24-month results of Ulysse registry: Ultrasound plasty to improve plain percutaneous angioplasty outcomes

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Disclosure

Speaker name:
Costantino Del Giudice

I have the following potential conflicts of interest to report:

- □ Consulting
- □ Employment in industry
- □ Stockholder of a healthcare company
- □ Owner of a healthcare company
- □ Other(s)

☒ I do not have any potential conflict of interest
Calcific lesions are a big challenge for interventionist higher % of calcium - higher risk of complication

Fitzgeraland et al. in a study on 41 patients evaluated % of calcium in the plaque during coronary and peripheral angioplasty with IVUS

31 patients (76%) had IVUS evidence of significant dissection or plaque fracture immediately after balloon dilation.

In 87% of these cases, the dissections were adjacent to the calcific portion of the vessel wall
Ultrasound plaque-plasty could be an option to treat calcific lesions

Previous experience by Siegel et al.\textsuperscript{1,2} demonstrated in vitro and in vivo the efficacy of ultrasound energy to treat calcific chronically occluded vascular lesions.

Action related to:
- the longitudinal and transverse rapid (20,000 cycles/sec) movement of the probe impacting on the rigid, noncompliant, atherosclerotic portion of the vessel.
- to cavitation or the generation of vapor-filled voids (bubbles) in tissues, fluids, or cells.

1) Siegel et al. Circulation 1988;78:1443-1448
2) Siegel et al. Circulation.1994;89:1587-1592.)
Between 10/1 - 11/30 2017 24 patients with CLI were enrolled and treated for BTK lesions with US-plasty using the KAPANI catheter associated to PTA

• Primary Objective - SAFETY
  - Freedom from MACE through 30 days: Death, Stroke, MI
  - Recurrence of CLI, Amputations, Acute Occlusion, Surgical Revascularizations

• Secondary Objective - PROCEDURAL SUCCESS
  - Angiographic Re-Stenosis at 6 month
  - TLR at 6 month
Methods and materials

- Vessel
- Longitudinal Waves
- Ultrasound Catheter
- ULTRASOUND Exposure 15sec/cm

Calcific Plaque
- Guidewire
- Radiopaque Tip

PTA
- Ballon
- Vessel
## Results

### Baseline Characteristics (n=24)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>78.3 ±5.4</td>
</tr>
<tr>
<td>Men</td>
<td>15/24 (66)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>18/22 (75)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>15/24 (63)</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>20/24 (83)</td>
</tr>
<tr>
<td>Smoker</td>
<td>18/22 (75)</td>
</tr>
<tr>
<td>Coronary disease</td>
<td>10/24 (41)</td>
</tr>
<tr>
<td>Renal Failure</td>
<td>9/24 (38)</td>
</tr>
<tr>
<td>Rutherford class</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>17/24 (71)</td>
</tr>
<tr>
<td>6</td>
<td>7/24 (29)</td>
</tr>
</tbody>
</table>

### Lesions Characteristics (n=37)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesion length, mm</td>
<td>125.2±35.2</td>
</tr>
<tr>
<td>PARC calcification score</td>
<td></td>
</tr>
<tr>
<td>moderate</td>
<td>15/37 (41)</td>
</tr>
<tr>
<td>severe</td>
<td>22/37 (59)</td>
</tr>
<tr>
<td>Stenosis (%)</td>
<td>91.4±12.0</td>
</tr>
<tr>
<td>CTO</td>
<td>9/35 (26)</td>
</tr>
<tr>
<td>Lumen diameter</td>
<td>0.2±0.4</td>
</tr>
</tbody>
</table>
Results

Pre

Post

6 M FU
## Results

### Procedural, Angiographic, and Clinical Outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lumen diameter post PTA</td>
<td>2.4 ± 0.5</td>
</tr>
<tr>
<td>Residual stenosis</td>
<td>5.4 ± 0.7</td>
</tr>
<tr>
<td>Periprocedural complications</td>
<td>0</td>
</tr>
<tr>
<td>6 M FU Primary patency</td>
<td>97.3%</td>
</tr>
<tr>
<td>6M FU CD-TLR</td>
<td>0</td>
</tr>
<tr>
<td>6 M FU MAE</td>
<td>0</td>
</tr>
</tbody>
</table>
Results

Mortality at 24 M FU: 2
CD-TLR at 24 M FU: 0
MAE at 24 M FU:
  Stroke: 0
  Myocardial infarction: 0
  Hospitalization: 1
  Major Amputation: 0
  Need of revascularization: 1
  CLI recurrence: 1

Freedom from restenosis

Lesion at risk:
- 1 M: 37
- 6 M: 34
- 12 M: 33
- 18 M: 33
- 24 M: 31
Conclusions

- Low-frequency, high-intensity ultrasound energy delivery followed by PTA is a safe approach to treat infra-popliteal atherosclerotic lesions.
- It can modify plaque morphology and may improve PTA outcomes.
- Limitations:
  - Small sample sizes
  - Retrospective
  - Plaque evaluation morphology
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