Commentary: Don’t throw the baby out with the bath water

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Surgical management of pathology involving the transverse aortic arch and adjacent aortic segments remains a technical challenge for surgeons and a significant undertaking for patients with a substantial risk of postoperative stroke, death, and other complications. Contemporary repair focuses not only on the arch and proximal aorta but also on the downstream aorta. The frozen elephant trunk (FET) approach to total aortic arch replacement aims to extend repair into the descending thoracic aorta by combining open and endovascular technology and commonly relies on a hybrid device that is part traditional open graft and part endovascular stent-graft. This approach is increasingly used to treat these complex aortic pathologies. Although there are several FET devices in use throughout the world, only one device is available in the United States—the recently approved Thoraflex Hybrid device (Terumo Aortic).

In this issue of the Journal, Ibrahim and colleagues, on behalf of the Canadian Thoracic Aortic Collaborative, review their use of the Thoraflex hybrid graft in 128 patients who had undergone total aortic arch replacement between September 2014 and May 2021. Their experience stems from the efforts of 5 contributing surgeons from 4 aortic centers. Their focus was on thromboembolic complications encountered in the early postoperative period. Thromboembolic complications were defined as the early development of a thrombus within the device’s 10- or 15-cm stented portion, any thromboemboli detected in upstream or downstream circulation, or both. The identification of these complications relied on clinical findings as well as prospective and retrospective imaging studies. The authors identified 15 (12%) patients who met these criteria, which included 6 (5%) patients with thrombus within the FET only (all of whom were without clinical manifestation), 7 (5%) with isolated downstream thromboembolic events, and 2 (2%) with both a thrombus within the FET and a downstream thromboembolic event. Of the 9 patients with a thromboembolic event, only 6 had clinical manifestations. The authors then compared these 15 patients with the 113 patients without such complications. There was no difference between the 2 groups regarding mortality, stroke, or spinal cord injury. However, they found that patients who experience thromboembolic complications were more likely to be shorter in height, to receive a device with a 15-cm stented portion, or to have an autoimmune disease. Therapeutic anticoagulation resolved thrombosis in most cases. Although the authors relied on a single FET device and were without a comparator device, they concluded that their study shows that thromboembolic complications occur at a significantly greater rate after total aortic arch repair using a Thoraflex device.

In the prospective US Investigational Device Exemption trial for the Thoraflex Hybrid device, in which the pending publication\(^5\) of 1-year clinical outcomes describes the experience of 74 patients who underwent repair at 12 centers (including our own), thromboembolic events were uncommon; they occurred in only 2 (3%) patients, and neither event resulted in death. Regarding our own center’s specific
experience with the Thoraflex device, we have employed 15 of these devices in the clinical trial and post-trial period—this included 12 devices with a 10-cm endograft. In the 14 patients with available early postoperative computed tomographic imaging studies, none were identified as having a thrombus within the device’s stented segment. Notably, 1 patient was postoperatively diagnosed with ischemic colitis but fully recovered before discharge.

With only 6 (5%) deaths in a series of 128 patients undergoing total arch replacement, the authors confirm that the FET approach yields excellent results. However, certain individuals and scenarios warrant caution; short patients may need early anticoagulation, the 15-cm endograft avoided when possible, and the smallest acceptable endograft routinely deployed. In addition, the authors infer those patients with autoimmune disorders may be at increased risk of thromboembolism from possible blood surface interactions within the device and may be inherently predisposed to clot formation. Further study of foreign surface interactions and computational fluid dynamics may elucidate threats from turbulence related to the arch’s curvature or the increased surface area in the 15-cm device. Standardized imaging surveillance remains critical to all aspects of aortic repair, including early and late postoperative periods.

References