Evidence and experience in FP-CTO recanalization

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Disclosure

Speaker name:

I have the following potential conflicts of interest to report:

☐ Consulting
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☒ I do not have any potential conflict of interest
Considerations of recanalization strategy by mechanism of plaque type
Appropriate EVT for mixed morphology in upcoming new devices era

- IVUS Imaging modalities
  - Fibrous Plaque
  - Deep Calcified plaque
  - Calcified Nodule
  - Concentric Calcium

- Atherectomy devices
  - TurboHawk (Medtronic)
  - Turbo-Elite laser (Spectranetics/DVx)
  - JETSTREAM (Boston Scientific)

- Devices
  - Lutonix 35DCB (BARD)
  - Impact 35DCB (Medtronic)
  - Ranger 18DCB (Boston Scientific)
  - ZilverPTX (COOK)
  - VIABAHN (GORE)
  - Eluvia DES (Boston Scientific)

Leave noting behind
Leave the right thing behind
Revascularization for FP-CTO


Intraluminal  Subintimal
Subintimal stenting for long CTO **without calcification**

-Angiography and IVUS assessment-

As endovascular therapy (EVT) technique for CTO lesions, **subintimal angioplasty** with atheroocclusive disease of the superficial femoral artery was first suggested by Bolia et al in 1989.


In this minimally invasive technique, a guidewire is intentionally placed between the intima and the media to create a new track along the vessel wall, bypassing the atherosclerotic occlusion.
## Subintimal versus Intraluminal Angioplasty

<table>
<thead>
<tr>
<th>Subintimal Angioplasty</th>
<th>Intraluminal Angioplasty</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Advantage</strong></td>
<td><strong>Advantage</strong></td>
</tr>
<tr>
<td>1. Simplicity</td>
<td>1. Response to the balloon is favorable</td>
</tr>
<tr>
<td>2. Low cost</td>
<td>2. Sufficient post stenotic dilation</td>
</tr>
<tr>
<td>3. Short procedure time</td>
<td>3. Favorable acute results</td>
</tr>
<tr>
<td><strong>Disadvantage</strong></td>
<td><strong>Disadvantage</strong></td>
</tr>
<tr>
<td>1. Insufficient dilation and recoil</td>
<td>1. Outcome depends on the experience of the surgeon</td>
</tr>
<tr>
<td>2. Re-entry often becomes difficult</td>
<td>2. High cost</td>
</tr>
<tr>
<td>(when the wire passes the distal true lumen after excessive reach beyond the subintimal space)</td>
<td>3. Long procedure time</td>
</tr>
<tr>
<td>3. The lesion may become longer than the original length</td>
<td></td>
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<tr>
<td>4. Serious complications (vessel rupture etc.)</td>
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Improved technical success and midterm patency with subintimal angioplasty compared to intraluminal angioplasty in FP long-CTO
Initial and 3-year results after subintimal vs. intraluminal approach for FP long-CTO

1) Technical success
   91% vs. 90% (p=.71)

2) Procedural time
   126 ± 63 min. vs 98 ± 49 min. (P = .003)
   ¾ pt with intraluminal approach were switched to subintimal approach

3) Perioperative complication
   11% vs. 13% (p=.34)

4) Patency
   Primary patency: 55% vs. 53% (p=.30)
   Secondary patency: 80% vs. 85% (p=.55)

# IVUS evidence in FP lesions treated with stent endo-approach

<table>
<thead>
<tr>
<th>First author</th>
<th>Journal</th>
<th>Number of participants</th>
<th>Follow-up duration</th>
<th>Predictor of restenosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Miki K</td>
<td>Circ J 2013</td>
<td>236 SFA lesions</td>
<td>34±5 M</td>
<td>LL, distal CSA, stent edge dissection *TLR</td>
</tr>
<tr>
<td>Iida O</td>
<td>JACC interv 2015</td>
<td>831 FP lesions 690 Pts</td>
<td>12±2 M</td>
<td>LL ≥16 cm Distal EEM ≤27 mm² MSA≤12 mm²</td>
</tr>
<tr>
<td>Miki K</td>
<td>JEVT 2016</td>
<td>112 FP lesions 97 Pts</td>
<td>6±1 M</td>
<td>LL, stent type MSA&lt;15.5mm²</td>
</tr>
<tr>
<td>Mori S</td>
<td>JAT 2016</td>
<td>45 FP lesions</td>
<td>12 M</td>
<td>Intramedial route proportion, distal CSA</td>
</tr>
</tbody>
</table>

Predictor of restenosis in FP treatment under IVUS evaluation
1) Lesion length, 2) distal CSA, 3) **MSA (stent expansion)**
Subintimal angioplasty

Subintimal angioplasty $\equiv$ insufficient MSA (minimum stent area) $\Rightarrow$ Restenosis

Study design: Prospective, multicenter registry

Subjects: 690 PAD Pt with 831 femoro-popliteal lesion treated with Zilver PTX

Primary endpoint: Primary patency, Incidence of stent thrombosis

Procedure: Initial: IVUS was routinely used for assessing vessel diameter.

12 months: restenosis was evaluated by follow-up angiography.
ZEPHYR sub-analysis (CTO, n=192)
Impact of subintimal stenting on outcomes

Intraplaque (inside the plaque)
- Intraluminal angioplasty

Subintimal (between the plaque and media)
- Subintimal angioplasty

Intramedia (between the media and adventitia)

- Intraluminal angioplasty

62% (n=119)
38% (n=73)

ZEPHYR sub-analysis
Impact of **subintimal stenting** on outcomes

**Intraluminal vs. Subintimal**

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<tr>
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<th>Intraluminal angioplasty</th>
<th>Subintimal angioplasty</th>
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<tr>
<td>at 1 year</td>
<td>35%</td>
<td>45%</td>
</tr>
<tr>
<td>at 2 years</td>
<td>51%</td>
<td>56%</td>
</tr>
</tbody>
</table>

*P = 0.648 at 1 year, P = 0.352 at 2 years*

ZEPHYR sub-analysis

Impact of subintimal stenting on outcomes

Interactions for restenosis between subintimal angioplasty and baseline characteristics

ZEPHYR sub-analysis
Impact of subintimal stenting on outcomes

Subintimal angioplasty in ESC guideline

**Femoropopliteal segment**

One of the main problems with endovascular therapy in this segment is the high prevalence of diffuse disease. Furthermore, different mechanical forces act on the superficial femoral artery. This artery is deformed repetitively in multiple directions by leg movements. A high technical success rate, due to technical developments and increasing operator experience, in combination with low risk, make endovascular therapy the preferred choice also in patients with long and complex femoropopliteal lesions.

Despite its widespread use, research data regarding subintimal angioplasty are sparse. There are no data comparing patency rates between intraluminal and subintimal angioplasty. However, in many interventions an unintentional subintimal passage is unavoidable. Regarding atherectomy, different devices are used with unclear long-term benefits. Currently there are niche indications in severely calcified lesions and non-stent areas (e.g. the common femoral and popliteal artery). However, there are some concerns regarding the risk of distal embolization with these devices.

ESC guideline mentioned widespread use of subintimal angioplasty in FP-CTO.
Subintimal approach for FP-CTO without severe calcification
IVUS was done after successful wire crossing
Post NSE scoring balloon therapy (6.0 × 40mm)
IVUS evaluation after successful NSE Tx

Post NSE Tx
(6.0 × 40mm)
Final Angiogram

Rt SFA 100% ⇒ 0%
(Viabahn 5.0*250mm, 6.0*150mm)
IVUS evaluation after Viabahn stentgraft Tx
My opinion: Clinical issues in recanalization for the FP-CTO is whether lesions complicate with severe calcification.
How do we overcome the severe Calc?
Clinical issues in FP-CTO is the lesion with severe calcified. Hopeless for optimal dilation (insufficient acute gain)

SMART stent => YOROI 36atm

Courtesy with Dr. Kozuki
Peripheral Arterial Calcium Scoring System

Primary patency according to **PACSS grade** (0 vs. 1-3 vs. 4)

PACSS grade 4 calcification was independently associated with restenosis after SFA-EVT.

My algorithm of recanalization strategy for FP-CTO focusing on "intimal tracking".

Vessel calcification

- (+) Long FP-CTO (>15cm, TASC C/D)
  - Subintimal tracking
    * Intentional approach with aggressive vessel prep

- (−) Subintimal tracking
  * Intentional approach

- (−) Short FP-CTO (<15cm, TASC A/B)
  - Intraluminal tracking
    * To penetrate the central with CTO wire
Subintimal stenting for long CTO with calcification - Intentional subintimal approach with 0.035 Terumo wire-
Subintimal stenting for long CTO **with calcification**

- Intentional subintimal approach with 0.035 Terumo wire-
Intraluminal tracking for short CTO *with calcification*

-To penetrate the central using *0.014 inch CTO wire (Asahi)*-
Representative case (initial angio) -80’s yr, HD, CLI, SFA-CTO-
How do you overcome “CTO with severe calcification”

**Under expansion**
- Risk for:
  - Stent thrombosis
  - Restenosis
  - Reocclusion

**Over expansion**
- Risk for:
  - Severe dissection
  - Vessel rupture
  - Surgical conversion
Representative case (pre-dilataion) -80’s yr, HD, CLI, SFA-CTO-

NSE 7.0*40 mm
Representative case (IVUS after NSE)
-80’s yr, HD, CLI, SFA-CTO-
Representative case (Viabahn implantation) - 80's yr, HD, CLI, SFA-CTO -

Viabahn 6.0*150 mm

JADE 6.0*80 mm
Representative case (Final angiogram)
-80’s yr, HD, CLI, SFA-CTO-
Representative case (IVUS after NSE) - 80’s yr, HD, CLI, SFA-CTO-
Summary
- Evidence and experience in FP-CTO recanalization-

• Several clinical studies demonstrated that long-term outcomes after subintimal approach was comparable to those after intraluminal approach.

• Our dates, which precisely assessed wire crossing lumen by IVUS, reported also similar results to priveous one.

• Aggressive vessel preparation would improve outcomes of subintimal approach.

• Subintimal approach is more practical than intraluminal approach in the view of safety, effectiveness, effort and cost.
Evidence and experience in FP-CTO recanalization

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