CFA Lesions Are Best Treated By Angioplasty And Stenting: 2-Year Results With The Supera Stent

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What about the endovascular alternatives?

POBA doesn’t work in the CFA

Scaffolds do work in the CFA

Use modern generation of self-expandable stents...

Disclosures

Y. Gouëffic reports:

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What about the endovascular alternatives?

Last trial some more in detail...

VMI-CFA trial
Prospective, multicenter, single arm trial to evaluate the Supera Peripheral Vascular Mimetic Implant Device (Abbott Vascular) for symptomatic (ABI 2-4) CFA disease treatment
VMI-CFA trial : endpoints

- **Primary endpoint**
  - Efficacy endpoint:
    - Primary patency @12 months (DUS PSVR< 2.5 - Core lab adjudicated*) in CFA without reintervention
  - Safety endpoint:
    - Periprocedural adverse events up to 30 days post procedure, as defined per ISO 14155:2011 (TLR, death, amputation)
  *EuroImaging Srl, Rome, Italy

- **Secondary endpoints**
  - Technical success rate
    - (successful crossing & angiographical At<30)%
  - Primary patency @ 6 & 24 months (same definition)
  - Freedom from TLR @ 6, 13 & 24 months
    - (repeat intervention to maintain/re-establish patency within region of treated arterial vessel & line in treated lesion edge)
  - Freedom from TLR @ 6, 13 & 24 months
    - (repeat intervention to maintain/re-establish patency within target vessel LIM, DFA, SFA, IM)
  - Clinical success @ 6, 12 & 24 months
    - (improvement in Rutherford classification)
  - Safety profile @ 6, 12 & 24 months
    - (death, TLR, amputation)

VMI-CFA trial : in/exclusion criteria

- **INCLUSION CRITERIA**
  - RB 2-4 classification
  - De novo/post PTOA lesions
  - Stenosis >50%/occlusions
  - Patent DFA
  - Good SFA run off

- **EXCLUSION CRITERIA**
  - RB 5-6 classification
  - In-stent lesions CFA
  - Previous surgery CFA
  - Occluded DFA/SFA
  - Non treatable inflow lesion
  - Thrombus
  - Debulking, DE technologies...

Azéma L. et al. EJVEVS, 41, 6 : June 2011 ; 787-793

VMI-CFA trial : patient/lesion characteristics

VMI-CFA trial : procedural characteristics

VMI-CFA trial : 2 year survival

VMI-CFA trial : 2 year primary patency*
VMI-CFA trial: primary patency subanalysis

* Freedom from >50% restenosis as indicated by DUS PSV-ratio <2.5 in the target lesion, CORE LAB ADJUDICATED

VMI-CFA trial: 2 year freedom from TLR*

* Repeat intervention to maintain/re-establish patency within region of treated arterial vessel + 5mm in treated lesion edge

VMI-CFA trial: 2 year freedom from TVR*

* Protocol deviation

VMI-CFA trial: Safety evaluation

Primary safety endpoint| 30 days| 6 months| 12 months| 24 months
---|---|---|---|---
Device or procedure related death (N)| 0| 0| 0| 0
CD-TLR (N)| 0| 1| 2| 2
Target limb major amputation (N)| 0| 0| 0| 0

From proof of concept towards randomizing... SUPERSURG RCT

* Physician initiated, prospective, multicenter, head to head RCT evaluating the safety & efficacy of the Supera treatment versus CFE in stenotic, restenotic or occlusive CFA lesions

* 286 patients, 1:1 randomized

* 12 centers (Belgium, the Netherlands, Switzerland, UK)
Take home messages

- In 2019, although CFE still remains the golden standard, the historical "no endovascular for this baby" statement is wrong.
- There are some indicative papers that show there is definitely a place for safer & efficient endovascular therapy in CFA treatment.
- Newer generation of devices, like the high crush resistant, repuncturable Supera stent, are facilitating this endo-approach.
- With this particular device, the VMI-CFA trial shows excellent 2 year results: primary patency of 92.8%, freedom TLR of 97.8%, clear clinical benefit & a very high safety profile.
- The head to head SUPERSURG-RCT (Supera vs CFE) will definitively clarify the CFA treatment discussion.