Comparison of thoracic aortic diameter changes after endograft placement in patients with traumatic and aneurysmal disease

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Objective: **The purpose of this study was to evaluate acute changes in aortic size before and after endograft placement for traumatic injury and aneurysmal disease. We hypothesize that there are inherent differences between trauma and aneurysm populations undergoing thoracic endovascular aortic repair (TEVAR) and that these factors may affect device choice and sizing for each group.**
Methods: **This retrospective study evaluated the existing digital imaging of traumatic injury and aneurysmal patients enrolled in the 0802 and 0803 multi-site trials that received the GORE Conformable TAG thoracic device. Pre- and post-treatment imaging was available for 70 traumatic injury and 54 aneurysmal patients. Post-treatment imaging was defined as being complete within 30 days of treatment. A standardized protocol was used to complete measurements of the proximal and distal maximum neck diameters through the use of the orthogonal view before imaging and at 30-day imaging. The resultant changes in diameter for each group were analyzed by means of *t*-tests.**
Results: **Mean increases in proximal (3.0 mm vs 2.0 mm; $P < .05$) and distal neck diameters (2.9 mm vs 0.7 mm; $P < .01$) after TEVAR are significantly greater in traumatic injury patients than in aneurysm patients between pretreatment and 30-day imaging. In both study populations, smaller pretreatment aortic neck diameters showed a larger change in neck diameter than did larger pretreatment aortic diameters. Aneurysm patients were oversized significantly more than were trauma patients at the proximal neck (9.1% vs 4.5%; $P < .05$). However, at the distal neck, the trauma patients were oversized more than were the aneurysm patients (17.5% vs 13.6%; $P = .06$). A strong correlation was found between the percentage of oversizing and change in the distal neck diameter after TEVAR in both patient groups.**
Conclusions: **The results suggest that there are differences between trauma and aneurysm populations. Careful device selection may contribute to the avoidance of complications related to both undersized and oversized devices. Short-term analysis shows that TEVAR can be successfully accomplished in both trauma and aneurysm groups over a wide sizing range. Further data regarding long-term device complications are needed to better characterize this relationship. (J Vasc Surg 2014;59:1241-6.)**

Thoracic endovascular aortic repair (TEVAR) has become a common practice for the treatment of thoracic aortic aneurysms that meet appropriate anatomic constraints.[1-4] This technology has been rapidly extended to the treatment of traumatic aortic injuries because of overall decreased morbidity and mortality rates compared with open surgical techniques.[5,6] In recent years, more patients have undergone TEVAR compared with open surgical repair for both indications.[7-13] The success of TEVAR is dependent on the ability of the endograft to seal off the area of disease or injury by appropriate fixation at the proximal and distal landing zones in the normal aorta. This is mainly accomplished by the radial force of the endograft, which is created by oversizing the device with respect to the aorta, with most device manufacturers recommending 10-20% oversize. Aortic diameters are also influenced by numerous factors before and after endovascular treatment, including relative elasticity, cardiac output, and volume status. We hypothesize that there are inherent differences between trauma and aneurysm populations undergoing TEVAR and that these factors may affect device choice and sizing for each group. The goal of this study was to examine changes in the size of the aorta after TEVAR in trauma and aneurysm groups. Our null hypothesis was that there is no difference in aortic diameter between pre- and post-treatment imaging or between trauma and aneurysm populations.

METHODS

Existing digital imaging of traumatic injury and aneurysmal patients enrolled in the GORE 0802 and 0803

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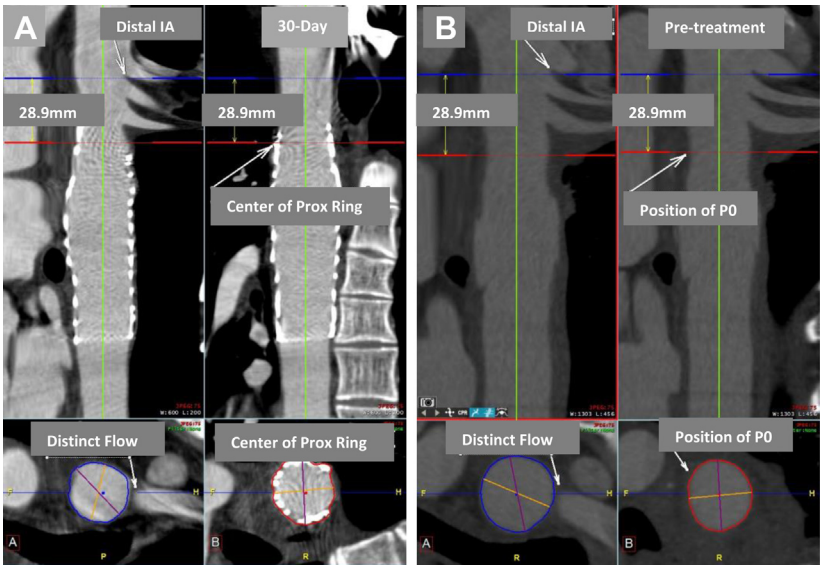

Fig 1. Proximal neck diameter measurement. **A,** Length measurement from innominate artery to the center of the proximal gold ring on 30-day image. **B,** Pretreatment measurement.

multi-site trials that received the GORE Conformable TAG (CTAG) thoracic device (manufactured by W. L. Gore and Associates, Flagstaff, Ariz) was evaluated by an independent core lab in a retrospective analysis. There were 29 sites in the United States participating in the TAG 0802 trauma study and 30 sites in the United States participating in the TAG 0803 aneurysm study. The studies enrolled a total of 101 traumatic injury patients and 66 aneurysm patients. Pretreatment and post-treatment imaging was received by the core lab for 124 patients (70 traumatic injury patients and 54 aneurysmal patients). Post-treatment imaging was defined as being complete within 30 days of placement of the TAG device.

A standardized protocol was used by a single experienced core lab observer to complete independent measurements of the proximal and distal maximum neck diameters with the use of TeraRecon Aquarius iNtuition (TeraRecon, Inc, Foster City, Calif). Through the use of orthogonal centerline views, the length from the innominate artery to the most proximal and distal device rings was first completed on the 30-day image (Fig 1). The innominate artery was defined as the location in which distinct flow could be observed, and the device ring was defined as the location in which a complete ring was visible. Aortic arch curvature results in some device rings were not orthogonal to the flow lumen. In these situations, the location in which the ring was observed on opposite sides of the aorta was selected for measurement because this represented the middle of the device ring. The length measured on the 30-day image was then measured on the pretreatment image by placing one marker at the innominate artery and measuring distally to the approximate locations of the proximal and distal rings determined on the 30-day image (Fig 1). The maximum proximal and distal neck intimal diameters were subsequently measured at these locations.

The CTAG device is available in diameters of 21-45 mm, which allows for the treatment of patients with aortic neck inner diameters of 16-42 mm. The oversizing window range of the CTAG device is from 6-33%. Device oversizing in the patients included in this study was assessed through the use of the nominal device diameters at the most proximal and distal rings, and the preprocedure intimal diameters were measured by the core lab observer [(device diameter minus intimal aortic neck diameter)/aortic intimal neck diameter]. The resultant changes in proximal and distal neck diameter for trauma and aneurysm patients were analyzed by means of *t*-tests.

RESULTS

There was a significant difference in the changes of the proximal and distal neck diameters from the pretreatment imaging and 30-day imaging in trauma and aneurysm patients (Table). Mean increases in the proximal (3.0 mm vs 2.0 mm; $P < .05$) and distal neck diameters (2.9 mm vs 0.7 mm; $P < .01$) after TEVAR were significantly greater in traumatic injury patients than aneurysm patients; this corresponded to a 12.5% increase in the proximal neck and 14.4% increase in the distal neck of trauma patients. In comparison, aneurysm patients showed a 6.9% increase in the proximal neck and a 2.7% increase in the distal neck diameter (Table). In addition, trauma patients had a greater range in which the proximal and distal neck diameters changed between the pretreatment imaging and 30-day imaging (Table).

In both study populations, there was an inverse correlation between pretreatment neck diameter and the percentage of change in the neck diameter between the

Table. Change in aortic neck diameter (mm and % difference) between pretreatment imaging and 30-day imaging in patients with trauma and patients with aneurysmal disease

	Traumatic injury	*Aneurysmal disease*	P *value (trauma vs aneurysm)*
Change in proximal neck diameter, mm			
Mean	2.98	2.06	.026
Standard deviation	2.50	1.86	
Difference in proximal neck diameter, %			
Mean	12.51	6.87	.0009
Standard deviation	10.97	6.17	
Change in distal neck diameter, mm			
Mean	2.89	0.67	<.0001
Standard deviation	1.82	1.76	
Difference in distal neck diameter, %			
Mean	14.43	2.65	<.0001
Standard deviation	10.35	5.63	

pretreatment imaging and 30-day imaging. Specifically, smaller pretreatment aortic neck diameters showed a larger change in neck diameter than did larger pretreatment aortic diameters after TEVAR (Fig 2). This correlation was slightly stronger in trauma patients compared with aneurysm patients. With a correlation coefficient of 0.68, the correlation was strongest in the distal neck diameter in trauma patients (Fig 2).

Aneurysm patients were oversized significantly more than were trauma patients at the proximal neck (9.1% vs 4.5%; $P < .05$). However, at the distal neck, the trauma patients were oversized more than were the aneurysm patients (17.5% vs 13.6%; $P = .06$). A strong correlation was found between the percentage of oversizing and the change in the distal neck diameter after TEVAR in the traumatic injury and aneurysm patients (Fig 3). With correlation coefficients of 0.7 and 0.65 for trauma and aneurysm patients, respectively, the degree of oversizing in the distal neck region of both patient groups correlated with the change in the distal neck diameter more so than did the proximal neck diameter (Fig 3). The correlation between degree of oversizing and the proximal neck diameter changes was weaker than that observed with the distal neck diameter in both study populations. In addition, percentage of oversizing was greater in smaller proximal and distal neck diameters in trauma and aneurysm patients.

DISCUSSION

This analysis shows that aortic diameters increase after TEVAR, but these increases were significantly greater in the trauma group. The average proximal neck size increased in trauma patients by 12.5% compared with 6.9% in aneurysm patients. Likewise, the average distal neck size increased by 14.4% in trauma patients compared with 2.7% in aneurysm patients.

One possible explanation for the larger diameter increase in trauma patients is that in general, these patients tend to be younger, without significant atherosclerotic disease. Multiple studies have shown that aortic compliance, or distensibility, decreases with age and with the presence of atherosclerotic disease.[14-18] It is reasonable to assume that our trauma population is similarly younger with more compliant aortas compared with the patients with aneurysmal disease who are more likely to be older, with atherosclerotic disease. This inherent difference may partially explain the larger diameter increases in the trauma group. The patients will be followed for 5 years, and the longitudinal data will show whether or not this trend persists for larger neck diameter increases in trauma patients compared with aneurysm patients.

Another possible explanation for the larger relative diameter increases in the trauma group is that the preprocedure aortic measurements were smaller as the result of hypovolemia and shock. Several studies have attempted to investigate the effects of hypovolemia on aortic diameters. With the use of a porcine model, intravascular ultrasound has been used to quantify aortic diameters at various degrees of hypovolemia. The descending thoracic aorta decreased in size on average by 30% with restoration of the original diameter after fluid resuscitation.[19] With the use of this model, the authors also showed that the pulsatility of the aorta during the cardiac cycle decreased from 9% under normovolemic conditions to 6% during hypovolemia.[20] The authors suggest that it may be appropriate to increase the degree of device oversizing in trauma patients to avoid inadvertent undersizing or to obtain repeat imaging after appropriate fluid resuscitation to obtain more accurate aortic diameters. Additionally, they suggest that cardiac-gated imaging may not be necessary in trauma patients because of decreased aortic pulsatility related to hypovolemia in these patients.[20] A study quantifying hypovolemic aortic changes in humans has also been reported by these investigators. They performed a retrospective review of a trauma registry and identified patients with hemodynamic instability. They found that after resuscitation, the aortas of trauma patients increased by 6-12% on average in the typical endograft fixation zones.[21] There is a high probability that a patient with a traumatically injured aorta is likely to have some degree of hypovolemia, which may therefore influence the size of the aorta, especially in comparison to patients who are treated electively for aneurysmal disease. This could account for the significant difference observed in our study in aortic diameter after TEVAR between trauma and aneurysm patients. Therefore, in patients with clinically suspected hypovolemia, clinical practice should include obtaining intraoperative measurements with intravascular ultrasound or repeat computed tomography if time permits. This could allow for more accurate device sizing.

There are serious consequences related to appropriate device sizing that make careful preprocedural imaging

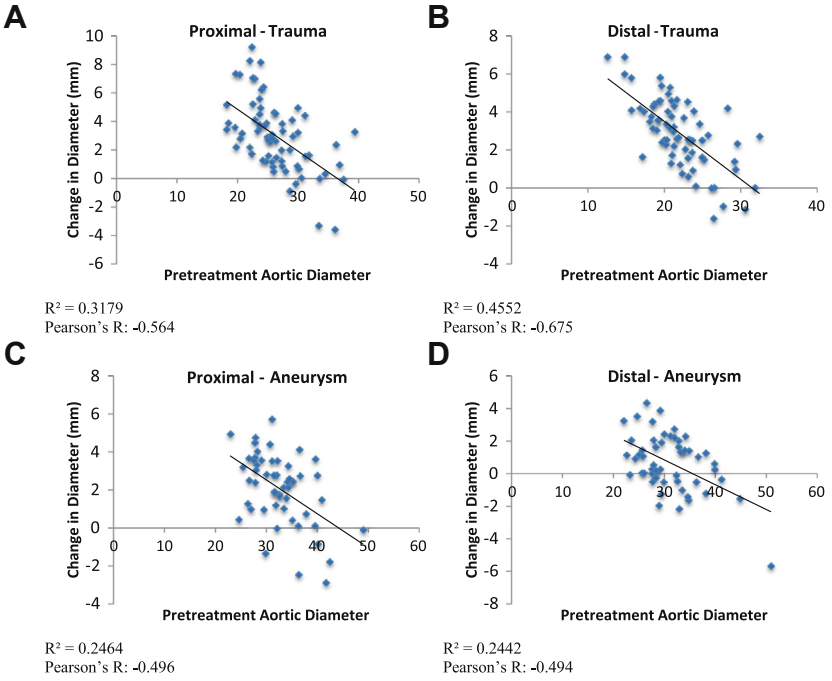

Fig 2. Scatterplots of pretreatment aortic diameters compared with changes in proximal/distal aortic neck diameters. **A,** Proximal trauma; **B,** distal trauma; **C,** proximal aneurysm; **D,** distal aneurysm.

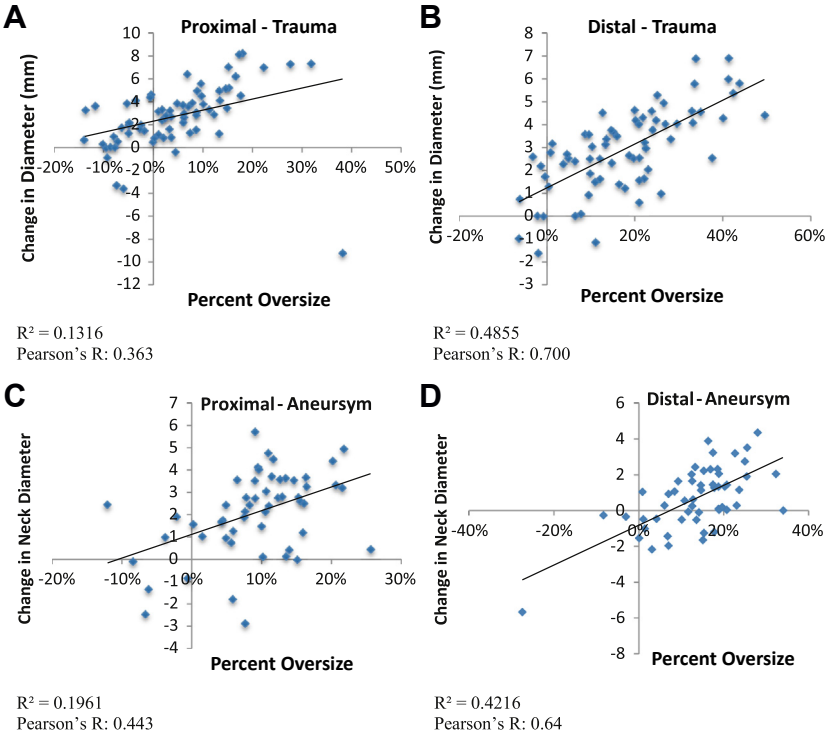

Fig 3. Scatterplots comparing percentage of oversize with changes in proximal/distal aortic neck diameters. **A,** Proximal trauma; **B,** distal trauma; **C,** proximal aneurysm; **D,** distal aneurysm.

and measurements essential. If the endograft is not appropriately sized, adequate fixation and sealing may be compromised. Devices that are undersized may result in type I endoleak and potential migration. Additionally, over time, most aortas increase in diameter related to normal age changes and as the result of progression of aneurysmal disease.[22-26] Endografts that are initially oversized may become undersized as these aortic changes progress, putting the device at risk of failure. In the current GORE 0803 aneurysm study, there are few endoleaks identified on the 1-month follow-up. The 1-month data showed eight (13.1%) aneurysm patients with an endoleak: one undetermined, two type I, and five type II.

On the other end of the spectrum, extreme device oversizing may result in device infolding and collapse or type I endoleaks, leading to treatment failure.[27-32] No cases of infolding or collapse were observed in this study; however, it is crucial to be aware of the potential impact that oversizing may have on inducing the aortic diameter change when selecting a particular endograft size. With an oversizing window that allows a broader range of treatment diameters with the conformable TAG, inappropriate sizing should be less likely to occur.

This study has limitations. The core lab did not have access to clinical information including patient characteristics such as age, the presence of shock, or blood pressure. The timing of the preprocedure computed tomographic scan with respect to volume resuscitation is unknown. In addition, there was a single core lab observer who could not be blinded to the type of treatment the patient received. Finally, we do not have information on intraprocedural imaging that may have influenced device choice and landing zone.

CONCLUSIONS

There was a significant increase in aortic diameter after TEVAR in the traumatic injury group and in patients treated for aneurysmal disease. The increase was significantly greater in trauma patients. These results suggest that there are inherent differences between these groups. Careful device selection may contribute to the avoidance of complications related to undersized and oversized devices. In addition, clinical practice should include intraoperative imaging if hypovolemia (not oversizing) is suspected. Short-term analysis shows that TEVAR with a device can be successfully accomplished in trauma and aneurysm groups over a wide sizing range. Further data regarding long-term device complications are needed to better characterize this relationship.

AUTHOR CONTRIBUTIONS

Conception and design: HA, JS, TS, MF, WJ, AA, JR, JM
Analysis and interpretation: HA, JS, TS, JM
Data collection: HA, TS
Writing the article: HA, JS
Critical revision of the article: HA, JS, TS, MF, WJ, AA, JR, JM
Final approval of the article: HA, JS, TS, MF, WJ, AA, JR, JM
Statistical analysis: HA
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Overall responsibility: HA

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