Early Canadian Experience with the Nexus Arch Graft

Thomas Lindsay MDCM FRCS FACS
Professor of Surgery
Chief, Division of Vascular Surgery
University Health Network
University of Toronto
Disclosure

Speaker name: Dr Thomas Lindsay

I have the following potential conflicts of interest to report:

Consulting

Endospan, Cook
Aortic Arch Pathology

- Arch and proximal descending aorta repair challenging by all methods
- Approaches
  - Open Surgery with elephant trunk (ET)
  - Arch debranching and EVAR
  - Grafts Cook, Endospan Nexus, others
- Pathology treated: aneurysm and dissection
- No approved grafts in Canada or USA
A systematic review and meta-analysis of hybrid aortic arch replacement

Konstantinos G. Moulakakis¹ ², Spyridon N. Mylonas³, Fotis Markakis¹, Thomas Kotsis³, John Kakisis¹, Christos D. Liapis¹

Results: Forty-six studies were eligible for the present meta-analysis: 26 studies with a total of 956 patients reported aortic arch debranching procedures, and 20 studies with 1,316 patients performed either ‘frozen’ or stented elephant trunk technique. The pooled estimate for 30-day/in-hospital mortality was 11.9% for the arch debranching group and 9.5% for the elephant trunk group. Cerebrovascular events of any severity were found to have occurred postoperatively at a pooled rate of 7.6% and 6.2%, while irreversible spinal cord injury symptoms were present in a pooled estimate of 3.6% and 5.0% in the arch debranching and elephant trunk group, respectively. Renal failure requiring dialysis occurred at 5.7% and 3.8% in both groups, while cardiac complications rate was 6.0% in the arch debranching cohort and pulmonary complication was 19.7% in the elephant trunk cohort.

Conclusions: Hybrid arch techniques provide a safe alternative to open repair with acceptable short- and mid-term results. However, stroke and mortality rates remain noteworthy. Future prospective trials that compare open conventional techniques with the hybrid method or the entirely endovascular methods are needed.
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.

- Improved outcomes in evolving area
- Early Canadian experience at our center was not as favorable
Nexus Arch Endograft

- Modular off the shelf design
- Minimizes ischemia to brain and limbs
- Reduced arch manipulation
- Nitinol construction, MRI compatible, 20 Fr
- Requires arch debranching
- Pre-operative hands on training on the elastomeric model of the specific subject treated
- Through and through positioning and controlled deployment
Pre Deployment Arch Debranching

Diagram showing the structures involved in pre-deployment arch debranching:
- Right Subclavian Artery (RSA)
- Right Common Carotid (RCC)
- Left Common Carotid (LCC)
- Left Subclavian Artery (LSA)
- Ascending Arch
- Descending Aorta

Annotations:
- To be bypassed (optional)
- To be occluded
Nexus Arch Endograft

• Two graft implantation programs
  • The FIM study is conducted in 3 centers (initiated in August 2014):
    • Switzerland (Zurich), Prof. Lachat
    • Czech Republic (Hradec Kralove), Prof. Krajina
    • Italy (Rome), Prof. Mangialardi
    • 7 subjects were enrolled up to now
  • Compassionate usage
    • 18 Nexus cases were performed, up to now, in the Compassionate Pathway:
      • Switzerland (Zurich), Prof. Lachat – 6 subjects
      • Italy (Rome), Prof. Mangialardi – 3 subjects
      • Italy (Modena), Prof. Coppi – 1 subject
      • Italy (Milan), Prof. Nano – 1 subject
      • Canada (Montreal), Prof. Abraham – 1 subject
      • Canada (Toronto), Prof. Lindsay – 5 subject
      • India (Chenai), Prof. Goppi – 1 subject
Toronto General Hospital Cases

- 5 cases to date
  - 3 Arch Aneurysms
  - 2 Dissections
    - Type B requiring proximal coverage
    - Previous Type A with enlarging descending false lumen
  - All had significant co-morbidities (Age, CHF, obesity, renal dysfunction)
- All cases had first stage
  - Carotid-Carotid Bypass
  - Carotid-Subclavian Bypass (1 carotid axillary bypass)
Clinical Details Case 1

- 81 yo male
- 2 saccular aneurysms
  - Mid Thoracic 8 cm
  - Distal arch 6.2 cm
Summary of Cases

- Complications
  - 1 graft exposure requiring replacement with femoral vein
  - 1 ascending hematoma evolving into dissection requiring repair
  - No proximal endoleaks
  - No Strokes, renal failure, spinal ischemia or early deaths
  - Documented sac shrinkage in one case

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Conclusions

• Novel modular design with minimal arch manipulation
• Arch debranching is still a major procedure
• Favorable early results with no mortality, spinal cord ischemia or strokes
• Applicable to arch aneurysms and type A dissections with ascending aortic grafts in place that require arch and descending aortic coverage
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