The efficacy of pedal artery revascularization, the final frontier of lower limbs intervention

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Disclosure

Speaker name: Tatsuya Nakama MD.

I have the following potential conflicts of interest to report:

- **Consulting**: Boston Scientific Japan, Century Medical Inc. TORAY
- Employment in industry: None
- Stockholder of a healthcare company: None
- Owner of a healthcare company: None
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  - Lifeline, Medikit, Medtronic, Orbus Neichi, Terumo,
Case overview; 40s Male, on dialysis

Non-DM
Non-healed ulcer during 9M follow-up
W1, I2, FIO (CS2)
Ambulatory status
Pure below-the-ankle disease
Plantar artery occlusion
Angioplasty was done to the plantar artery.
Final angiogram
Clinical course is very well

Complete wound healing @ 1 month
No recurrence during 8 months follow-up
Should we treat BTA disease?

YES!!  But it include many many problems
Problems of BTA intervention

- **Technical difficulty**
  Not easy compared to conventional BTK intervention

- **Lack of strong evidence**
  No backbone; publication about BTA intervention is few
Problems of BTA intervention

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Pre-recorded live case CCT@LINC

Control
- R5 with infection ESRD
- 3VD with Type IIa pedal

Need only 45 min
- Distal puncture
- Retrograde subintimal approach → Rendezvous

Need up to 3 hours
- Planter loop technique ×
- Subintimal approach ×
- Hydrodynamic boost ○
Technical success rate of BTA EVT

- Data from Italy 85 - 87%
- Data from Japan 89 - 93%

All of data were from retrospective study (Challenging lesion may be excluded)
We need standard technique for BTA angioplasty, like BTK diseases
Problems of BTA intervention

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  Not easy compared to conventional BTK intervention

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<table>
<thead>
<tr>
<th>Authors</th>
<th>Year</th>
<th>Journal</th>
<th>Study type</th>
<th>Pts (Fts)</th>
<th>Outcomes</th>
<th>Success rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manzi M.</td>
<td>2009</td>
<td>JCS</td>
<td>Pro. (SC)</td>
<td>135</td>
<td>TS: 85</td>
<td>85%</td>
</tr>
<tr>
<td>M.F. Abdelhamid</td>
<td>2010</td>
<td>EJVES</td>
<td>Single arm</td>
<td>39 (42)</td>
<td>TS: 88% AFS: 71, LS: 82</td>
<td>88%</td>
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<tr>
<td>Zhu YQ.</td>
<td>2010</td>
<td>JEVT</td>
<td>Case series(SC)</td>
<td>8</td>
<td>TS: 63, LS:100</td>
<td>63%</td>
</tr>
<tr>
<td>Kawarada O.</td>
<td>2011</td>
<td>JEVT</td>
<td>Retro (SC)</td>
<td>31 (40)</td>
<td>AFS: 70, LS: 91</td>
<td>93%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(100% Stent)</td>
<td></td>
</tr>
<tr>
<td>Katsanos K.</td>
<td>2013</td>
<td>CIR</td>
<td>Retro (SC)</td>
<td>47 (40)</td>
<td>ISR: 64 (1Y) AFS: 89, LS: 95 (3Y)</td>
<td>95.2%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(45% Stent)</td>
<td></td>
</tr>
<tr>
<td>Palena LM.</td>
<td>2014</td>
<td>CCI</td>
<td>Retro (SC)</td>
<td>38</td>
<td>TCPO2↑ LS: 100, AFS: 82</td>
<td>87%</td>
</tr>
<tr>
<td>Nakama T.</td>
<td>2016</td>
<td>JEVST</td>
<td>BTA vs No-BTA</td>
<td>29 (32)</td>
<td>LS 93 vs 83 WH 93 vs 60</td>
<td>93%</td>
</tr>
<tr>
<td>Nakama T.</td>
<td>2017</td>
<td>JACC CI</td>
<td>BTA vs No-BTA</td>
<td>257</td>
<td>LS: 89 vs 88 WH: 58 vs 37</td>
<td>89%</td>
</tr>
<tr>
<td>Teymen B.</td>
<td>2018</td>
<td>JIC</td>
<td>BTA vs No-BTA</td>
<td>45</td>
<td>Patency 84 vs 52 LS 100 vs 92</td>
<td>86%</td>
</tr>
</tbody>
</table>
Only 3 comparison (2-Arm) study

Japanese data

Nakama et al, JEV'T 2016; 23: 83-91

Turkey data

No difference in Limb salvage
Result from Japanese data

BTA angioplasty improve wound healing

93% vs. 60% 59% vs. 38%
Only one multi-center study

Higher Rate of wound healing
59% vs. 38%

Faster Time to wound healing
211d vs. 365d

Only one multi-center study

**Higher**
Rate of wound healing
59% vs. 38%

**Faster**
Time to wound healing
211d vs. 365d

Positive data for limbs salvage rate

Log rank p=0.028

Type 2 PAA 95%
Type 3 PAA 90%
Type 2 Non-PAA 87%
Type 3 Non-PAA

Only: 75%

Type 3 pedal patients may need BTA angioplasty

Tsubakimoto et al. Presented @LINC 2018, CVIT 2018 LBCT
BTA angioplasty may improve the durability of treated BTK lesion

Comparison of drug eluting balloon angioplasty to infrapopliteal artery critical lesions with or without additional pedal artery angioplasty in patients with diabetes mellitus and critical limb ischemia

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Background: The purpose of this study is to investigate the feasibility and outcome of balloon angioplasty for the treatment of below the ankle (BTA) lesions in addition to below the knee (BTK) lesions in diabetic patients with critical limb ischemia (CLI).

Methods: Inclusion criteria are diabetes mellitus (DM), CLI (Rutherford class 4 or higher) and revascularized significant stenosis or occlusion of at least 1 below-the-knee vessel with incomplete or no pedal loop. Target BTK vessel restenosis and reocclusion at 1-year follow-up was the primary end point whereas minor or major amputation at 1-year follow-up was the secondary end point.

Results: From July 2012 to June 2016, 40 diabetic patients identified with BTK with additionally BTA lesions were identified. Three patients were lost to follow-up, leaving 37 patients. In 20 patients both BTK and BTA lesion (BTA group) was revascularized whereas only BTK lesion was treated in 25 patients (BTK group). The primary end point is 15.8% in BTA group and 47.8% in BTK group (p=0.059; P > 0.05). Minor or major amputation rate at 1-year follow-up was 15.8% in BTA group and 24.8% in BTA group (p=0.190; P > 0.05).

Conclusion: Our study shows that additional BTA angioplasty to BTK intervention may improve the primary patency rate and have higher event free rate, which slightly missed the margin of statistically significance. RIS decreased significantly more in BTA group compared to BTK group, which reflected that the outcome of intervention is better with additional BTA angioplasty.

Keywords
below the ankle, below the knee, critical limb ischemia, diabetes mellitus, drug eluting balloons
Higher durability → Positive effect on LS

BTK and BTA angioplasty was done with DCB Av. Rutherford 4.5 (Half of Pts were 5 or 6)

Summary for evidence of BTA angioplasty

There is not enough evidence about BTA angioplasty

- Only 9 Article (from Pub Med, exclude some case series)
- Only 1 Multi-center study
- Only 3 Comparison study
- Only 464 patient data is available
- No RCT & No well designed Prospective trials

Success rate is **NOT perfect** (around 85%)

No difference in LS, AFS, but improve WH combination with drug technology

→ Possible positive effect on durability and LS
We need **High level evidence** of BTA angioplasty
Conclusion... Urgent needs!!

1. **Standardization of technique**
   
   Not only for limited Pts, but also for all CLI Pts

2. **Scientific discussion regarding indication**
   
   Discussion depends on the objective findings

3. **Accumulation of both Exp. and Evid.**
   
   Well designed prospective multi-center trials
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