Gore Conformable TAG (CTAG) Device for TEVAR: 2-Year Multicenter Trial Results

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Disclosures

- Clinical Investigator – paid to UAB
  - Gore, Medtronic, Endologix, Lombard, Aptus, Trivascular, Cordis
- Consultant – paid to UAB
  - Gore, Medtronic, Trivascular, Lombard, Aptus, Terumo
- Equity Shareholder
  - None

Background

- TEVAR approved 2005
  - TAG, Talent, TX2, Valiant
- Approved for degenerative aortic disease
  - Used for trauma, dissection, coarctation, etc
  - Failure modes found when used off label
- New endografts developed

Conformable TAG Design Modifications

- Modified Stent Frame
  - Flared scallops eliminated
  - Increased wire diameter
  - Ninth apex added to stent pattern

AIM

- Prove safety and efficacy of new endograft for approval by FDA
- Multicenter study, regulatory study
- Non-randomized, prospective data collection

Endpoints

- Freedom from major device event at 30 days
- Secondary endpoints
  - Any adverse events
  - Procedural outcomes
    - Devices implanted
    - Procedural time
    - Blood Loss
Patient Demographics
- 51 patients + 15 continued access = 66
- 59% male, 41% female
- 85% white
- Median age 72 years
- Aneurysm diameter – 60.1 mm
  - 42% saccular
  - 58% fusiform

Procedural Results
- Time 118 minutes
- Blood Loss 125 cc
- Length covered 17 cm
- Devices used 1.7

Patients treated with ≤ 2 grafts

Device Results – 30 days
- 98% device success
  - One patient failed delivery
- No compression, fracture, migration, or aneurysm rupture
- 15.0% endoleak at 30 days
  - Type 1A 1
  - Type 2 4
  - Indeterminate 4

Endoleak Rates Among GORE Regulatory Studies for TAA

30 day Results
- Mortality 1 patient 1.5%
  - Multiorgan failure after bowel ischemia, renal failure, respiratory failure
- Morbidity 15 patients 22.7%
  - Cardiac 5 7.6%
  - Pulmonary 4 6.1%
  - Stroke 2 3.0%
  - SCI 2 (1 permanent) 3.0%
CTAG – 2 year Results

2 Year Results published March

Endoleak by Corelab
57 patients, 50 w CT imaging

Type 1 2 3 4 5
Indeterminate

Endoleak

Type 1

Type 2

Type 3

Type 4

Indeterminate

CTAG – 2 year Results

Updated Results – 4 years

Endoleak by Corelab
41 patients, 31 with CT imaging

Type 1

Type 2

Type 3

Type 4

Indeterminate

CTAG – 2 year Results

Secondary Aortic Intervention – 60 mos after index procedure

- Treated Jan 2010
- Indeterminate endoleak with ↑diameter to 6.3 cm
- Jan 2015:
  - Carotid → Subclavian bypass
  - Redo TEVAR

CTAG – 2 year Results

Proximal CTAG to Zone 1

Jan 2010

Mar 2015

CTAG – 2 year Results

Mortality – 5 years

- 22 patients expired
- 3 patients – ARM
  - 10 days – MSOF
  - 12 mos – ascending aneurysm
  - 16 mos – iliac rupture during distal repair

CTAG – 2 year Results

Conclusions

- Conformable thoracic aortic endograft (CTAG) met the regulatory requirements of safety and efficacy for FDA approval for treatment of aneurysm disease
- Modified endograft has improved early results compared to other endografts
- CTAG remains durable and effective
- Some late mortalities related to further aortic failure