The Nellix System Could Change the Paradigm for Endovascular Aneurysm Surgery

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Disclosures

Endologix – Research funding / Consultancy

PI – Global Registry
Endovascular Aneurysm Sealing (EVAS) - Nellix
Changing the Paradigm for AAA Therapy

- Novel / revolutionary technology
  - Increase applicability of therapy (on and off IFU)
  - Addresses complications of EVAR – improves outcomes
  - Facilitate off shelf solution for complex problems
  - Durable outcomes
EVAS – Expanding Patient Applicability

% Compliant  % Not Compliant

Nellix  Medtronic Endurant  Zenith Flex  Gore Excluder
Applicability of EVAS In Cases Difficult for EVAR
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Are Clinical Results of EVAS as Good as EVAR?

- EVAS in early clinical adoption
  - Global Registry – 300 patients 5y (3 cohorts – 110 off IFU)
    - 30d mortality -1%
    - 1 endoleak at 30d (0.3%) (+3 interventions for proximal endoleak)
    - 3 interventions for limb occlusion (1%)
  - Long term data – when is enough??
EVAR and Sac Complications
Addressing Complications of EVAR- Type 2 Endoleak

- EVAS designed to fill AAA sac – abolish retrograde flow

- Significance of Type 2 endoleaks – clinical / surveillance?

- Ability of EVAS to abolish Type 2 endoleaks?
Significance of Type 2 Endoleak?

- Type 2 endoleaks associated with increased rate of sac expansion and aortic rupture

- Type 2 endoleaks increase complexity of surveillance programmes and necessity for CT

- Treatment of Type 2 endoleaks ineffective

- Some Type 2 endoleaks are dangerous and EVAR would be improved by their absence
Overall Endoleak Rates Six Months

- EVAS Forward Global Registry: Mean follow-up 6 months
- 1-year results shown for Aorfix and Incraft (6 month data not reported)
EVAS – Expanding Patient Applicability (Off IFU)

- Complex juxta- and supra-renal reconstructions

- Treatment of complications post-EVAR

- Treatment of ruptured AAA
Applicability of EVAS In Complex Disease
Applicability of EVAS In Juxta-Renal AAA
Nellix Parallel Grafts – SGVI Experience

- 23 patients in last 12 months

- All unsuitable for fEVR / bEVR, infra-renal graft, open repair

- 14 single, 5 double, 4 triple

- All procedures technically successful

- No visceral stent occlusions in follow up
Nellix Parallel Grafts – SGVI Experience

- No elective peri-operative mortality
  - 1 TIA
  - 1 limb occlusion
  - 1 late Type 1 endoleak
  - 1 renal stent stenosis
Applicability of EVAS In Failed EVAR
Endovascular Aneurysm Sealing (EVAS)

- Disruptive, revolutionary, technology
- Significantly increases endovascular options
- Abolishes Type 2 endoleaks – efficacy / surveillance
- Change paradigm for endovascular aneurysm therapy ??
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