The trials and tribulations of hawking in the tibials

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Disclosure
Speaker name: Vikram Puttaswamy

I have the following potential conflicts of interest to report:

- Receipt of grants/research support
  Details:
- Receipt of honoraria and travel support
  Details:
- Employment in industry
  Details:
- Shareholder in a healthcare company
  Details:
- Owner of a healthcare company
  Details:

I do not have any potential conflicts of interest to report
The standard endovascular options in tibial arteries

• Angioplasty – is the mainstay
  • POBA or DCB?
    • Leaves nothing behind, but significant dissection and recoil occurs

• Stents
  • Self expanding / balloon expandable
  • BMS or DES?
    • All stent options are likely to affect mean luminal diameter, possibly reducing flow in these small vessels

• Very limited clinical data to tell us what is the best treatment option
• Where does atherectomy sit as far as results in the tibials are concerned and where does it fit in our treatment algorithm?

• From the limited clinical data available, directional atherectomy using the Hawk system, is the obvious choice of atherectomy system to use in the tibial arteries
Atherectomy Trials – 30 day to 1 year outcomes

<table>
<thead>
<tr>
<th>Trial</th>
<th>Patient Number</th>
<th>Core Lab Adjudicate</th>
<th>Citation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Directional Atherectomy</strong></td>
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<tr>
<td><strong>Laser Atherectomy</strong></td>
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<td><strong>Rotational Atherectomy</strong></td>
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<td><strong>Orbital Atherectomy</strong></td>
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<td><strong>OCT Atherectomy</strong></td>
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</table>
Primary patency by duplex ultrasound at 12 months (PSVR ≤2.4 with no clinically-driven reintervention); Patency value determined by Kaplan-Meier analysis.

DEFINITIVE LE Patency – CLI patients

Primary Patency (%)

<table>
<thead>
<tr>
<th></th>
<th>SFA</th>
<th>Popliteal</th>
<th>Infrapopliteal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Length:</td>
<td>8.6 cm</td>
<td>5.4 cm</td>
<td>6.0 cm</td>
</tr>
<tr>
<td>Number of Lesions:</td>
<td>135</td>
<td>48</td>
<td>96</td>
</tr>
</tbody>
</table>

HawkOne™ Directional Atherectomy System

Treat All Morphologies
Treat all atherosclerotic plaque efficiently and effectively, including severe calcium

Procedural Efficiency
Streamline procedural efficiency with improved crossing and cleaning capabilities

Note: Product claims for the HawkOne™ device are made in comparison to the TurboHawk™ platform.

Indications, contraindications, warnings, and instructions for use can be found in the product labeling supplied with each device.

CAUTION: Federal (USA) law restricts these devices to sale by or on the order of a physician.
# Directional Atherectomy Systems: TurboHawk™ and HawkOne™ Device Specifications

<table>
<thead>
<tr>
<th>Model Name</th>
<th>Catalog Number</th>
<th>Vessel Diameter (mm)</th>
<th>Sheath Compatibility (Fr)</th>
<th>Crossing Profile (mm)</th>
<th>Working Length¹ (cm)</th>
<th>Effective Length² (cm)</th>
<th>Tip Length (cm)</th>
<th>Max. Cut Length (mm)</th>
<th>Packing Device</th>
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</thead>
<tbody>
<tr>
<td>HawkOne LS</td>
<td>H1-LS</td>
<td>3.5 to 7.0</td>
<td>7</td>
<td>2.6</td>
<td>114</td>
<td>107</td>
<td>6.6</td>
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<td>9.6</td>
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<td>Extended Tip</td>
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<tr>
<td>HawkOne M</td>
<td>H1-M</td>
<td>3.0 – 7.0</td>
<td>6</td>
<td>2.2</td>
<td>135</td>
<td>129</td>
<td>5.9</td>
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<td>6F</td>
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<tr>
<td>HawkOne S</td>
<td>H1-S</td>
<td>2.0 – 4.0</td>
<td>6</td>
<td>2.2</td>
<td>151</td>
<td>145</td>
<td>5.9</td>
<td>40</td>
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<tr>
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<td>THS-SC-C</td>
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<td>129</td>
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<tr>
<td>Extended tip</td>
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<tr>
<td>Calcium</td>
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</table>

¹ HawkOne™ Working Length- Distal end of pre-loaded flush tool, in the proximal position, to the distal end of tip.

² HawkOne™ Effective Length- Distal end of pre-loaded flush tool, in the proximal position, to the proximal end of cutter window.
Registry for Hawk Directional Atherectomy
(Oct 2016 - Jan 2019)

- A single arm, prospective registry of patients with infrainguinal arterial disease requiring intervention with the TurboHawk or HawkOne atherectomy devices

- All patients were protected with SpiderFX filters

- The majority of atherectomised lesions were treated with drug-coated balloons

- Tibial vessel atherectomies were treated with intra op intra-arterial nitrates post op dual antiplatelet agents

- Patients were followed up postoperatively at regular intervals with clinical review and duplex ultrasound

- Endpoints primary patency (duplex defined with PSVR > 2.4) TLR, and MAE most importantly, major amputation rates
Registry for Hawk Directional Atherectomy
(Oct 2016- Jan 2019)

- Treated over 200 patients with Hawk directional atherectomy devices
  - Multiple vessels per leg / multiple separate lesions per leg

- Preliminary data assessment of 218 legs in 170 patients

- 152 infra-popliteal vessels

- HawkOne devices were always used in conjunction with SpiderFX filters
  - Mean Age 79yo
  - 47% F 53% M
  - Over 80% of tibial cases were for CLI
  - Lesion length ranged from 2 cm to >25 cm

- Combination therapy using a DCB: 91.4% or with POBA only: 8.6%

- Tibial DCB platforms

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Model</th>
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<tbody>
<tr>
<td>Medtronic</td>
<td>InPact</td>
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<tr>
<td>Bard</td>
<td>Lutonix</td>
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<tr>
<td>Biotronik</td>
<td>Passeo 18 Lux</td>
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<tr>
<td>iVascular</td>
<td>Luminor</td>
</tr>
</tbody>
</table>

Lesions treated by vessel location

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Lesion Count

- SFA: 122
- Popliteal: 85
- Tibioperone: 65
- Anterior tibial: 47
- Posterior tibial: 22
- Peroneal: 18
- CFA: 14
```
Registry for Hawk Directional Atherectomy
(Oct 2016 - Jan 2019)

TOTAL COHORT
PRIMARY PATENCY
1 year 75.2% (69.9 – 81.0)
2 years 60.9% (52.2 – 70.9)

PRIMARY ASSISTED PATENCY
1 year 85.9% (81.5 – 90.6)
2 years 76.0% (67.8 – 85.1)

SECONDARY PATENCY
1 year 89.0% (84.9 – 93.3)
2 years 82.9% (75.4 – 91.3)

Freedom from Target Lesion Revascularisation (fTLR)
1 year 83.7% (79.1 – 88.5)
2 years 68.3% (59.7 – 78.2)

373 vessels treated
495 identified lesions

Femoropopliteal
n = 221
Infrapopliteal
n = 152
Hawk Directional Atherectomy in the Tibial Arteries

- Tibial arteries treated (n=152)
  - TPT 65
  - AT 47
  - PT 22
  - PA 18

- 99% initial technical success with intention to treat
  - 1 Excessive debris in filter requiring removal with sheath
  - 1 Excessive filter wire wrap requiring exchange of device

- All patients had debris of some form, caught in the filter device

- 1 unrelated mortality

- Major adverse events (MAE - 2%)
  - 2 groin site complications requiring reintervention
  - 3 non flow limiting dissections - no bailout stenting
  - 2 distal embolization requiring thrombolysis and endo-thrombectomy
  - 2 tibial artery perforations / controlled with angioplasty and no other treatment was required
  - 3 AVF - none required treatment
  - No open conversions
Hawk Directional Atherectomy in the Tibial Arteries
(Oct 2016 - Jan 2019)

Tibial Lesions
n = 152
TPT  65
AT   47
PA   18
PT   22

Freedom from Target Lesion Revascularisation (fTLR) (Tibial Cohort)
1 year  74.1% (65.2 – 84.1)
2 years 66.2% (53.5 – 81.8)

Patency rates of directional atherectomy (tibial cohort)

PRIMARY PATENCY
1 year 60.9% (51.2 – 72.6)
2 years 57.6% (46.8 – 70.8)

PRIMARY ASSISTED PATENCY
1 year 76.8% (68.2 – 86.4)
2 years 72.9% (62.4 – 85.2)

SECONDARY PATENCY
1 year 81.7% (73.7 – 90.6)
2 years 77.2% (66.3 – 89.9)
Hawk Directional Atherectomy in the Tibial Arteries  
(Oct 2016 - Jan 2019)
Interim Discussion of Hawk DA in the Tibial vessels

• Very hard to study tibial vessels using usual criteria and methods in the more proximal, larger vessels
  – The vessels are small / lesions heterogeneous / lesion length can be difficult to quantify
  – Post op assessment is not straightforward, especially duplex criteria, even when using a experienced sonographers in a dedicated vascular laboratory

• We are still analysing other factors in our study that we have recorded that may affect patency and TLR such as
  – lesion length
  – lesion proximity to ankle
  – patency of plantar arch and foot vessels
Conclusion- Hawk DA in tibial vessels

- Directional atherectomy with the HawkOne device, has a role in treating tibial vessels.

- There is a significant learning curve in the use of directional atherectomy and I would recommend progressing to this small diameter vessel bed only after becoming very proficient at using it in larger vessels.

- It can decrease the chance of dissection when applied as a preparation tool for angioplasty and may be best used in conjunction with drug coated balloons.
Hawk Directional Atherectomy in tibial vessels

- That when used in trained hands is safe and unlikely to be associated with major adverse events
- It may need to be performed, a number of times, on the same vessel, to continue perfusion to the foot and eliminate CLI
- If performed effectively and in conjunction with a robust surveillance program can lead to very low major amputation rates in CLI patients
- Further assessment in the way of detailed registries and possibly RCT’s are needed to define its ideal role
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