Histological Evaluation Of Adventitial Injury From Directional Atherectomy: Value of OCT Guidance*

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Conflicts of interest:
Consultancy for Medtronic

Current devices for directional atherectomy

HawkONE (Medtronic) – Fluoroscopy-guided atherectomy

Pantheris (Avinger) – OCT-guided atherectomy

Which is the benefit of directional atherectomy?
Comparison to other devices

Bail Out Stent Rates Across Atherectomy Trials

<table>
<thead>
<tr>
<th>Device</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hawk ONE (Medtronic)</td>
<td>22%</td>
</tr>
<tr>
<td>DEFINITIVE LE</td>
<td>23%</td>
</tr>
<tr>
<td>Silver- / TurboHawk</td>
<td>31%</td>
</tr>
<tr>
<td>DEFINITIVE CA++</td>
<td>35%</td>
</tr>
<tr>
<td>Definitive AR</td>
<td>41%</td>
</tr>
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<td>Definitive AR</td>
<td>41%</td>
</tr>
<tr>
<td>Excite ISR CELO Laser</td>
<td>54%</td>
</tr>
<tr>
<td>JETStream</td>
<td>68%</td>
</tr>
<tr>
<td>IN.PACT SFA (DCB Arm)</td>
<td>87%</td>
</tr>
<tr>
<td>IP Global</td>
<td>88%</td>
</tr>
<tr>
<td>IP Global</td>
<td>91%</td>
</tr>
<tr>
<td>IP Global</td>
<td>95%</td>
</tr>
</tbody>
</table>

Limitations of directional atherectomy

# 1: High restenosis rate as standalone therapy

Patency Rates Across SFA Trials

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<th>Device</th>
<th>Rate</th>
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<tbody>
<tr>
<td>DEFINITIVE LE</td>
<td>78%</td>
</tr>
<tr>
<td>JETStream</td>
<td>77%</td>
</tr>
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<td>DEFINITIVE LE</td>
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<td>Definitive AR</td>
<td>95%</td>
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</table>

Limitations of directional atherectomy

# 2: Aneurysmatic degeneration after DAART

Risk factor analysis
Adventitial or medial injury
OR: 228, 95%CI: 44 to 999, p<0.0001

The role of adventitial layer during DA

1-year restenosis rate
With adventitial or medial injury: 97%
Without injury: 11%

Risk factor analysis
Adventitial or medial injury
OR: 228, 95%CI: 44 to 999, p<0.0001
Research question
Which is the impact of OCT-guidance in a device for directional atherectomy?

Study design
- 95 patients
- Type of atherectomy was left to the discretion of the surgeon
- Aim: <30% residual stenosis post DA
- Exclusion criteria: in-stent restenosis

Early outcome
- Histological analysis
- Early outcome: histological analysis

Late outcome
- Restenosis rate, aneurysmatic degeneration

Awaited in 2019

Tissue analysis and measurement
- Plaque segments

Histological analysis
- Adventitial injury by HawkOne

- Right SFA
- Intravascular recanalization
- 1st round Hawk One
- 2nd round Hawk One
- DCB
- DAART

Histological analysis
- Adventitial injury by HawkOne
- Right SFA
- 2nd round Hawk One

Adventitia in CFA lesions
- 0.81% adventitia
Histological analysis
Advenitial injury by Pantheris

Results
Overall

Number of segments

<table>
<thead>
<tr>
<th>Segment Type</th>
<th>Number of Segments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Without</td>
<td>109 (86%)</td>
</tr>
<tr>
<td>With</td>
<td>18 (14%)</td>
</tr>
</tbody>
</table>

Mean area per segment

<table>
<thead>
<tr>
<th>Segment Type</th>
<th>Mean Area (mm²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Without</td>
<td>0.13 ± 0.66</td>
</tr>
<tr>
<td>With</td>
<td>0.13 ± 0.66</td>
</tr>
</tbody>
</table>

Advenitia

- N=18
- No embolizations
- 1 perforation in HawkOne group

Results
Classified by devices

HAWKONE
Fluoroscopy-guided
N=98 (77%)

PANTHERIS
OCT-guided
N=29 (23%)

Without adventitia

- N=14 (14.3%)
- N=4 (13.8%)

With adventitia

- N=1 (0.84%)
- N=1 (0.76%)

Results
% of adventitia

HAWKONE
Fluoroscopy-guided
N=98 (77%)

PANTHERIS
OCT-guided
N=29 (23%)

<table>
<thead>
<tr>
<th>Device Type</th>
<th>Median % (IQR)</th>
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<tr>
<td>HawkOne 6F</td>
<td>1.54% (0.73-3.64)</td>
</tr>
<tr>
<td>Pantheris 6F</td>
<td>1.79% (0.76-3.13)</td>
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</table>

Possible explanations
Cutting depth

HawkOne

- 6F Device:
  - Cutter Height: 0.009" (0.23 mm)
  - Cut Depth: 0.36 mm (H1-M), 0.34 mm (H1-S)

TurboHawk SX-C

- 6F Device:
  - Cutter Height: 0.009" (0.23 mm)
  - Cut Depth: 0.37 mm

Possible explanations
OCT imaging is not located directly in the blade

- Uncontrolled cutting due to the apposition balloon?
- You are checking the depth of the cutting after you have already done it.
Conclusions

• There was no difference in the rate and the percentage of adventitial injury after OCT-guided atherectomy compared to FG-atherectomy
• No difference in the adverse events intraoperatively at both groups
• The 1-year results will assess the restenosis and aneurysm rate in both groups (2019)
• As regards the adventitial injury, we cannot confirm the added value of the current type of OCT-guided atherectomy