The STABLE Trial

Joseph Lombardi, MD, describes the Zenith Dissection Endovascular System and the STABLE trial, designed to evaluate patients with complicated type B aortic dissections.

How is the STABLE trial different from the others?

The STABLE trial is the only trial specifically designed to treat patients with complicated type B aortic dissections. It is the only trial that has a pathology-specific device for type B aortic dissections.

Within the trial, can you treat acute and chronic dissections?

Yes. The trial is designed to incorporate patients who fail medical therapy early. Patients who are found to have expanding aneurysms early on are eligible for treatment provided they fall within a 3-month window from presentation.

Can you tell us about the Zenith Dissection Endovascular System (Cook Medical, Bloomington, IN) and its components?

The dissection system is composed of a proximal TX2 component, which has recently been FDA approved. That component is designed to seal the primary entry of the dissection. The second component is the uncovered stent component. That is designed to support the true lumen and minimize membrane or flap mobility, promote wall apposition of the dissected intima, and allow for realignment of re-entry tears. Ultimately, it helps promote false lumen thrombosis.

Are there dissections in which you may opt to use the bare stent alone or the stent graft alone?

Coverage of the primary entry tear with a stent graft will always be a part of the treatment. Situations in which just a single TX2 device could be deployed alone, without the uncovered component, do exist but are infrequent. Perhaps there may be applications in the future for just an uncovered stent, but not within the scope of this current trial.

The largest series using this system is in Melbourne, Australia. Who are those investigators and what results have they had?

Drs. Peter Mossop and Ian Nixon in Melbourne, Australia, developed this technique. They started with a more primitive version of the stent in which they had to deploy multiple stainless steel Gianturco Z-stents (Cook Medical) within the true lumen to support it. Ultimately, over time, it was thought that tying or suturing these stents together in an elongated version of what they started with would provide a better delivery and ease of use. They have had great success with this. To date, their published data have shown excellent results for these complicated patients.

With this treatment, how do you address access to side branches?

After the TX2 stent graft is deployed and the second uncovered dissection component is delivered, the operator has the option of accessing branches that might still be at risk for malperfusion. This allows for the operator to direct a catheter into these branch vessels and treat the patient through the uncovered stent for persistent malperfusion. The stent provides a way of both supporting the true lumen and crossing these vital branched vessels, while providing accessibility to these vessels in the event that malperfusion is still an issue.

The traditional way of treating type B dissections is medical therapy. Has that "standard of care" been an impediment to enrollment in the STABLE trial?

Enrollment has been steady with complicated varieties of aortic dissection with the standard of care well respected by our investigators. Any patient with an uncomplicated type

B dissection who is successfully treated with medical therapy is a "treatment success" provided they are carefully followed for early and late complications. However, there are subsets of these patients who fail and need intervention. All of the patients who present with a type B aortic dissection who are stable with medical therapy are under intense scrutiny as a result of the trial. Overall, this helps us find some of those patients who fail adequate medical therapy early on, giving us a better chance to provide successful treatment. I think overall the trial has given us a heightened sense of awareness, better early management, and follow-up care.

Is the survival rate at 5 years acceptable enough with medical therapy that it is not worth entertaining an alternative treatment?

At 5 years, the International Registry of Aortic Dissections showed that regardless of whether the patient had endovascular treatment, open surgical treatment, or medical therapy, the survival rate is between 76% and 82%. However, these were vastly different patient populations in comparison. The medical patients were stable, and the others were not. Medical therapy alone for complicated early type B dissection would produce dismal results, and a 5-year survival estimate may be unrealistic. Treating aortic dissection is a patient-specific process, possibly requiring many different modes of therapy/intervention, and perhaps we may find that combinations and sequences of treatments ultimately hold the best strategies.

The TX2 graft has barbs at its proximal end. Is this any concern is stent grafting type B dissections?

The TX2 has been through a clinical US pivotal trial and a large series throughout the world, treating for both thoracic aortic aneurysms and aortic dissections. Intimal damage from the barbs has never been shown in any of these areas. The barbs are always positioned in a normal landing zone of a nondissected or relatively "healthy" aorta. Furthermore, the TX2 data show a 0% migration rate for the pivotal trial. When compared with other devices, you may find migration rates as high as 15% to 17%, making active fixation a really nice option for such a dynamic area of the aorta. ■

Joseph Lombardi, MD, is Associate Professor of Surgery, and Director, Jefferson Aortic Center, Division of Vascular & Endovascular Surgery, Thomas Jefferson University Hospital in Philadelphia, Pennsylvania. He has disclosed that he is a consultant to Cook Medical and the Global Principal Investigator of the STABLE Trial. Dr. Lombardi may be reached at (215) 955-8304.