Type B Aortic Dissection

Are aortic endografts changing the treatment paradigm?

BY ROSS MILNER, MD

Aortic dissection is a complex aortic pathology with associated high morbidity and mortality rates. The treatment of an aortic dissection that involves the ascending aorta (Stanford type A or DeBakey type I or II [Figure 1]) requires urgent surgical repair. The treatment of an aortic dissection that originates distal to the left subclavian artery (Stanford type B or DeBakey type III) has been historically treated by medical management with hypertension control. This recommendation is altered when patients present with intestinal or lower-extremity malperfusion. Patients with persistent back pain, despite adequate blood pressure control, may also require repair.

Endovascular repair of type B aortic dissection with a thoracic endograft is becoming more widely applied internationally. The history of this approach, reported series and current clinical trials, and future directions will be discussed.

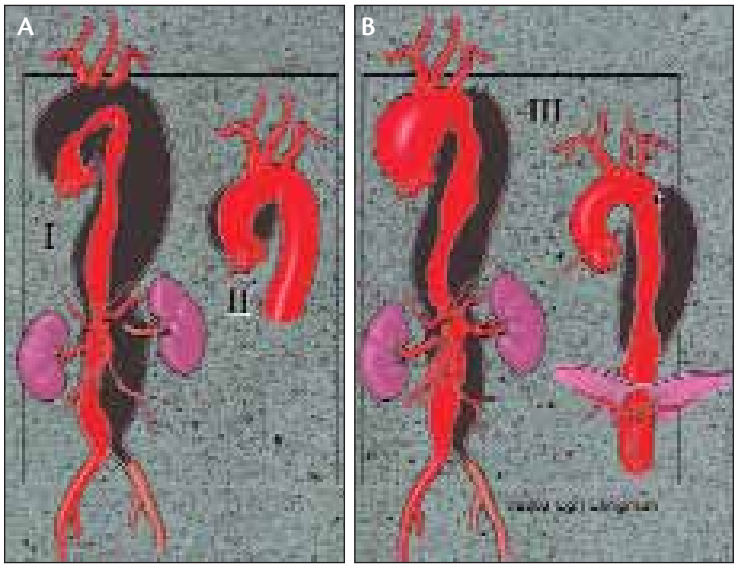

Figure 1. Classification of aortic dissection. DeBakey type I and II dissections and Stanford type A dissections (A). DeBakey type III dissection and a Stanford type B dissection (B).

INITIAL REPORTS

The initial enthusiasm for the endovascular treatment of type B aortic dissection using a thoracic endograft arose from a set of publications in the *New England Journal of Medicine* in 1999. Christoph A. Nienaber, MD, and Michael D. Dake, MD, reported an early experience with dissections in separate articles in the same issue.[1,2] Nienaber prospectively compared 12 patients who underwent stent placement against 12 patients who underwent surgical repair. There were no reported complications or mortalities in the endovas-

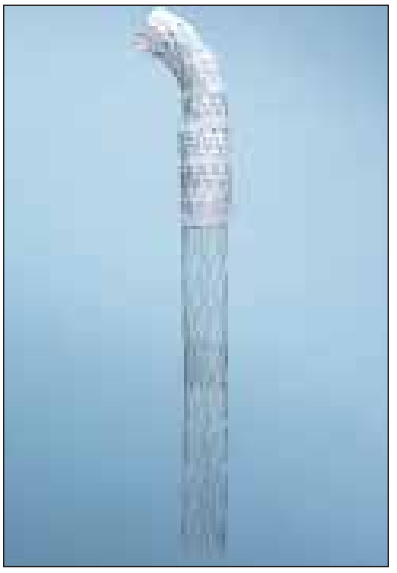

Figure 2. TX2 dissection device by Cook. This device has covered stents proximally and bare-metal stents distally.

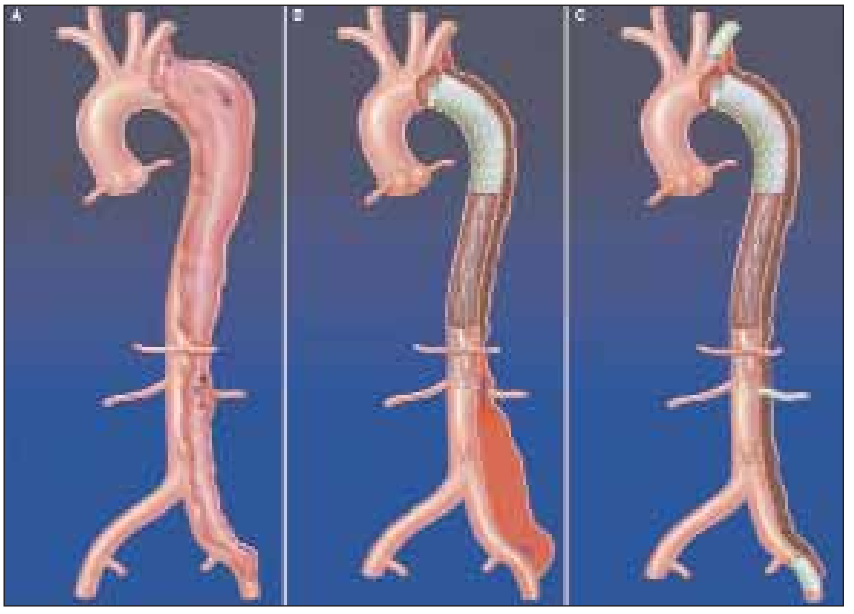

Figure 3. Use of the TX2 dissection device and additional stents in the left renal artery and left iliac artery to treat malperfusion and additional entry tears. Type B aortic dissection (A). Left renal artery malperfusion and re-entry tear in the left external iliac artery after placement of the TX2 dissection device (B). Covered stent placement to treat the left renal artery and left external iliac artery (C).

cular group. There were four deaths (33% mortality rate) and five serious complications in the surgical group. In light of this success, the investigators concluded, "Endoluminal repair may be useful for interventional reconstruction of thoracic aortic dissection."

Dake et al reported on four patients with a tear in the descending thoracic aorta, who also presented with a type A dissection, and 15 patients with a type B aortic dissection. They were able to place an endoluminal device successfully in all patients. In addition to a high rate of false-lumen thrombosis (79%), they reported a high rate (76%) of revascularization of compromised branch vessels. There were no deaths in this group over 13 months of follow-up evaluation. The investigators concluded, "These initial results suggest that stent-graft coverage of the primary entry tear may be a promising new treatment for selected patients with acute aortic dissection. This technique requires further evaluation, however, to assess its therapeutic potential fully."

Both groups used homemade devices to treat these initial patients. Thoracic endograft technology has significantly improved in the decade since these exciting reports. In the US, the only currently FDA-approved thoracic endograft is the TAG device by Gore & Associates (Flagstaff, AZ), which is approved for the treatment of thoracic aortic aneurysms only. The treatment of type B aortic dissections is considered off-label use. Cook Medical (Bloomington, IN) and Medtronic CardioVascular, Endovascular Innovations (Santa Rosa, CA) expect to gain FDA approval for their thoracic endografts later this year or in early 2008. These devices are also only going to be indicated for aneurysmal disease. All of the manufacturers are involved in or are planning trials to allow for expanded indications for treatment, including aortic dissection.

CURRENT REPORTS AND CLINICAL TRIALS

Eggebrecht and colleagues recently published a meta-analysis of 39 published reports with at least three patients who presented with type B aortic dissection treated by endovascular means.[3] All devices were inserted in a retrograde fashion, and a total of 609 patients were treated. The procedural success rate was very high (98%). The major complication rate was relatively high at 11%. The neurologic complication rate was 2.9%, with a 1.9% rate of stroke and a .9% risk of paraplegia. The 30-day mortality rate was 5.3% and was more common in acute versus chronic dissection patients. Kaplan-Meier analysis revealed a survival rate of 88% at 2 years. The investigators concluded, "Both acute and midterm mortality of this novel treatment strategy appear to favorably compare with surgical treatment, but further studies are necessary to compare stent-graft placement with medical treatment in uncomplicated

aneurysmal disease."

A randomized study has been performed by Nienaber et al using the Medtronic Talent device for the treatment of type B aortic dissection. The initial study design was reported in 2005.[4] Patients were randomized to medical management (hypertension control) versus endovascular treatment. All patients included had to have a patent false lumen at 14 days to be randomized. One hundred thirty-six patients have been included and will be followed for 24 months. The 1-year follow-up is not yet published, but preliminary results in presentations have not shown a difference in outcome between the two groups. Further follow-up and analysis of patient selection will be performed.

One additional trial for aortic dissection has been completed in the US (TAG Complex Pathology Trial). This trial was performed by Gore using the TAG device for traumatic transection, type B aortic dissection, and ruptured thoracic aneurysms at a small number of enrolling sites and was led by Richard Cambria, MD, as the National Principal Investigator. A total of 20 patients were prospectively enrolled in each group. The dissection patients had to present with complications of the dissection to be included in the trial. The enrollment is complete for the trial, but data are not yet reported in the literature.

A more important trial in terms of the evaluation of endovascular therapy for type B aortic dissection will be the ADSORB trial by Gore & Associates. This proposed clinical trial will include patients with acute, uncomplicated type B aortic dissections. Two hundred fifty patients will be randomized in approximately 30 major European centers of excellence. Patients will be randomized to best medical therapy versus endovascular treatment with the TAG device and best medical therapy. The major endpoints will be false-lumen thrombosis and aortic rupture.

FUTURE DIRECTIONS

The major evolution in endovascular therapy for type B aortic dissection will likely be the development of dissection-specific devices. Cook has designed a device that may allow for the more durable therapy of type B aortic dissection that involves visceral vessel malperfusion (Figure 2). The TX2 dissection device is designed to treat the entry tear with a covered stent design proximally. In addition, the bare-metal stent design in the distal portion can provide stability to the true lumen in the visceral segment of the aorta. Finally, additional covered or bare-metal stents can be used to treat additional vessels compromised by the dissection or additional entry tears (Figure 3).

Device design is not the only important evolution that will occur in the endovascular treatment of type B aortic dissection. The appropriate selection of patients to be treated is potentially even more important. The initial enthusiasm to treat all patients who present with an acute, type B aortic dissection has waned with the preliminary report from the INSTEAD trial and the risk of complications.[5] There are also reports of conversion to a type A aortic dissection with fatal results when treating acute type B aortic dissection.[6] Patients who present with malperfusion will likely benefit from endovascular therapy with a thoracic endograft. This is also true for patients with expansion of the false lumen in the early follow-up period. The proposed clinical trials will help us understand the role of endovascular therapy in the patient who presents without complications.

CONCLUSION

Endovascular management of type B aortic dissection has been promising in the early reports in the literature and in continued analysis. The current devices are not specific to aortic dissection and need to evolve to treat this problem. Significant complications are reported in the literature that can lead to poor neurologic outcomes and death. The appropriate patients to treat with an endoluminal approach are still being determined, but there is great enthusiasm for the benefit of this approach. ■

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