Below the Ankle Interventions in 2024:
Techniques, Devices and Should Balloons be Drug Coated or Not

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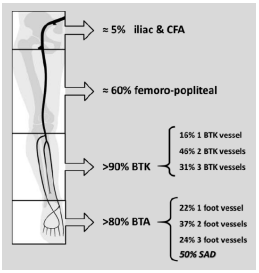
Disclosure Statement of Financial Interest

I, (insert name) DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

1.Patterns of PAD in CLTI patients



80% of CLTI pts present some degree of BTA vessel disease, and 50% of SAD

Ferraresi R LINC 2020

2.When is BTA indicated?

Angiosome concept:

- An understanding of foot angiosome anatomy is useful for predicting healing and planning arterial revascularization
- **A review of the literature, including the most recent systematic reviews and meta-analyses, indicates improved wound healing is achieved when the angiosome concept is followed**
- The greatest value of angiosome-based revascularization is in patients with lesion(s) limited to a single angiosome, or to achieve optimal healing of amputation sites
- Future research should focus on proper identification of (imaging) modalities to determine the hemodynamic and functional changes before and after revascularization, thus identifying the "real" angiosome and directing optimal therapy

According to this concept it seems reasonable to pursue BTA angioplasty to provide direct flow to the wound

Jos van den Berg; SEMINARS IN VASCULAR SURGERY 31(2018)56e65

2.When is BTA indicated?

Challenges with BTA disease:

- Beyond crossing and treating tibial disease, inframalleolar disease has been associated with repeat revascularization and higher amputations rates
- Revascularization of below-the-ankle arteries requires even further advanced skillsets with a much higher understanding of pedal anatomy and wire escalation techniques, and a careful approach to prevent damage to the pedal arteries
- A common challenge with tibial and pedal endo- vascular therapy is vessel size assessment and balloon undersizing, as these arteries are chronically occluded and underfilled
- Furthermore, following angioplasty alone, early elastic recoil can result in mean lumen diameter decrease of 29% even within 15 minutes
- Proper vessel sizing and treatment are essential in obtaining maximal acute luminal gain and ensuring long-term patency, as discussed subsequently

Shishehbor M et al; J Am Coll Cardiol Intv 2024;17:589–607

3. BTA_ FACTS/DATA

Below-the-Ankle Angioplasty in Patients with Critical Limb Ischemia: A Systematic Review and Meta-Analysis [Eline Huizing et al J Vasc Interv Radiol 2019; 30:1361–1368]

BTA artery PTA → 10 studies/524 legs

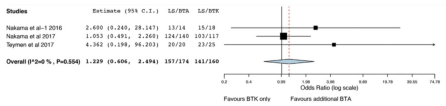
- Huge technical heterogeneity: POBA, DCB, DES, BMS, ped-plant-loop, SUBI-ENDO, retrograde approach, angiosome-guided, blush-guided……
- Retrospective studies / not randomized studies / relative small sample size
- It is difficult to understand the criteria used to apply or not BTA PTA
- Moderate quality according to the MINORS score

- BTA angioplasty is safe & feasible with high technical success → 63-95%
- Mean 12-months limb salvage rate 87.7% without significant statistical difference between additional BTA-PTA and BTK-PTA only
- Mean 12-months composite end-point of amputation-free survival was 76.8%, without a significant statistical difference between additional BTA-PTA and BTK-PTA only

3. BTA_ FACTS/DATA

Twelve-Month Outcomes

- The difference in the limb salvage rate between additional BTA angioplasty and BTK-treated arteries only was not statistically significant (OR, 1.23; 95% CI, 0.61-2.49)

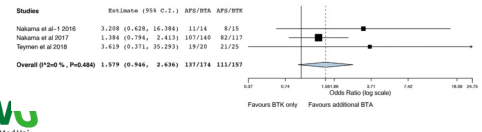


Eline Huizing et al J Vasc Interv Radiol 2019; 30:1361–1368

3. BTA_ FACTS/DATA

Twelve-Month Outcomes

- No statistically significant difference was found in the amputation-free survival rate when additional BTA angioplasty and BTK angioplasty only was compared (OR, 1.58; 95% CI, 0.95–2.64)



Eline Huizing et al J Vasc Interv Radiol 2019; 30:1361–1368

3. BTA_ FACTS/DATA

Impact of Endovascular Pedal Artery Revascularisation on Wound Healing in Patients With Critical Limb Ischaemia [Jung HW et al; Eur J Vasc Endovasc Surg (2019) 58, 854-863.]

Retrospective analysis single centre cohort 239 patients EVR of IP arteries in CLTI; PAR was attempted in 141 patients
After propensity score matching there were 87 pairs of patients with and without PAR

- PAR was achieved in 60.9% of the PAR group
- Direct angiosome flow was more frequently obtained in the PAR group than in the non-PAR group (81.6% vs. 34.5%; p < .001)
- Subintimal angioplasty (47.1% vs. 29.9%; p =.019) and pedal plantar loop technique (18.4% vs. 0%; p < .001) were more frequent in the PAR group

12 Month FU

- PAR group greater freedom from major amputation (96.3% vs. 84.2%; p = .009)
- Wound healing rate, overall survival, major adverse limb event, and freedom from re-intervention did not differ significantly between the two groups
- However, the patient subgroup with successful PAR showed a higher wound healing rate than the non-PAR group (76.0% vs. 67.0%; p= .031)

Successful PAR was identified as independent predictor for improved wound healing [[HR] 1.564, p=0.022]

3. BTA_ FACTS/DATA

Prediction of Technical Failure of Inframalleolar Angioplasty in Patients with Chronic Limb Threatening Ischaemia [Yusuke S et al; Eur J Vasc Endovasc Surg 2022 Jun;63(6):852-863.]

To determine anatomically evaluated predictors of the technical failure of inframalleolar angioplasty (IMA), develop a predictive model for unsuccessful IMA, and investigate the effect of IMA on clinical outcomes in patients with chronic limb threatening ischaemia (CLTI)

- Single centre retrospective observational study enrolled 159 patients with CLTI who underwent IMA for de novo occluded lesions between November 2017 and May 2021. These patients were divided into two groups: the Failed IMA group (n= 62) and the Successful IMA group (n =97)
- **No target vessel outflow (OR 39.8, 95% CI 10.7 e 148, p < .001), medial artery calcification (MAC) grade (OR 4.91, 95% CI 1.40 e 17.3, p = .010), and occluded pedal arch (OR 5.2, 95% CI 1.2 e 22.7, p = .030) were identified as independent predictors of IMA technical failure**
- The patients in the Successful IMA group had a significantly higher proportion of wound healing at 12 months than those in the Failed IMA group (log rank p=.030)
- **IMA technical failure was associated with a significant change in the proportion of wound healing (HR 0.59, 95% CI 0.37e 0.94, p= .030).**

3. BTA_ FACTS/DATA

Clinical Outcomes of Additional Below-The Ankle Intervention Compared to BelowThe-Knee Intervention Alone: A Post-Hoc Analysis of a Prospective Multicenter Study [Metser G et al; J Endovasc Ther 2023 Oct;30(5):711-720. doi: 10.1177/15266028221092981. Epub 2022 May 3]

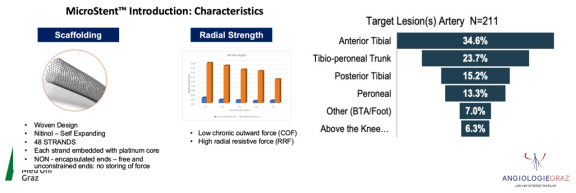
To investigate the clinical implication of additional below-the-ankle (BTA) intervention in patients with chronic limb-threatening ischemia (CLTI) undergoing below-the-knee (BTK) intervention.

- Subgroup analysis was performed using data from the LIBERTY trial
- Participants were then stratified into 2 treatment groups according to whether at least one lesion intervened on was BTA (n=66) or not (n=273)
- **Conclusion: Patients with disease requiring intervention to BTA lesions have a potential increased amputation rate in the short term, but BTA intervention carries a potential survival benefit in the long term when compared to BTK intervention alone**

3. BTA_ FACTS/DATA

A HEAL Study Update –Now Including Below the Ankle Treatment for Wound Healing

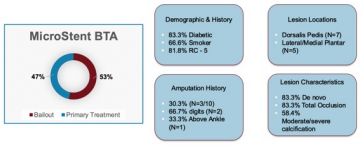
[presented by Thomas Zeller at AMP 2024]



3. BTA_ FACTS/DATA

A HEAL Study Update –Now Including Below the Ankle Treatment for Wound Healing
[presented by Thomas Zeller at AMP 2024]

Below the Ankle Experience: 12 Lesions, 15 Implanted Stents



3. BTA_ FACTS/DATA

A HEAL Study Update –Now Including Below the Ankle Treatment for Wound Healing
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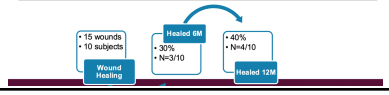
Primary Outcomes and Wound Healing

Primary Outcomes	
Primary Patency 6M Freedom From Occlusion Freedom From CD-TLR	85.7%, N=6/7 85.7% 100%
Primary Safety 6M,12M Freedom From POD +MALE including major amp	100%
Technical Success	91.7% , N=11/12 8.3%, N=1/12, Persistent Residual Stenosis >30%



3. BTA_ FACTS/DATA

Below-the-Ankle Orbital Atherectomy in Chronic Limb-Threatening Ischemia Patients as a Bailout Strategy for Limb Salvage: Early Clinical Experience
[Palena LM et al; Cardiovasc Revasc Med; 2022 Sep:42:121-126.doi: 10.1016/j.carrev.2022.03.015.Epub 2022 Mar 24.]

12 patients (mean age 69.4 ± 14.7; range 57 to 85 years) who were affected by diabetes underwent orbital atherectomy below the knee and ankle arterial segments

- Orbital atherectomy was performed in 3 cases in Anterior tibial (AT) and dorsalis pedis (Ped) arteries + Posterior tibial (PT) and Lateral Plantar (Lat Plan), 5 cases in PT and Lat Plan arteries, 1 case of PT and Medial Plantar, 1 case of Peroneal and Plan Lat, and 2 cases of AT and Ped
- After atherectomy, a drug-coated balloon (DCB) was used
- Technical success was achieved in 11 (91.6%) cases
- No deaths were registered during the follow-up
- Limb salvage rate was 100%, and no major amputations
- Amputation-free survival was 50%
- Freedom from CD-TLR was 100% at 30 days and 91.7% at 6-months
- One patient underwent a TLR at three months

4. Personal opinion

- Currently available evidence suggests that additional BTA angioplasty is a safe and feasible procedure
- If you consider BTA
  - Recognize foot vessel anatomy
  - Consider collateral vessels
  - Be brave in BAD pts
  - Be extremely careful in SAD pts
- High-quality research is needed to clarify the benefits of additional BTA angioplasty

4. Personal opinion

- To answer the question what kind of devices:
- I do not know the answer yet due to lacking data

Thank you for your attention