Treatment strategy for Femoropopliteal CLTI

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I have the following potential conflicts of interest to report:

**Consulting:** Boston Scientific, BD, Century Medical Inc., Medtronic

**Employment in industry:** None

**Stockholder of a healthcare company:** None

**Owner of a healthcare company:** None

**Honoraria received from:** Abbot Vascular, Asahi Intecc., Boston Scientific, BD, COOK, Cordis, NIPRO, KANEKA, Medikit, Medtronic, Orbus Neich, Terumo
Many kinds of “Barrier” for restenosis

- **Scaffold**
  - Recoil
  - Dissection

- **Drug**
  - Neointima

- **Drug + Scaffold**
  - Recoil
  - Dissection
  - Neointima

- **Graft + Scaffold**
  - Recoil
  - Dissection
  - Neointima

- **Interwoven stent**
  - Recoil
  - Dissection
  - Neointima
  - Calcium
From SCAI expert consensus 2018

**Use of Drug Eluting Stent**

<table>
<thead>
<tr>
<th>Drug-eluting stents</th>
<th>COR</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. CFA bifurcation lesion</td>
<td>IIA</td>
<td>C-EO</td>
</tr>
<tr>
<td>2. Above knee popliteal lesion</td>
<td>I</td>
<td>B-R</td>
</tr>
<tr>
<td>3. Ostial SFA lesion</td>
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<td>B-R</td>
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<td>6. Diffuse SFA lesion</td>
<td>I</td>
<td>B-NR</td>
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<tr>
<td>7. Moderate to severe calcified, focal lesion</td>
<td>I</td>
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<td>10. Chronic total occlusion, focal lesion</td>
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<td>B-NR</td>
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<tr>
<td>13. ISFR, focal lesion</td>
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<td>C-LD</td>
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<tr>
<td>14. ISFR, intermediate lesion</td>
<td>IIA</td>
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<tr>
<td>15. ISFR, diffuse lesion</td>
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**Use of DCB**

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**DES/ DCB use is strongly recommended With high level evidences**

B-R: based on RCT, B-NR: based on non-RCT, C-LD: based on limited data, C-EO: based on Expert opinion,
Pros and Cons of stent-based (DES-based) strategy

• **Pros for Stent-based strategy**
  - Quick and Simple
  - Reduce procedural time
  - Avoid the acute failure due to recoil or dissection
  - Avoid the down stream effect

• **Cons for stent-based strategy**
  - Risk of stent thrombosis
  - Long-term DAPT (bleeding risk)
  - Possibly extent the lesion length
  - Difficult to find “healthy zone” as a stent landing zone
common consensus for FP disease

For Claudicant

*DCB favor strategy*
-preserve the future option
-Avoid stent disease

For CLTI

*DES favor strategy*
-Simple and quick procedure
-Avoid downstream effect
CLTI with **multifocal FP** + BTK lesion
3 DES were deployed for FP stenosis
Final angiogram showed good result

STENT based strategy is simple, quick and promising
However... dark side of stent strategy

Stent thrombosis; 47 days after DES deployment (DAPT was continued)
Flow was recovered... but...

Limb status became worse.... Clinical status was not recovered.
Stent itself does not improve the patency

There is no significant difference
DCB alone
&
DCB + STENT

Result of **High-dose DCB** for CLTI in Japan

Nakamura M et al. Presentation in JET Talks 2020

### Complications within 12M

<table>
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<th>RCC 1-3 (Claudicant)</th>
<th>RCC 4-6 (CLTI cohort)</th>
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<tr>
<td><strong>Major Adverse Event (MAE)</strong></td>
<td></td>
<td></td>
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<tr>
<td>All cause of death, n (%)</td>
<td>9 (6.0)</td>
<td>13 (17.3)</td>
</tr>
<tr>
<td>Target limb amputation, n (%)</td>
<td>0 (0.0)</td>
<td>1 (1.3)</td>
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<tr>
<td>Clinical driven TLR, n (%)</td>
<td>6 (4.0)</td>
<td>10 (13.3)</td>
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<tr>
<td>Treatment site thrombosis, n (%)</td>
<td>2 (1.3)</td>
<td>0 (0.0)</td>
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<tr>
<td>Any TLR, n (%)</td>
<td>7 (4.6)</td>
<td>8 (10.7)</td>
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Does the downstream effect negatively affect?

Role of Angioplasty with Drug-coated balloon for chronic ISchemia in wound Healing

Participant Flow

Between April 2014 and March 2019, Ischemic wound underwent FP-EVT

1131 limbs (980 pts)

Unavailable data
72 limbs (58 pts)

1059 limbs (922 pts) were enrolled

DCB
144 limbs (136 pts)

Non-DCB
915 limbs (786 pts)

DCB for CLTI patient is safe and effective strategy

Wound healing rate@12M

73.2% vs. 65.0%

Log rank test
p=0.13

Primary patency@12M

83.6% vs. 64.8%

Log rank test
p<0.001

Learn from experience and evidences

• Stent based strategy is simple, quick and promising: No recoil, dissection and downstream effect
  → considered as **basic strategy** for CLTI patients

• Stent itself **does not improve the patency**

• **NO difference** safety and efficacy between claudicant and CLTI in Japanese PMS study

• **Comparable wound healing rate and better patency** were observed in real world clinical setting CLTI patients
Lutonix Rx: user friendly, **low dose DCB**

1. Low dose (2.0μg/mm²) PTX
2. 4.5Fr compatible
3. 0.014-inch GW compatible
4. Rapid exchange system

Fit for CLTI procedure
Slender sheath and 0.014 GW
Potentially reduce the downstream effect?
Summary of Presentation

- Stent-based strategy is basic strategy for CLTI
- However, stent-based strategy sometimes includes several problems, like risk of Stent thrombosis.
- Japanese PMS data showed acceptable result of DCB for CLTI Downstream effect may not worsen the outcomes of CLTI patients
- **DCB-based strategy** is reasonable and important option for CLTI patients.
Treatment strategy for Femoropopliteal CLTI

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