Value of DEBs to Treat Renal Artery Lesions, Recurrent Lesions and ISR

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Disclosures

- Consultant / Speaker / Proctor / Advisory Board
  - Abbott
  - Bayer-Medrad
  - Bard
  - Boston Scientific
  - Cook
  - Cordis
  - Ev 3-Covidien
  - Medtronic
  - Spectranetics
  - TriReme Medical
  - Volcano
  - W.L. Gore & Associates

Background

- Renal artery stenosis is a frequent pathology that can be correlated with hypertension
- In recent years renal stenting has become less popular due to little benefit when compared with medical therapy
- In-stent restenosis occurred in 15-25%
- FMD is still considered a complex pathology to manage

Study

To evaluate the role of DCB in pathologies compromising the lumen of the renal arteries:
- In Stent Restenosis – ISR
- Fibro Muscular Disparlasis – FMD

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No dedicated DCBs are available for renal artery application
"off-label" use of commercially available 0.035" In.PACT Admiral DCB
- Pre-evaluation: USCD + DSA (stenosis ≥70%)
- Pre-dilatation: ISR and FMD (1 mm undersized balloon)
- In.Pact Admiral DCB (Medtronic)
- Medical therapy post-procedure: Clopidogrel 4 weeks, Aspirin indefinitely
- F.U. 1 – 6 – 12 – yearly clinical evaluation + USCD

### Patients Population: FMD

<table>
<thead>
<tr>
<th>Pt</th>
<th>Age</th>
<th>Type of Lesions</th>
<th>DCB Ø (mm)</th>
<th>Inflat. Time (s)</th>
<th>Pre Dil ± Yes/No</th>
<th>F.U. ± Yes/No</th>
<th>Medical Therapy</th>
<th>Pressure pre</th>
<th>Pressure Post</th>
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<tbody>
<tr>
<td>1</td>
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<td>PTA/Inpact Admiral</td>
<td>6</td>
<td>60</td>
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<td>150/80</td>
<td>120/65</td>
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### Patients Population: ISR

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<th>Inflat. Time (s)</th>
<th>Pre Dil ± Yes/No</th>
<th>F.U. ± Yes/No</th>
<th>Medical Therapy</th>
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<td>Inpact Admiral</td>
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<td>No</td>
<td>8</td>
<td>No</td>
<td>160/80</td>
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### Results

- Technical success: 100%
- Mean F.U.: 22.5 ± 1.3 mos (6 – 39 mos)
- No restenosis
- No recurrence of symptoms
- No further treatments
- USCD: patent renal artery in all patients (resistive index 0.8)
- Medication: 14/16 pts. (87.5%) reduction of medical therapy
- Reduction of BP (Δ 13.75 mmHg Sist. - 8.12 mmHg Diast.) in all patients

F.F., Female, 30y
Hypertension (BP 175/100 mmHg) not responding to medical therapy
Nephrectomy Lt kidney
FMD Rt kidney
June '99 USCD: multiple severe stenoses Rt. RA (1.3 mt/sec.)

BP: 175/100 mmHg

Nov. '99 PTA (BP 170/95 mmHg)
Feb. '00 PTA
Pregnant
Nov '02: Stent
Pregnant
Nov '07: PTA + Restenting
Jan '09: Cutting Balloon
Sept '09: DCB (BP 170/90 mmHg)
BP always under control with medical therapy
Conclusions

- DCB are nowadays considered a valid tool to increase the patency rate in the peripheral vessels
- DCB improves outcome in renal artery pathologies
- Their activity is more important in patients with FMD
- For these reasons they can become, in a near future, the first line therapy
- Further studies are necessary to confirm these data
- Study limitation includes no evaluation of the glomerular filtration
- The use of dedicated devices can increase results avoiding some technical difficulties

BP: 140/80 mmHg – w/o medication

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