Calcification in BTK Arteries and Recanalization Techniques for CTOs

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Disclosure

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I have the following potential conflicts of interest to report:

- Bard Peripheral Vascular: Consultant
- Boston Scientific: Consultant, Research
- CardioFlow: Board of Directors, Stock, Research
- Cardiovascular Systems, Inc: Consultant
- Medtronic: Consultant
- Micromedical Solutions: Chief Medical Officer
- Philips: Consultant
- PQ Bypass: Research
- Terumo: Consultant
For the last 10 years Preclinical pathology led us down the path of tibials are equal to coronary. Today we know better

- TIBIALS:
- CORONARIES
The reality between real world tibial disease, and the path taken to develop treatments options

**This is what we test**

A

**This is what we treat**

B

**This is what we treat**

C

**HOW is the Drug going to make its way to the target cells?**

Pre-clinical work showed that you can achieve much better drug delivery if you accept the fact that Coronaries = Tibial arteries

C is misleading example that a DCB may work here. We all know vessel prep is as important as DCB in this lesion.
Answers from pre-clinical work

Tibial arteries have proximal athero-sclerotic disease which is also combined with unusual eccentric and concentric diseases of the vessel wall and the amount of loss of the vessel lumen.
What we test on vs what we Rx

SO BACK TO REALITY:
3 pre-clinical studies that are guaranteed to prevent Taxol/exipient from reaching the circumferential target cells:
1. combined neo-intimal hyperplasia
2. combined neointimal calcifo-elastic barrier
3. pure distance barrier
4. **severely thickened elastic rings**
5. elastin fibers and strains in the neo-intimal tissue
6. **plate of calcium with possible ossification within**
7. the list does not end here.

In addition to the list above, under-sizing makes the journey of drug delivery to the target cells nearly impossible.

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In the past 10 years we were led to believe tibials are similar to the coronary arteries.

We did a lot of work, trial, research based on a conceptual assumption. Now we know they are NOT the same.
Bone formation in the presence of near circumferential medial sheet calcification with presence with lacunae containing osteoblasts and bone marrow

Medial microcalcification (black dots) of the media artery showing adaptive intimal thickening.
How to Treat Calcified Tibial Arteries

1. Find a way to break the 1\textsuperscript{st} inner layer
2. Then must penetrate the 2\textsuperscript{nd} layer in order to get to the 3\textsuperscript{rd} layer
3. A plate of calcium with significant osteoblasts & bone marrow
4. Severely thickened external elastic lamina
5. Intertwined between all the layers is elasto-calcinosis (the ghost of recoil)
How to Treat Calcified Tibial Arteries

1. Find a way to break the 1\textsuperscript{st} inner layer
   a. Balloon Angioplasty
   b. Specialty Balloons
   c. Non-aggressive Atherectomy

2. Then must penetrate the 2\textsuperscript{nd} layer In order to get to the 3\textsuperscript{rd} layer
   a. Cutting Balloon
   b. Aggressive Atherectomy
   c. High Pressure Balloon Angioplasty

3. A plate of calcium with significant osteoblasts & bone marrow
   a. Have a Viabahn Stent ready
   b. Deep wall Dissection & Balloon Ring Elimination Indicates Successful luminal gain
   c. If #2 doesn’t happen, then prepare for pave, vessel rupture & Viabahn placement +/- Supera stent

4. Severely thickened external elastic lamina
   a. No currently available therapy

5. Intertwined between all the layers is elasto-calcinosis (the ghost of recoil)
   a. No currently available therapy
Radiograph

A B C D E F G H I

SFA POP ATA

Calc Calc Calc CTO Calc Calc Calc

E F G H I
• Tibial disease is mainly in the vessel wall. As you can see here, debulking with precision is a necessary treatment that unfortunately doesn’t exist today.

• Tibial wall disease gives the false illusion of a smaller lumen, hence the common undersizing when treating tibial arteries.

• This is a vessel that can not be successfully treated with current technology.

• Arterial-venous flow reversal is the most likely option left to address such ossified arteries.

• Future technology will be able to help with this type of disease.
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