The Arsenal AAA Sac Filling System For EVAR: How Does it Work, What is Its Value, Early Results

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Disclosure
Speaker name: Andrew Holden

I have the following potential conflicts of interest to report:
- Receipt of grants/research support
- Receipt of honoraria and travel support
- Participation in a company sponsored speakers’ bureau
- Employment in industry
- Shareholder in a healthcare company
- Owner of a healthcare company

I do not have any potential conflict of interest
Medical Advisory Board Member for Arsenal Medical

EVAR has higher reintervention rates than OSR

- Higher re-intervention rate reduces the benefit of EVAR compared to OSR over the long term
  - Imaging surveillance costs
  - Exposure to radiation and contrast nephropathy

Endoleaks are the Main Cause of EVAR Reinterventions

- Up to 60% of reinterventions are caused by endoleaks
- Up to 70% of endoleak reinterventions are caused by Type 2

Reintervention Strategies for Type 2 endoleaks have high failure rates

- Sac growth continues in 42-56% of patients after reintervention
  - 19% and 38% failure rates with translumbar and transarterial embolization, respectively
  - 28-40% of Type 2 endoleaks require multiple interventions
  - 11/35 (31%) of patients with reintervention for Type 2 required late conversion to open surgery

Reintervention Strategies for Type 2 endoleaks have high failure rates

- MR 1 Month
- CT 6 Months

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Reintervention 7 Months – Trans-lumbar Embolization

IMA Embolized (Amplatzer 4) Sac Filled (Cyanoacrylate)

Further Reintervention 13 Months Persistent Type 2 Endoleak and Sac Expansion

Endovascular aneurysm sealing
Prophylactic branch and/or partial sac embolization\(^1,2\)
- Significantly lower freedom from Type 2 endoleaks
  - at 6 months, but not long-term
  - no survival benefit
- 10% of patients receiving pre-EVAR embolization exhibited sac growth

Nellix EVAS technology\(^3\)
- Early learning curve experience in challenging anatomic group
- Type 2 endoleak rate of 2%
- 91% freedom from reintervention at 17 months mean follow up

Reductions in post-EVAR reintervention rates may be realised with sac sealing and stabilization technologies

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Open Surgical Repair and Sac Revision @ 18 months

Endovascular aneurysm sealing
Sac Sealing Product for Aortic Aneurysms
- Funded by Medtronic plc

ResQFoam for incompressible hemorrhage
- United States Military funding

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Arsenal Sac Sealing Product: Proposed Clinical Benefits

Reduce Type 2 endoleaks rates
- Completely seal the entire sac
- Penetrate and occlude branch vessels
- Preserve the ability to re-intervene when necessary

Stabilize the sac and stent graft
- Reduce risk of Type 3 endoleaks and migration with Type 1 endoleaks

Long term goal to reduce the need for surveillance

Arsenal Sac Sealing Product Concept

- Build upon the performance of clinically proven stent grafts
- Direct filling of the aneurysm sac after graft placement
- Not limited by aneurysm geometry

Product Design Features

- Implant material engineered specifically for sac sealing
  - Room temperature storage
  - Limited on-site preparation
- Catheter tracked into the aneurysm (after the graft deployed) through a pre-existing 8F sheath placed initially in the aneurysm sac
- Physician initiated automated injection, 4 - 6 minutes
- Automatically stops when sac sealing complete

Polymer properties engineered for Sac Sealing

- Thick, flowable dispensed material

Fills and Seals the excluded aneurysm sac

- Material flows into opens areas around stent graft
- Forms a skin as the outer layer solidifies
- Occludes aortic branches with limited penetration

Comprehensive testing in difficult geometries

- Broad range of aneurysm geometries
- Simulated branch vessel flows
- Forms a durable, elastic solid implant
Preparing for First in Human Studies

- Polymer optimized to maintain graft visibility
- Biocompatibility studies underway
- First in Human clinical study in 2017

Conclusions

- Increasing awareness that T2EL and long term durability of conventional EVAR is problematic
- Direct treatment of the aneurysm sac may (replicating open surgical repair) address these issues
- Arsenal sac sealing product offers the potential to seal the aneurysm sac after conventional EVAR with proven stent grafts
- Early clinical experience expected in 2017