The Importance of Conformability and Sizing in TEVAR

Achieving effective outcomes in trauma patients with blunt aortic injury.

BY MARK A. FARBER, MD, FACS

The management of patients who suffer blunt aortic injury (BAI) has drastically changed since the approval of stent grafts to treat aortic disease. At most major trauma centers, thoracic endovascular aortic repair (TEVAR) has now become the treatment of choice.[1] With the recent approval of the Conformable GORE® TAG® Device (Gore & Associates, Flagstaff, AZ) for isolated lesions, BAI is now an on-label treatment option for patients. Although these devices were originally designed for treating aneurysmal disease, they have found success in treating BAI.[2] However, distinct differences exist between these two patient populations. Based on clinical trial data from the United States,[3-5] the average age of patients who are treated with TEVAR for thoracic aortic aneurysms is 71 years. In comparison, the average patient age is 40 years in 100 patients treated at the University of North Carolina during the past 20 years who presented with a traumatic aortic injury.

As individuals age, not only does the aorta enlarge, but the radius of curvature also increases. Whether this is the result of increases in aortic stiffness or a natural process is difficult to determine. It does, however, have a significant impact on device performance in the proximal thoracic aorta. Despite the overwhelming acceptance of TEVAR for treating BAI, when planning these procedures, there are certain aspects to be aware of, which are crucial to achieving successful outcomes; most notably, these are device sizing and conformability.

SUPPORTING DATA FOR BAI TREATMENT WITH TEVAR

Numerous studies have been published showing a decrease in operative mortality, hospital mortality, and morbidity rates by employing TEVAR in patients with BAI.[6,7] Although spinal cord ischemia has been reported after TEVAR, it is exceedingly rare, and published data suggest that it occurs less frequently compared to open repair. Recent meta-analysis indicated that complications of paraplegia and stroke are also reduced with TEVAR.[7]

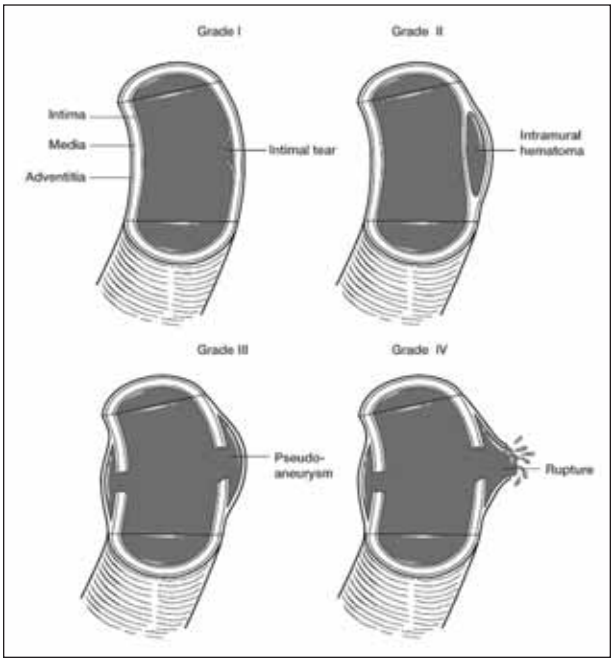

Figure 1. Grading classification for BAI.

There is evidence that not all BAIs require repair. Using the grading system described by Azizzadeh et al,[8] minimal aortic injures involving intimal defects (classified as grade I) (Figure 1) are unlikely to result in rupture or pseudo-aneurysm development, and therefore, conservative management with observation and blood pressure control is warranted. For severe injuries (grades III–IV), repair is advocated to prevent rupture and

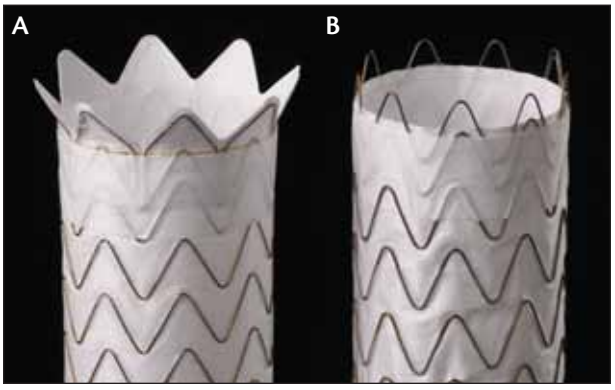

Figure 2. The original GORE® TAG® Device (A) and the new Conformable GORE® TAG® Device (B) (Gore & Associates).

pseudoaneurysm formation. Before the advent of stent grafts, some practitioners employed the technique of delayed repair in patients with intramural hematomas (grade II injuries). By doing so, the patients were able to recover from concomitant injuries, such as lung and cardiac contusions, enabling improved results with operative repair of their aortic injury. This has been less of a concern when endovascular repair is performed because few, if any, patients have contraindications to repair, as single-lung ventilation, cardiopulmonary bypass, and heparin are not required. In addition, cardiac stress is minimized with an endovascular approach.

SIZING

Once repair has been deemed necessary, critical planning is required to achieve favorable results. Axial imaging alone should be avoided, as it can lead to inaccurate diameter determination due to tortuosity and angulation. Imaging inspection using three-dimensional (3D) planning software is essential. The thoracic aorta can be very tortuous and the radius of curvature severe, especially in young patients. As such, 3D planning software can easily create orthogonal diameters throughout the treatment region. By inspecting the proximal and distal aspects of the treatment region, the aortic diameter can be measured. For most injuries, this involves the distal aortic arch region just distal to the left common carotid artery extending caudally for approximately 10 cm. In some cases, the left subclavian artery can be spared when the injury occurs more distally. However, critical evaluation of the aortic arch curvature should be undertaken.

Despite critical orthogonal inspection, diameter measurements using this method can still be inaccurate. Trauma patients with severe hypovolemia can experience aortic contraction, and the diameter can be underestimated by as much as 5% to 40%.[9,10] This can result in potential problems because undersized devices can exhibit a type I endoleak, persistent lesion perfusion, and bleeding. Oversizing the device would help minimize this risk; however, excessive oversizing can also

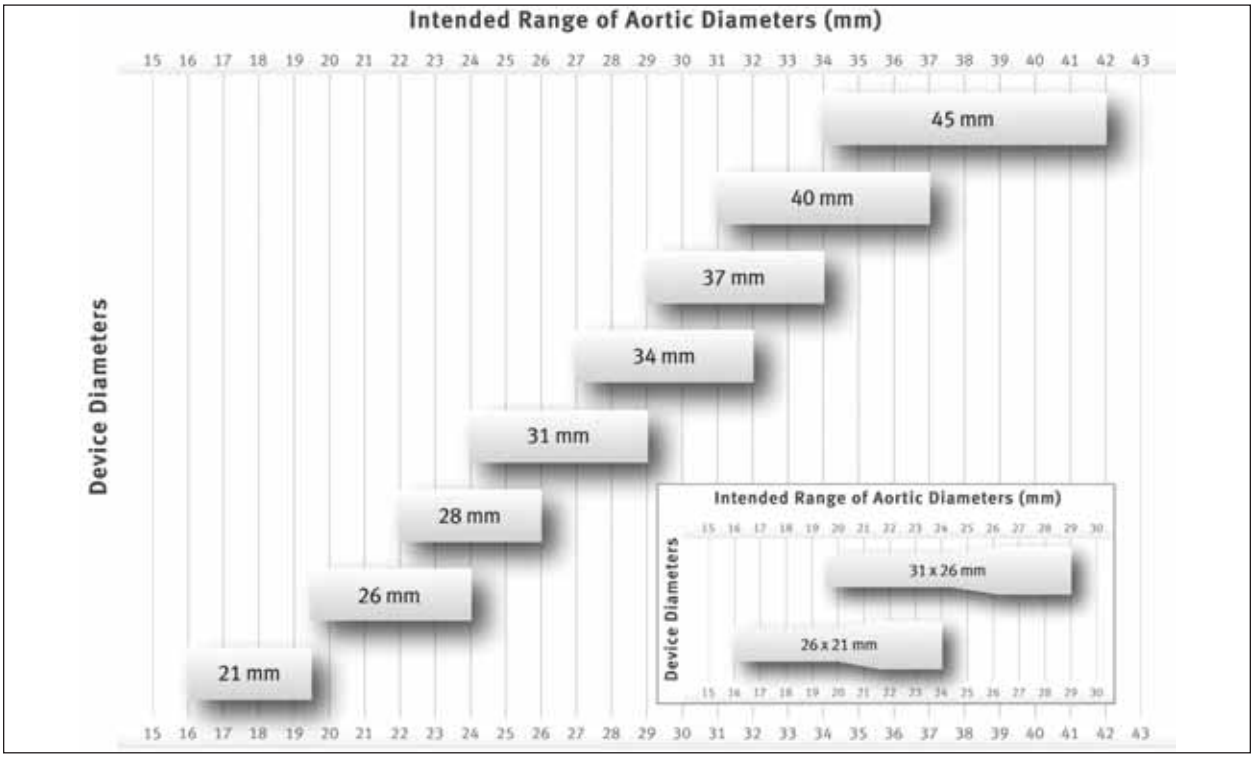

Figure 3. Conformable GORE® TAG® Device oversizing chart.

lead to significant problems inherent to each individual device.

Device compression is a rare occurrence, but it has significant implications when it occurs. A study by the American Association for the Surgery of Trauma reports an incidence of 0.8%, whereas a recent study showed a 0.4% incidence with use of the GORE® TAG® Device.[11] Device compression has been shown in various studies to be associated with graft oversizing, which is more likely to occur with small aortic lumens.[12] However, it may also be related to a lack of aortic arch conformability. This is a potentially dangerous complication that, if not remedied, can result in acute device failure, which is associated with significant morbidity and mortality from aortic occlusion.

Avoiding this recognized complication can often be accomplished by utilizing intravascular ultrasound during the procedure in transection patients. One must keep in mind, however, that intravascular ultrasound generally underestimates the aortic diameter measurements by 2 to 3 mm compared to computed tomography. This technique can help further define the true diameter, because generally, the patients have undergone fluid resuscitation between the imaging study and the procedure.

Additional information can also be gained using the intravascular ultrasound catheter, including the exact location of the injury and the extent of the injury into the proximal aspect of the aorta. However, added procedural time is one drawback to using this technique.

CONFORMABILITY

As previously mentioned, the radius of aortic curvature is smaller in patients with BAI. This is potentially problematic for devices that are designed to mimic the stiffness of older patients with thoracic aneurysms. As such, their conformability is not ideal along the lesser curvature of the arch. This can potentially result in proximal endoleaks, especially in patients with traumatic injury because the injury is typically located at the ligamentum arteriosum on the inner curvature of the arch where the seal length is less due to the aforementioned device malapposition.

When coupled with the increased aortic impulse in young patients, a lack of proximal conformability can also result in the development of aortic pseudocoarctation from compression of the device. Although malapposition to the inner aortic curve has occurred with numerous devices, it rarely results in significant hemodynamic compromise in patients with degenerative thoracic aortic aneurysms because of the reduced aortic impulse in elderly patients and the greater aortic curvature. The degree to which conformability occurs is also related to the position of the device within the curvature of the arch.

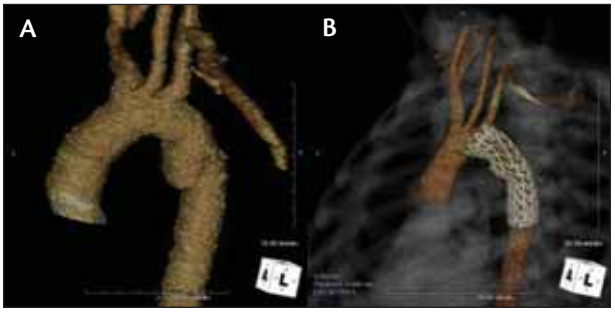

Figure 4. Aortic transection in a patient with a small radius of curvature (A). Aortic transection repair with the Conformable GORE® TAG® Device (B). Note the degree of conformability.

Inspection of the anticipated device location in relation to the arch curvature using 3D imaging can also reveal potential conformability problems, and alterations in deployment position are often made based on this information. Recognition of this problem and careful planning of the procedure can help minimize this potential complication with TEVAR for BAI.

Both device collapse and conformability are not always predictable occurrences and as such, cannot always be avoided. They can, however, be treated when they occur. Reported success in correcting these complications includes the placement of a second device in a more favorable position or placement of a Palmaz stent (Cordis Corporation, Bridgewater, NJ) at the proximal aspect of the device.[13] Both of these solutions involve added procedural costs and procedural time and are also not without potential complications themselves. If proximal treatment extension is required into zone 1 of the aorta, then extra-anatomic bypass may be required to ensure adequate cerebral perfusion.

FUTURE DIRECTIONS

Gore has redesigned their GORE® TAG® Device to help avoid the problems of sizing and conformability. The modified polytetrafluoroethylene graft and stent-to-graft attachment configuration adds increased conformability while maintaining its original characteristics of device profile and ease of delivery (Figure 2). Modifications to the stent, including an increased wire diameter and additional apex to the circumference, have also allowed for increased oversizing windows (Figure 3), permitting significantly wider treatment ranges for any given device diameter. Whereas the previous iteration of the device generally yielded one device size for a specific diameter, there are now as many as three different sizes available for a specific aortic inner diameter.

Targeting the upper limit of the oversizing range is generally used in the treatment of older patients with

aneurysmal disease to maximize radial force in the proximal and distal sealing regions. In contrast, patients with dissections and transections generally require less resistance to migration, and device sizing is based on matching diameters appropriately. Choosing the best device diameter is often difficult and governed by the location of the implant in conjunction with the degree of aortic constriction from hypovolemia. In severely curved regions, increased oversizing aids in inner curvature apposition, so long as it is within the appropriate size range for the device. Determining the appropriate size to compensate for hypovolemia and curvature is often based on experience.

Gore & Associates recognized that aortic diameters vary significantly in patients with transections and has designed tapered versions of their device to appropriately manage patients so that distal device oversizing does not occur. The proximal and distal device diameters vary by 5 mm, which allows for improved accommodation to the true aortic diameter in patients with non-aneurysmal disease.

Early results with the Conformable GORE® TAG® Device appear to mimic prior outcomes in patients with thoracic aortic aneurysms, and the US Food and Drug Administration has approved it for use in aneurysmal disease and, more recently, other isolated lesions, including aortic transection (not including dissections). The device is also being studied in aortic dissection. Early experience with the device shows that it conforms extremely well to the aortic arch (Figure 4). Whether the clinical trial data support its use in this additional pathology is yet to be determined; however, given previous experience with thoracic aortic aneurysms and aortic transection, many of us are optimistic.

CONCLUSION

Current data suggest that the endovascular treatment of BAI results in improved outcomes. There are, however, procedure-specific complications that can occur. Proper planning is required to avoid errors in device oversizing and conformability, using centerline software algorithms. Recognition of these issues, in addition to next-generation devices designed to mitigate these problems, should only improve on the impressive results being reported with the expansion of endovascular technology for treating BAI. ■

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