Focal Force Balloon plus DEB
A new strategy for vascular access stenosis treatment

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I have the following potential conflicts of interest to report:

☐ Consulting
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☒ I do not have any potential conflict of interest
our experience

• Retrospective analysis of prospectively collected data on vascular access (VA) stenosis

• 36 mths: January 2015 – December 2017
• Critical stenosis:
  – Morphologic (50% according to NKF Guidelines);
  – Haemodynamic signs during HD
• Pre-dilatation:
  – High pressure balloon
    Powerflex™, Cordis, Fremont, US-CA
  – Cutting balloon
    FLEXTOME™ Cutting Balloon™, Boston Scientific, Natick US-MA
  – Focal Force balloon
    Advance® Enforcer™, Cook Medical, Bloomington US-IN

• Paclitaxel coated PTA balloon (3 minute)
  – Aperto®, Cardionovum GmbH, Bonn D
  – Lutonix®, Bard PV, Tempe US-AZ
  – In.pact™, Medtronic, Minneapolis US-MN
follow-up setting

Haemodynamic data

Doppler US (2 mths)
# 221 pts (2:3 F:M)

Mean age: 68 ± 13 years (range 37 - 87; IQR 62 – 77)

• Type of VA
  – graft: 115 (52.0%)
  – native vessels: 106 (48.9%)

• Diagnosis:
  – 125 (56.6%) haemodynamic signs during HD
  – 53 (24.0%) DUS routine screening
  – 43 (19.4%) intraoperative completion angiography

DATA ARE INTERIM AND SUBJECT TO CHANGE
results: pre-dilatation devices

High pressure
97 (43.9%)

Cutting
52 (23.5%)

Focal-force
72 (32.6%)

DATA ARE INTERIM AND SUBJECT TO CHANGE
Intraoperative complications: 7 (2.3%)
- circuit thrombosis: 4
  - surgical thrombectomy,
- vein rupture: 3
  - angioplasty re-do (n = 2)
  - stent-graft (n = 1, excluded from further analysis).

CVC needed for regular HD: 0
results: follow-up

• Follow-up
  – Pts lost: 0
  – Mean follow-up time: 20 ± 8 mths (range 1 – 36)
  – FU index*: 0.86

• Mortality: 7.2% (not related to the procedure)

*Completeness of Follow-Up Determines Validity of Study Findings: Results of a Prospective Repeated Measures Cohort Study
Von Allmen RS, Weiss S, Tevæearai HT, Kuemmerli C, Tinner C, Carrel TP, Schmidli J, Dick
PLoS One. 2015;10(10):e0140817

INDEX OF FOLLOW-UP = FOLLOW-UP COVERED BY STUDY / POTENTIAL FOLLOW-UP DURATION

DATA ARE INTERIM AND SUBJECT TO CHANGE
Overall # angioplasty: 323

131 (59.3%) pts: free from restenosis
90 (40.7%) pts: stenosis recurrence (192 treatments)
  – 2 treatments: 68 (30.8%) pts
  – 3 treatments: 14 (6.3%) pts
  – 4 treatments: 5 (2.3%) pts
  – 5 treatments: 3 (1.3%) pts

DATA ARE INTERIM AND SUBJECT TO CHANGE
free from restenosis survival

131 treatments

6m: 88.0%
12m: 75.6%
24m: 40.6%
36m: 40.6%

DATA ARE INTERIM AND SUBJECT TO CHANGE
overall circuit patency

323 treatments

6m: 99.2%
12m: 92.5%
24m: 84.8%
36m: 84.8%

DATA ARE INTERIM AND SUBJECT TO CHANGE
Univariate analysis of risk factors (log rank):

- Age of the circuit ($p = 0.017$)
- Previous treatment with conventional angioplasty ($p = < 0.001$)
- Type of balloon of pre-dilatation ($p = 0.001$)

Multivariable analysis (COX regression):

- Previous treatment with conventional angioplasty
  HR: $3.86$, $95\%$ CI: $1.94 - 7.72$, $p < 0.001$
- Type of balloon of pre-dilatation
  HR: $0.592$, $95\%$ CI: $0.369 - 0.950$, $p = 0.030$
restenosis: predilatation

DATA ARE INTERIM AND SUBJECT TO CHANGE
restenosis: predilatation

<table>
<thead>
<tr>
<th>Type of balloon</th>
<th>6 mths</th>
<th>12 mths</th>
<th>24 mths</th>
<th>36 mths</th>
</tr>
</thead>
<tbody>
<tr>
<td>High pressure</td>
<td>84.5%</td>
<td>69.0%</td>
<td>26.1%</td>
<td>26.1%</td>
</tr>
<tr>
<td>Cutting</td>
<td>91.7%</td>
<td>66.7%</td>
<td>58.3%</td>
<td>-</td>
</tr>
<tr>
<td>Focal Force</td>
<td>94.6%</td>
<td>87.9%</td>
<td>87.9% (22mths)</td>
<td>-</td>
</tr>
</tbody>
</table>

DATA ARE INTERIM AND SUBJECT TO CHANGE
Vessel Lumen

Neointimal hyperplasia

High fibrosis
Low # cells

PACLITAXEL TARGET

Low fibrosis
High # Cells

UNIVERSITY OF INSUBRIA – CONSORZIO MIA: PICROSIRIUS RED STAIN ON AV GRAFT STENOSIS
Intimal fibromuscular hyperplasia at the venous anastomosis of PTFE Grafts in Hemodialysis Patients.
S. Swedberg et al.
Circulation.1989;80(6):1726-1736

Two population of macrophage / monocite and fibroblasts
Final Remarks

1. Important role of pre-dilatation for DEB

2. Better results of ‘scoring balloons’ over plain balloons

3. New generation of focal force balloon less invasive than ‘cutting’