Eur J Vasc Endovasc Surg (2016) 51, 380–385

Editor's Choice – Subsequent Results for Arch Aneurysm Repair with Inner Branched Endografts,☆

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WHAT THIS STUDY ADDS

This study reports early outcomes following endovascular repair of arch aneurysms in patients unfit for open surgery and is the first evaluation of arch aneurysm endovascular repair performed after the initial learning curve.

Objectives: The aim was to evaluate the current results of aortic arch aneurysm repair using inner branched endografts performed in three high volume aortic endovascular centers and to compare them to the pioneering global experience with this technology.

Methods: Included patients underwent repair of aortic arch aneurysms >55 mm in diameter using inner branched endograft technology between April 2013 and November 2014. All patients were deemed unfit for open surgery. Inner branches were designed to perfuse the brachiocephalic trunk and the left common carotid artery in all cases. A left subclavian artery (LSA) revascularization was performed prior to the arch endovascular repair. Data were collected retrospectively in an electronic database. Parameters included length of procedure, fluoroscopy time, contrast volume, technical success, presence of endoleaks, early and late complications, and mortality.

Results: Twenty-seven patients were included in the study. Technical success was achieved in all cases. No patients died during the 30 day post-operative period. Early neurologic events included two major strokes (7.4%) and one minor stroke (3.7%). Transient spinal cord ischemia with full recovery was observed in two patients (7.4%). Four patients (14.8%) underwent early (<30 day) re-interventions; these were for an access complication, an ischemic limb and exploration of the left ventricle through a sternotomy in two patients. During follow up (median 12 months), one patient (3.7%) died from a remote thoraco-abdominal aneurysm rupture. There were three Type 2 endoleaks (11.1%). Two re-interventions (7.4%) were performed, one to treat a Type 2 endoleak and one to treat a septic false aneurysm. A significant decrease in overall mortality was observed when comparing patients from the early experience with patients from the current report.

Conclusions: The early outcomes associated with this technology are favorable. Branched endografting of aortic arch aneurysms should be considered in patients unfit for open surgery.

Article history: Received 10 September 2015, Accepted 8 December 2015, Available online 23 January 2016

Keywords: Aortic arch aneurysm, Inner branched endograft, Endovascular repair

INTRODUCTION

Aortic arch aneurysm repair remains a major surgical challenge. Various strategies have been developed in order to limit the morbidity and mortality associated with open surgical repair, the major concern being neurologic morbidity with a reported rate of peri-operative stroke ranging from 5% to 12%.[1] Selective cerebral perfusion associated with deep hypothermia during circulatory arrest appears to reduce neurologic morbidity.[2] Hybrid[3] and endovascular techniques have been developed in an attempt to limit the morbidity associated with the treatment of arch aneurysms, especially in "high risk patients'. Although the hybrid technique is considered minimally invasive, because it avoids aortic cross-clamping 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%.[3,4]

☆ This work was presented at the 2015 annual meeting of the ESVS, Porto, Portugal.

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http://dx.doi.org/10.1016/j.ejvs.2015.12.002

The first multicenter study of endovascular repair with an inner branched device was published in 2014, and was performed for patients deemed unfit for open surgery.[5] This pioneering series reported a learning curve, primarily linked to patient selection (anatomic and physiologic criteria), and was associated with a high risk of stroke and mortality. To provide a dataset reflective of contemporary results of inner branched endograft procedures in high volume centers, the outcomes of this technique were assessed in the three aortic endovascular centers which have the largest experience worldwide subsequent to the initial series. The outcomes were compared with the outcomes of the pioneering experience.[5] All patients from the pioneering study were excluded from this current report.

METHODS

Population

Between April 2013 and November 2014, all patients who were treated for aortic arch aneurysms using the Cook Medical (Bloomington, IN, USA) inner branched arch endograft at three endovascular centers experienced in performing the procedure were included in the study. Of importance, all enrolled patients were separate from those analyzed in the 2014 paper evaluating the early arch branched endograft experience.[5] Indication for treatment was a maximal aortic diameter >55 mm, or rapid growth of an aneurysm (>10 mm over 12 months). All patients were ASA III/IV and deemed unfit for open surgery after multidisciplinary evaluation among cardiac and vascular surgeons, cardiologists, and anesthesiologists. Informed consent was obtained for each patient and the study was approved by the local ethics committee at each center.

Anatomic and physiologic inclusion and exclusion criteria are described below. They are similar to those published in the "early experience" paper, except for prior aortic valve replacement, which is no longer considered an exclusion criterion.[5]

Anatomic criteria

1. Arch aneurysms and chronic dissections
2. Sealing zone within the ascending aorta ≤38 mm in diameter and ≥40 mm length
3. Innominate artery ≤20 mm in diameter and ≥20 mm in sealing zone length
4. Iliac access able to accommodate 22F or 24F sheaths (conduits should be staged).

Physiologic criteria

1. Minimum 2 year life expectancy
2. Negative cardiac stress test (in the setting a positive stress test, cardiology clearance required)
3. No Class III or IV congestive heart failure (CHF)
4. No stroke or myocardial infarction within the last 12 months
5. No significant carotid bifurcation disease (≥70% stenosis by NASCET criteria)
6. Estimated Glomerular Filtration Rate (eGFR) by MDRD method ≥ 45 mL/min/1.73 m^2.

Analysis of pre-operative thoraco-abdominal computed tomographic angiography (CTA) was performed on a 3D workstation.

Device

The device implanted in all patients was a branched endograft manufactured by Cook Medical (Bloomington, IN, USA). It is a custom made device designed according to each patient's anatomy with two inner side branches for the innominate trunk (IT) and the left common carotid (LCC). The device is loaded in a 22F or 24F hydrophilic sheath. The sheath is curved in order to facilitate progression and self alignment in the aortic arch. The bridging component for the IT is manufactured with low profile graft fabric and loaded into a short 14F or 16F Flexor delivery system (Cook Medical). A commercially available self expandable covered stent, Fluency (CR Bard, Murray Hill, NJ, USA) or Viabahn (WL Gore, Flagstaff, AZ, USA), was used as the bridging component for the LCC.

A modified delivery system with a bullet nose tip inserted in a cartridge has been developed for patients with a mechanical aortic valve.[6]

Procedure

Procedure steps have not changed since the initial experience.[5] A left subclavian artery (LSA) revascularization (transposition or bypass to the LCC) is always performed before the arch endovascular repair in a one or two step procedure. In order to deliver the components, three arterial access sites are required:

1. Femoral access to insert the endograft over a stiff wire positioned through the aortic valve into the left ventricle.
2. Right common carotid or right axillary access to catheterize the innominate internal side branch and to insert the covered stent bridging the branch to the IT.
3. Left axillary or brachial 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 IU/kg (target activated clotting time [ACT] > 300 seconds), catheters and/or sheaths are placed to mark the origins of the innominate artery and LCC or LSA, a catheter is positioned close to 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 graft is verified outside the patient to get accustomed to the numerous radio-opaque markers 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. If the branches along with their associated markers are positioned adequately, the graft is deployed under cardiac output reduction using rapid