

Endovascular Repair of an Isolated Descending Thoracic Aortic Aneurysm With the Relay® Thoracic Stent-Graft System

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The incidence of thoracic aneurysms has increased from 5.9 to 13.9 cases per 100,000 people in the last 20 years.¹ In elderly patients with increased medical comorbidities, endovascular repair has become a reliable alternative to open repair in the treatment of patients with isolated descending thoracic aortic aneurysms. Several studies have delineated decreasing perioperative morbidity and mortality when compared to open thoracic or thoracoabdominal approaches.²⁻⁷ Since the late 1990s, diverse thoracic stent-grafts have been approved outside the United States. Several medical device companies and independent physicians have evaluated these devices in United States clinical trials, and four commercial devices for thoracic endovascular aortic repair (TEVAR) are currently approved for use in the United States. Published early and midterm results regarding the use of these devices have been favorable and supportive of the therapy in comparison to standard surgical repair. We report a case of a patient presenting with a complex isolated descending thoracic aneurysm successfully treated with TEVAR using the Relay thoracic stent-graft system (Bolton Medical, Inc., Sunrise, FL) as part of our participation in the phase II clinical trials for this device. The phase II Clinical Study of the Safety and Efficacy of the Relay Thoracic Stent-Graft in Patients with Thoracic Aortic Pathology recently led to the FDA approval of this new thoracic stent-graft.

CASE REPORT

A 79-year-old man with a significant history of hypertension and previous open infrarenal abdominal aortic

aneurysm tube graft repair had been followed at our clinic for an asymptomatic descending thoracic aneurysm. At his most recent visit, the thoracic aneurysm had expanded, and a computed tomography angiogram (CTA) revealed a 5.5 cm isolated descending thoracic aortic aneurysm with a severe angulation at its distal extent (Figure 1A). The descending aorta made an approximately 90° turn at its most posterior aspect with evidence of lumen compromise (Figure 1A). In addition to this severe aortic buckling, moderate bilateral iliac tortuosity added to the patient's anatomic complexities (Figure 1B). There was no history of aortic dissection. Because the aneurysm started approximately 4 cm from

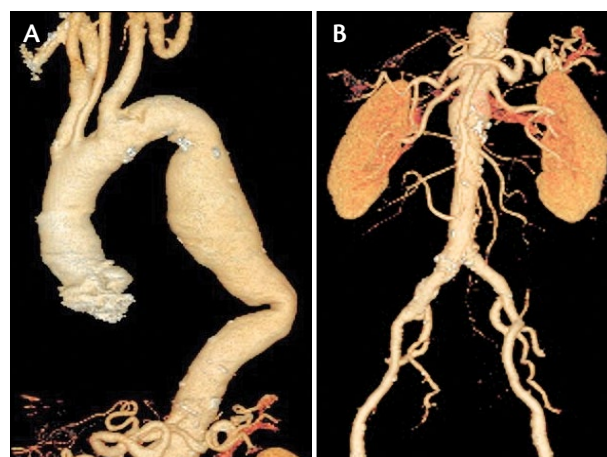


Figure 1. Preoperative 3D CTA revealing an isolated descending thoracic aortic aneurysm with severe aortic buckling (A) and moderate bilateral iliac tortuosity (B).

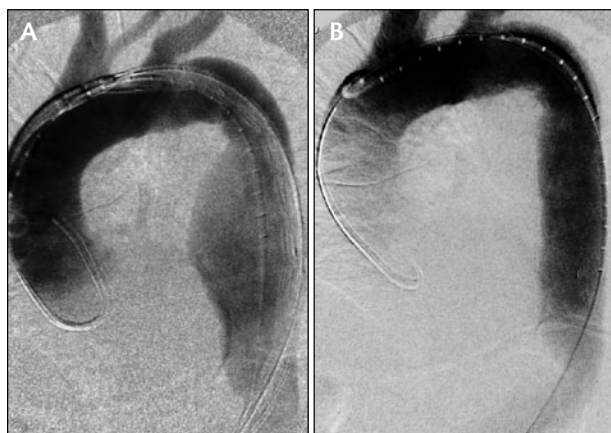


Figure 2. A predeployment aortogram shows the proximal extent of the descending thoracic aneurysm (A). The post-deployment aortogram shows repaired aneurysm with no endoleak (B).

the takeoff of the left subclavian artery and was limited to the thoracic aorta, we decided that the anatomy was well suited for TEVAR, and the patient was consented and enrolled in the Relay phase II trial. A 34 mm X 250 mm single-segment Relay endograft was advanced over a superstiff guidewire from the right common femoral artery and delivered into the aortic arch. The dual-sheath delivery system enabled the Relay endograft to track effortlessly through the iliac system and the aortic angulation in a smooth and controlled fashion. The takeoff of the left subclavian and left carotid arteries were then marked after an arch injection with a left anterior oblique view (Figure 2A). Partial opening of the Relay graft enabled us to accurately position the proximal bare stent across the left subclavian artery and the covered stent right at its ostium (Figure 3B). The endograft was then fully deployed with the distal extent well above the celiac artery. Completion aortogram showed absence of any endoleak and patent arch vessels (Figure 2B). Postoperatively, the patient had an uncomplicated course and was discharged to home on postoperative day 2. The initial postoperative CTA confirmed accurate positioning as well as excellent conformability of the Relay endograft at the level of the aortic arch and across the distal aortic angulation (Figure 3A and 3B). Significant aneurysm sac shrinkage was noted on a 2-year follow-up CTA (Figure 4). A 5-year follow-up CTA revealed a stable stent-graft without any migration and absence of residual aneurysmal sac in the descending thoracic aorta.

DISCUSSION

In the nearly 20 years that endovascular treatment of thoracic aortic pathologies has been performed, numer-

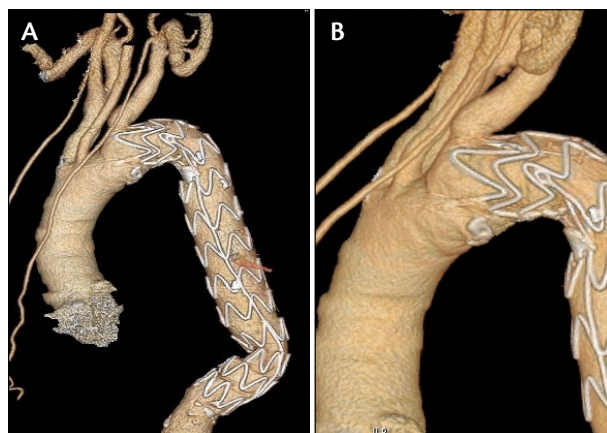


Figure 3. Postoperative 3D CTA shows excellent positioning of the stent-graft with total aneurysm sac exclusion (A). Note the precise positioning of the uncovered portion of the proximal stent at the left subclavian artery (B).

ous investigators have demonstrated its safety, efficacy, and comparable results to open surgical repair with less morbidity and mortality. Successful TEVAR requires complete endovascular sac exclusion, which relies upon exact positioning of the graft in order to achieve adequate fixation and sealing. Another important factor in the selection, planning, conduct, and outcome of endovascular aortic aneurysm repair is the degree of aortoiliac tortuosity. Excessive tortuosity may cause difficulty in gaining access to the aneurysm and in the deployment of the stent-graft, and it may result in unstable fixation.⁸ Tortuosity has been implicated as a cause of late complications and endograft failure through progressive distortion and limb retraction.⁹ Not all patient anatomy is suitable for endovascular repair, and device-related complications such as endoleaks, stent-graft collapse, and migration, could occur.

The optimal aortic stent-graft needs to be highly flexible and conform perfectly to the aortic wall and should also withstand aortic movement and blood flow. Reliable trackability of the delivery system is also crucial to achieve precise positioning.

In our preoperative assessment of this patient's anatomy, we believed he would be a good candidate for the phase II trial involving the Relay thoracic stent-graft system. This endograft is designed specifically for thoracic aorta disease repair and has the advantage of additional columnar support, achieved by a helical nitinol backbone wire that helps preserve torque response and flexibility. We have found that this design feature, combined with the dual-sheath delivery system, improves the device's ability to track through severe aortic angulations. In addition, the oblique backbone at the outer half of the

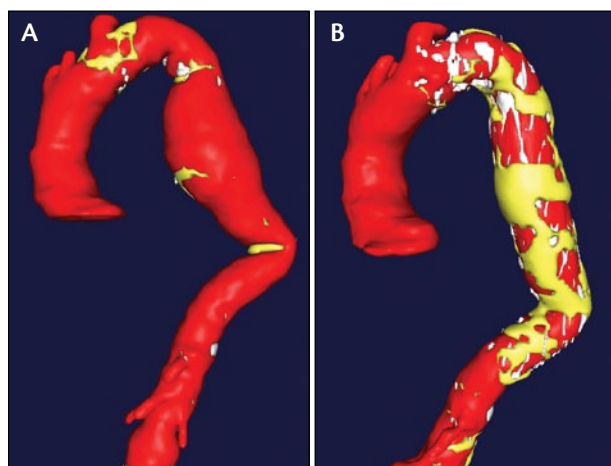


Figure 4. Three-dimensional M2S reconstructions (M2S Inc., West Lebanon, NH) of the preoperative thoracic aorta (A) and a 2-year follow-up image (B) displaying significant aneurysm sac (yellow) remodeling and relief of aortic buckling.

stent-graft tends to rotate toward its intended position during application, allowing for precise delivery to increase accuracy of positioning. The nitinol wire starts proximally below the second ring, which allows for relatively independent movement of the first and second stent-graft rings for optimal apposition in the aortic arch. The radial force of the stent-graft is also greatest at the proximal ring in order to provide the highest radial load for sealing and fixation.¹⁰ Seemingly, these attributes contributed to the successful outcome of our patient and will make this graft a safe and effective choice in the future for patients with challenging thoracic aortic anatomy.

In conclusion, we have demonstrated a successful TEVAR outcome in a patient with difficult anatomy using the Relay stent-graft system without perioperative complications. The device's durability is evidenced by a 5-year follow-up with complete aneurysm sac shrinkage and absence of migration. Anatomic aortoiliac complexities such as those illustrated in our patient can account for both technical and treatment failures in patients undergoing TEVAR. Structural and delivery design improvements in the Relay stent-graft system may have

the potential to increase the feasibility and success of endovascular repair in this cohort of patients with complex anatomy. ■

Francis P. Cuzzo, MD, is a vascular surgery fellow with the Division of Vascular Surgery, Eastern Virginia Medical School in Norfolk, Virginia. He has disclosed that he has no financial interests related to this article.

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