Commentary: Frozen elephant trunk hybrid arch device arrives in the United States

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Coselli and colleagues report the rigorously collected 1-year data for the industry-sponsored US Food and Drug Administration trial on the Thoraflex Hybrid arch device (Terumo Aortic). The prefabricated stent-supported elephant trunk device facilitates subsequent endovascular or open distal aortic repair, and, in some cases, eliminates the need for subsequent repair. In total, 74 patients were prospectively enrolled in 12 expert aortic centers with a wide variety of aortic pathology. This cohort had a high rate of previous sternotomy (46%) and concomitant procedures (59%). A range of techniques were used in terms of device length, distal anastomotic site, supra-aortic vessel treatment, and perfusion management, reflecting the expected variability of aortic anatomy and surgeon practice. Results were favorable, given this complex cohort and consistent with the previously reported experiences from the international community.

Some cautionary notes deserve mention. The distal stented segment of this graft carries a risk of spinal cord ischemia that is greater than that of conventional elephant trunk procedures. In this series, the rate of persistent paraplegia/paraparesis at 30 days was 5%, similar to our experience and that of a recent meta-analysis. The authors note that all events occurred with the 150-mm length device. We agree and have restricted our use almost exclusively to the 100-mm length device. Furthermore, we would suggest that patients with chronic dissection may be at greatest risk of spinal cord ischemia due to altered flow dynamics in the false lumen and may therefore benefit from prophylactic cerebrospinal fluid drainage.

One observed benefit of this approach is the complete avoidance of type 1A endoleaks with the surgically sewn proximal anastomosis, which remains the Achilles’ heel of off-label techniques. In this study, there was a high rate of planned distal procedures, which occurred in 41% of...
patients at a median of 122 days and were mostly endovascular. The versatility of this device allows a select group of patients to receive complete repair in a single stage. In those with distal disease, it has facilitated the completion of a planned multistage approach to multisegmental aortic pathology. Attention should be given to further reducing the delay to planned distal intervention. More data, however, will be required to examine retrograde flow and false lumen management in patients with chronic aortic dissection.

We congratulate the authors on this important trial that signals the entry of this device to the US market. Long-term imaging and clinical end points from a larger group of patients will clarify the role that innovative device will ultimately play in treating patients with complex aortic pathology.

References