NEW DAWN:
1-year results of the combination DCBs and Supera stent for the treatment of long femoropoliteal lesions

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Disclosure

Speaker’s name: Peter Goverde

- I have the following potential conflicts of interest to report:

  Grant/Research Support/Consulting Fees/Honoraria:

  Abbott Vascular; Angioslide; Bard Peripheral Vascular; Bentley; B Braun endovascular; Cardionovum; Cordis Cardinal Health; CTI; IMDS; Ivascular; Getinge group; Stille; Ziehm Imaging
Real patients with real issues
Anatomical challenges of SFA and popliteal artery
What with challenging lesions, like heavily calcified, in the femoropoliteal region?
Where is the cut-off point?

- **Treating:**
  - Longer & longer lesions
  - More calcified lesions
- **Put in a long scaffold/stent**
- **What with:**
  - In stent stenosis/ occlusions
  - Stent fractures
  - Recurrent /progressive disease
  - Leaving nothing behind?
Supera Biomimetic Stent
(Abbott Vascular)
AURORAA Registry

Antwerp Supera in Opliteal & Superficial Femoral Artery
60 month data

- Physician initiated, single center, prospective
- Start June 2010 - July 2011 117 patients
- 88.89% involving distal SFA + popliteal
- Highly diseased, heavily calcified lesions
  - TASC II C & D lesions
    - 58.12% calcifications
    - 47.86% stenotic disease
    - 52.12% occlusive disease
- Mean lesion length +/- 14 cm; Supera length +/- 16 cm
Vascular Clinic ZNA
Supera follow-up: AURORAA

Case example 2010
Vascular Clinic ZNA
Supera follow-up: AURORAA

Case example  5 year later
Case example 5 year later

Vascular Clinic ZNA
Supera follow-up: AURORAA

IT WORKS!!

2010 2015
Vascular Clinic ZNA
Supera follow-up: AURORAA

<table>
<thead>
<tr>
<th>Duration</th>
<th>Primary Patency</th>
<th>Calcified Patency</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 m</td>
<td>91.9%</td>
<td>91.1%</td>
</tr>
<tr>
<td>12 m</td>
<td>80.8%</td>
<td>79.4%</td>
</tr>
<tr>
<td>18 m</td>
<td>76.07%</td>
<td>75%</td>
</tr>
<tr>
<td>24 m</td>
<td>73.5%</td>
<td>73.5%</td>
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<tr>
<td>30 m</td>
<td>71.8%</td>
<td>70.6%</td>
</tr>
<tr>
<td>36 m</td>
<td>70.08%</td>
<td>69.1%</td>
</tr>
<tr>
<td>48 m</td>
<td>66.67%</td>
<td>64.7%</td>
</tr>
<tr>
<td>60 m</td>
<td><strong>63.25%</strong></td>
<td><strong>58.82%</strong></td>
</tr>
</tbody>
</table>
Can we ameliorate the outcome of long stents ... or is it not necessary??

- Excellent results with DCBs
- But also there, we need sometimes a scaffold
- Combine Stent & DCB
  - DEBAS trial
  - Biolux4Ever trial
  - **Rapid RCT**: Supera stent + Legflow DCB
    Cardionovum
Let’s combine Supera with DCB

Short-term Results of the RAPID Randomized Trial of the Legflow Paclitaxel-Eluting Balloon With Supera Stenting vs Supera Stenting. Alone for the Treatment of Intermediate and Long Superficial Femoral Artery Lesions

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Abstract
RAPID trial

- The multicenter RAPID trial
- randomized (1:1)
- 160 patients (mean age 67 years; 102 men)
- Rutherford category 2–6 ischemia
- Legflow DCB + Supera stent or Supera stent alone
- in intermediate to long SFA lesions (mean lesion length 15.8±7.4 vs 15.8±7.6 cm, respectively).
- The efficacy outcome was primary patency, defined as freedom from restenosis on duplex ultrasound or angiography.

J Endovasc Ther 2017 Dec 10;24(6):783-792.
Results:
Baseline characteristics were similar between groups.

In the intention-to-treat analysis, the estimated primary patency at 1 year:
- 68.3% (95% CI 56.7% to 79.9%) in the PEB + Supera group vs
- 62.0% (95% CI 49.1% to 74.9%) in the Supera group (p=0.900).

Per-protocol analysis showed a 12-month primary patency estimate of:
- 74.7% (95% CI 63.1% to 86.3%) in the PEB + Supera group vs
- 62.0% (95% CI 49.1% to 74.9%) in the control group (p=0.273).

Secondary patency estimates at 12 months (per-protocol analysis) were:
- 89.0% (95% CI 80.6% to 97.4%) vs
- 98.0% (95% CI 94.1% to 100%; p=0.484);

The estimates for freedom from clinically driven target lesion revascularization (CD-TLR) were:
- 83.0% (95% CI 72.8% to 93.2%) and 77.8% (95% CI 66.6% to 89.0%; p=0.277), respectively.

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Who included???

Department of Interventional Radiology, St Antonius Hospital, Nieuwegein, the Netherlands; Department of Vascular Surgery, St Antonius Hospital, Nieuwegein, the Netherlands; Department of Vascular Surgery, Maasstad Hospital, Rotterdam, the Netherlands; Department of Interventional Radiology, Maasstad Hospital, Rotterdam, the Netherlands; Department of Interventional Radiology, Albert Schweitzer Hospital, Dordrecht, the Netherlands; Department of Vascular Surgery, Albert Schweitzer Hospital, Dordrecht, the Netherlands; Department of Vascular Surgery, Elisabeth Tweesteden Hospital, Tilburg, the Netherlands; Department of Interventional Radiology, Elisabeth Tweesteden Hospital, Tilburg, the Netherlands; Department of Interventional Radiology, Zuyderland Medical Centre, Heerlen, the Netherlands; Department of Vascular Surgery, Zuyderland Medical Centre, Heerlen, the Netherlands; Clinic for Vascular and Endovascular Surgery, University Hospital Heidelberg, Germany; Department of Vascular Surgery, Medical Centre Leeuwarden, the Netherlands; Department of Interventional Radiology, Medical Centre Leeuwarden, the Netherlands; Department of Interventional Radiology, Scheper Hospital, Emmen, the Netherlands; Department of Vascular Surgery, Scheper Hospital, Emmen, the Netherlands.

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What went wrong??

• …” The deployment system allows the physician to stack Supera stents in certain cases”

• ….” The RAPID trial was designed to test safety and efficacy of the Legflow paclitaxel-eluting balloon (PEB; Cardionovum GmbH, Bonn, Germany) in combination with primary Supera stenting in patients with intermediate to long SFA lesions compared to primary Supera stenting alone.”

• ……” Seven patients in the PEB + Supera group were not included in the per-protocol analysis (Figure 1) owing to geographic miss in 5 and severe lengthening of the Supera stent requiring surgical exploration in 2.

• .... “In the latter 2 patients, vessel preparation of the SFA before stenting was insufficient due to an undersized balloon relative to the Supera stent diameter. “

• ...“One patient in the PEB + Supera group and 3 patients in the Supera group were lost to follow-up due to withdrawal of consent.

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NEW DAWN
LutoNix & LEGflow DCB & Aurora
follow-up evaluation
Preliminary results
Vascular Clinic ZNA Supera follow-up: NEW DAWN preliminary results

• Physician initiated, single center, retrospective evaluation
• Bare Balloon / DCB therapy (min 2-3 min inflation time/balloon & Supera stent as Bail out
• DCB : Legflow Cardionovum & Lutonix Bard PV
• Configuration : DCB -1 mm = Supera diameter
• 2 operators
• Start July 2014 - July 2016 : at the moment : 54 patients

• 74.1 % involving distal SFA + popliteal
• Highly diseased, but less heavily calcified lesions
  – TASC II B,C & D lesions
    • 38.9 % calcifications (> 50% circumferential Ca)
    • 51.9 % stenotic disease (> 75%)
    • 52.12 % occlusive disease
Patient Characteristics:

- Diabetes (type 1 & 2):
  - 48.14%

- Rutherford 2: 2 patients
  - 3.7%

- Rutherford 3-4: 42 patients
  - 77.8%

- Rutherford 5-6: 10 patients
  - 18.5%
Vascular Clinic ZNA Supera follow-up: NEW DAWN preliminary results

- **Mean lesion length**: 187.8 mm (120 – 340 mm)
- **Mean DCB length**: 211.1 mm (150 – 370 mm)
- **Mean Stent length**: 197.6 mm (120 – 350 mm)

- **Mean number DCBs**: 2.1 DCB/pt
  - 27 Lutonix in 16 pts
  - 87 Legflow in 38 pts
- **Mean number stents**: 1,24 stents/pt
- **Mean number outflow vessels**: 2.07
Post procedure: aspirin (life) + clopidogrel (3mo)
Follow-up: 3, 6, 12, 18, 24, months ultrasound
Death: 0

RX control @ 12 mo
– +/- 30% of patients
– At random
– NO STENT FRACTURES
## Vascular Clinic ZNA Supera follow-up: NEW DAWN preliminary results

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>6 months</th>
<th>12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary patency</strong></td>
<td>All</td>
<td>92.6 %</td>
<td>87.04 %</td>
</tr>
<tr>
<td></td>
<td>Non calc</td>
<td>96.97 %</td>
<td>90.91 %</td>
</tr>
<tr>
<td></td>
<td>Calc</td>
<td>85.71 %</td>
<td>80.95 %</td>
</tr>
<tr>
<td><strong>Secondary patency</strong></td>
<td>All</td>
<td>100%</td>
<td>94.44 %</td>
</tr>
<tr>
<td></td>
<td>Non calc</td>
<td>100%</td>
<td>96.97 %</td>
</tr>
<tr>
<td></td>
<td>Calc</td>
<td>100%</td>
<td>90.48 %</td>
</tr>
<tr>
<td><strong>Freedom TLR</strong></td>
<td>All</td>
<td>98.15 %</td>
<td>94.44 %</td>
</tr>
<tr>
<td></td>
<td>Non calc</td>
<td>100%</td>
<td>96.97</td>
</tr>
<tr>
<td></td>
<td>Calc</td>
<td>95.24 %</td>
<td>90.48</td>
</tr>
</tbody>
</table>
Conclusions

✓ THE SUPERA stent can deal with challenging heavily calcified lesions

✓ PROVEN LONG-TERM EFFICACY & DURABILITY

✓ So what with combination Supera & DCB??

✓ Combination of DCB & Supera stent as bail-out option seems to be beneficiary to the outcome from one side, but not from the other

✓ We need new data to confirm this !!!!!!!
Thank You For Your attention
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