Valiant Navion: what have we learned about this next Generation TEVAR device: 1-year results from the global clinical trial and new morphometry insights

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Disclosure

Speaker name: ..............................................Verzini...................................................

I have the following potential conflicts of interest to report:

- [x] Consulting for Medtronic,
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

- [ ] I do not have any potential conflict of interest
Valiant Navion Clinical Trial

- Prospective, multi-center, single-arm trials in North America & EU
- 100 subjects enrolled from 2016-2018
- 47% from 15 OUS centers
- 53% from 18 US centers
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- 40% Female
  - 70.8 ± 8.9 yrs old

- 25% PAU
- 47% Fusiform
- 28% Saccular

- Hypertension: 87.0%
- Hyperlipidemia: 69.7%
- CAD: 33.0%
- COPD: 31.3%
- AAA: 24.0%
- Ascending TAA: 11.0%
One Year Trial Outcomes

FF ACM
89.8%

FF ARM
97.0%

FF Sec Procedures
94.8%

FF Type I EL
94.4%

FF Type Ia EL
97.6%

FF Type II EL
95.4%

Increase: 2.6% (2/76) increase
Stable: 81.6% (62/76) stable
Decrease: 15.8% (12/76) decrease
Thoracic Aorta Morphometry

01 Pre-procedural to one month
Effect of the stent graft implantation on native anatomy

02 One month to one year
One-year changes in morphology and effects on stent graft

Pre-procedure 1 month 1 year
Effect of Stent Graft on Native Anatomy

**Tortuosity** = \( \frac{\text{centerline length}}{\text{end to end length}} \)

73.7% severe access artery tortuosity

100% success in advancing and deploying graft

Stent graft conforms to the native anatomy during implant and did not inhibit natural tortuosity changes at 1yr

* indicates p<0.05 compared to tortuosity measurement at prior follow up
Morphological Changes at One Year

Aortic Elongation
- LSA to celiac: 272.6 to 279.8mm (+2.6%)
- LCC to proximal fabric: 57.4 to 58.6mm (+2.1%)
- Distal fabric to celiac: 72.4 to 76.6mm (+5.5%)

Aortic Dilation
- Proximal attachment zone (+1.5mm, 4.8%)
- Distal attachment zone (+2.8mm, 8.5%)

Morphological changes could potentially compromise original seal zones particularly at the distal end.
Valiant Navion Clinical Trial - Patient Case

**One Month**
- Short proximal seal zone and no distal seal

**One Year**
- **Day 379**
  - Type IB endoleak
  - 16.9mm sac increase
- **Day 448**
  - Valiant Captivia, abdominal aortic coils, Jotec stent in SMA
  - EL resolved at end of secondary procedures
One Year Navion Trial Conclusions

Positive patient outcomes
- Low ACM, ARM, and secondary procedures
- Stent graft conforms to native aorta tortuosity and maintains conformability over time

Morphological changes at one year
- Aortic elongation and dilation occur, particularly at the DISTAL end

Actionable Lessons
- Must consider distal attachment zone in pre-case planning as well as adjunctive procedures in short landing zones
- Good seal zones play a role in sac regression and reduced risk of endoleaks

Quantified Evidence of the Conformability of Valiant Navion
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