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

Gunnar Tepe MD
RoMed Rosenheim

Disclosure

- I have the following potential conflicts of interest to report:
- Shockwave Medical study support

Lithoplasty System Vascular Applications

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

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Lithoplasty System Pre/Post Intervention Images

- Pre Intervention Images

Safety

- Dissections: 1% (Grade D or greater)
- Embolization: 1%
- Perforations, abrupt closure, slow/no reflow or thrombosis: 0

Effectiveness

- Residual Stenosis: 23.8%
- Acute Gain: 2.9 mm
- Follow-Up 30 days: 100%
- Freedom from TLR: 100%
- Patency: 100%
- Medical Events: 3.6%
- 6 months: 96.8%
- Freedom from TLR: 76.7%
- Patency: -

DISRUPT PAD and BTK Safety & Effectiveness

DISRUPT PAD I
35 subjects, 3 sites

DISRUPT PAD II
60 subjects, 8 sites

DISRUPT BTK
20 subjects, 3 sites
21 lesions

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.
After Treatment with Turbohawk

Hawk Reocclusion treated with Viabahn

New restenosis 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

Disrupt PAD III Study Design

Moderate and severely calcified femoropopliteal arteries
Rutherford 2 to 4
RVD 4-7, stenosis ≥70%
Lesion length 5–18 cm occlusive or ≤10 cm CTO

Treatment arm (N=167)
Lithoplasty + IN.PACT DCB

Control arm (N=167)
PTA + IN.PACT DCB

334 subjects
45 global sites
Randomization 1:1
24 months follow-up

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 stave 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.