A TREATMENT ALGORITHM FOR DRUG ELUTING TECHNOLOGIES

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Medical Decision Making

- **Anatomy Attributes** (lesion location, morphology, length, etc)
- **Device Attributes** (scaffolding, anti-restenosis, fractures, etc)
- **Evidence-Based Medicine** (EBM-MDM)
- **Cost-effectiveness analysis** (Societal gains and monetary savings)
Claudication

- Lifestyle impairment
- Walking distance
- Exercise therapy
- Risk factor modification
- Lesion anatomy

Conservative approach
LESS STENTING

Critical leg ischaemia

- Limb salvage
- Comorbidities
- Limited life expectancy
- Quality of life
- Lesion anatomy

Aggressive treatment
MORE STENTING
## Endovascular technologies

<table>
<thead>
<tr>
<th>Step</th>
<th>Wires</th>
<th>Ather</th>
<th>PTA</th>
<th>BMS</th>
<th>DCB</th>
<th>DES</th>
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<tbody>
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<td>Paclitax</td>
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<td>X</td>
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Leaving Nothing behind and Unmet needs:
vessel recoil, plaque resistance, severe dissections
**Paclitaxel**
Interferes with cell division at the M phase, after DNA synthesis has occurred. Cells are in an abnormal state with twice the normal DNA content, which leads to **cell death by apoptosis**.

**Sirolimus & Everolimus**
Interfere with cell growth at the G1/S transition, before DNA synthesis has occurred. Cells return to the resting phase (G0) **without dying** and can reenter the cell cycle later again.
Paclitaxel concentrations in arterial tissue are comparable with regard to $C_{\text{max}}$ values and concentrations at 2 months post-treatment.
Network of SFA evidence

Technical success

Balloons vs Nitinol Stents
Balloons vs Covered Stents
Bare vs Covered Stents

Balloons
Uncovered nitinol stents ≈ 95.4%
Covered nitinol stents ≈ 97.5%

Bail-out
Δ≈22%

Long-term: Probability best

Vascular Restenosis

- Paclitaxel-coated Balloons
- Paclitaxel-eluting Stents
- Covered Nitinol Stents
- Sirolimus-Eluting Stents
- Bare Nitinol Stents
- Plain balloon angioplasty

Cumulative Rank Probabilities (%)

Freedom from TLR

- Paclitaxel-coated Balloons
- Paclitaxel-eluting Stents
- Sirolimus-Eluting Stents
- Covered Nitinol Stents
- Bare Nitinol Stents
- Plain balloon angioplasty

Cumulative Rank Probabilities (%)

DCB versus DES in long lesions

n=228 patients and propensity score analysis
lesion length 19cm and bail-out stenting 18.3%

ZILVER-PTX

83.4%

64.1%

LEVANT 2

Improved patency

Zilver-PTX

89.1%

76.7%

No difference

Log-Rank p-value = 0.003

Log-Rank p-value = 0.964
### Limitations of RCTs so far

<table>
<thead>
<tr>
<th>Variable</th>
<th>ZILVER-PTX</th>
<th>DCB</th>
<th>Notes</th>
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</thead>
<tbody>
<tr>
<td>CLI</td>
<td>10%</td>
<td>4-6%</td>
<td>DEBELLUM 36%</td>
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<tr>
<td>CTOs</td>
<td>30%</td>
<td>13-41%</td>
<td>ISR excluded</td>
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<tr>
<td>Length</td>
<td>5.4cm</td>
<td>4.0-8.1cm</td>
<td>Mostly TASC A &amp; B</td>
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<tr>
<td>Stenting</td>
<td>100%</td>
<td>Very low</td>
<td>IN.PACT SFA: 7.3 vs 11.6%</td>
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Real-life practice: 1 in 4 will need a Stent
DES & DCB synergies

Lesion complexity (length, CTO, calcium, etc)

DCB

DES

Rutherford Becker classification (CLI)
Primary DES versus DCB and stent?
BASIL 3 funded for CLI
Conclusions

• Paclitaxel proven anti-restenotic effect in the femoropopliteal artery

• Paclitaxel-stents ballanced against paclitaxel-balloons according to clinical indications
Thank You
A treatment algorithm for drug eluting technologies

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