First experience with a Sirolimus coated balloon* for peripheral vessels combined in various techniques of closed and open endovascular procedures in 90 cases

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* MagicTouch Angioplasty, Sirolimus coated balloon for peripheral vessels
Disclosure

Speaker name:

I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

✓ I do not have any potential conflict of interest
Dr. Peter Metzger, HCM, vascular surgeon, Head of vascular surgery division General hospital St. Johann in Tirol, Austria

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SCOPE OF DRUG COATED BALLOON
IN PERIPHERAL APPLICATION

• Virtue of “leaving nothing behind” hence maintain the original artery anatomy

• Homogenous drug transfer to the vessel wall

• Avoid chronic inflammation because of absence of polymers

• Reduced DAPT duration

• Easy lesion crossing/deliverability by balloon in small calibre vessels
MagicTouch PTA

by Concept Medical

is the world 1st functional and still the only commercially available Sirolimus coated balloon for peripheral vessels, with CE approval obtained in October 2019.

- All MagicTouch balloons utilize proprietary NANOLUTE™ coating technology, which ensures:
  - Low in-transit drug loss
  - Faster uptake of the drug in the tissue
  - Increased bio-availability of the drug

- NANOLUTE™ combines scaling down the size of the sirolimus and excipient particle to nano-level, which allows easier uptake of the drug to the tissue, with specific phospholipid based carrier, which encapsulates the drug particles fully, in order to increase Sirolimus lipophilicity.

- The functionality of NANOLUTE™ has been tested in several pre-clinical trials which proved that Sirolimus stays inside of artery wall, in effective concentration, up to 14 days post inflation. Additionally, Sirolimus presence has been detected in all 3 arterial layers, hence drug is retained for longer period of time in the tissue.
ONGOING CLINICAL STUDIES

**XTREME - FIM**
- PI: Dr. Souren Doni
- Sponsored, Observational, Prospective, all-comers, Indian real-world Registry
- 39 Patients
- Closed

**X-TOSI**
- PI: Prof. Eduard Choke
- Sponsored, Observational, Prospective, all-comers, single arm, real-world
- 50 Patients
- Closed

**FUTURE BTK - ASIA**
- PI: Prof. Birinder Choke
- Sponsored, Randomized, Double blind, Multicenter (n=200 SCI-1, PTA)
- 219 Patients
- 22 Patients Enrolled

**FUTURE SFA- ASIA**
- PI: Prof. Edward Choke
- Sponsored, Randomized, Double blind, Multicenter (n=200 SCI-2, PTA)
- 279 Patients
- 22 Patients Enrolled

**DEBATE BTK DUAL**
- PI: Dr. Francesco Limino
- Randomized, Single arm, Multicenter trial
- 172 Patients
- Closed

**SirPAD - Zurich**
- PI: Prof. Valcher
- TT, Randomized, Open label, all-comers
- 1132 Patients
- 140 Patients Enrolled

**SIDRINA - Germany**
- PI: Dr. UE Fridigerler
- TT, Randomized, Open label, Multicenter trial, IFA
- 478 Patients
- 281 Patients Enrolled

**Upcoming**

**MATSAS - Spain**
- PI: Dr. Menierre
- Co-PI: Dr. Chandra Kumar
- Prospective, single center, OCT and hemodynamics study
- 150 Patients
- Coming Soon

**LIMIES - Germany**
- PI: Dr. UE Fridigerler
- TT, Randomized, Open label, Multicenter trial, IFA
- 250 Patients
- Coming Soon
Clinical efficacy of the Magic Touch PTA Sirolimus coated balloon for BTK lesions with 90 patients enrolled in a period from 04/2020 to 06/2022 (26 months)

- All patients were treated with Fontaine classification III (n=56/62 %) to IV (n=34/38%)

- 62 patients of 90/56 % were diabetic patients

- 3 patients/3.6 % were dialysis patients and 32 patients/35 % were patients suffering from severe coronary artery disease.
Target lesion location (all pat. POP II - BTK):

- popliteal (BTK): 12 patients
- proximal crural (BTK): 63 patients
- distal crural/pedal (BTK): 15 patients

34 procedures were made in hybrid-technique (combined with bypass or TEA)  

- n=12 PAT/13.4%

56 procedures were made in endovascular-technique  

- n=63 PAT/69.5%
- n=15 PAT/17.07%
RESULTS - period from 04/2020 to 06/2022 (26 months)

6 patients reached 6 month follow up, 5 patients with full patency after 6 mths (83 %),

55 patients reached 12 month follow up, 44 patients with full patency after 12 mths (80 %),

29 patients reached 24 month follow up, 23 patients with full patency after 24 mths (79,3 %).
CASES
Male, 78y
Male, 52y
Stenosis
Run off – improved
Male, 65y
Conclusion

This Sirolimus coated balloon for peripheral vessels shows high immediate technical performance and adequate short-term efficacy and safety. Further data will follow.
Thanks for your attention!

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