Shockwave Lithoplasty - Indications And Results: Use In Combination With DCBs

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Disclosure

- I have the following potential conflicts of interest to report:
  - Shockwave Medical study support
The Shockwave Medical Lithoplasty System is intended for lithotripsy-enhanced balloon dilatation of lesions, including calcified lesions, in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries. Not for use in the coronary or cerebral vasculature.
Goal of Lithoplasty

- Obtain a better lumen with PTA
- Avoid stents
- Overcome the main limitation of DCB: severe calcium
DISRUPT BTK assessed Lithoplasty performance in a difficult-to-treat CLI population

<table>
<thead>
<tr>
<th>Vessels</th>
<th>Femoral/Popliteal Arteries</th>
<th>Tibial/Peroneal Arteries</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rutherford 2</td>
<td>33.7% (32)</td>
<td></td>
</tr>
<tr>
<td>Rutherford 3</td>
<td>65.3% (62)</td>
<td>20.0% (4)</td>
</tr>
<tr>
<td>Rutherford 4</td>
<td>1.1% (1)</td>
<td>5.0% (1)</td>
</tr>
<tr>
<td>Rutherford 5</td>
<td></td>
<td>75.0% (15)</td>
</tr>
</tbody>
</table>

**Calcification**

<table>
<thead>
<tr>
<th></th>
<th>DISRUPT PAD I</th>
<th>DISRUPT BTK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moderate</td>
<td>44.2% (42)</td>
<td>52.4% (11)</td>
</tr>
<tr>
<td>Severe</td>
<td>54.7% (52)</td>
<td>47.6% (10)</td>
</tr>
</tbody>
</table>

**Angiographic Findings**

<table>
<thead>
<tr>
<th></th>
<th>DISRUPT PAD I</th>
<th>DISRUPT BTK</th>
</tr>
</thead>
<tbody>
<tr>
<td>RVD (mm)</td>
<td>5.3</td>
<td>3.2</td>
</tr>
<tr>
<td>Lesion length</td>
<td>71.9</td>
<td>52.2</td>
</tr>
<tr>
<td>Calcified length</td>
<td>92.5</td>
<td>72.1</td>
</tr>
<tr>
<td>CTO</td>
<td>18.9% (18)</td>
<td>9.5% (2)</td>
</tr>
</tbody>
</table>

DISRUPT PAD & DISRUPT BTK categorized calcified lesions as per PARC definitions. Both studies utilized independent core labs and clinical events committees. DISRUPT BTK data based on European studies.
**DISRUPT PAD and BTK Safety & Effectiveness**

*Lithoplasty has a strong safety and effectiveness profile above- and below-the-knee*

<table>
<thead>
<tr>
<th>Safety</th>
<th>DISRUPT PAD I (35 subjects, 3 sites) + DISRUPT PAD II (60 subjects, 8 sites)</th>
<th>DISRUPT BTK (20 subjects, 3 sites)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dissections</td>
<td>1% (1) Grade D or greater, 1% (1) stent placed</td>
<td>0 Grade D or greater</td>
</tr>
<tr>
<td>Embolization</td>
<td>0 Embolic Events, 8% EPD Usage</td>
<td>0 Embolic Events</td>
</tr>
<tr>
<td>Perforations, abrupt</td>
<td>0 Complications</td>
<td>0 Complications</td>
</tr>
<tr>
<td>closure, slow/no reflow</td>
<td></td>
<td></td>
</tr>
<tr>
<td>or thrombosis</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Effectiveness**

| Residual Stenosis       | 23.8%                                                                        | 26.2%                            |
| Acute Gain              | 2.9mm                                                                        | 1.5mm                            |

**Follow-Up**

| 30 days                 | 100% Freedom from TLR, 100% Patency                                        | 100% Freedom from TLR, 0% MAE (death, amp. or MI) |
| 6 months                | 96.8% Freedom from TLR, 76.7% Patency                                       | -                                |

DISRUPT PAD & DISRUPT BTK categorized calcified lesions as per PARC definitions. Both studies utilized independent core labs and clinical events committees. DISRUPT BTK data based on European studies.
Severe Calcium Acts as a Barrier to DCB

12 month Results

Primary Patency

LLL

Calcium distribution evaluation by CTA (circumferential) and DSA (longitudinal)

Case 1
Pre Intervention Images
After Treatment with Turbohawk
Hawk Reocclusion treated with Viabahn
New restonosis treated with Lithoplasty
Plus DCB
Lessons Learned

Atherectomy failed after 6 months

Lithoplasty + DCB with sustained benefit after 6 and 12 months in severe calcification
Case 2
Treatment with DCB
Follow up

6 months 12 months 36 months
Lithoplasty
After Lithoplasty and after DCB
Lessons Learned

In DCBs restenosis occurs especially if calcium is present

Lithoplasty + DCB might be useful

Follow-Up 6 and 12 months
Lithoplasty as primary therapy
Results:
• Low rate of vascular complications
  • Provisional stenting (1.1%)
• Consistent effectiveness
  • High acute gain (3.0 mm)
  • Low residuals stenosis (23.8%)
  • Sustained 6 month results

Combination therapy
• Goal is to assess the optimal therapy to dilate heavily calcified lesions.
• All patients who do not receive a stent will be treated with a drug-coated balloon.
**Disrupt PAD III Study Design**

Study Design: Randomized study of the Shockwave Medical Peripheral Lithoplasty System with DCB versus standard balloon angioplasty with DCB to treat moderate and severely calcified femoropopliteal arteries (Disrupt PAD III).

Objective: The objective is to assess the optimal therapy to dilate heavily calcified lesions with Lithoplasty® versus traditional angioplasty, in achieving less than 30 % stenosis without the need for a stent. In addition, all patients who do not receive a stent will be treated with a drug-coated balloon.
Summary

High acute gains and low residual stenosis determine outcomes and are difficult to achieve in calcified lesions.

Calcified lesions limit effectiveness of drug-coated balloons.

Calcified lesions respond poorly to treatment and require high use of stents.

DISRUPT PAD III is the largest, randomized study in a difficult to treat, calcified patient population.

The goal is to provide level one evidence on the best treatment strategy for calcified lesions in a leave nothing behind strategy.