The role of bioabsorbable stents in the superficial femoral artery

What is going on?

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Disclosures

Speaker name:

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I have the following potential conflicts of interest to report:

X Consulting

☐ Employment in industry

☐ Shareholder in a healthcare company

☐ Owner of a healthcare company

☐ Other(s)

☐ I do not have any potential conflict of interest
Challenges in the SFA

Conclusions

- Atherosclerotic lesions in the SFA are often multiple, long, eccentric and calcified.
- Inflammatory response after angioplasty seems more pronounced than in other areas.
- It serves a high resistance outflow bed, is the longest conduit artery with low wall shear stress.
- Dynamic deformations e.g. during walking exert important biomechanical forces on the wall.
- The ideal mechanical implant should mimic or conform to the vessel instead of resisting it.
Metallic stents in the SFA

**Short Term +++**
- Eliminate acute thrombosis by dissection flaps
- Reduce vessel recoil and rest-stenosis
- Positive influence on early constrictive remodeling

**Long Term ---**
- Thrombogenic
- Continuous stress on the wall enhancing intimal hyperplasia
- Alter mechanical properties of the vessel
- Impede late positive remodeling
- Promote difficult to treat in-stent restenosis
Drug-eluting devices

Drug-eluting stents
- Diminish smooth muscle cell proliferation and intimal hyperplasia
- Equivocal results in the SFA (>< coronaries)
- Same disadvantages as BMS in the long-term

Drug-eluting balloons
- Similar effect on cell proliferation and intimal hyperplasia
- Promising results in the SFA
- No foreign object is left in place
- No effect on early thrombosis and vessel recoil
Bio-resorbable stents or scaffolds

Goal

– Provide the early advantages of a stent, without its long term disadvantages

– Leave the stent in place only for the time that is needed

Igaki-Tamai: first resorbable stent
Theoretical advantages

- Immediate scaffolding after PTA
- Prevent early constrictive remodeling
- No chronic foreign body reaction
- Leaves vessel “uncaged”
  - Return of natural vasoactivity
  - Allows late positive adaptive remodeling
  - No permanent distortion of mechanical properties
- Shorten period on dual antiplatelet therapy
- No problem to perform reintervention or treat restenosis
- Imaging by MRA, OCT etc is facilitated
Bioabsorbable stents - devices

- Bio-resorbable polymers
  - PLLA
    - IGAKI-TAMAI
    - ABSORB - BVS
    - ELIXIR-DESolve
  - Other polymers
    - REVA-stent
    - IDEAL stent
    - STANZA stent

- Resorbable metals
  - Mg alloy
    - AMS - DREAMS
Experience in coronaries

- Equivocal early experiences
  - Mechanical integrity is best preserved at least 6 months to provide enough support
  - Drug-elution seems indicated to prevent early intimal proliferation

- Latest studies: excellent results
  - Bioabsorbable Vascular Scaffold (Abbott)
    - Everolimus eluting - PLLA scaffold
    - Absorb A + B study (Serruys, Lancet 2009)
  - DREAMS (Biotronik)
    - Paclitaxel eluting – Mg alloy
    - Biosolve–I study (Haude, Lancet 2013)
**ABSORB A - 5 Year Clinical Results**

<table>
<thead>
<tr>
<th>Hierarchical</th>
<th>6 Months</th>
<th>12 Months</th>
<th>4 Years</th>
<th>5 Years</th>
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<tbody>
<tr>
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<td>30 Patients</td>
<td>29 Patients</td>
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<tr>
<td>Ischemia Driven MACE, % (%)</td>
<td>3.3% (1)^*</td>
<td>3.4% (1)^*</td>
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<td>MI, % (%)</td>
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<td>Q-Wave MI</td>
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<td>Non Q-Wave MI</td>
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<td>Ischemia Driven TLR, %</td>
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No new MACE events between 6 months and 5 years
No scaffold thrombosis up to 5 years

*One patient withdrew consent after 6 months.
**This patient also underwent a TLR, not qualified as ID-TLR (DS = 42%) followed by post-procedural troponin qualified as non-Q MI and died from his Hodgkin’s disease at 868 days post-procedure.
Experience in BTK vessels

- AMS (bioresorbable Mg alloy)
  - No advantage over PTA alone

Absorb BTK (Abbott BVS)
- Results awaited
Experience in the SFA

- Perseus I and II
  - Remedy stent (Kyoto Med)
  - Non-randomized study
  - I: Native SFA lesions <4.5cm
  - II: lesions iup to 15 cms
  - Technical success: 100%

- GAIA – DEB
  - Mono centre non-RCT
  - 20 patients
  - DEB (Admiral In.Pact) + Remedy
  - Restenosis rate @ 6mth: 10.8%
Belgian Remedy study

- Prospective multicentre registry in 12 centres – 100 patients
- Symptomatic (Rutherford 2-5) SFA-lesion ≤ 75 mm
- Interim results
  - 95 patients
  - Mean lesion length: 38 mm
  - Technical success: 98%
  - Freedom from TLR:
    - 1mth: 99%, 6mth: 82%; 12 mth: 79%
  - Primary patency @6mth: 71%
  - Secondary patency @6mth: 89%
Esprit – BVS study

- Single-arm multi-centre study in claudicants with single de novo-lesion in SFA or iliac artery
- Vessel diameter 5.5-6.5 cm
- Lesion length ≤ 50 mm
- Treatment with one 6.0 x 58 Esprit BVS
- Angiographic FU @ 12 mth
- 35 patients
- 100% procedural success
Conclusions

- The SFA remains a challenging area for endovascular treatment
- Bioreabsorbable stents potentially combine the best of two worlds
- Theoretical advantages are attractive, also in SFA
- Optimal duration of mechanical integrity and absorption process remains a question
- Drug-elution seems indicated
- Results with newer bioreabsorbable stents are awaited