How do I treat BTK/CLI with DCB: Past experience and a new beginning

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Disclosure

Speaker name:
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I have the following potential conflicts of interest to report:

- Consulting: Cook, Medtronic
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest
Mechanism of Balloon Angioplasty Failure

- Elastic Recoil (hours)
- F.L. Dissection (immediate)
- Thrombosis (up to 4 weeks)
- Negative remodeling (months)

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<th>POBA</th>
<th>DCB</th>
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<td>Elastic Recoil</td>
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<td>Negative remodeling</td>
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Optimize the angioplasty result before DCB
Lesion preparation:
Is angiographic result reliable?

The patient leaves the cathlab already with restenosis
Optimal result must be defined by angio and Duplex toghether

30% residual stenosis by QVA
DCB should touch vessel wall for antiproliferative effect
No touch > No effect!!!
The media is the target site for drug action and antiproliferative effect.
Subintimal vs. intraluminal recanalization using DCB

**Subintimal**
More dissection = more risk of mechanical reocclusion
The drug is delivered directly into the media = more paclitaxel at the target site = more antiproliferative effect

**Intraluminal recanalization**
Less dissection = low risk of mechanical reocclusion
The drug is delivered into the intimal lumen surface and has to migrate into the media: calcification and plaque burden may limit the absorption = less paclitaxel at the target site means less antiproliferative effect
How do we deal with complex BTK occlusion in future trials
Functional assessment in subintimal recanalization
Early (2 weeks) reocclusion assessed by duplex

Patient with Rutherford 5 and pain
If not recognized becomes DCB failure
Mechanical TLR
DCB still effective at 6 months

2 weeks post procedure
Stent in TPT
Post MTLR
6-month
6-month
IN.PACT BTK Study

European Prospective, multi-center, randomized (1:1) study (N=60)
Evaluate efficacy and safety of the IN.PACT 014 DCB vs. PTA in the treatment of CTOs in the infrapopliteal arteries.
IN.PACT BTK - Study design

**Key Eligibility criteria**

- Documented CLI in the target limb
- RC 4 or 5
- RVD 2-4 mm
- Successful pre-dilatation of the (entire) target lesion
- No prior stent(s) or bypass surgery within the target vessel(s)

**Endpoints**

- **Primary Endpoint:** Late lumen loss (LLL) at 9 months
- **Secondary Endpoints:**
  - Composite Safety Endpoint
  - MAE rate
  - Status of wound healing
  - Thrombosis at the target lesion
  - Clinical & device success

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[1] including stents placed within target vessels during the index procedure prior to randomization; [2] A composite of freedom from device- and procedure-related mortality within 30 days, freedom from major target limb amputation and freedom from clinically-driven TLR within 9 months post-index procedure; [3] Status defined as completely healed - improvement - unchanged – worsened; [4] Device success is defined as successful drug delivery, balloon inflation, deflation and retrieval of the intact study device without burst below the rated burst pressure (RBP). Clinical success is defined as residual stenosis of ≤ 30% without procedural complications (death, major target limb amputation, thrombosis of the target lesion, or TVR)

ClinicalTrials.gov Identifier: NCT02963649
Conclusions

- Do optimal balloon angioplasty achieving good anatomical and functional result
- Apply DCB with proper sizing and long inflation time
- Check the vessel with Duplex at discharge and 3 weeks later
- Follow healing surveillance program
- Fast track strategy for reintervention in case of vessel occlusion in not healing patients
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