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

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Disclosures

Consultant for BD
Basilic Vein
Superior Vena Cava
Cephalic Vein
Subclavian Vein
Axillary Vein
Brachiocephalic Vein
Basilic Vein
Superior Vena Cava
Cephalic Vein
Subclavian Vein
Axillary Vein
Brachiocephalic Vein
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

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!!!!
The Study
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
<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>
Diameter 8-12mm vs 5-7mm

Survival probability

Strata Diameter.7=0 Diameter.7=1

Time

Survival probability

$\text{Diameter.7.1::dat$Diameter.7}$

$p = 0.025$
Diameter Adjusted Patency Curves

The image depicts a graph showing survival rates over time for different variables. The y-axis represents the survival rate, ranging from 0.00 to 1.00, and the x-axis represents time, ranging from 0 to 900. The graph includes multiple survival curves, each identified by a color and a variable number (5, 7, 9, 12, 6, 8, 10). The curves illustrate how survival rates decrease over time for each variable.
Conclusion

In this European Multi-center Retrospective Analysis, Drug-Coated Balloons used for the treatment of symptomatic Central Venous Stenosis in Dialysis patients was safe.

Efficacy was comparable to previous RCTs.

Balloon Size had a significant effect on patency rates.
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