Global experience with an inner branched arch endograft

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Background: Branched endografts are a new option to treat arch aneurysm in high-risk patients.

Methods and results: We performed a retrospective multicenter analysis of all patients with arch aneurysms treated with a new branched endograft designed with 2 inner branches to perfuse the supra aortic trunks. Thirty-eight patients were included. The median age was 71 years (range, 64-74 years). An American Society of Anesthesiologists score of 3 or 4 was reported in 89.5% (95% confidence interval [CI], 79.7-99.3) of patients. The 30-day mortality rate was 13.2% (95% CI, 2.2-24.2). Technical success was obtained in 32 patients (84.2% [95% CI, 72.4-95.9]). Early secondary procedures were performed in 4 patients (10.5% [95% CI, 0.7-20.3]). Early cerebrovascular complications were diagnosed in 6 patients (15.8% [95% CI, 4.0-27.6]), including 4 transient ischemic attacks, 1 stroke, and 1 subarachnoid hemorrhage. The median follow-up was 12 months (range, 6-12 months). During follow-up, no aneurysm-related death was detected. Secondary procedures during follow-up were performed in 3 patients (9.1% [95% CI, 0.0-19.1]), including 1 conversion to open surgery. We compared the first 10 patients (early experience group) with the subsequent 28 patients. Intraoperative complications and secondary procedures were significantly higher in the early experience group. Although not statistically significant, the early mortality was higher in the early experience group (30% [95% CI, 0.0-60.0]) versus the remainder (7.1% [95% CI, 0.0-16.9]; $P = .066$). Being part of the early experience group and ascending aortic diameter $\geq$38 mm were found to be associated to higher rates of combined early mortality and neurologic complications.

Conclusions: Our preliminary study confirms the feasibility and safety of the endovascular repair of arch aneurysms in selected patients who may not have other conventional options. Clinical trial registration information: Thoracic IDE NCT00583817, FDA IDE# 000101. (J Thorac Cardiovasc Surg 2014;148:1709-16)

Surgical repair of aneurysms involving the aortic arch is technically challenging. Historically, these aneurysms have been treated with surgical techniques requiring cardiopulmonary bypass and deep hypothermic circulatory arrest with a mortality rate ranging from 2% to 16.5% and a stroke rate ranging from 2% to 18%.[1,2] Hybrid arch repair combines a procedure to secure a proximal landing zone with concomitant endovascular endograft placement in the aortic arch. Although this technique is considered minimally invasive, because it avoids aortic crossclamping and hypothermic circulatory arrest, the morbidity and mortality remains high, with a mortality rate ranging from 0% to 15% and a stroke rate from 0% to 11%.[3] Continued development and evolution of endografts has allowed for the application of total endovascular repair of complex aortic aneurysms involving the visceral segment with fenestrated and branched endografts.[4-6] Good initial results with this later generation of endografts have broadened its use to the aortic arch in high-risk patients.[7-9]

Here we present the multicenter evaluation of the endovascular exclusion of arch aneurysms with branched endografts designed with 2 inner branches to perfuse the supra-aortic trunks. We report our initial experience of all patients treated with this device during the study period, which includes the learning curve in patient selection and implantation at all centers.

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Abbreviations and Acronyms

ASA = American Society of Anesthesiologists
CTA = computed tomography angiography
EE = early experience
LCC = left common carotid
LE = late experience
LSA = left subclavian artery
LVEF = left ventricular ejection fraction

METHODS

Ten centers participated in this retrospective study (Table 1), which was approved by and met the necessary specifications of the investigational review board at each center. Informed consent was obtained from all patients. Physicians initiated this study under an investigational device exemption protocol in the United States.

From September 2009 to May 2013, all patients who presented with aortic arch dilation deemed unfit for surgery and with an appropriate anatomy for a double inner-branched custom-made endograft treatment were enrolled. Multidisciplinary teams, including cardiovascular surgeons, were involved in the decision making at all centers. Indication for treatment was aortic diameter >55 mm or rapid growth (>10 mm during the past 12 months). The physicians involved with the initial experience agreed on the following inclusion criteria.

Anatomic Criteria

Anatomic criteria included arch aneurysms and chronic dissections, no prior aortic valve replacement (biological or mechanical valves), ascending aortic length ≥50 mm (measured from sinotubular junction to origin of innominate artery), sealing zone within the ascending aorta ≥40 mm length and ≤38 mm diameter, innominate artery ≤20 mm in diameter and ≥20 mm in sealing zone length, and iliac access able to accommodate 22F or 24F sheaths (conduits should be staged).

Physiologic Criteria

Physiologic criteria included a minimum of 2-year life expectancy, negative stress test (in the setting a positive stress test cardiology clearance required), no class III or IV congestive heart failure, no stroke or myocardial infarction within the past year, no significant carotid bifurcation disease ≥75% stenosis by North American Symptomatic Carotid Endarterectomy Trial criteria, and estimated glomerular filtration rate by modification of diet in renal disease method ≥45 mL/min/1.73m^2.

All patients received anatomic computed tomography angiography (CTA) and physiologic evaluation before treatment. Not all patients in our study met the recommended selection criteria, and in those patients, exceptions were made at the discretion of the treating surgeon. These exceptions were physiologic: renal insufficiency (estimated glomerular filtration rate <45 mL/min) in 4 cases (associated with LVEF <40% in 2 cases and with home oxygen in 1 case), LVFE <40% alone in 1 case, and mechanical aortic valve and LVFE <40% in 1 case. In addition, 11 patients had an aortic ascending aorta ≥38 mm.

Device

Patients were treated with a branched endograft manufactured by Cook Medical (Bloomington, Ind) designed to adapt to each patient's anatomy (Figure 1). Graft designs were agreed upon by at least 2 investigators at different sites. There are 2 internal side branches (Figure 2, *A*) with an enlarged external opening at their distal ends (Figure 2, *B*). Markers are placed on both ends of each inner side branch to facilitate positioning under fluoroscopy. The ends of the endograft are wide and flexible, whereas the middle—the side branch bearing portion—is narrow and straight (Figure 2, *C*). The design objective was to separate the orifices of the side branches from the orifices of the supra-aortic trunks, preserving perigraft flow and facilitating branch cannulation. The device is loaded into a curved introducer (Figure 3), with a hydrophilic sheath. The curved system facilitates alignment of the branches with the greater curve of the aortic arch. The bridging component for the innominate artery is manufactured with low-profile graft fabric and loaded into a short 14F Flexor delivery system (Cook Medical). A commercially available covered stent Fluency (CR Bard, Murray Hill, NJ) or Viabahn (WL Gore, Flagstaff, Ariz) was used as the bridging component for the left common carotid (LCC) artery.

Procedure

A left subclavian artery (LSA) revascularization is performed before the arch endovascular repair in a 1-step or 2-step procedure (preferred option). To deliver the components, 3 arterial accesses are needed. First, femoral access to insert the endograft over a stiff wire positioned through the aortic valve into to the left ventricle. Second, right common carotid or right axillary access to catheterize the innominate internal side branch and to insert the covered stent bridging the side branch to the innominate trunk. Finally, left axillary access to catheterize the LCC through the LSA transposition or bypass, and the LCC internal side branch to deliver the covered stent bridging the side branch to the LCC.

After systemic heparinization with 100 international units/kg (target activated clotting time >300 seconds), catheters and/or sheaths are placed to mark the origins of the innominate artery and LCC or LSA, a pigtail catheter is positioned into the apex of the left ventricle from the femoral access, and a stiff wire (Lunderquist; Cook Medical) is advanced through this catheter. The position of the tip of the stiff wire is constantly visualized. Under fluoroscopy, the orientation of the main body of the graft is verified outside the patient and then delivered over the stiff wire to the aortic arch. The tapered short tip is brought through the aortic valve into the left ventricle. An angiogram is performed, the branches along with their associated markers are positioned adequately, and the graft is deployed under rapid pacing (or other cardiac output suppression technique). Normal cardiac output is resumed before withdrawing the tapered tip of the delivery system and the stiff wire from the left ventricle. The side branches are catheterized from the target vessels and sheaths are positioned into the inner side branches. Appropriate bridging limbs and covered stents are advanced through the access sheaths into the target vessels and deployed. On-table angiography is conducted to confirm complete exclusion of the aneurysm and patency of the branches.

Data Collection

Each center collected demographics, medical history, American Society of Anesthesiologists (ASA) score, aortic arch dilation etiology, proximal landing zone diameter and length, device information, procedure specifics, length of hospitalization, and intraoperative and postoperative events for their patients.

Early events were defined as events occurring within the first 30 postoperative days and late events as events occurring after. Overall mortality included both early mortality and mortality during follow-up.

Data was pooled in an anonymous database housed in a secure location at 1 institution. Planned follow-up included clinical examination and CTA scan evaluation postoperatively, at 6 months, at 12 months, and yearly thereafter.

Technical success, clinical success, and intraoperative and postoperative morbidity and mortality were reported in accordance with the reporting standards.[10]

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