The Bolton Relay TEVAR Device With A Proximal Scallop: Can It Serve As An Off-The-Shelf Device?

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Disclosure
Speaker name: Jean-Marc ALSAC
- Speaker and consultant for educational training
  - ABS BOLTON Medical
  - GORE Medical
  - ENDOLOGIX

Concept of proximal scallop
- Improve proximal sealing zone
- Inner curvature of the arch
- Preserve SAT perfusion
- Without any catheterisation
debranching / chimney / branch

Custom made Scallops

Parisian experience
- Sept 2012 - Nov 2015
- 18 consecutive patients (13 ♂, 74 ± 8 y-o)
- for TAA involving the arch:
  - 10 Sacciform TAA
  - 8 Fusiform TAA / 3 previous TEVAR + type I A endoleak.
- Follow-up by CTscans: 1 / 6 mo / 1 year
Materials

• Custom made Stentgraft: RELAY Plus ©
  – Proximal Bare stent with capture
  – Median diameter = 38 mm (34 to 46)
  – Median length = 150 mm (120 to 250)
  – 10 Tapered / 22 to 26 Fr
  – 8 Additional distal stentgrafts
  – Available within 3 weeks

Patients anatomy

Targeted proximal sealing zones

Zone 2: 3 patients
Zone 1: 13 patients
Zone 0: 2 patients

Results

Immediate

• 100% implantation success
• Scallop position:
  – 3 LSA
  – 13 LCCA
  – 2 IA
Results

Immediate

• 100% implantation success
• Scallop position :
  – 3 LSA
  – 13 LCCA
  – 2 IA
• All targeted SAT patent
• No endoleak

SAT additional revascularizations

• 2 LCCA : Cervical inter-carotid bypasses
• 2 LSA : Cervical carotid-subclavian bypasses

Immediate results

• 2 LCCA : Cervical inter-carotid bypasses
• 2 LSA : Cervical carotid-subclavian bypasses

Immediate results

• 2 LSA were occluded by vascular plug after coverage

Mid-term Follow-up

• Median follow-up = 25 months (1 - 45)
• No proximal endoleak
• Patency of all targeted SAT / No stroke
• 1 distal IB endoleak treated with extension

Advantages of the Bolton Relay TEVAR Device With A Proximal Scallop

• Usefull to deal with short necks issues in TEVAR
• Precise and Reproducible deployment in the arch
• Avoid Debranching / Chimney / Branch procedures
• No canulation in the arch / No need to cross the valve
• Safe and efficient 2 years outcomes
• Custom-made Available within 3 weeks

SAT additional revascularizations

• median hospital stay = 4 days (3 - 7)
• 1 ischemic posterior stroke : (5.5 %)
  – Zone 1 with left carotido-subclavian bypass + LSA embolization
• 1 death at day 4 by fatal myocardial infarction: (5.5 %)
  – Zone 1 with No retrograde dissection on post mortem study

Postoperative course

• No proximal endoleak
• Patency of all targeted SAT / No stroke
• 1 distal IB endoleak treated with extension
Off the shelf scalloped stentgraft for acute aortic syndromes:
- Traumatic injuries of thoracic aorta
- Acute Type B dissections
- Ruptured TAA

Define a Standardized device to fit all
Obtain reimbursement

An off-the-shelf device ?

- Standardized proximal scallop (fits 90%)
  - Width = 20 mm (related to diameter)
  - Length = 30 mm

- Larger experience is necessary = French multicentric study
  - 50 patients / with 1 year of prospective Follow-Up
  - 14 enrolled so far with safe results

Take Home Message...

If you think about DEBRANCHING,
Ask yourself for a PROXIMAL SCALLOP
If SAT ostia are involved in the disease
Then go for BRANCHES

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