating the risk of developing pelvic ischemic complications, many involve off-label use of commercially available devices (for chimney/snorkel and trifurcated graft techniques) or use of physician-modified endografts. Oftentimes, brachial artery access is needed for delivery of stent-grafts into the hypogastric arteries, adding additional procedural complexity and risks. There are also anatomic limitations that may preclude the use of certain techniques, such as a requirement for a long common iliac artery (CIA) length to be able to perform the trifurcated endografts technique. Moreover, chimney/snorkel and trifurcated graft techniques may have increased risks of endoleak from gutters, component separation, and limb occlusions.

Open surgical repair is also still used, although with decreasing frequency, to preserve hypogastric artery perfusion in patients with aortoiliac aneurysms. This may involve a hybrid approach with an external iliac–to–internal iliac bypass and EVAR or a completely open surgical aneurysm repair. Although open repair may have better durability than EVAR, the obvious downside is the increased risk of morbidity and mortality associated with open versus endovascular repairs. Open repair itself also has associated risks of colonic ischemia and sexual dysfunction due to autonomic sympathetic nerve injury that may make endovascular therapy with iliac preservation a more attractive alternative.

Dr. Fernández Noya: At the beginning of the EVAR era, I think that the most common approach was the coil-and-cover technique with the placement of some form of occlusion in the internal iliac and then extended down into the external iliac. Due to some of the complications seen with internal iliac occlusion, we started to change our approach by trying to preserve the internal iliacs. We began using the "bell-bottom" technique, which is a technically easy approach, but has a high rate of endoleaks at follow-up due to early device failure because we are landing the graft in an unhealthy area.

After the initial experience and the publications from Lobato et al,[1] we began using parallel grafting techniques to preserve the internal iliacs. The advantage of this approach is that the material needed is usually in our daily armamentarium, but some disadvantages are that we don't have long-term follow-up, potential compression of parallel grafts, and brachial/axillary access increases the risk of thrombosis and potentially stroke.

Dr. Neale: Iliac branch devices have been available for many years now in Australia, before concepts such as chimneys and snorkels were even considered. Prior to their availability, if there was considerable concern for major morbidity related to IIA occlusion, most surgeons would have considered this a reason for open abdominal aortic aneurysm repair with surgical preservation of at least one IIA. The obvious disadvantage of this is increased complexity for open repair and increased morbidity/mortality with the open procedure. The advantage, of course, is a good long-term outcome. If endovascular repair were preferred, then patency of the contralateral IIA would have been considered the main deciding factor.

If a good contralateral IIA were to be maintained, then the risk of major morbidity (colonic ischemia) would be deemed very low. Buttock claudication on the side of occlusion would be quite likely and accepted early, recognizing that many would improve (although not always completely) over approximately 3 months. If there was no improvement, consideration could then be given to further surgical reconstruction with external iliac artery (EIA)-IIA bypass (this is rarely considered at the time of initial repair in the presence of a patent contralateral IIA).

Prior to branch devices, if the contralateral IIA was occluded or the CIA was unsuitable as a landing zone bilaterally, then this may have been cause for open repair. In some patients, EIA-IIA bypass at the same time as EVAR has been utilized. This is considered a lesser procedure than formal open repair, as the EIA-IIA bypass can be done through an extraperitoneal approach in the appropriate iliac fossa. However, this would generally only be done unilaterally. If preservation of both IIAs was preferred, open repair would have been the most likely solution, although with higher morbidity/mortality associated with the procedure. The other approach early on was simply "flaring" into a dilated CIA with custom flared limbs or the use of large-diameter cuffs to extend a limb. The obvious concern here was late failure of these flared devices due to ongoing aneurysmal dilatation.

How has the iliac aneurysm treatment paradigm shifted since iliac branch devices became available in your region? If there has been a significant shift, how quickly did the transition from embolization to preservation occur? What do you feel were the key reasons for this change?

Dr. Fernández Noya: Since iliac branch devices became available, we have changed our daily practice in these patients. Our first option is to try to maintain the patency of both internal iliacs, even in the cases when we need to use bilateral devices. The transition was quick and smooth, because if you have experience with EVAR, there isn't a long learning curve to use iliac branch devices safely. I think that the branch iliac technique is technically less challenging than the parallel stent-graft techniques, and for these reasons, we shifted our practice.

We started our experience using the COOK® ZENITH® Iliac Branch Device, with good results. As vascular surgeons, we always sought to preserve the arterial patency, and at the beginning of our practice with the branch devices, we had some technical limitations, especially in the angulated anatomies. We switched to using the GORE® EXCLUDER® Iliac Branch Endoprosthesis,* and we now feel comfortable and secure treating our patients, even those who present with the most challenging cases (angulated or bilateral), because the device is easy to use, conformable, low profile, and specifically designed for the iliac anatomy.

Dr. Neale: Iliac branch devices became available in Australia after fenestration technology. Most Australian surgeons therefore became comfortable with complex endovascular techniques very early. The transition to adding iliac branch devices into the armamentarium of Australian surgeons was relatively easy and taken up quite early. The fact that much of the early experience and development of these devices occurred in Australia (along with fenestrated technology) meant that Australian surgeons had good early exposure to these concepts. Being a country with a relatively small population and limited numbers of vascular surgeons, the training and uptake of these techniques among the vascular surgical community was also quite rapid. However, in the early experience, most surgeons would initially have considered branch devices mainly where the contralateral IIA was already occluded or in a situation where it was required to occlude one and preserve the other.

As experience increased, however, preservation of both IIAs, where possible, was quite quickly accepted by many as the best possible option, recognizing that not all IIAs can be preserved (either due to anatomy or IIA aneurysms). The increase in availability of more branch devices has increased the number of cases where IIA preservation can be performed due to different characteristics of different devices.

Prof. Schneider: A paradigm shift has not yet taken place in the United States because we have not had access to iliac branch devices, but I do predict that a real paradigm shift is coming. Recognizing the significant impact of buttock claudication and erectile dysfunction on patient QOL, some physicians have adopted various techniques for iliac preservation into their practice. That being said, many physicians in the United States still treat aortoiliac aneurysms with traditional coil-and-cover techniques. I expect that to change once iliac branch devices become commercially available in the United States.

This paradigm shift will be driven by a growing appreciation for the frequency and negative effects of pelvic ischemic complications after EVAR with hypogastric artery coil-and-cover techniques on patient QOL. Once iliac branch devices are available and more physicians become comfortable with the technology, I predict that it will become the preferred approach in the United States. Given the choice, most patients will opt for treatment with an iliac branch device or seek out a physician who offers the technology. Although there may be some increased cost associated with use of iliac branch devices, it will likely be offset by the costs associated with the alternative endovascular techniques (coils and added stent-graft components), as well as the beneficial impact on patient outcomes.

How would you describe the "value of preservation" based on your experience with the various iliac aneurysm treatment options?

Dr. Neale: In early experience with stent-grafts using IIA embolization and extension to the EIA, it was generally believed that the risk of colonic ischemia was low (as long as one IIA remained patent) and that buttock claudication/erectile dysfunction was a reasonable trade-off for the morbidity of open repair (particularly in the older patient group). These risks, however, were less acceptable in a younger patient population, leading to decisions to undergo open repair rather than EVAR in those patients in whom it was considered unacceptable (especially risks of erectile dysfunction in younger men). The options for preservation of IIA flow (either unilateral or even bilateral) have therefore considerably changed the management options, particularly in the younger patient cohort, allowing the benefits of minimally invasive repair in a group of patients who would potentially have been subjected to higher risks.

As time has gone on, good long-term outcomes have been seen with these devices, and it is now generally considered reasonable to attempt preservation of all IIAs wherever possible, particularly in the younger population. The overall procedural risk is reduced compared to open surgery, as well as the risks of adverse outcomes such

*CE Mark Approved. Caution: Investigational Device. Limited by United States law to Investigational Use.

as colonic ischemia, erectile dysfunction, and buttock claudication, thereby maintaining QOL of the patient.

With an increase in the number of available devices, more patients can be treated in this way. As more patients are treated with IIA preservation, the ease with which these procedures can generally be performed becomes apparent, with minimal increase in operating time or risk utilizing these techniques. Ultimately, this reduces the likelihood for secondary interventions due to complications of the procedure or late failures, as can be seen with suboptimal procedures without IIA preservation (such as IIA embolization or "flared" limbs). Although these may seem like simpler options in the short term, they are more likely to lead to more complex repairs at a later date. Early IIA preservation with branched devices therefore becomes preferable, confirming the value of preservation.

Prof. Schneider: I have had patients come back with complaints of buttock claudication after hypogastric artery coil embolization, and for a significant number of patients, this is a very bothersome and persistent problem that affects them on a daily basis. To avoid this complication, I have tried to preserve hypogastric artery perfusion whenever appropriate, and I have tried most of the described iliac aneurysm treatment options. I have also been fortunate to have access to iliac branch devices through clinical trials, and these are valuable devices that can improve the way we treat patients with iliac aneurysms. Importantly, when we successfully preserve pelvic perfusion during EVAR, patients do not get buttock claudication or other pelvic ischemia complications.

All of the various treatment options to preserve pelvic perfusion can be used to successfully treat iliac aneurysms and to prevent ischemic complications. The availability of dedicated iliac branch device systems can make the treatment simpler and safer and, hopefully, with even better long-term outcomes. Of course, the treatment of each patient should be individualized, taking into account patient age, lifestyle, sexual function, and anatomy. Traditional coil-and-cover approaches may still be appropriate for some elderly patients who are sedentary or who have pre-existing erectile dysfunction and have poor anatomy for an iliac branch device. However, the majority of patients with suitable anatomy are best served by pelvic preservation with an iliac branch device. In my opinion, preservation of pelvic perfusion should be one of the primary goals during treatment of aortoiliac aneurysms with EVAR.

Dr. Fernández Noya: Our goal is to preserve arterial patency in the vast majority of our procedures. At the beginning of our EVAR experience, we had some important complications due to internal iliac occlusion, even in the staged procedures. These complications were typically observed in the first hours after the procedure but we were usually satisfied with the initial outcome. Initially, the patients were really happy because the procedure went well without complications. However, at short-term follow-up, "minor complications" (eg, buttock claudication and sexual dysfunction) were observed when they came back to our office, and they were not so happy because their QOL was worse after the procedure, and these symptoms can last a lifetime in up to 50% of these patients.

QOL is actually one of the more important items in the follow-up of our patients. If QOL diminishes after our procedures, we can't be satisfied. For this reason, we must always try to preserve or improve patients' QOL using all the tools in our armamentarium. ■

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Initial Experience With the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis

An overview of device characteristics and case reports from the first three worldwide implantation procedures.

BY GUSTAVO S. ODERICH, MD, AND PIERRE GALVAGNI SILVEIRA, MD, PHD

Endovascular aortic aneurysm repair (EVAR) has become the first choice of treatment in patients with abdominal aortic aneurysms (AAAs) and suitable anatomy. Approximately 40% of the patients do not meet the anatomical requirements for EVAR because of inadequate necks or involvement of side branches. In these patients, innovative techniques to incorporate the visceral arteries have expanded the indications of EVAR using parallel, fenestrated, and branched stent-grafts. Large clinical series and systematic reviews have shown high technical success and lower morbidity and mortality rates compared to historical open surgical repair.[1-5]

Current challenges with the techniques of visceral endovascular incorporation are the limited physician access to fenestrated and branched stent-grafts, excessive time delay required for patient-specific customizations, and lack of a bridging stent-graft that is specially designed to target the visceral arteries. The GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE) introduces a novel concept, which is based on the GORE® EXCLUDER® AAA Device platform using a nitinol stent frame and conformable ePTFE technology. The device is intended to be used with the balloon-expandable GORE® VIABAHN® BX Endoprosthesis or the self-expandable GORE® VIABAHN® Endoprosthesis covered stent-grafts, offering two alternative options to tailor treatment to the patient's anatomy. It is currently being investigated in early feasibility clinical trials intended for endovascular repair of thoracoabdominal and pararenal aortic aneurysms. The first implantation was performed by Dr. Pierre Galvagni Silveira and colleagues at the Universidade Federal de Santa Catarina in Florianopolis, Brazil, and the first United States implantation was recently performed by Dr. Gustavo Oderich and the Mayo Clinic team in Rochester, Minnesota. This preliminary report summarizes the device characteristics and the initial clinical experience with the first three patients treated worldwide.

DEVICE DESCRIPTION

The TAMBE is an off-the-shelf, modular, multi-component system (Figure 1) composed of a proximal multibranched aortic component, a distal bifurcated component, and iliac limb extensions. The preferred side branch component is a specially designed balloon-expandable covered stent-graft, the GORE VIABAHN BX Endoprosthesis. Unique characteristics of the GORE VIABAHN BX Endoprosthesis bridging stent-graft are that it couples the radial force, reliable deployment, and relative low profile (7–8 F) of a balloon-expandable stent-graft with flexibility comparable to a self-expandable stent-graft. The side branch components have CBAS® Heparin Surface.

The TAMBE has been designed with retrograde renal portals. The first three clinical cases that are described herein used two retrograde renal portals and two antegrade portals for the celiac axis and superior mesenteric artery (SMA). Device dimensions include proximal diameters of 26, 31, and 37 mm; length of 215 mm; and distal diameter of 20 mm. An alternate configuration is being evaluated, utilizing four antegrade portals. This antegrade configuration is not yet approved for use in existing clinical studies. A 22-F transfemoral introducer is required for the aortic device, and a 12-F brachial or axillary artery introducer is needed for access into the antegrade portals.

Figure 1. The GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis with two antegrade portals for the celiac axis and SMA and two retrograde portals for the renal arteries. The portals are bridged to the target visceral arteries using a GORE® VIABAHN® BX Endoprosthesis, which is also shown.

The aortic component allows for placement of through-and-through preloaded guidewires, eliminating the need to catheterize the portal to access the target vessel. To facilitate placement of the guidewires and prevent guidewire wrapping within the aorta, a specially designed triple-lumen catheter is inserted from the brachial approach and exteriorized via the femoral access.

ANATOMICAL FEASIBILITY

Anatomical feasibility of the TAMBE is based on predictable anatomy of the visceral arteries as previously reported by Mendes and colleagues.[6] It is anticipated that > 80% of patients with complex abdominal or thoracoabdominal aortic aneurysms (TAAAs) will meet the requirement of vessel incorporation. Limitations precluding anatomical feasibility include excessive angulation, unsuitable targets because of small diameter, occlusive disease or early bifurcation, and previous open or endovascular aortic repair with a short distance between the renal arteries and the aortic bifurcation.

TECHNIQUE

The initial experience with the TAMBE and a general approach to endovascular TAAA repair are outlined in the following sections. Variations in this technique reflect physician preference, center experience, and patient anatomy.

Perioperative Management

Preventive measures for spinal cord injury have been adopted in most centers with larger clinical experience with endovascular TAAA repair. These measures have been applied to all patients undergoing endovascular TAAA repair with > 5 cm coverage above the celiac artery. At the Mayo Clinic, preventive measures have included permissive hypertension with target mean arterial pressure ≥ 80 mm Hg, routine prophylactic cerebrospinal fluid drainage, early lower limb reperfusion, neuromonitoring to adjust intraoperative cerebrospinal fluid pressure and mean arterial pressure goals, and staged repairs for extensive TAAAs.

Preadmission is considered in patients with chronic kidney disease and an estimated glomerular filtration rate < 60 mL/min and those of advanced age and very complex anatomy. Patients undergo gentle bowel preparation with intravenous hydration with bicarbonate infusion and oral acetylcysteine. Acetylsalicylic acid is started or continued prior to the operation. Perioperative antibiotics are administrated intravenously prior to incision and are redosed up to 24 hours after the procedure.

General Approach

The operation is performed under general endotracheal anesthesia with fixed imaging in a hybrid endovascular suite. Ideally, the option of fusion imaging facilitates branch catheterization and minimizes contrast use. Intraoperative blood salvage ("cell-saver") may be considered if difficulties or prolonged operating time are anticipated. The use of iodinated contrast is minimized using small hand injections and diluted contrast for aortography.

Patients are positioned supine with the imaging unit oriented from the head of the table. Arterial access is achieved via bilateral femoral and left brachial approaches. The brachial artery is accessed high in the axilla, unless the artery is small (< 4 mm), in which case, it can be accessed in the infraclavicular fossa. Percutaneous bilateral femoral access is used whenever possible, except for in patients with high femoral bifurcations or dense calcifications. The patient is systemically heparinized with an intravenous bolus of heparin (80–100 units/kg), which is administered immediately after femoral and brachial access are established. The activated clotting time is kept > 250 seconds and is rechecked every 30 minutes. A continuous drip of heparin (500–1,000 units/ hour) is also started, and diuresis is induced with intravenous mannitol and/or furosemide.

Device Deployment

There is variation in the deployment sequence of the TAMBE in the first three cases. Figures 2 through 4 reflect preferences used in the third TAMBE case, which was performed at the Mayo Clinic, to optimize lower ischemia reperfusion. After through-and-through access is established (Figure 2A), the device is loaded in the three guidewires and advanced into position with the

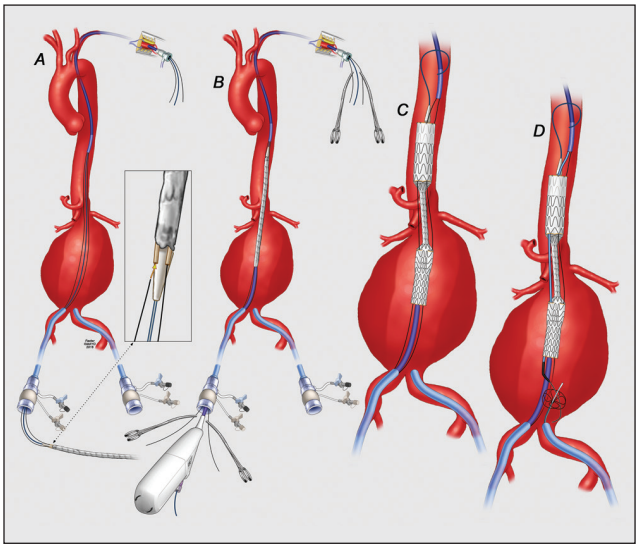

Figure 2. Procedure steps include placement of through-and-through preloaded wires (A), device positioning with antegrade portals above the celiac axis and SMA and retrograde portals below the renal arteries (B), partial deployment (C), and rerouting of guidewires to the left femoral access site using a snare (D).

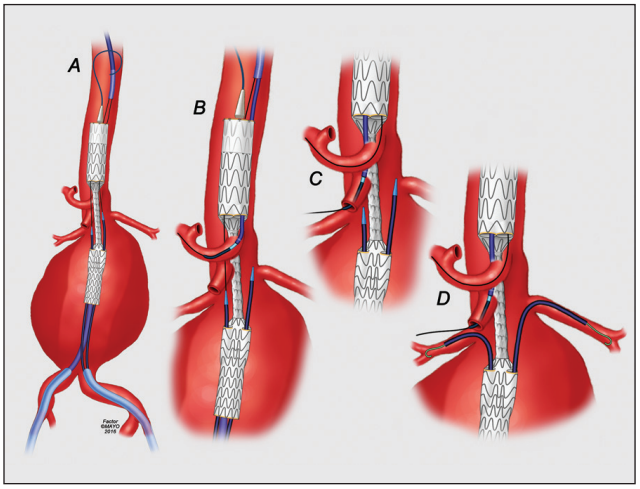

Figure 3. Placement of 7-F COOK® FLEXOR® ANSEL Guiding Sheaths into the renal portals (A) followed by selective catheterization of the celiac axis (B), SMA (C), and renal arteries (D).

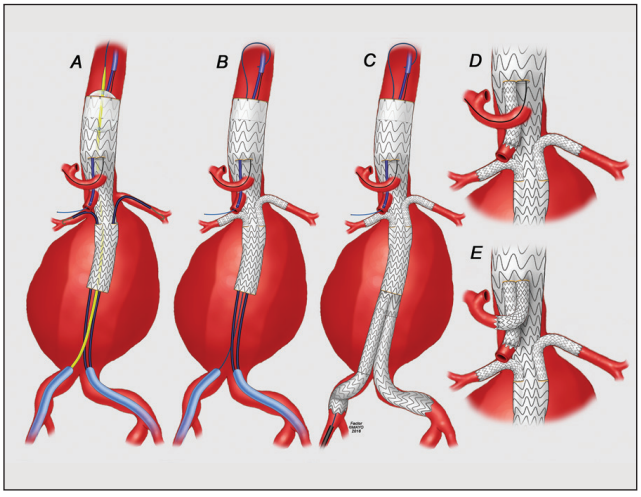

Figure 4. Dilatation of the proximal neck after device deployment (A) followed by placement of renal stent-grafts (B) and bifurcated distal device and iliac limbs with restoration of lower limb perfusion (C). The procedure is completed by placing the SMA and celiac stent-grafts (D, E).

antegrade portals above the celiac and SMA and both renal portals approximately 2 to 3 cm below the renal arteries (Figure 2B). The device has a stepwise deployment system, which allows the top part of the device to be partially constrained and the mid-segment to be completely constrained, facilitating branch vessel catheterization (Figure 2C). Catheters are advanced sequentially from the brachial access via each of the preloaded 0.014-inch guidewires and used to reroute the wires to the left femoral approach using a snare (Figure 2D).

Using the preloaded guidewires, 7-F COOK® FLEXOR® ANSEL Guiding Sheaths are advanced into the renal portals (Figure 3A). An 8-F COOK® FLEXOR® RAABE Guiding Sheath is advanced from the left brachial approach into the celiac axis portal (Figure 3B). The celiac axis is catheterized using a "buddy" catheter and TERUMO RADIFOCUS® GLIDEWIRE® ADVANTAGE Guidewire, which is exchanged for a 0.018-inch stiff guidewire that is placed within the distal splenic artery. The sheath is withdrawn over the 0.018-inch wire and reintroduced over the preloaded SMA guidewire into the SMA portal (Figure 3C). The SMA is catheterized, and an 8-F COOK FLEXOR RAABE Guiding Sheath is advanced over a 0.035-inch COOK® AMPLATZ Fixed Core Wire Guide into the SMA. Both preloaded 0.014-inch through-and-through guidewires are withdrawn via the renal sheaths to allow space within the 12-F brachial sheath. Sequential renal catheterization is performed via the femoral approach (Figure 3D), and the 7-F COOK FLEXOR ANSEL Guiding Sheaths are advanced into each of the renal arteries over 0.035-inch COOK® ROSEN Wire Guides.

The TAMBE is completely deployed once all vessels are secured. This step is optional, given that the device can be kept constrained and the side branches can be deployed even prior to completely opening the mid-segment. However, to minimize lower extremity ischemia time and to allow immediate balloon dilatation of the proximal landing zone, the device can also be completely deployed as depicted in Figure 4A. A COOK® CODA® Balloon Catheter is used to dilate the proximal sealing zone and the visceral segment of the aorta. The renal GORE VIABAHN BX Endoprosthesis stent-grafts are deployed first (Figure 4B), followed by placement of the bifurcated distal device and iliac limbs (Figure 4C). Flow is restored to both lower extremities while femoral guidewire access is maintained using a percutaneous technique. The procedure is completed by placing the SMA and celiac GORE VIABAHN BX Endoprosthesis stent-grafts in a sequential fashion (Figure 4D and 4E), followed by completion angiography.

EARLY FEASIBILITY STUDIES

The early feasibility studies aim to evaluate the first-in-human experience with the TAMBE in 10 patients enrolled in up to six United States centers and one non–United States center. For the United States early feasibility study, the National Principal Investigator for the early feasibility study is Dr. Michel Makaroun from the University of Pittsburgh Medical Center. Inclusion criteria for the study are restrictive to select patients who fit ideal anatomical conditions for branch vessel incorporation, without excessive tortuosity, angulation, occlusive disease, or excessive aortic debris. Anatomical requirements are aneurysm involvement of the renal and mesenteric arteries that is not suitable for EVAR using standard devices, presence of parallel-walled sealing zones in the distal thoracic and in the common iliac arteries, four-vessel visceral branch anatomy with minimum diameter of 4 mm, no early bifurcation or significant occlusive disease,

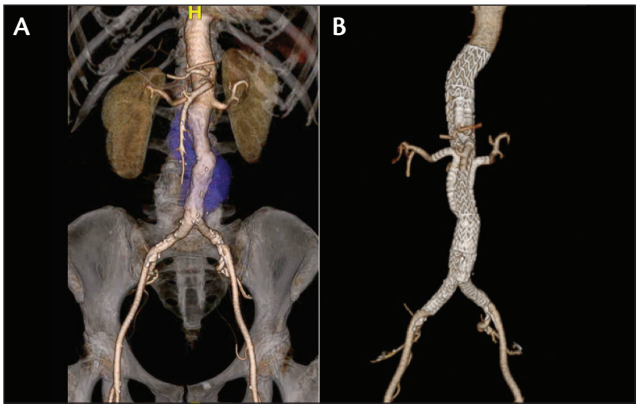

Figure 5. The first worldwide case performed in Florianopolis, Brazil, by Dr. Pierre Galvagni and colleagues at the Universidade Federal de Santa Catarina. Preoperative (A) and postoperative (B) CTA demonstrating widely patent stent-grafts and no endoleak at 1 year.

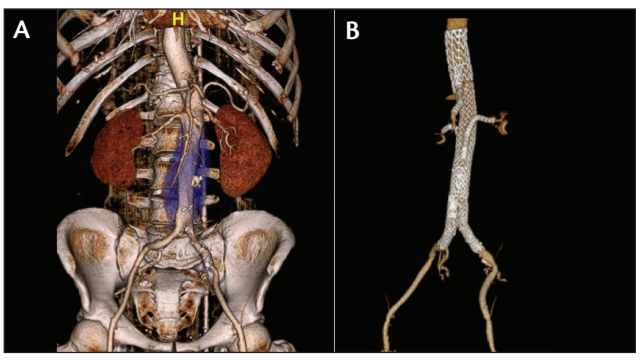

Figure 6. The second worldwide case performed in Florianopolis, Brazil, by Dr. Pierre Galvagni and colleagues at the Universidade Federal de Santa Catarina. Preoperative (A) and postoperative (B) CTA demonstrating widely patent stent-grafts and no endoleak at 1 year.

absence of significant atheromatous debris within the aorta, and no previous open repair or EVAR.

Preliminary Early Results

Three patients have been successfully implanted with 100% technical success and no branch vessel complications, endoleaks, ruptures, or conversions. The following sections provide a brief description of these first three cases.

Cases 1 and 2

The first and second TAMBE implants were performed in Florianopolis, Brazil, by Dr. Pierre Galvagni Silveira and colleagues at the Universidade Federal de Santa Catarina. The first patient was a 68-year-old woman with a 5.2-cm complex AAA (Figure 5), and the second was a 56-year-old man with a 5.6-cm complex AAA (Figure 6). The first patient had a history of hypertension and chronic obstructive pulmonary disease, and the second had hypertension. Implantation of the TAMBE was completed with no technical problems in either patient, with widely patent branches and no postoperative complications. The patients were dismissed from the intensive care unit on the first day and from the hospital on the fourth and third postoperative days, respectively. The first patient developed an occlusion of the right common femoral artery access site early after dismissal, which required a 1-day readmission to the hospital for open surgical thrombectomy. Both patients completed 1-year follow-up with no other complications and had repeat computed tomographic angiography (CTA) studies, which demonstrated successful aneurysm exclusion with no endoleaks, no sac enlargement, and widely patent side stent-grafts.

Case 3

The third patient was a 79-year-old man with large 9-cm type IV TAAA. His medical history was notable for past smoking, hypertension, hyperlipidemia, ischemic cardiomyopathy, and moderate chronic obstructive pulmonary disease. CTA demonstrated a large 9-cm aneurysm with aortic irregularity starting at the level of the celiac axis (Figure 7). The patient underwent endovascular repair using the TAMBE and was dismissed home on postoperative day 3 with no complications.

DISCUSSION

The TAMBE is currently under investigation and offers the potential benefits of an off-the-shelf stent-graft with wide anatomical applicability and ease of technical implantation using conformable technology and a specifically designed bridging stent-graft. The retrograde renal portal offers potential advantages in select patients with an up-going renal artery configuration or in those with a narrow aortic segment and limited space between the SMA and renal origins to fit an all-antegrade design. Off-the-shelf availability will decrease or eliminate any time delay in treating a large aneurysm, which currently averages a minimum of 8 weeks with patient-specific stent-grafts. Finally, the versatility of multiple branches, preloaded guidewires, constrained mid-segment, and stepwise deployment system all facilitate procedural steps, decreasing the need for a high degree of precision during device implantation, which is a requirement for fenestrated stent-grafts.[3]

The TAMBE is the first TAAA device design to be developed with a specific bridging stent-graft. Characteristics of this stent-graft include its balloon-expandable platform with the benefits of reliable deployment and radial force needed to treat visceral targets, coupled with conformability and flexibility, which is comparable to what can be achieved with a self-expandable platform. Results of this stent-graft combination need to be compared with traditional visceral incorporation techniques using either fenestrations or

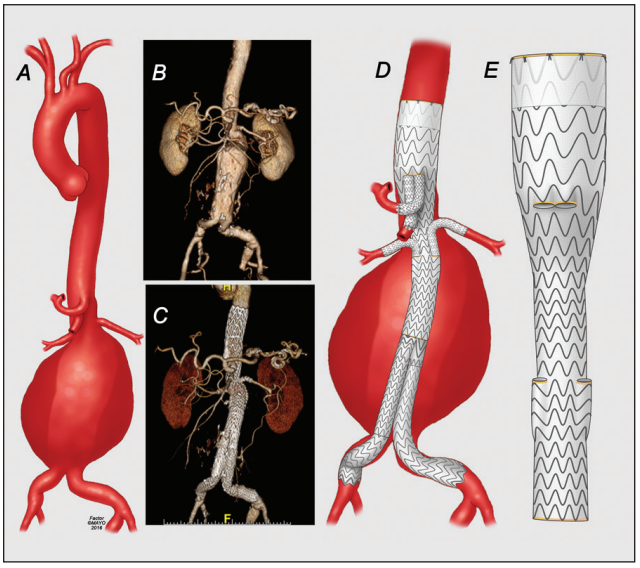

Figure 7. The third worldwide and first United States case performed at the Mayo Clinic in Rochester, Minnesota, by Dr. Gustavo Oderich and colleagues. Artist depiction shows the aneurysm (A) and preoperative (B) and postoperative (C) CTA. Artist depiction of the treated aneurysm (D) and the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (E).

branches. Previous studies have shown that occlusion rates are exceptionally low for renal fenestrations (2%–5% at 5 years), but some disadvantages are the risk of type I or III endoleaks originating from the fenestration attachment or even branch disconnection, particularly when fenestrations are to target vessels that originate from large aortic segments.[1-5] Unfortunately, there is no consensus on the ideal stent-graft, and investigators have used a wide combination of self-expandable stent-grafts or balloon-expandable covered stent-grafts, with or without reinforcement with a self-expandable bare-metal stent-graft, limiting future comparisons. Although the GORE VIABAHN BX Endoprosthesis has all the ideal characteristics that are needed to optimize patency and seal with the portals and target vessels, long-term data with larger clinical experiences are needed using retrograde designs for adequate comparisons with other fenestrated, branched, and parallel stent-graft techniques.

Simplification of the procedure steps is a critical area of improvement when dealing with complex EVAR cases. The TAMBE uses preloaded guidewire systems, which have been previously described with fenestrated and branched endografts. The guidewires eliminate the need to catheterize the portals prior to catheterization of the branch itself. Because the bridging stent-graft is balloon expandable and conforms, several of the steps needed with self-expandable stent-grafts (postdilatation and reinforcement with bare-metal stent-grafts) are eliminated. These improvements, which aim to simplify procedure steps, may help to significantly reduce procedure time and the deleterious consequences of prolonged lower extremity ischemia, including the risk of spinal cord injury and other systemic complications. Still, there are important limitations to the TAMBE, as with any other endovascular technique used to incorporate visceral branches. The most important limitations are inadequate renal artery anatomy because of small diameter, multiple accessory renal arteries, or early bifurcation; difficult access; and lack of adequate landing zones.

CONCLUSION

Techniques of branch vessel incorporation continue to evolve. The TAMBE offers a novel concept using ePTFE and conformable technology. Its use with the GORE VIABAHN BX Endoprosthesis stent-graft to target visceral arteries will greatly facilitate steps of the procedure. The experience accumulated in select centers during the early feasibility study allows for initial testing and proof of concept of this design with first-in-human application in order to evaluate device concept with respect to clinical safety and functionality. ■

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Long-Term Data Supporting the Conformable GORE® TAG® Thoracic Endoprosthesis in DTA Pathologies

An overview of the recent data that confirm positive results when using this device to treat both acute and chronic conditions of the descending thoracic aorta.

BY MARK A. FARBER, MD; RICHARD CAMBRIA, MD; AND WILLIAM JORDAN, MD

In 2005, the GORE® TAG® Thoracic Endoprosthesis was approved by the US Food and Drug Administration (FDA) for the endovascular treatment of aneurysms of the descending thoracic aorta (DTA). Since then, physicians have used endovascular devices to treat a wide variety of conditions affecting the thoracic aorta. Under direction from the FDA, approved devices would subsequently receive broad approval for treating DTA lesions, including aneurysmal disease, traumatic transections, and type B aortic dissections. The first device to successfully obtain approval through this expanded process was the Conformable GORE® TAG® Thoracic Endoprosthesis (Figure 1).

Although approval generally hinges upon 1-year endpoint criteria, post-approval studies and follow-up data out to 5 years are mandated by the FDA. The Conformable GORE TAG Device began the regulatory process with the FDA in 2011, and since that time, there has been a significant amount of data collected supporting its use in all pathologies of the DTA. This article concentrates on longer-term clinical study data supporting its continued use in managing patients with both acute and chronic DTA conditions.

THORACIC AORTIC ANEURYSMS

The initial Conformable GORE TAG Device IDE was undertaken in patients with aneurysmal pathology. In this clinical trial (Thoracic Endoprosthesis for Treatment of Aneurysm of the Descending Thoracic Aortic, TAG 08-03), the Conformable GORE TAG Device was implanted in 66 patients with aneurysms involving the DTA. The clinical trial data were published in March 2015.[1] As of December 2015, there has only been one reported aortic rupture at 3.6 years that occurred in a segment separate from the treated area. There have been no device compressions or fractures associated with the device. The mean follow-up of this cohort is now 43.5 months, with 24 (36%) of the 66 patients having completed their 5-year follow-up protocol and 43 (65%) having data reported through 4 years of follow-up. Endoleaks have been reported in four patients at 4 years and include one type I, two type II, and one that was indeterminate. One device finding included the presence of clinically insignificant thrombus on the initial postoperative CT scan, while another patient had clinically insignificant interdevice movement, as the aneurysm changed morphology from core lab analysis.

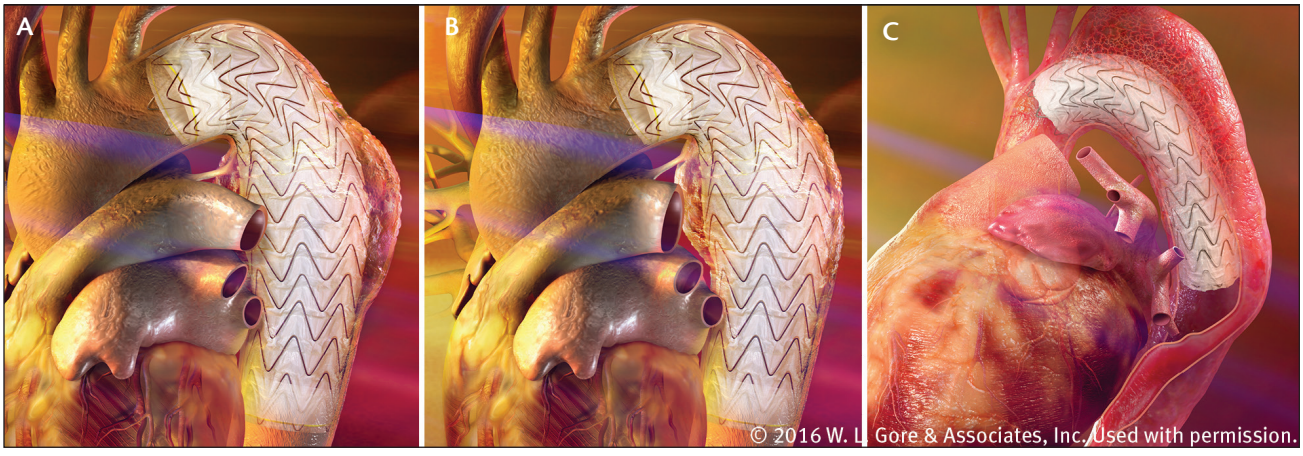

Figure 1. The Conformable GORE® TAG® Thoracic Endoprosthesis pictured is an artist's rendering in all three major etiologies: treatment of an aneurysm (A), traumatic transection (B), and type B aortic dissection (C).

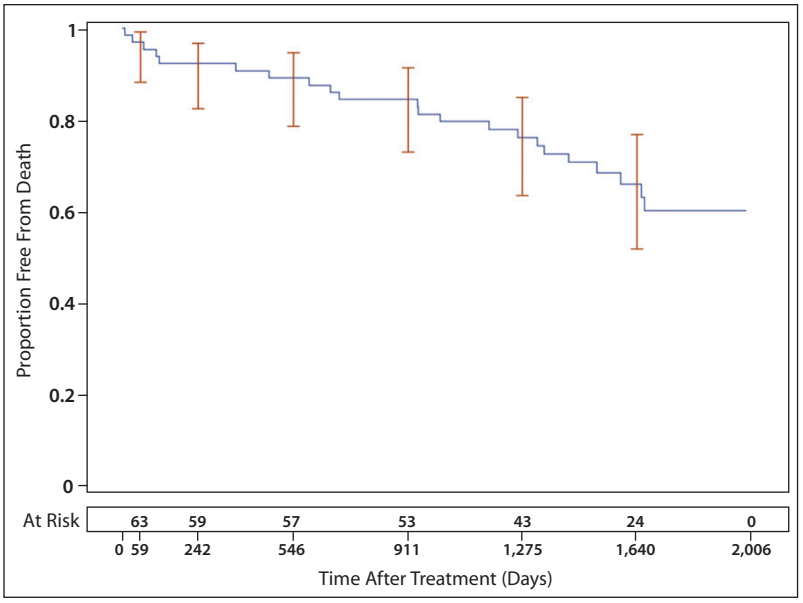

Figure 2. Kaplan-Meier freedom from all-cause mortality as seen in the Thoracic Endoprosthesis for Treatment of Aneurysm of the Descending Thoracic Aortic trial (TAG 08-03).

During follow-up, freedom from aneurysm-related mortality based on Kaplan-Meier analysis was 89% at 5 years. Similarly, freedom from all-cause mortality at 3 and 5 years was 84% and 66%, respectively (Figure 2). At 3 years, 95% of patients had a stable or decreasing aneurysm diameter based upon core lab analysis of axial imaging.

Overall, thoracic endovascular aortic repair (TEVAR) continues to gain wider acceptance and has become more routine throughout the United States. Within 2 years after the GORE TAG Thoracic Endoprosthesis became the first commercially approved TEVAR device, endovascular treatment for intact aneurysms of the DTA rose to 60%.[2] The second-generation Conformable GORE TAG Device was designed to treat multiple pathologies, provided physicians with expanded oversizing for a customized radial fit, and broadened the treatment range of aortic diameters. As our experience grows with treating more challenging patients, the Conformable GORE TAG Device has demonstrated positive results and may provide a platform for further expansion to treat even more complex aneurysm pathology.

AORTIC TRANSECTIONS

Since FDA approval of thoracic endovascular devices for transections, TEVAR has become the gold standard for treating aortic transections at most major medical centers. The last planned open aortic transection repair at the University of North Carolina was performed nearly a decade ago in 2007. The original clinical trial (Evaluation of the Conformable GORE TAG Device for Treatment of Traumatic Transection, TAG 08-02) investigating the Conformable GORE TAG Device for blunt traumatic aortic injury involved 51 subjects.[3] Prior to approval of the Conformable GORE TAG Device for transection, an additional 50 patients were enrolled through a continued access protocol. Although a high incidence of smoking has been associated with the development of aneurysmal disease, it may come as a surprise that only 37.6% of the trauma patients were smokers. This was at a time when the incidence of smoking was decreasing. In 2013, the Centers for Disease Control and Prevention reported that 42.1 million (17.8%) of adults in the United States were current smokers.

In the trial, technical success for the procedure in these polytrauma patients was 100%, with a mean follow-up of 41.5 months. During follow-up, there was only one reported type II endoleak, and no intervention was required. There were no compressions, ruptures, fractures, or other device-related problems identified. Based on centerline imaging, no patient has experienced a > 5-mm increase in lesion diameter. It should be noted, however, that the compliance with follow-up for this cohort was lower than that reported in the aneurysm- or dissection-related studies with the Conformable GORE TAG Device. Only 60% of the patients have had CT scans performed through 3 years of follow-up. This is most likely related to the younger, more transient patient population being treated. Even with limited CT follow-up, long-term survival is quite good, reaching 90% at 5 years.

These is some concern about the significant percentage of trauma patients who are lost to follow-up because most vascular specialists advocate life-long surveillance of patients treated with endovascular aortic repair. However, we must remember the transient nature of the younger patients being treated and council them appropriately about routine surveillance. We must also consider their cumulative radiation exposure, as they are a relatively younger patient population. The aforementioned long-term data suggest a low incidence of late complications. If this trend continues, it may be reasonable to liberalize the rigorous yearly examination of blunt thoracic aortic injury patients in an effort to reduce their radiation exposure.

TYPE B AORTIC DISSECTIONS

The final etiology to receive FDA approval for the Conformable GORE TAG Device involved type B aortic dissections. The Conformable GORE TAG Device trial (Evaluation of the Conformable GORE TAG Thoracic Endoprosthesis for Treatment of Acute Complicated Type B Aortic Dissection, TAG 08-01) focused on 50

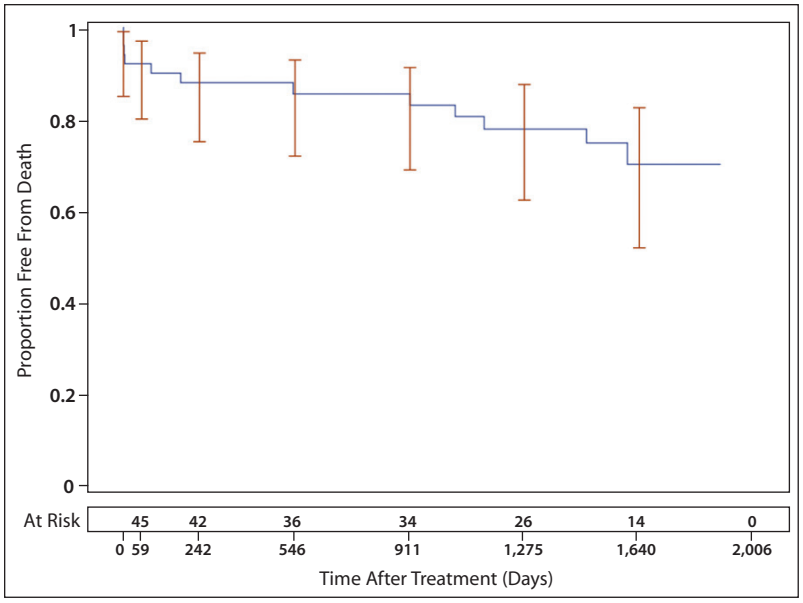

Figure 3. Kaplan-Meier freedom from all-cause mortality as seen in the Evaluation of the Conformable GORE® TAG® Thoracic Endoprosthesis for Treatment of Acute Complicated Type B Aortic Dissection trial (TAG 08-01).

patients with acute, complicated type B dissections, wherein all patients had malperfusion and/or rupture. For this cohort of patients, an all-cause 30-day mortality rate of 8% was impressive. Eighty percent of the eligible patients in this cohort have undergone CT evaluation at each of the follow-up time intervals through the first 3 years. The mean follow-up at the time of this publication is 37.9 months. Within the first 2 years, there was an 18% secondary intervention rate. Most of these secondary interventions were acute and involved everything from leg fasciotomy to colon resection, etc.

A single late open thoracic abdominal aortic aneurysm repair was performed.[4] There was some initial concern that early intervention may lead to increased complications and secondary interventions as a result of the fragile nature of the aorta. In the initial report, there were 13 secondary procedures in nine patients. However, during the subsequent follow-up period, there have been only two additional secondary interventions that were dissection related. These two procedures occurred between the 1- and 2-year time intervals and included open surgical repair of the thoracic dissection secondary to proximal attachment zone failure and an infrarenal endovascular exclusion for involvement of the infrarenal aorta.

There have been two device-related complications that were lethal, including a DTA perforation during the index procedure and an arch dissection that occurred 89 days after device implantation. Eighty-seven percent of the patients have an absence of ongoing endoleaks. To date, there have been only three type I and five type II endoleaks reported. All type I endoleaks have been corrected with secondary interventions. This was accomplished with false lumen embolization strategies and left subclavian artery embolization. Kaplan-Meier analysis of freedom from death shows a 78% survival rate out to 3 years. This compares favorably to historical outcomes for open repair (Figure 3).

Although it has become the standard of care to perform TEVAR for acute, complicated type B dissection, the appropriateness and timing of TEVAR in patients with uncomplicated type B dissection remains controversial. There are several recent trials that have compared the efficacy of current management options for uncomplicated type B aortic dissections. Initial publications of the short- and midterm outcomes suggest the efficacy of stent-graft placement (TEVAR) in these patients by improving aortic remodeling and providing a survival benefit, as optimal medical therapy (OMT) is associated with a > 10% mortality rate for patients with a chronic type B dissection over 5 years. A recent natural history study demonstrated that patients who are initially managed with medical therapy alone had a 6-year intervention-free survival rate of only 41%.[5]

The Gore ADSORB (TAG 05-04) Clinical Study by Brunkwall et al evaluated uncomplicated type B dissection patients treated in the acute setting (< 14 days).[6] This study involved 17 high-volume European centers and compared OMT and OMT plus TEVAR in patients who had symptoms for < 14 days as opposed to the INSTEAD trial,[7] which compared patients with subacute type B dissections.

Trial enrollment has been completed, and the 1-year data have been reported.[8] The 30-day mortality for both OMT and TEVAR was 0%; however, there were three crossovers from the OMT group to the TEVAR group due to disease progression in the first week. One-year follow-up data revealed two failures in the OMT group (aneurysmal dilatation and malperfusion) and one death in the TEVAR group from a non–dissection-related cardiac arrest. The only statistically significant difference of note was the rate of incomplete false lumen thrombosis, which was 97% in the OMT group and 43% in the TEVAR group. Furthermore, the false lumen was noted to increase in size in the OMT group, whereas the false lumen decreased in the TEVAR group. Similarly, the true lumen became larger in the TEVAR group and remained unchanged in the OMT group. Although longer follow-up intervals are needed to validate the data, some conclusions that can be drawn from these data are that TEVAR is safe at 1 year, with improved aortic

remodeling compared to OMT alone. The implantation of a thoracic stent-graft appears to promote aortic remodeling, false lumen thrombosis, and reduced false lumen diameter. Preliminary data indicate that TEVAR, when applied in the acute phase of the disease, will have a positive impact on the potential late complications of type B dissections, namely, false lumen aneurysmal formation.

Although the TEVAR experience has been used in many patients with acute, complicated type B dissections, the September 2013 FDA approval of the Conformable GORE TAG Device provided an indication for use in all type B dissections without discrimination as to acuity or dissection-related complications. This current real-world application of TEVAR in type B dissections covers a spectrum of clinical circumstances. In lieu of specific device postmarket studies, the FDA, industry, and medical professional societies, such as the Society for Vascular Surgery, have combined to study the long-term anatomic and clinical outcomes when TEVAR is applied to all acute and chronic type B dissections.

CONCLUSION

Long-term data indicate that the Conformable GORE TAG Device has performed and continues to perform well in all three etiologies studied in clinical trials, without significant device-related complications. These data support the continued use of the Conformable GORE TAG Device in the treatment of DTA pathologies. Through these and other device changes, TEVAR results justify the continued shift away from open surgical repair and OMT across the spectrum of thoracic aortic pathologies. ■

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Chronic Type B Dissection: Rules of Engagement for TEVAR

Endovascular solutions in the management of chronic type B dissections.

BY IBRAHIM SULTAN, MD; NIMESH D. DESAI, MD, PHD; AND JOSEPH E. BAVARIA, MD

Aortic dissection is a lifelong disease that goes to the grave with most patients. As E. Stanley Crawford mentioned in his seminal article, "No patient should be considered cured of the disease," which holds true to date.[1] Patients who present up to 2 weeks after the inciting event are considered to have an acute type B dissection. Those who present between 15 and 90 days are classified as subacute, and patients presenting after 3 months are considered to have a chronic type B aortic dissection (TBAD). Chronic TBAD dissections are a result of medically managed acute (uncomplicated or complicated) type B dissections or residual type B dissections after surgical repair of a type A dissection. Patients may present to an aortic specialist in either the acute or subacute phase of a TBAD or at a later date in the chronic setting with complications of the disease such as aneurysmal degeneration, low-grade malperfusion, or rupture.

Although TEVAR is increasingly utilized for acute TBAD, the use of thoracic endovascular aortic repair (TEVAR) has been slowly adopted in the setting of chronic TBAD because of the complex anatomy and pathology associated with the disease. Open surgical treatment of chronic TBAD continues to remain the standard of care, but it comes with significant morbidity including stroke, paraplegia, renal failure, and need for long-term ventilator support. However, the rate of such complications has significantly decreased over the past 2 decades. TEVAR has demonstrated decreased mortality and spinal cord ischemia compared to open surgical repair, albeit with a higher reintervention rate.[2] Chronic TBAD poses unique challenges, but surgeons and experienced centers familiar with the predictors of clinical success and aortic remodeling have reported excellent outcomes.[2,3] At the University of Pennsylvania, we have adopted a team-based approach consisting of vascular and cardiovascular surgeons along with cardiothoracic anesthesiologists and intensivists.

The consistent use of the criteria described in the following sections, which we refer to as our "rules of engagement," have allowed us to optimize short- and long-term outcomes in our patients with chronic TBAD.

RULES OF ENGAGEMENT: THE GOOD PATIENT

Initial Patient Assessment

Case planning is critical for any patient undergoing TEVAR, and this begins in the office or hospital when the patient is first seen. All patients are worked up appropriately with a CT angiography with three-dimensional reconstruction and, if needed, echocardiography, carotid duplex scanning, pulmonary function tests, and coronary catheterization. Any history of previous aortic repair should be taken into account, particularly in the abdominal aorta, as this puts the patient at a higher risk for spinal ischemia, and these patients would benefit from a spinal drain. After the initial patient evaluation, there are several other key factors that we consider in determining endovascular treatment success.

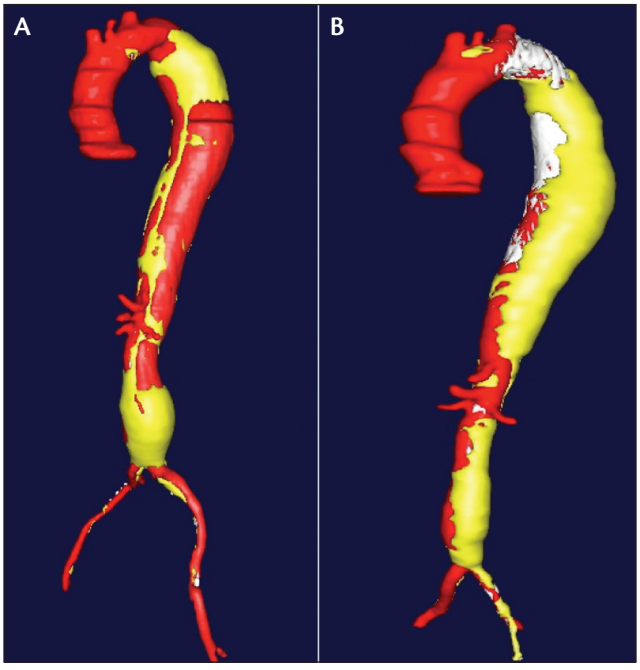

Figure 1. Predictors of good aortic remodeling. An ideal candidate with a good proximal landing zone and all four visceral vessels originating from the true lumen (A). Thrombosis of the false lumen at 1 year (B).

Importance of the True Lumen

With widespread use of imaging, more patients are seen with complex chronic TBAD where the true lumen can be quite small and can be compressed from the false lumen, thus causing a pseudocoarctation. These patients may present with progressive malperfusion. We believe

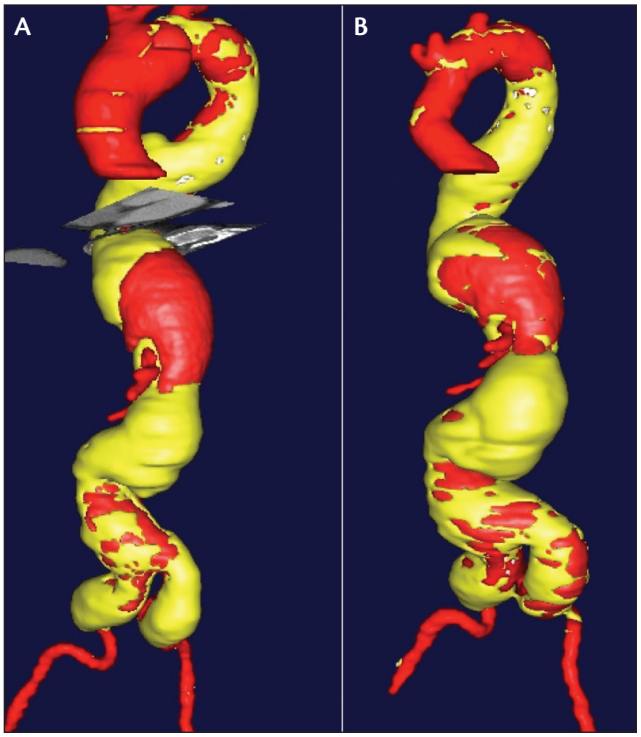

Figure 2. Predictors of poor aortic remodeling. Complex multiple fenestrations in the distal thoracic aorta and all four visceral branches not from the true lumen (A). One-year follow-up showed continued false lumen expansion and aneurysmal degeneration of the distal aorta (B).

that with a greater number of visceral vessels originating from the true lumen, better occlusion of the false lumen is likely, resulting in more effective overall treatment with TEVAR. The best-case scenario is when the celiac artery, superior mesenteric artery, and both renal arteries originate from the true lumen (Figure 1). The worst scenario occurs when all four visceral vessels originate from the false lumen. When most, if not all, abdominal vessels originate from the true lumen, this anatomy minimizes distal large re-entry sites and promotes remodeling, which is optimal for the long-term survival of such patients (Figure 2).

Solid Caliber Proximal Landing Zone

A good proximal landing zone is critical in achieving endovascular success, avoiding any endoleaks, and for future aortic remodeling. We recommend having approximately 1.5 to 2 cm of landing zone in the proximal aorta in which the most proximal part is nondissected. Frequently, this involves covering the left subclavian artery. Because most of these cases are performed electively, almost all of these patients can undergo a subclavian transposition or a carotid-subclavian bypass prior to TEVAR. It is imperative that the TEVAR procedure be performed within 5 to 7 days of the subclavian transposition/bypass in order to ensure that it does not clot off. The recent innovation of

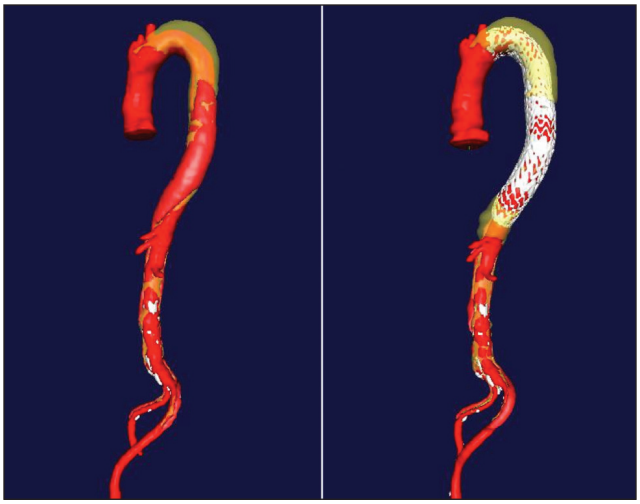

Figure 3. Use of Conformable GORE® TAG® Thoracic Endoprosthesis up to the celiac artery for better aortic remodeling. Of note, two grafts were used in this patient.

branched stent-graft devices, such as the investigational GORE® TAG® Thoracic Branch Endoprosthesis (TBE), allow landing into zone 2 while maintaining side branch patency.[4] This technology is being studied in aneurysms, and future applications may include additional pathologies such as chronic TBAD.

Primary Tear Site Coverage

One of the fundamental concepts in treating chronic TBAD is to cover the primary tear site. Inadequate coverage can lead to endoleak, persistent false lumen flow, or potentially cause a retrograde type A dissection in some patients. We also cover the descending aorta down to the celiac artery in all patients. This allows for better coverage of secondary tear sites, full expansion of the true lumen, and thrombosis of the false lumen over a larger portion of the aorta (Figure 3).

Pseudocoarctation of the Distal Landing Zone

It is not uncommon for patients with chronic TBAD to present with a distal pseudocoarctation. This occurs when a large false lumen severely compresses the true lumen. Many patients may experience low-grade visceral malperfusion or worsening renal function. We use IVUS in all patients undergoing TEVAR for chronic TBAD, but in patients with a small true lumen, IVUS is an invaluable tool in maintaining true lumen access and to assess compliance of the septum. Moreover, a very small true lumen may not allow the use of several standard stent-grafts that would otherwise be used in the treatment of chronic TBAD.

DO THE RULES OF ENGAGEMENT MATTER?

We firmly believe that if you keep these rules in mind when planning a TEVAR procedure for chronic TBAD,

the outcome is likely to be successful. In our series of 31 patients, we had four failures that presented with a persistent patent false lumen on surveillance imaging. Among these four patients, the rules of engagement were intact in only one patient. Eighty-seven percent of the patients underwent aortic remodeling in this series.[3]

Significant progress has been made during the past decades in decreasing mortality and stroke in patients who present with chronic TBAD and undergo open surgery or TEVAR. Paraplegia is significantly lower in patients undergoing TEVAR compared to open thoracoabdominal aortic surgery.[5] We use somatosensory-evoked potentials in all patients undergoing TEVAR. We do not use spinal drains in every patient; however, spinal drains are critical in patients who are at higher risk for spinal ischemia, such as those who have had abdominal aortic procedures or when the plan is to cover the left subclavian artery without revascularization.

CONCLUSION

The aorta in chronic TBAD has complex anatomy or abnormal histology that is quite different than what one encounters in an atherosclerotic aneurysm or even an acute TBAD. Although most experienced centers have been able to treat patients empirically, we have begun to understand the group of patients who would benefit from TEVAR for chronic TBAD. Our clinical experience demonstrates that good results can be achieved using TEVAR in the treatment of chronic TBAD by following our "rules of engagement." ■

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Understanding the Predictors of Aneurysmal Degeneration in Type B Dissection

A case example illustrating when early endovascular intervention may provide the best outcome.

BY DITTMAR BÖCKLER, MD, PHD; MARIUS ANTE; AND MORITZ S. BISCHOFF, MD

A patient presenting with a type B aortic dissection may be categorized into distinct dissection subcategories. These subcategory descriptions are acute complicated, acute uncomplicated, chronic de novo/classic, or residual type B dissection following surgical repair of a type A dissection. Current treatment options are best medical therapy (BMT), thoracic endovascular aortic repair (TEVAR), and open surgical repair.

TEVAR has been established as a valuable treatment option for patients presenting with complications, due to better outcomes, including reduced in-hospital and longer-term complications.[1,2] Patients with complications such as organ malperfusion, limb ischemia, impending rupture, and periaortic bleeding carry a substantial risk of early mortality, with mortality rates of up to 9% under BMT.[3,4] A review of these patients reveals that they have an increased in-hospital mortality of up to 35.4%. Increasingly, physicians are using TEVAR for patients with recurrent pain and refractory hypertension and are moving away from BMT alone. Overall, results achieved with TEVAR have been encouraging in patients with acute complicated type B aortic dissections.[5,6]

However, controversy still exists around using TEVAR in patients with uncomplicated type B aortic dissections (Figure 1). According to current guidelines, BMT remains the recommended standard treatment for uncomplicated patients.[1-4] Despite the initial success of BMT in the acute management of uncomplicated type B dissections, long-term complications resulting from aortic degeneration, disease progression, and aortic-associated mortality remain a concern. A closer look shows that acute uncomplicated type B aortic dissection patients who are treated conservatively with BMT have a 10% 30-day mortality rate, with up to 25% of patients needing intervention within the first 4 years. Some studies indicate that 20% to 50% of patients with uncomplicated type B dissections will experience disease progression and eventually require intervention.[7,8] Therefore, it is clear that these patients should be monitored closely for any development of complications or morphological changes that may require intervention.

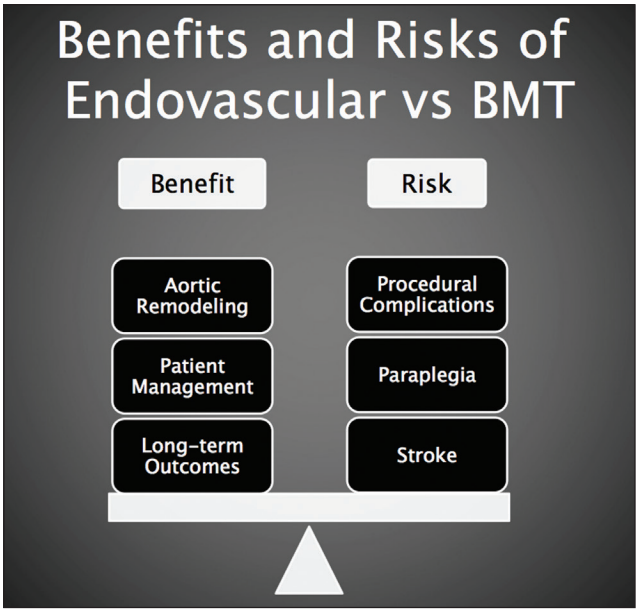

Figure 1. Balance of benefits and risks of endovascular therapy for type B dissections.

One reason for intervention is aneurysmal dilatation. Estimated rupture rates of the false lumen rise to up to 30% once diameters reach 6 cm, with an associated mortality ranging from 20% to 40% within 5 years.[7-10] Unfortunately, TEVAR in these progressive chronic type B dissections has been noted to be less effective with regard to aortic remodeling, which affects long-term patient outcomes.

Preoperative imaging of dissection patients can help identify impending rupture, recognize arterial compromise, and detect vulnerable anatomy, as this information may subsequently assist physicians in anticipating future complications. These predictive

TABLE 1. SUMMARY OF HIGH-RISK PREDICTORS OF DISEASE PROGRESSION IN TYPE B AORTIC DISSECTION

• Primary entry tear diameter ≥ 10 mm
• Primary entry tear location on the concavity of the thoracic aorta
• Total aortic diameter ≥ 40 mm
• False lumen diameter ≥ 22 mm
• Partial false lumen thrombosis
• Fusiform index ≥ 0.64

factors for progression and adverse events can help to identify high-risk patients who could benefit from early TEVAR rather than BMT alone. In other words, using imaging to predict a poor future prognosis could be very useful in selecting patients for whom more aggressive management may yield improved short-term and long-term outcomes.

Dake recently published a treatment algorithm for the assessment of all type B aortic dissections.[11] Within the algorithm, he consolidated several published high-risk predictors (Table 1) for late aortic events in acute uncomplicated type B dissection patients. Six high-risk factors were identified: (1) a primary entry tear ≥ 10 mm in diameter, (2) an entry tear located at the concavity of the distal aortic arch, (3) a maximum aortic diameter ≥ 40 mm with a patent primary entry tear site, (4) a large false lumen diameter ≥ 22 mm at the upper descending thoracic aorta, (5) partial false lumen thrombosis, and (6) a fusiform index ≥ 0.64. Patients who fulfill one or more of these predictors may benefit from early intervention. At the very least, they should be closely observed.

Further evidence for another high-risk patient subgroup was recently published. In a 5-year, retrospective, single-center study on 164 uncomplicated type B patients, Lavingia et al concluded that volumetric analysis of the initial index CT scan is able to predict aortic growth and the need for future intervention.[12] A true lumen volume/false lumen volume ratio of < 0.8 was highly predictive for requiring an intervention.

The following case report illustrates the six literature-based predictors highlighted by Dake in one of our dissection patients. It is a retrospective evaluation of a patient who presented with an acute uncomplicated type B dissection. Morphological analysis was completed on the patient's initial presentation contrast-enhanced CT angiography (CTA). Each predictor was measured according to the originally published reference. The same analysis was conducted on the patient's 1-year follow-up CTA. The 1-year follow-up imaging allowed for tracking of disease progression/aneurysmal degeneration and for determining whether the patient could have potentially benefited from an early TEVAR intervention.

Figure 2. Initial preoperative three-dimensional VR- CTA scan showing a classic Stanford type B dissection from a left anterior oblique perspective.

CASE REPORT

A 56-year-old man with a history of untreated arterial hypertension was admitted with a primary episode of chest pain in December 2009. An initial contrast-enhanced CTA was performed at the time of admission to the emergency department and revealed an acute uncomplicated type B aortic dissection (Figure 2). Otherwise, he reported to be in good health. The patient was enrolled in the Gore ADSORB Clinical Study (TAG 05-04)[13] and was randomized to BMT only.

From the CTA at initial presentation, the primary entry tear size was measured on an axial slice. Evangelista et al demonstrated that large entry tears ≥ 10 mm (hazard ratio [HR], 5.8; $P > .001$) in proximal aortic locations are associated with false lumen expansion.[14] On the initial

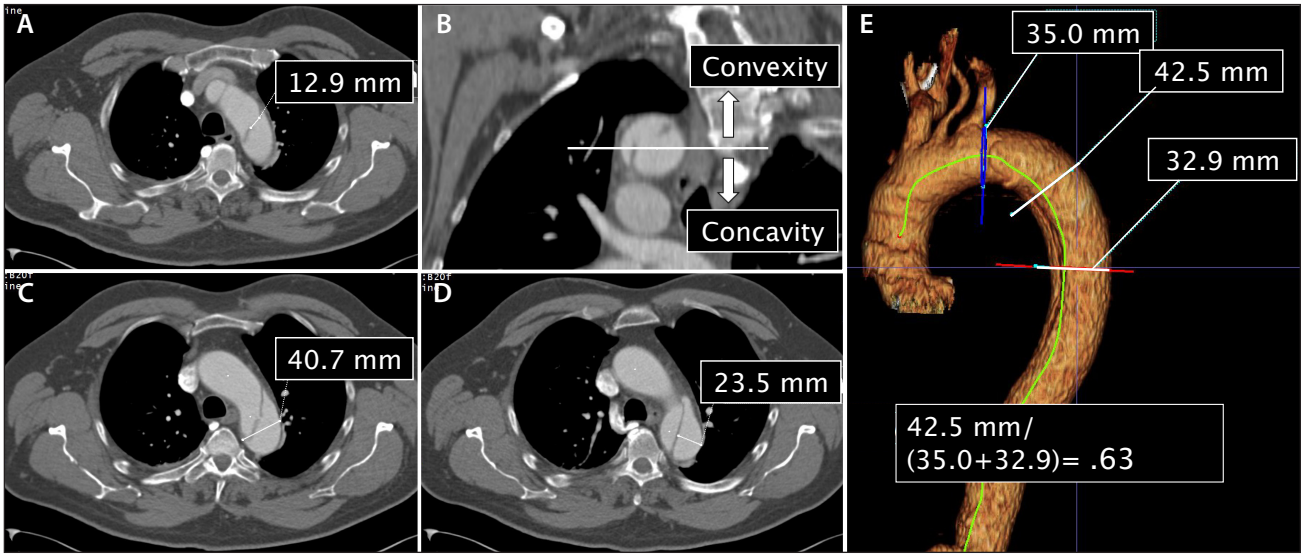

Figure 3. Measurements from our case based on predictors from the literature. At initial presentation, primary entry tear in zone 3 (A), primary entry tear location (B), total aortic diameter (C), false lumen measurement (D), and Marui fusiform index (E).

presentation of our patient, one slice captured a primary entry tear of 12.9 mm in zone 3, which was distal to the left subclavian artery (Figure 3A).

Defining an additional high-risk subgroup, Loewe et al showed that patients with a primary entry tear within the concavity of the aortic arch do have a significantly higher risk for primary complications compared to cases in which the primary entry site is located within the arch's convexity (convexity 21% vs concavity 61%; $P = .003$; HR, 1.8; 95% confidence interval [CI], 1–3.2).[15,16] Our patient had the tear located on the convexity of the aorta (Figure 3B).

One of the well-established predictors for late aortic enlargement is the existence of a maximum total aortic diameter ≥ 40 mm during the acute phase ($P < .001$) with a patent primary entry site in the thoracic aorta ($P = .001$).[17] The initial total aortic diameter near the level of the primary entry tear measured in our patient was 40.7 mm (Figure 3C).

In 2007, Song and colleagues published an article stating that a large false lumen diameter ≥ 22 mm at the upper descending thoracic aorta on the initial CT scan predicts late aneurysm dilatation with many more adverse outcomes warranting early interventions ($P < .001$).[18] The measurement on initial CT for the reported patient was 23.5 mm (Figure 3D).

Marui et al developed a "fusiform index" that expresses the degree of fusiform dilatation of the proximal descending aorta during the acute phase of aortic type B dissection.[19] The index is calculated by dividing the maximum total aortic diameter by the sum of the diameter of the proximal nondissected aorta (typically zone 2), and the total aortic diameter of the descending aorta at the pulmonary level. A fusiform index of ≥ 0.64 is considered to be the threshold for late aortic events. In our patient, the fusiform index was 0.63 (Figure 3E).

At the 1-year follow-up CTA required for the Gore ADSORB Clinical Study, changes in all the aforementioned measurements could be observed (Figure 4). This patient's condition progressed with overall aortic growth (Figure 5). In addition, the false lumen now showed partial thrombosis in the distal thoracic aorta. Partial thrombosis of the false lumen, as compared with complete patency, is a significant independent predictor of post-discharge mortality (HR, 2.69; 95% CI, 1.45–4.98; $P = .002$).[20] The changes noted at 1 year indicate that the patient's aorta will likely continue to grow/deteriorate and require future intervention beyond BMT.

DISCUSSION

For any type B dissection patient, it is important to conduct a risk assessment at an early stage to determine the merits of medical, endovascular, or surgical intervention. In the acute phase of the disease, patients may present with clinical conditions characterized by absence of complications in almost 50% of the cases.[21] However, despite initial stable conditions, these "uncomplicated" patients may develop complications and have an in-hospital mortality rate of up to 10%.[22]

This case report is representative for a group of patients with acute uncomplicated type B dissection who could potentially benefit from early TEVAR. The identification of uncomplicated type B dissection patients who are potentially prone to future deterioration may enable the treating physicians to achieve better long-term outcomes by preemptive interventions. TEVAR results for dissection

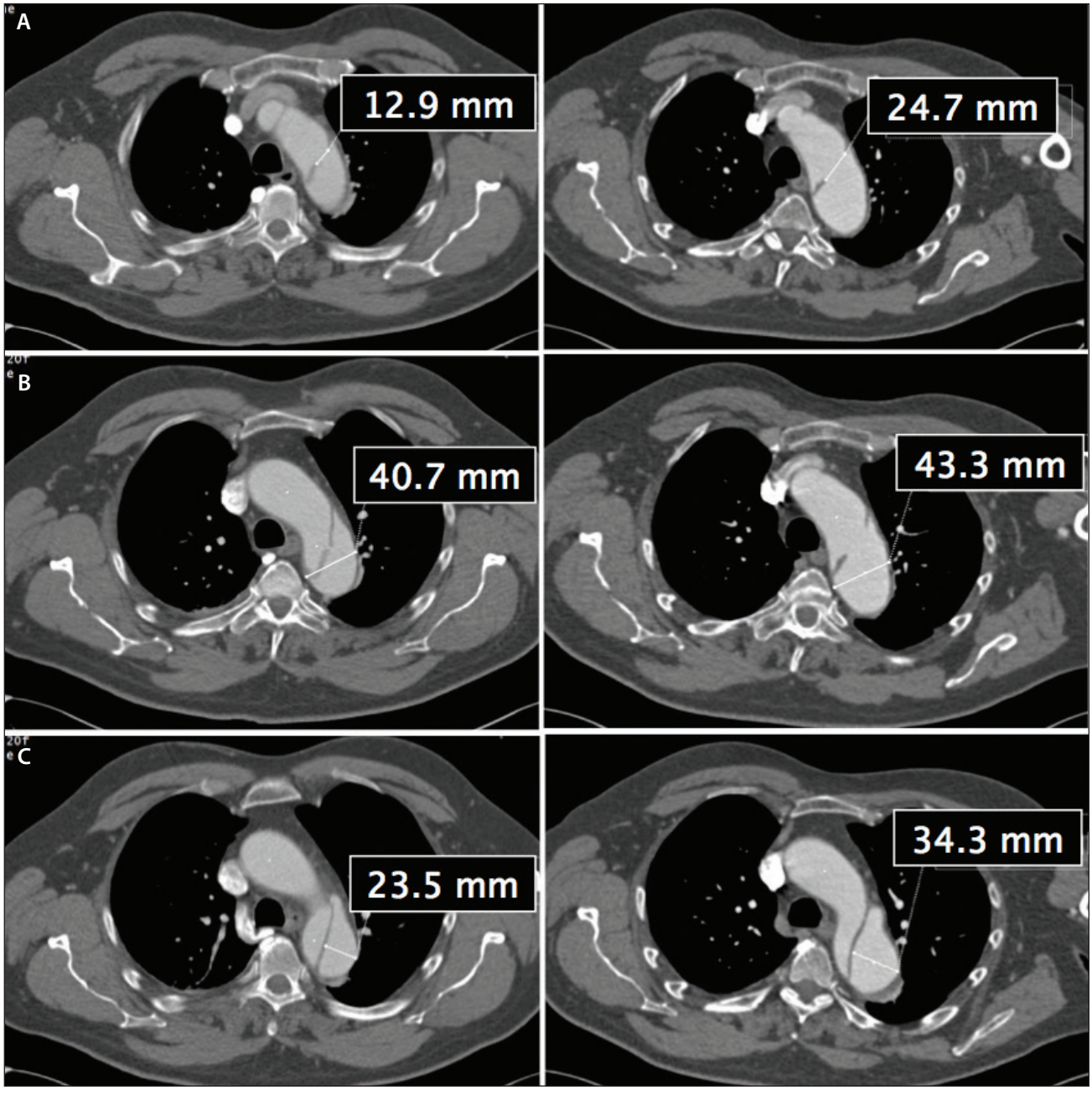

Figure 4. Initial CTA imaging (left panels) versus 1-year follow-up CTA (right panels) showing primary entry tear measurement (A), total aortic diameter (B), and false lumen measurement (C).

are promising and offer optimal aortic remodeling when performed in an acute setting.

Despite favorable results, the complications related to the procedure should be considered.[8] Stroke is reported to occur in 3% to 10% of patients due to the manipulation of catheters in the arch/ascending aorta and is more common in patients with severe atherosclerosis in the aortic arch.[23] Although rare in dissection, spinal cord ischemia has been shown to be related to the extent of the covered aorta, previous aortic surgery, and hypotension at presentation. Arm ischemia, paraparesis, and paraplegia may occur from branch vessel occlusion. In the case of intentional left subclavian artery coverage, revascularization of the left subclavian artery can prevent stroke, paraplegia, and/or death. Revascularization is recommended in stable patients.[4] Retrograde type A dissection has been reported to occur in < 2% of patients, but it is associated with devastating clinical outcomes. There is also increased risk associated with balloon dilation, proximal bare stents, and rigid noncompliant devices.[24] Due to the previously mentioned complications, it is

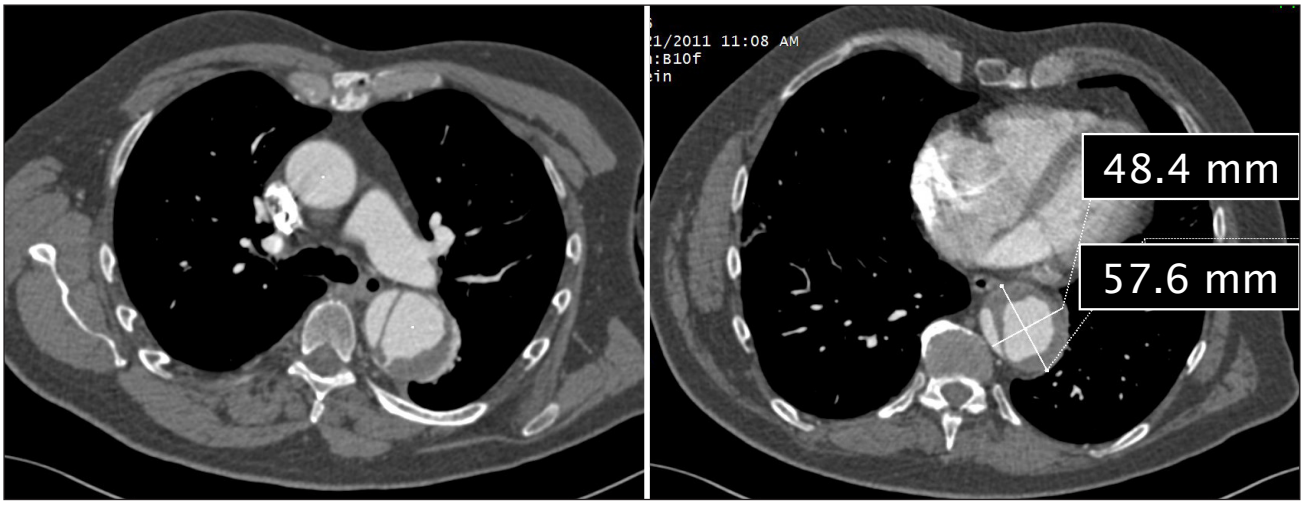

Figure 5. Partial thrombosis of the false lumen in the descending thoracic aorta.

necessary to carefully balance the benefits and risks when making clinical decisions.

Despite increasing evidence of good outcomes, questions remain open for debate in terms of which high-risk patients might benefit from early TEVAR. Is multiple device use for extended coverage necessary to achieve maximum aortic remodeling? What is the right timing for intervention and for optimal aortic remodeling after TEVAR?[25] Do we have the ideal stent-graft to conform to the challenging anatomy of type B dissections?[26] What is the optimal follow-up schedule for both conservatively as well as interventionally treated patients? And finally, which imaging technique is best?

CONCLUSION

In current clinical practice, endovascular stent-graft therapy is increasingly considered as an alternative to medical management alone for selected patients with acute uncomplicated type B dissection. Several groups have identified image-based predictive factors that correlate to high-risk patient subgroups. Once identified, these patients may benefit from earlier and more aggressive endovascular therapy. Further retrospective and prospective studies are needed to fully understand and confirm independent predictors of adverse outcomes.[27] As outcomes for these high-risk predictors are increasingly monitored, the importance and affect of each risk factor addressed in this systematic review will be elucidated. In summary, the trend continues toward early intervention in the management of acute uncomplicated dissection.[28] ■

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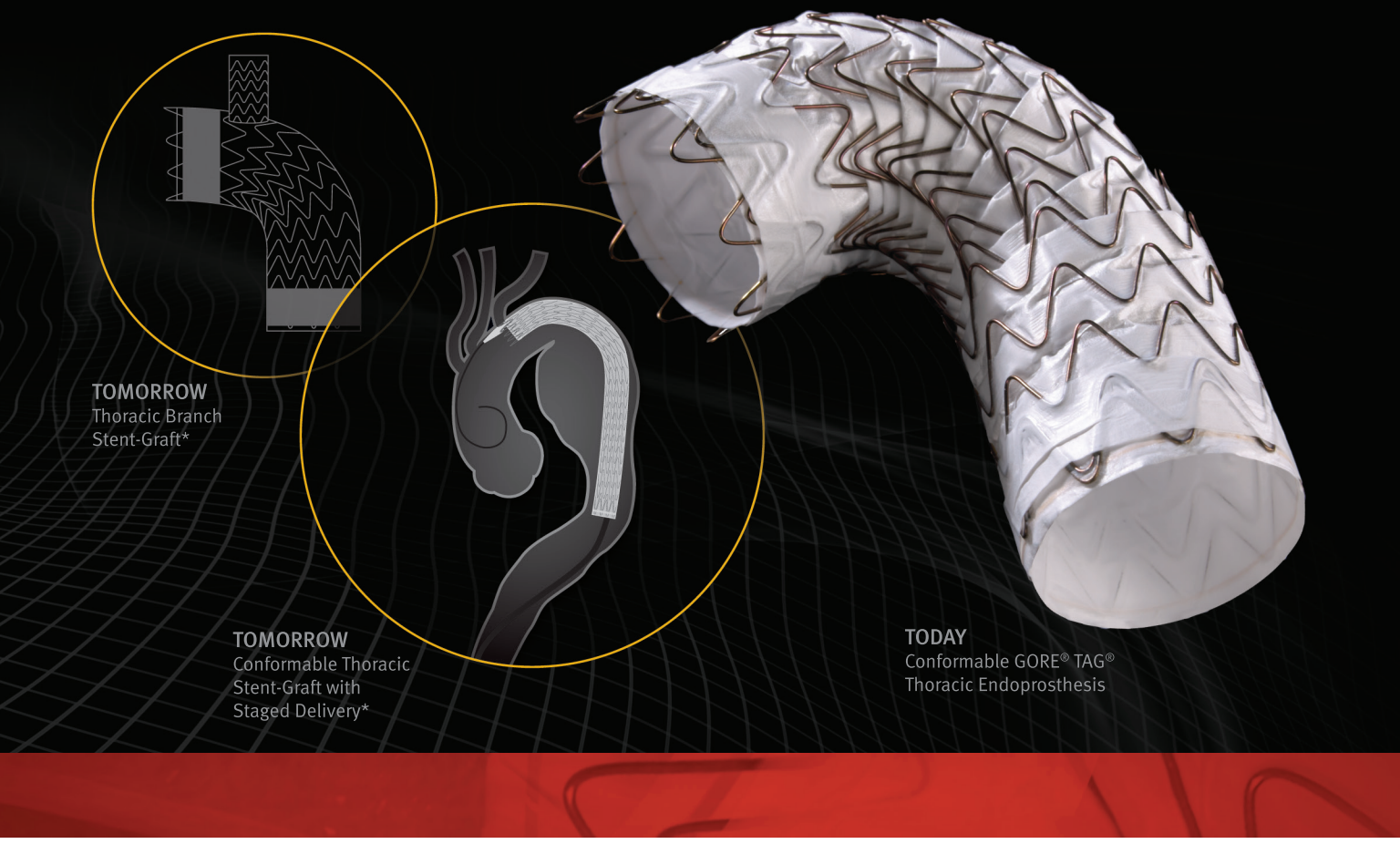

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