LUTONIX® Drug Coated Balloon
Patras Single Center Experience

Assistant Prof Dimitrios Karnabatidis
Patras I.R. Dpt
Greece
Disclaimer

- The opinions and clinical experiences presented herein are for informational purposes only and may not be predictive for all cases. Individual results may vary depending on a variety of patient specific attributes.

- The results and data presented herein reflect Dr. Karnabatidis’ clinical experience in a single-center, investigator-initiated and funded study. These results have not been published or peer-reviewed. Bard /Lutonix has not sponsored or funded these studies, nor has Bard/Lutonix validated underlying test methods or data presented herein.

- These results are presented for general education purposes only and may not be predictive for all patients or of Lutonix DCB usage.
Disclaimer, continued

• The physician has been compensated by Lutonix for the time and effort to present this information.

• Any discussion regarding Bard products during the presentation today is limited to information that is consistent with the CE Marking and clearances for those products. Please consult Bard/Lutonix product labels and inserts for any indications, contraindications, hazards, warnings, cautions and instructions for use.
LUTONIX® DCB in Vascular Access

Single-Center Retrospective Analysis
January 2014 – August 2015

45 patients
67 interventions
75 LUTONIX® DCB

39 patients
61 interventions
69 LUTONIX® DCB

6 patients
6 interventions
6 LUTONIX® DCB

*Lesions distal to cephalic arch not included*
Baseline Variables

Number of Patients: 39 (23 men; 59%)

<table>
<thead>
<tr>
<th>Vascular Access</th>
<th>39</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>AVF</td>
<td>20</td>
<td>51.3%</td>
</tr>
<tr>
<td>AVG</td>
<td>19</td>
<td>48.7%</td>
</tr>
<tr>
<td>De Novo</td>
<td>14</td>
<td>35.9%</td>
</tr>
<tr>
<td>Re-intervention</td>
<td>25</td>
<td>64.1%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Side</th>
<th>39</th>
</tr>
</thead>
<tbody>
<tr>
<td>Left</td>
<td>23</td>
</tr>
<tr>
<td>Right</td>
<td>16</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Site</th>
<th>39</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cephalic</td>
<td>23</td>
</tr>
<tr>
<td>Axillary</td>
<td>14</td>
</tr>
<tr>
<td>Basilic</td>
<td>2</td>
</tr>
</tbody>
</table>

Balloon diameter: 6.59mm
Balloon length: 73.41mm
Target Lesion Primary Patency

Median Survival: 326 days
@ 6 months: 75%
2012 JEVT Patras RCT (AVG + AVF) INPACT™ (Invatec-Medtronic, Brescia, Italy) vs. PTA at 6 months: 70%

2014 JVIR prospective single-arm (AVF) SeQuent Please™ (B Braun, Berlin, Germany) at 6 months: 70%

* Clinical Results reported in the literature with DCBs in the published literature may be different from LUTONIX® DCB outcomes. Different devices and study designs may yield different clinical results.
Median Survival: **Fistula 326 Vs. 237 Graft**

(p=0.15 Log-rank test; HR: 0.4909 95% CI: 0.1862–1.294)
LUTONIX® DCB Re-Interventions

39 patients
61 Interventions
69 LUTONIX® DCB

14 Patients received a 2\textsuperscript{nd} or 3\textsuperscript{rd} or 4\textsuperscript{th} DCB angioplasty
Comparison of 1\textsuperscript{st} vs. 2\textsuperscript{nd} intervention in a longitudinal manner
Median Survival: 1\textsuperscript{ST} Int 179.5 Vs. 278 2\textsuperscript{nd} Int
(p=0.0452 Log-rank test; HR: 2.623 95% CI: 1.021–6.740)
Summary

LUTONIX® DCB Retro Analysis in this single center study showed:

• DCB results in AVF were better compared to AVG
• Additional intervention showed more favorable results
DCB for Symptomatic CVS
Randomized Single-Center Control Trial Interim Results*

* - Data presented are preliminary, single-site reported and subject to change upon finalization / adjudication
Aim

To compare the Safety and Effectiveness of:

- DCB vs. PTA for the treatment
- Symptomatic Central Venous Stenosis
- AVGs and AVFs
Inclusion Criteria

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

“Real Life Inclusion Criteria”
Randomization

Angiographic verification
Lesion diameter visual estimation

If DCB group: predilation with 1mm smaller PTA balloon + PCB ± post dilation

If PTA group: HPB ± Post dilation with higher diameter HPB and/or longer inflation
Devices

DCB group:

**LUTONIX**® 035

PTA group:

Flowchart
Follow-up DCB

Previous PTA

DCB

PTA

Follow-up PTA
Endpoints

Primary:
Target Lesion Primary Patency @ 6 months

Secondary:
Minor or Major Complications
Longitudinal Comparison of treatments
Baseline Variables

20 patients in each group

Baseline variables were equally distributed between the two groups

Two patients from the PTA group were lost to f-up
Baseline Variables

For DCB Group
23 devices in 20 patients
15 used in 12 subclavian veins
4 in Vena Cava
4 in Anonymous Vein
Median Survival: LUTONIX® 176.5 days Vs. 124.5 days PTA
p=0.03 (Log-rank); HR: 0.4415 (95% CI: 0.2103-0.9271)
Median Survival: LUTONIX® 177 days Vs. 91 days PTA
p=0.01 (Log-rank); HR: 2.999 (95% CI: 1.306-6.888)
15/20 cases
Conclusion

These single-center clinical experiences of the LUTONIX® DCB in the treatment of AV stenosis are encouraging and warrant further investigation such as well designed randomized studies.
LUTONIX® Drug Coated Balloon
Patras Single Center Experience

Assistant Prof Dimitrios Karnabatidis
Patras I.R. Dpt
Greece