Cotavance Paclitaxel Coated Balloon vs. Uncoated Balloon Angioplasty for Treatment of In-Stent Restenosis in SFA and the Popliteal Arteries:
The COPA CABANA Trial
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on behalf of the Copa Cabana trial group

Disclosures
No Disclosures

Rationale
• The occurrence of SFA in-stent restenosis (ISR) is high
• With stenting increasingly performed in the SFA, an increasing number of patients will require repeat treatment for ISR
• Currently there is no consensus about the treatment of choice
• Registry data indicate superiority of drug-eluting balloons
• 3 prospective randomized trials DCB vs. PTA
  (FAIR – In.Pact DCB, PEP: RS by DUS (core lab)
  PACUBA – Eurocor DCB, PEP: RS by diff. measurem. (no CL)
  COPA – Cotavance DCB, PEP: LLL by DSA (core lab)

Copa Cabana Trial
Investigator Initiated, Corelab adjudicated, Prospective, Multicenter, Randomized Trial
- Objective: to assess safety and efficacy of PTA with drug-eluting balloon (Cotavance, Medrad [Medtronic]) vs. standard PTA for the treatment of symptomatic SFA-ISR
- Primary Endpoint: LLL at 6 months by ia DSA corelab adjudication

Major Inclusion Criteria
1. ISR > 3 months prior to enrollment
2. Rutherford 2 - 5
3. At least one run off vessel to the foot
4. Maximum treated length SFA – POP II: up to 27 cm

Major Exclusion Criteria
1. Patients with more than two lesions
2. Not able to cross the lesion
3. Stent fractures 2 - 4
4. Inflow lesion not being successfully treated
5. Acute thrombosis
6. Planned major amputation (above the ankle)
Primary endpoint: Late Lumen Loss (difference between angiographic Minimal Lumen Diameter immediately and 6 months post index procedure)
Assessment performed by an independent core lab.
**Results, TLR**

- Survival Functions

**Results, LLL**

- Late lumen loss (LLL) at 6 month follow-up visit (ITT)

**Results, Double Dose at 6 months**

- 88 Patients
- Rutherford 2-5
- DCB n=47
- POBA n=41
- In case of TLR
- Double Dose DCB
- DD n=14

**Conclusions**

- The in-stent RS treatment with Cotavance DCBs is safe and effective
- At 6 months follow-up Cotavance DCB is associated with significantly lower LLL and higher freedom from TLR
- Long-term follow-up will show if the results maintain over time

**Discussion**

**What differs from FAIR?**

1. The DCB
2. Longer follow-up (24 months)
3. Two angiographic follow-ups with core lab assessment
4. The double dose DCB group