DCBs for the Treatment of Symptomatic CVS in Dialysis Access. A European Multicenter Retrospective Study of 87 patients.

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Why do we get CVS in Dialysis?

Prior or Current use of foreign materials
Cardiac rhythm-related devices
PICC lines
Ports
Central Venous Catheters (specially left-sided - subclavian)
Stenosis of venous outflow due to Dialysis

Teruya TH et al.: Symptomatic subclavian vein stenosis and occlusion in hemodialysis patients with transvenous pacemakers.
Treatment
Facts & Figures
PTA first (Technical failure: 10-30%)
Patency Rates: 28.9% @ 6 months

High-Pressure Balloon PTA
Patency Rates: 60% @ 6 months
Main Problem → Elastic recoil

Stent Placement: More aggressive treatment
Patency: As low as 25% @ 1 year

Agarwal AK et al.: How should symptomatic central vein stenosis be managed in hemodialysis patients? Semin Dialysis 2014 May-Jun;27(3):278-81
Evidence so far..
Massmann et al. 2015

Retrospective analysis
Diabetic ESRD pts with AVFs
25 Restenotic Non-Occlusive Lesions treated with
   Elutax SV DCB: 20 times (10 pts)
   Plain Balloon Angioplasty: 32 times (15 pts)
Study included axillary veins
No vessel preparation
Outcome Measure: Freedom from target lesion revascularization
   Significant difference in favor of DCB
Kitrou et al. 2017

RCT including 40 subjects (20 in each group)

De novo, Restenotic & Occluded Lesions were included

Device under investigation: Lutonix DCB

Primary Endpoint: Clinically-assessed intervention-free period

Significant difference in favor of DCB
What is the evidence so far?

<30 pts!!!!
Purpose

This was a multi-center single-arm retrospective analysis evaluating the outcomes of DCB use for the treatment of symptomatic central venous stenosis in arteriovenous dialysis access.
Baseline Characteristics

Number of Patients: 87
Number of Physicians Involved: 17 physicians
Centers participating: 11

- Interventional Radiology Dpt, Patras University Hospital, Greece
- Schön Klinik, Düsseldorf, Germany
- Institut Mutualiste Montsouris, Paris, France
- 2nd Radiology Dpt, Attikon University Hospital, Athens, Greece
- Policlinico Umberto I, Rome, Italy
- Hospital "S. Eugenio" Rome, Italy
- Ambroise Paré University Hospital, Paris, France
- Lumiar Vascular Access Center, NephroCare, Portugal
- St. Franziskus Hospital, Muenster, Germany
- Center for Vascular and Endovascular Surgery, University Hospital of Muenster, Germany
- Barts Health, NHS Trust, London, UK
**Inclusion Criteria**
Age >18 years and <90 years
Patient on Dialysis with an ipsilateral Arteriovenous Fistula (AVF) or Graft (AVG)
Stenosed central vein (Subclavian Vein, Innominate Vein, Superior Vena Cava)
Clinical Signs of Central Venous Stenosis
- Arm swelling, pain, tenderness, and/or erythema of the ipsilateral extremity
- Ipsilateral breast swelling
- Neck swelling
- Visible collateral venous network
- Inadequate dialysis performance

**Exclusion Criteria**
Stenosis <50% verified with DSA by visual estimation
Dialysis Access thrombosis
Pregnancy
Infected vascular access
Clinically assessed intervention-free period of the treated segment at 6 months: A dialysis access circuit with no need for clinically driven target lesion repeat intervention for symptom recurrence and angiographic verification of the presence of CVS.

Procedure-related Minor & Major Complications
Results
## In numbers

<table>
<thead>
<tr>
<th>Outcome Measures</th>
<th>@6 months</th>
<th>@12 months</th>
<th>@24 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>TLPP</td>
<td>62.7%</td>
<td>34.6%</td>
<td>23.3%</td>
</tr>
<tr>
<td>ACS</td>
<td>87.7%</td>
<td>78.5%</td>
<td>67.6%</td>
</tr>
<tr>
<td>PS</td>
<td>95%</td>
<td>91%</td>
<td>79.7%</td>
</tr>
</tbody>
</table>
### Cox Regression Analysis

#### Hazard ratio

<table>
<thead>
<tr>
<th>Variable</th>
<th>Hazard Ratio (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Age</td>
<td>0.99 (0.97 - 1.01)</td>
<td>0.319</td>
</tr>
<tr>
<td>Access Age</td>
<td>1.00 (0.88 - 1.14)</td>
<td>0.974</td>
</tr>
<tr>
<td>Diabetes</td>
<td>0.54 (0.26 - 1.11)</td>
<td>0.092</td>
</tr>
<tr>
<td>CAD</td>
<td>0.53 (0.29 - 1.10)</td>
<td>0.088</td>
</tr>
<tr>
<td>PAD</td>
<td>1.12 (0.55 - 2.26)</td>
<td>0.752</td>
</tr>
<tr>
<td>Clopidogrel</td>
<td>0.95 (0.47 - 1.91)</td>
<td>0.886</td>
</tr>
<tr>
<td>Aspirin</td>
<td>0.93 (0.47 - 1.82)</td>
<td>0.831</td>
</tr>
<tr>
<td>Heparin</td>
<td>0.99 (0.38 - 2.58)</td>
<td>0.991</td>
</tr>
<tr>
<td>Statins</td>
<td>0.92 (0.49 - 1.71)</td>
<td>0.789</td>
</tr>
<tr>
<td>Artery</td>
<td>0.42 (0.13 - 1.14)</td>
<td>0.09</td>
</tr>
<tr>
<td>Vein</td>
<td>0.93 (0.54 - 1.64)</td>
<td>0.705</td>
</tr>
<tr>
<td>ISR</td>
<td>0.48 (0.18 - 1.27)</td>
<td>0.138</td>
</tr>
<tr>
<td>Lines</td>
<td>0.69 (0.33 - 1.43)</td>
<td>0.321</td>
</tr>
<tr>
<td>Left side</td>
<td>0.49 (0.20 - 1.19)</td>
<td>0.114</td>
</tr>
<tr>
<td>Lesion</td>
<td>0.58 (0.27 - 1.23)</td>
<td>0.154</td>
</tr>
<tr>
<td>D</td>
<td>0.72 (0.57 - 0.91)</td>
<td>0.006</td>
</tr>
<tr>
<td>L</td>
<td>0.99 (0.97 - 1.01)</td>
<td>0.462</td>
</tr>
</tbody>
</table>

# Events: 56; Global p-value (Log-Rank): 0.089564
AIC: 419.89; Concordance Index: 0.68
Diameter 8-12mm vs 5-7mm

Strata

Diameter.7=0
Diameter.7=1

\[ p = 0.025 \]
Conclusion

In this European Multi-center Retrospective Analysis, DCBs used for the treatment of symptomatic CVS in Dialysis patients was safe.

Efficacy was consistent compared to previous RCTs.
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