Are There Clinical Advantages Of Micromesh Covered And Dual Layer Stent Designs Over Closed Cell Stents In CAS

Unmet Need In The CAS Market – Sustained Embolic Protection

Optimizing Outcomes = sustained embolic protection

Dual Layer Stent Designs

Disclosure

Speaker name: S. Müller-Hülsbeck

- I have the following potential conflicts of interest to report:
  - Consulting: Terumo, Boston Scientific, GE
  - Employment in industry
    - Stockholder of a healthcare company
    - Owner of a healthcare company
  - Other(s)
    - I do not have any potential conflict of interest

Optimizing Outcomes = sustained embolic protection

- Recognizing lesion location and characteristics
- Matching the right technology to each disease state
- Lesion specific CAS
- Ideal:
  - One stent fits all!
  - Flexibility, conformability, radial force, plaque penetration and

- MicroNet™ is a bio-stable mesh woven from a single strand of 20μm Polyethylene Terephthalate (PET): pore size 165μm

- CARENET: 30 pts, EPDs were used in all procedures
  - Procedure success 100%
  - Procedural complications 0%
  - 30-day MAE cardiac or cerebrovascular
  - New ipsilateral ischemic lesions at 48 h 37.0%
  - 30-day DWI MRI showed complete resolution of all but 1 periprocedural lesion and only 1 new minor lesion in relation to the 48-h scan

- CGUARD
Dual Layer Stent Designs

- MicroNet™ is a bio-stable mesh woven from a single strand of 20μm Polyethylene Terephthalate (PET): pore size 165μm
  - 30 pts
    - Procedure success: 100%
    - Procedural complications: 0%
    - 30-day MAE cardiac or cerebrovascular: 0%
    - 6-months MAE cardiac or cerebrovascular: 0%

Gore® Terumo®

- double layer micromesh nitinol scaffold, up to 50% deployment full re-sheathable and repositionable; pore size 375μm
  - 6 pts
    - Procedure success: 100%
    - Procedural complications: 0%
    - 30-day MAE cardiac or cerebrovascular: 0%
    - 6-months MAE cardiac or cerebrovascular: 0%

- Flensburg RoadSaver™
  - Symptomatic n=62
    - 3.2% TIA @ 30 days (n=2*)
* TIA
* Hyperperfusion syndrome
  - ECA patent

- Asymptomatic n=8
  - 0% TIA @ 30 days
  - ECA patent

- FIM
  - GORE® Carotid Stent – Study (SCAFFOLD)
    - 50 sites in the US, Europe, and Japan
    - 312 subjects (max 40 at each site)
    - enrolled nearly 300 patients, and are close to the 312 needed to finish enrollment. There will be a 1 year follow up, so results will not likely be available till early/mid 2018

- Open Cell NiTi Frame, closed Cell lattice on outside of NiTi Frame, bound CBAS Heparin: pore size 500μm
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    - 50 sites in the US, Europe, and Japan
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**Ideal Pore Size**

- **CGUARD**
- **GORE**
- **TERUMO**

**Closed cell stent**
**Open cell stent**

* Average in lesion at expanded state

**Were do we stand?**

- CREST: postprocedural ipsilateral stroke over the 10-year follow-up occurred in 6.9%
  - 2502 pts, multi-center, prospective
  - RX Acculink stent and, whenever feasible, RX Accunet device
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  - periprocedural MAE cerebrovascular event 5.2%
  - symptomatic status is of relevance in the context of periprocedural risk

Brott TG, Howard G, Roubin GS, Meschia JF, Mackey A, Brooks W, Moore WS, Hill MD, Mantese VA, Clark WM,

**Were do we stand?**

- "Currently, most symptomatic patients are inappropriate candidates for CAS. Improved CAS technology referable to stent design and embolic protection strategies may alter this conclusion in the future."
  - Possible options to improve CAS outcomes:
    1. Modification of vascular risk factors — plaque stabilization
    2. Better patient selection
    3. Improved CAS skills/techniques
    4. Improved technology for CAS — better EPDs (flow reversal and proximal occlusion) and better stents (membrane-covered, ultra-closed cell, and biodegradable)


**Switching from single to dual layer stent?**

- Yes?
  - Will likely be the default strategy stent for CAS

- And no?
  - Clinical outcome differences need to be demonstrated

Competitive trial data are still pending!

The role of EPDs needs to be reevaluated!