Results Of Aortic Arch Repair By TEVAR With The Cook Internally Branched Device
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Introduction:
Aneurysms involving the aortic arch represent some of the most complex challenges to the cardiothoracic and endovascular surgeon. Traditionally, arch replacement has involved a median sternotomy or thoracotomy and graft implantation with or without an elephant trunk for descending thoracic aortic disease. These aneurysms typically occur in elderly frail patients who tolerate thoracotomy and aortic cross clamping poorly. Subsequently, morbidity and mortality associated with open repair is high, with reported mortality rates of up to 36% for patients over 75 years (1). Many patients are therefore rejected for open surgery based on high risk co-morbidities.

The aortic arch has been described as the ‘Final Frontier’ of both conventional open and endovascular surgery. In both cases the challenge is to protect the brain from ischaemic injury, global hypoperfusion or embolic cerebrovascular occlusion. Recently extra-anatomical bypass or de-branching of the neck vessels followed by thoracic stent-graft placement has allowed avoidance of thoracotomy, though still with significant morbidity.

The aortic arch presents complex anatomy and physiology which challenge the long term integrity of the repair. Blood flow in the aortic arch generates high forces and pulsatile flow creates a wide diameter variation (2). The arch has a tortuous three dimensional path and the positions of the supra aortic vessels are less predictable than in the rest of the aorta. Further, there is variation in diameter from the ascending aorta, to the transverse and distal arch.

Inadequate apposition or conformability of an endograft in the inner curve of the aortic arch may cause difficulty with proximal seal and fixation, resulting in type I endoleaks. Following placement, the dynamic strain in the aortic arch may cause migration, fractures, or disconnection of the device components. This has caused difficulties with existing devices and endovascular repair of the arch has so far been limited to Zones 1, 2 and 3.

A device for total endovascular arch replacement has been introduced which attempts to address the above issues. It is a modification of the existing basic structure of the TX2 (Cook® Medical, Bloomington, In.) thoracic stent-graft, and allows a totally endovascular solution to arch pathology obviating the need for extra-anatomical bypass.

Branched Arch Devices:
First Generation Device
Although the first reported branch device (3) demonstrated the technical feasibility, primary success rate was only 60%, with failures attributed to endoleaks and access site issues. Transfemoral access may be difficult because of the length and tortuosity of the route. Alternative access sites have been tried (4). Chuter et al report the first branched arch device to be inserted into the aorta via the right common carotid artery (5). It consisted of a bifurcated graft with a small diameter limb engaging in the brachiophecalic artery and a larger diameter limb extending distally into the arch to be accessed by a second endograft inserted from the groin to complete the repair. An extra-anatomic carotid/carotid/subclavian
bypass was necessary to safeguard cerebral perfusion. Although there were a number of successes, a third of the patients suffered strokes and this type of device has been abandoned in favour of the next generation of branched arch devices.

**Next Generation Device**
The current design of the branched arch device is based on a stent-graft delivered via the transfemoral route. This fully custom-made device (Cook® Medical) incorporates two internalised sleeves for the brachiocephalic and left carotid branches with large funnel openings to aid retrograde cannulation (Fig.1). The graft is mounted on a pre-curved Nitinol cannula that automatically facilitates its alignment along the outer curve of the arch. In addition the graft is mounted onto the cannula with a spiral tethering wire, wound round the cannula, which minimises rotation; these ensure that both funnels are reliably delivered to the outer curvature of the arch.

The most proximal portion of the device has a "pro-form" shape, facilitating alignment along the curve of the ascending aorta and around towards the transverse portion of the arch. The ascending aorta should not be larger than 40mm and the proximal diameter of the stent graft can be up to 46mm in diameter to obtain a good haemostatic seal. The portion of the graft containing the openings of the internalised sleeves (the funnels) is reduced in diameter which allows continued antegrade cerebral blood flow through the graft during deployment and prior to completion with the innominate and carotid branches. Diameter reducing ties attached to trigger wires are also a standard feature. Multiple gold markers outline the funnels. The most proximal branch is 12mm in diameter, and is intended for connection with the brachiocephalic artery. The distal branch is 8mm in diameter and connects with the left common carotid artery.

A surgical conduit is placed to the right subclavian artery and a left carotid-subclavian bypass is performed. A radio-opaque tipped sheath marks the innominate artery origin. Once the stent-graft has been introduced via the transfemoral route its longitudinal position can be ascertained relative to the innominate artery, with the funnel gold markers fully proximal to the innominate orifice. The graft is then unsheathed under rapid overpacing to minimize aortic movement and reduce wind-socking. All trigger wires are then removed apart from the wire securing the distal stent graft. Both sleeves are retrogradely cannulated and a bridging stent graft is then positioned from the right subclavian conduit preserving the innominate artery bifurcation. The left carotid bridging stent graft is then brought in from the ipsilateral brachial artery. The origin of the left subclavian artery may be embolized from this access to prevent a Type 2 Endoleak. During the procedure anticoagulation should be maintained at an ACT of 300-350 ACT to reduce stroke risk. Completion angiogram is performed at the end of the procedure.

The first version of this device was used in 2009. So far 10 centres have used this device worldwide and participated in a retrospective study (Haulon et al. Article in press). Indication for treatment was aortic diameter above 55mm or rapid growth (greater than 10 mm during last 12 months). All patients enrolled in this study were deemed unfit for open surgery.

**Results:**
Thirty-eight patients were treated with a double inner-branch aortic arch endograft. None of the patients treated had any evidence of connective tissue disorders. A previous ascending aortic replacement had been performed in 32% of the patients. The median operative time
was 250 minutes [150-767]. Perioperative complications were observed in 18.4% (7/38) of patients. The 30-day mortality rate was 13% (5/38).

Technical success was obtained in 32 patients (84.2%). Technical failures were: three deaths occurring within the first 24 hours following surgery, one proximal type 1 endoleak diagnosed on completion angiogram, one failure to catheterize the innominate branch, and one coverage of the supra aortic trunks requiring conversion to a chimney technique.

Endoleaks were diagnosed on the discharge postoperative CT scan in 11 patients (29%), including 5 type 1 endoleaks (13%), 3 type 2 endoleaks (8%), 1 type 3 endoleak (3%) and two endoleaks of undetermined origin (5%).

The median follow up was 12 months [1-24]. Twenty five patients had a minimum 6-month follow up. During follow-up, no aneurysm related death was depicted.

**Conclusion:**
Currently, this technique is reserved for high surgical risk patients. It is not suitable for patients with extensive atheromatous disease of the arch due to high risk of embolisation. Remodelling of the aortic arch over time may affect the stability of these devices, and long-term patency remains a concern; long term follow up is needed to determine this.

The device is evolving and an off-the-shelf iteration will be soon be on the market; its future use may include acute type A dissections. A recent series looking at CT configuration suggested that around 13% of patients with a type A dissection (i.e. those whose entry tear was located in the arch) may be suitable for an arch branch device(6).

In summary, endovascular stent grafting of arch aneurysms is evolving and use of transfemoral branched devices is now a feasible option. Branch orientation and catheterisation in the arch can be technically demanding and the current branched arch device has been designed to address these problems. Although results from initial experience are mixed, mortalities have not been as a result of technical problems. This branch device offers an option to patients with no other available treatment. It is too early in development to determine whether this is the future of arch replacement but preliminary results are encouraging.

References:

Figure 1

1a External view of stent-graft showing funnel orifices and internalised sleeves (arrows)
1b Trigger wire wound around the central cannula (arrows)
1c Diameter reducing ties and the pre-curved cannula (arrows)