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Endovascular treatment of thoracoabdominal aortic aneurysm using physician-modified endografts

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Objective: **To report an initial experience with physician-modified thoracic endografts for endovascular treatment of thoracoabdominal aortic aneurysm (TAAA).**

Methods: **Single-center cohort study of the treatment of TAAA using a physician-modified fenestrated thoracic endograft for patients deemed to be at high risk of open repair. The cohort includes 21 patients in a prospective physician-sponsored U.S. Food and Drug Administration-approved investigational device exemption study and three patients treated outside the investigational device exemption. The procedure involves physician modification of a Cook TX2 thoracic stent graft with reinforced fenestrations. Branch stents were iCast balloon expandable stents. Treatment success was defined as successful aneurysm exclusion with freedom from permanent organ system dysfunction and return to preoperative level of independent functional status.**

Results: **Twenty-four consecutive patients were treated. Twenty-one patients (88%) met the endpoint of treatment success at a mean of 11 months follow-up. One patient (4%) died within 30 days due to complications of spinal cord injury (SCI). One patient (4%) died 4 months postoperatively after a prolonged recovery from surgery. One other patient (4%) is alive 13 months after operation with permanent SCI. One renal reintervention has been required. No device failures have occurred.**

Conclusions: **Early-term data suggest that physician-modified fenestrated thoracic endografts can be used to safely and effectively treat TAAA in patients at high risk of open repair. Physician-modified devices perform similarly to commercially manufactured grafts in terms of treatment success, SCI, perioperative death, and clinical outcome at short-term follow-up. Physician modification is immediately available and allows for a high level of customizability. Procedure success is contingent upon careful preoperative planning, patient selection, experienced providers, and a high volume center. (J Vasc Surg 2015;62:1160-7.)**

Thoracoabdominal aortic aneurysms (TAAAs) are a complex management challenge. A decision about operative repair is a balance between the risk of surgery and the risk of aneurysm rupture. Open aortic replacement has served as the standard of care and has undergone major improvements over the last 20 years.[1] Centers of excellence have reported good results in retrospective, unmonitored case series.[1-3] Larger population-based datasets, however, reveal that those results are not seen outside such centers.[4,5] Thus far, survival has been used as the primary outcome measure of these case series. Few data are available about postoperative functional status and disability resulting from the operative repair. Significant morbidity is common following open repair, with only 52% of patients having a "good" outcome at 1 year in one large study from a center of excellence.[6] Given the morbidity of open repair, many patients are deemed ineligible for repair and are left untreated.[7]

Endovascular repair of infrarenal and thoracic aortic aneurysms carries a lower risk of perioperative death and major morbidity compared with open repair.[8,9] That benefit comes with less definitive long-term effectiveness and a higher incidence of aortic reintervention. It is hoped that endovascular therapy of TAAA may yield effective aneurysm exclusion with preservation of functional status, thereby preserving quality as well as duration of life. Furthermore, less invasive therapy may make more patients eligible for treatment. Several centers in the U.S. and around the world have demonstrated excellent results using a commercially manufactured stent graft in both custom and off-the-shelf designs in patients deemed to be at high risk of open repair.[10-12] The devices used in these reports are not widely available in the U.S., and as such, physicians have sought alternative means for endovascular treatment of TAAA. One such technique utilizes individual surgeon modification of commercial endografts, called fenestrated-branched devices, to treat these aneurysms.[13-16] Similar techniques have been used to treat juxta-renal aneurysms with excellent results.[13,16,17] Few data are available for physician-modified endografts for TAAA, as these procedures have been done mostly outside of U.S. Food and

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Drug Administration (FDA)-approved studies and have gone unreported. Uncertainty remains about the safety, effectiveness, and durability of this therapy.

This study reports the initial consecutive case series of physician-modified endovascular grafts for treatment of TAAA done under a FDA-approved physician-sponsored investigational device exemption (IDE).

METHODS

Study design. This initial single-center, nonrandomized, prospective clinical trial was conducted under a physician-sponsored IDE-approved by the FDA and the University of Washington Human Subjects Division (study name: B-TEVAR IDE). The study is registered with www.clinicaltrials.gov.

Given the experimental nature of this technique, study approval was limited to high-risk patients.

All subjects were deemed to be at high risk of open repair in the judgment of the principle investigator. Furthermore, all subjects were evaluated by a second physician to confirm that they were at high risk of open repair. The second physician review was performed by a staff anesthesiologist or surgeon in the Cardiothoracic Intensive Care Unit. High-risk status was based on both anatomic and physiologic criteria. Anatomic criteria included reoperative aortic surgery, other prior nonaortic abdominal or thoracic surgery, and obesity. Physiologic criteria included advanced age, limited preoperative functional status, any advanced organ system dysfunction, or a clinical assessment of frailty. No prespecified criteria were used to define high risk. Rather, a subjective assessment of these various factors was used in each individual patient by physicians experienced in the care of these patients.

Anatomic study inclusion criteria include: TAAA size >5.5 cm, and/or symptomatic, and/or rapidly expanding; anatomy suitable for the device with ≤5 target visceral vessels (mesenteric and/or renal) measuring 4 to 10 mm in diameter; proximal seal/fixation of a minimum 2.5 cm of healthy thoracic aorta; and suitable distal seal in the infrarenal aorta or iliac vessels.

Exclusion criteria include: free rupture with hemodynamic instability; ongoing infection; connective tissue disease diagnosis; and life expectancy of <1 year despite successful aneurysm exclusion. All patients provided informed written consent to participate and understood the study involved off-label physician modification of the endograft.

Study follow-up consisted of physical examination and laboratory assessment of renal function as well as computed tomography (CT) imaging. Visits occurred at 1, 6, and 12 months postoperatively and annually thereafter. Postoperative imaging consists of a contrast-enhanced arterial-phase CT angiogram with fine cuts performed on the same schedule. For subjects with compromised renal function, a noncontrast CT scan with fine cuts as well as aortic and branch duplex was used. Imaging review was performed by the principle investigator. A Clinical Events Committee comprised of physicians uninvolved in the study adjudicated all major adverse events. Data was audited for accuracy and completeness by an external reviewer on a monthly basis.

Fig 1. Intraoperative photograph of the completed physician-modified endograft showing the reinforced fenestrations and diameter reducing ties. *B-TEVAR*, Branched thoracic endovascular aortic repair.

Patient population. Between November 2011 and April 2015, 24 patients with TAAA underwent endovascular repair using the physician-modified TX2 endograft at the University of Washington. Twenty-one patients were treated as a part of the B-TEVAR IDE study. Three patients treated outside the IDE study presented with symptomatic aneurysms. Two patients were treated prior to approval of the IDE. One patient was treated on a compassionate use basis concurrent with the IDE as he did not meet study inclusion criteria. Specifically, the patient had advanced heart failure and chronic renal insufficiency and presented with a symptomatic TAAA and was not thought to have a >1 year life expectancy. The same technique and follow-up protocol was used for the patients treated within and outside the IDE. All patients were started on aspirin and statin medications unless contraindicated.

Devices. The physician-modified graft utilizes Cook TX2 (Cook Medical, Bloomington, Ind) devices. Detailed preoperative anatomic planning is done according to a prescribed process using a 3D workstation (TeraRecon Inc, Foster City, Calif). The device is unsheathed on a back table under sterile conditions. Reinforced fenestrations are created with Atrium SST PTFE (Atrium Medical Corp, Hudson, NH) and Fibered Platinum coils (Boston Scientific, Marlborough, Mass). Permanent and temporary diameter reducing ties are created using Gore (W. L. Gore Inc, Flagstaff, Ariz) and Chromic Gut sutures, respectively (Fig 1). Once the modifications are complete, the device is reconstrained in its original delivery sheath. Graft modification takes 2 hours and is completed before the patient is put under anesthesia.

The modified device consists of three segments: the proximal fixation/seal zone, the peri-visceral fenestrated segment, and the distal seal/fixation zone. The proximal and distal segments are constrained with temporary reducing ties to allow for device manipulation for