Update on the Gore Retrograde Single Branched Endograft Device for Treating Aortic Arch Lesions: Advantages, Precautions, and Results

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LSA Coverage in TEVAR

- ~40% of TEVAR procedures result in coverage of the LSA (Fecior et al., J Endovasc Ther 2017)
  - May be necessary for endovascular landing zone and size
  - Enables a longer and straighter landing zone in arch
  - Potentially less bird-beaking
- Current options for LSA management:
  - LSA coverage without revascularization
  - LSA revascularization
    - Bypass
    - Transposition
    - Chemically aneurysm
    - Branch or fenestration
  - Less common.
  - Limited availability or supporting data

LSA Management – What are the risks of current options?

- Risks of LSA coverage without revascularization
  - Nerve injury
  - Stroke
  - Limb ischemia
  - Other bypass-related surgical complications
  - Bleeding
  - Infection
- Risks of surgical LSA revascularization
  - Nerve injury
  - Stroke
  - Limb ischemia
  - Other bypass-related surgical complications

Current Strategies for LSA Management

In balancing risks between surgical or no revascularization, treatment strategies are ranging:
- LSA revascularization in every patient
- LSA revascularization in every selected patient
- Selective LSA revascularization
- LSA revascularization only when anatomically indicated

Future State: Fully endovascular devices to enable perfusion and reduce surgical risk of LSA revascularization

GORE® TAG® Thoracic Branch Endoprosthesis

0% Incidence compared to 25% nerve injury in patients with surgical revascularization

Eliminates risk of prehensile nerve injury
**Future State:**
Fully endovascular devices to enable perfusion and reduce surgical risk of LSA revascularization

**Risks of Endovascular LSA revascularization**
- Spasm
- Branch occlusion
- Procedure-related complications

**Risks of Surgical LSA revascularization**
- Neuro dysesthesia
- Spasm
- Lymphatic leakage
- Hypersensitivity complications

**Lessons Learned:**
- Reduced Arch Manipulation
- Sizing of through-and-through wire in the descending aorta
- Side branch portal allows for feasible device positioning

**Lessons Learned:**
Device Flushing
- Allow back bleed through the device when it is half in/half out of the endovascular graft to flush delivery system

**LSA Revascularization: Stroke Impact**
- Rationale of LSA coverage and relation to Stroke (Whisnant et al., AATS 2016)
  - LSA coverage with revascularization has lower stroke rate than LSA coverage alone (LSA 8.1%, LSA w/ revascularization 5.1%)
- Medtronic MOTHER Registry (Patterson, JVS 2014)
  - 8.8% with LSA revascularization vs 5.6% with LSA revascularization
  - Overall stroke rate higher in Zone 2 but not significant

**LSA Revascularization: Reducing Access Requirements for Implanted Devices**
- Single femoral access

**5 Fr Access Reduces Surgical Invasiveness**
- Through 1 year (N=199 procedures)
I might update to "flexible device rotational positioning"
Lessons Learned: Balloon throughout Side Branch for Optimal Patency Outcomes

Conclusions

- Selective revascularization is currently the “standard of care” for TEVAR patients with Zone 2 coverage.
  - <35% patients currently receive initial LSA revascularization.
- Some evidence suggests that revascularization may result in better clinical and PCI rates but not statistically significant.
- Surgical revascularization also presents risk, including nerve injury, stroke, and lymphedema.
- Next generation TEVAR devices intend to stabilize LSA patency while reducing surgical risk.
- Feasibility study for the GORE® TAG Thoracic Branch Endoprosthesis would risk associated with surgical revascularization, but without adding additional risk to the procedure.
- This feasibility study continues to provide lessons on procedures in endovascular arch procedures.