PCB for Symptomatic CVS of DA
Randomized Control Trial

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Disclosure

Speaker name:
Dr. D. Karnabatidis

I have the following potential conflicts of interest to report:

- Consulting (Bard, Medtronic, Boston, Alvimedica, Rondis)
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest
Facts & Figures

Anatomic location (Distal to cephalic arch):
Subclavian
Brachiocephalic
SVC

Main cause of CVS in dialysis patients:
Prior insertion of foreign materials
(CVCs, PICCs, Ports, Cardiac-Rhythm Related Devices)
Stenosis of venous outflow due to dialysis use

Facts & Figures

PTA first (Technical failure: 10-30%)

Patency Rates:
- 28.9% @ 6 months
- 25% @ 1 year

High-Pressure Balloon PTA

Patency Rates:
- 60% @ 6 months
- 30% @ 1 year (60% with repeated angioplasty BUT no stent placement)

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
PCB in Dialysis Access

2015 Kitrou et al EJR (prospective):
40 patients (AVF+AVG) – 20 DCB
@12 months: 35% vs. 5% (p<0.001)

2015 Kitrou et al JVIR (prospective):
40 patients (AVF) – 20 DCB
@12 months: 20% vs. 0% (p=0.03)

2017 Kitrou et al CVIR (retrospective):
39 pts (AVF+AVG) – 39 DCB
@6 months: 72.2%
The Study
CLINICAL STUDY

Paclitaxel-Coated Balloons for the Treatment of Symptomatic Central Venous Stenosis in Dialysis Access: Results from a Randomized Controlled Trial

Panagiotis M. Kitrou, MD, MSc, PhD, Panagiotis Papadimatos, MD, Stavros Spiliopoulos, MD, PhD, Konstantinos Katsanos, MD, MSc, PhD, Nicolaos Christeas, MD, Elias Brountzos, MD, PhD, and Dimitrios Karnabatidis, MD, PhD
Purpose

To compare the Safety and Effectiveness
Of PCB vs. PTA for the treatment
Of Symptomatic Central Venous Stenosis
Of AVGs and AVFs
Inclusion Criteria

Symptomatic Central Venous Stenosis
Ipsilateral AVGs + AVFs
Distal to Cephalic Arch (Subclavian, Brachiocephalic, VC)
Angiographic Verification
De Novo + Restenosis
Multiple Stenosis treated

“Real Life Inclusion Criteria”

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Devices

PCB group:
Lutonix® 035 (C.R.BARD New Jersey, USA)

PTA group:
Atlas Gold, Conquest, Dorado, Mustang etc

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Flowchart
Kitrou et al., Paclitaxel-Coated Balloons for the Treatment of Symptomatic Central Venous Stenosis in Dialysis Access: Results from a Randomized Controlled Trial. JVIR 2017
Endpoints

Primary:
Clinically-assessed Intervention-Free Period (IFP) @ 6 months

Secondary:
Minor or Major Complications
Longitudinal Comparison of treatments

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Baseline Variables

40 pts (20 pts in each group)

20 months recruitment period

Baseline variables equally distributed b/w groups

Two patients from PTA group were lost to f-up

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## Baseline Variables

<table>
<thead>
<tr>
<th></th>
<th>Group PCB</th>
<th>Group PTA</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number of pts</strong></td>
<td>20</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td><strong>Male</strong></td>
<td>13</td>
<td>14</td>
<td>n.s.</td>
</tr>
<tr>
<td><strong>Vascular Access</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AVG</td>
<td>10</td>
<td>11</td>
<td>n.s.</td>
</tr>
<tr>
<td>AVF</td>
<td>10</td>
<td>9</td>
<td>n.s.</td>
</tr>
<tr>
<td>Age</td>
<td>2.83</td>
<td>2.42</td>
<td>n.s.</td>
</tr>
<tr>
<td>Prior CVC insertion</td>
<td>13</td>
<td>12</td>
<td>n.s.</td>
</tr>
<tr>
<td>De novo lesions</td>
<td>5</td>
<td>8</td>
<td>n.s.</td>
</tr>
<tr>
<td><strong>Lesion site</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subclavian</td>
<td>12</td>
<td>13</td>
<td>n.s.</td>
</tr>
<tr>
<td>Anonymous</td>
<td>5</td>
<td>5</td>
<td>n.s.</td>
</tr>
<tr>
<td>SVC</td>
<td>3</td>
<td>2</td>
<td>n.s.</td>
</tr>
</tbody>
</table>

*Kitrou et al., Paclitaxel-Coated Balloons for the Treatment of Symptomatic Central Venous Stenosis in Dialysis Access: Results from a Randomized Controlled Trial. JVIR 2017*
Baseline Variables

For PCB Group

23 devices in 20 patients
15 used in 12 Subclavian veins
4 in Brachiocephalic Vein
4 in Superior Vena Cava

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Results
Median Survival: PCB group 179 days vs. 124.5 days PTA group
HR: 0.4212 (CI: 0.2041 – 0.8690); p=0.019 (Log-rank Mantel-Cox Test)
@ 6 months: 50% (10/20) vs. 28.5% (4/18)

Kitrou et al., Paclitaxel-Coated Balloons for the Treatment of Symptomatic Central Venous Stenosis in Dialysis Access: Results from a Randomized Controlled Trial. JVIR 2017
Longitudinal Analysis

Median Survival: PCB group 177 days vs. 91 days PTA group
HR: 0.3384 (CI: 0.1479 – 0.7742); p=0.01 (Log-rank Mantel-Cox Test)
15 cases of restenosis in PCB group

Kitrou et al., Paclitaxel-Coated Balloons for the Treatment of Symptomatic Central Venous Stenosis in Dialysis Access: Results from a Randomized Controlled Trial. JVIR 2017
Limitations

Small number of patients
Unable to perform sub-group analysis in order to answer certain interesting questions
Single-Center
No Core Lab

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Conclusion

In this RCT, PCBs had significantly better results compared to PTA in the treatment of symptomatic central venous stenosis of vascular access.

Larger multi-center trials with larger number of subjects are needed to prove abovementioned results in order to change standard of practice.

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