BIBLIOS STUDY

Belgium-**I**talian prospective, single-arm, multicentre study to evaluate the efficacy and safety of **B**TK treatment with **L**uminor-14 Pacltaxel coated Percutaneous Transluminal Angioplasty Balloon catheter of **I**-Vascular **O**f 150 **S**ubjects with Critical Limb Ischemia

PI: K. Deloose

Biblios Study

Objective:

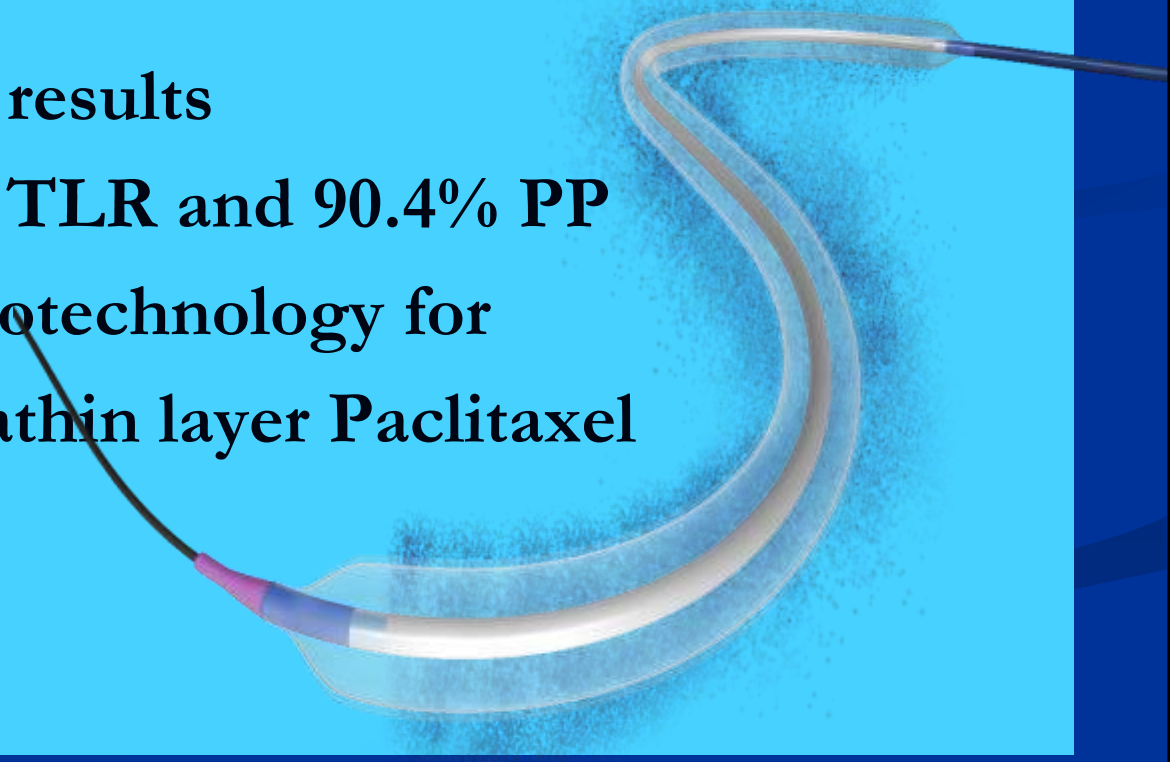
Clinical investigation to access the safety and efficacy of the Luminor-14 DCB for the treatment of infrapopliteal lesions in 150 subjects with critical limb ischemia

Luminor-14m Paclitaxel coated DCB

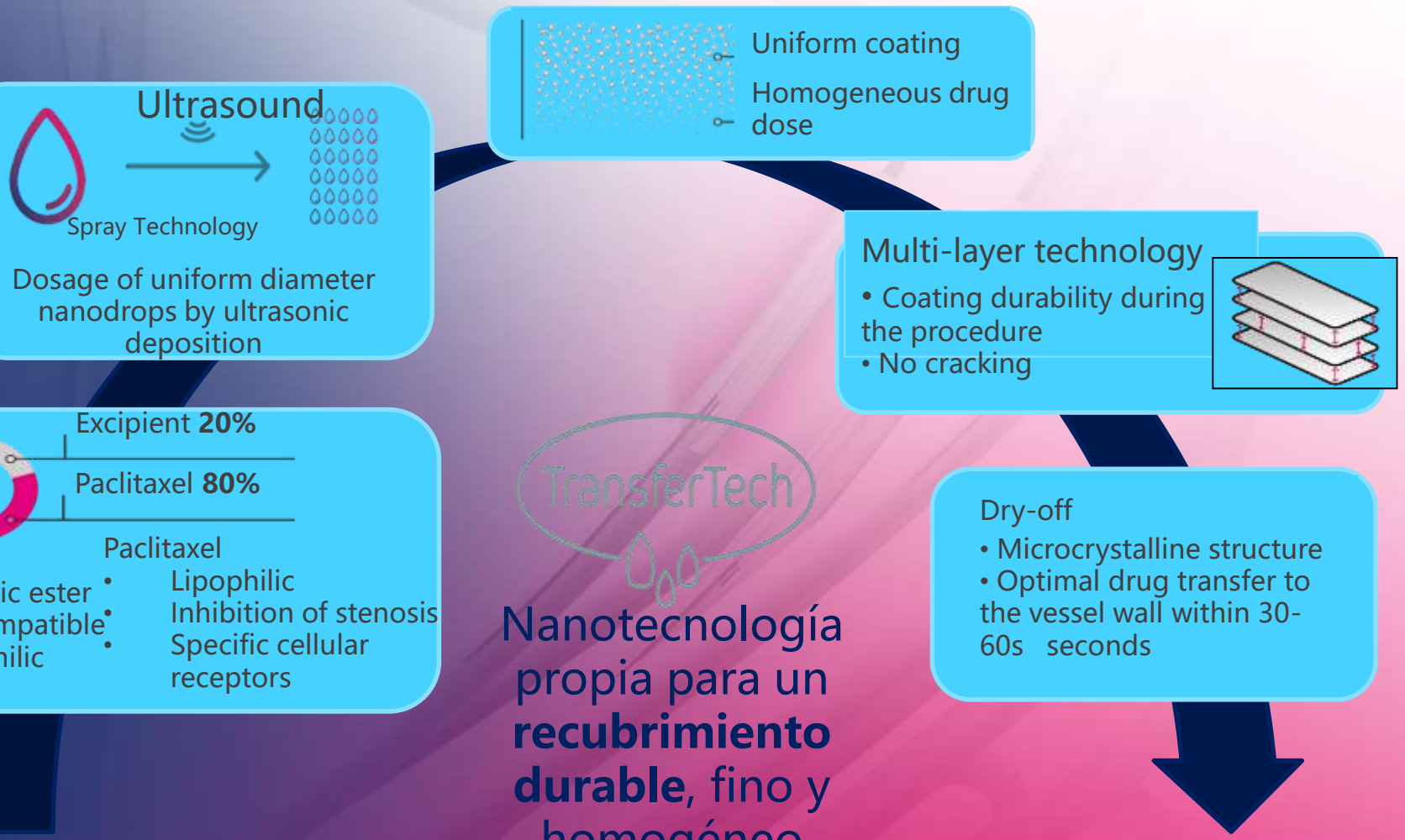
- Durable Coating to minimize drug loss
- Outstanding size range 0.014”- 0.018”- 0.035” GW compatibility
- Best DCB in SFA results

  98.7% freedom of TLR and 90.4% PP
- Transfertech: nanotechnology for

  uniform and ultrathin layer Paclitaxel



Coating process

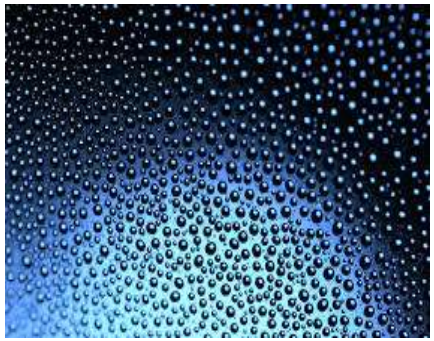


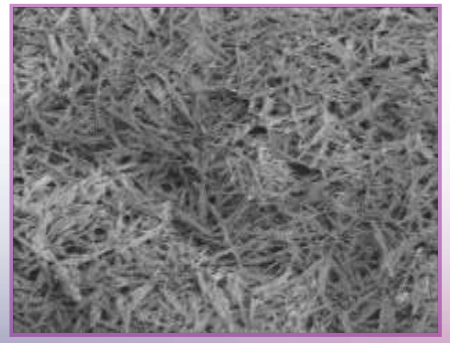
Nanotecnología propia para un **recubrimiento durable**, fino y homogéneo

TransferTech

Technological features

Dosage of uniform diameter nanodrops by direct spray ultrasonic deposition





SEM: magnify: x 1000

- **Ultrathin multilayer coating:**
  - Increases adhesion to balloon
    - Lower loss related to manipulation
  - Improves durability:
    - Lower loss during navigation
  - Improves coating flexibility
- **Homogeneous distribution of drug**
  - Same dose along the entire length
- **Excellent drug Transfer**
  - Fast absorbtion 30- 60 sec

Crystalline Paclitaxel

Biblios study
Primary Endpoints:

1 Efficacy endpoint @ 6 month: Freedom from Male

Freedom from major adverse limb events (MALE) at 6 month defined as absence of above-ankle target limb amputation or major re-intervention to the target lesion(s) (i.e. new bypass, trombectomy, thrombolysis)

2 Safety endpoint @ 30 days:

Freedom from Male or POD

Peri-operative death (POD) at days, device or procedure related or any other cause

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Secondary Endpoints

1 Target vessel functional Flow Assessment @ 6 and 12 months

defined as the presence of bloodflow using duplex. If angiography is available within the 12 month visit it should be used instead of duplex.

2 Freedom from CD-TLR @ 6 and 12 months

defined as absence of any reintervention due to clinical deterioration, defined as:

- worsening of the patient's quality of life (EQ5D-questionnaire)
- worsening of Rutherford category with minimal 1 class
- worsening of wound status

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Secondary Endpoints

3 Amputation free survival @ 6 and 12 months

defined as alive with freedom from any above-the-ankle target limb amputation

4 Limb salvage @ 6 and 12 months

defined as freedom from any above-the-ankle target limb amputation at 6 and 12 months

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Secondary Endpoints

5 Procedural succes

defined as restoration of at least 1 below-the-knee (BTK) artery within <30 % residual stenosis in the final angiogram and outflow to the foot

6 Wound healing status

based on three parameters: the wound's diameter, the wound's depth and the % granulation tissue

7 Wound healing time !!!

defined as the number of days needed for the wound to heal completely after the index procedure

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Inclusion criteria

- Rutherford Classification 5
- Significant degree of stenosis >70% or chronic total occlusion (CTO)
- P3 to the ankle-joint level (not below-the-ankle)
- Wifi tissue loss grade 1-2 at baseline
- Wifi foot infection grade 0-2 at baseline
- Wifi ischemia grade 2-3 at baseline

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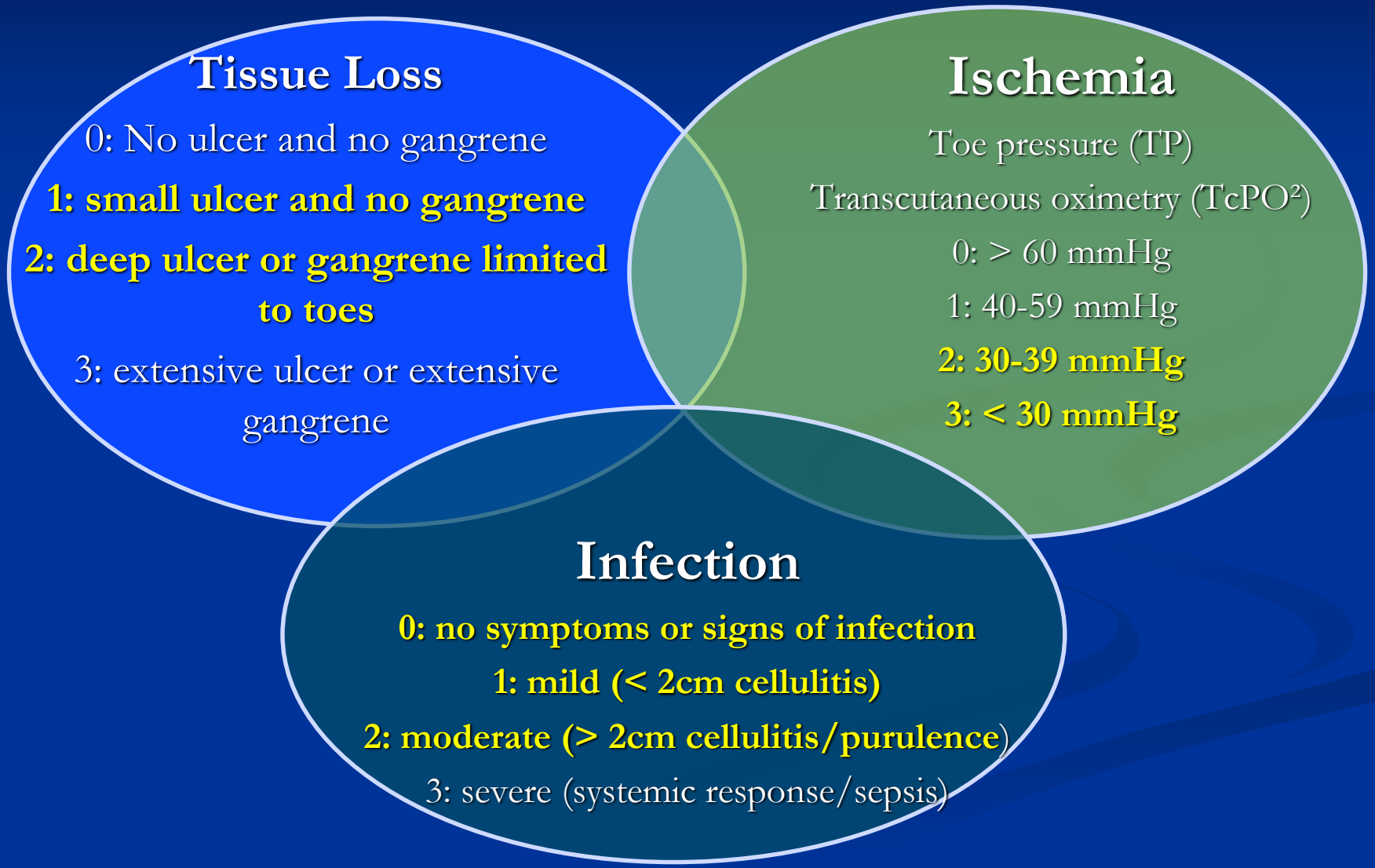
Inclusion criteria

- Target vessel should give direct or indirect run-off to the foot
- Successful predilatation of the target lesion (<30 % residual stenosis)
- In-flow lesions can be included if lesions are treated successfully (residual stenosis<30%) with same DCB platform and bail-out stenting with BMS

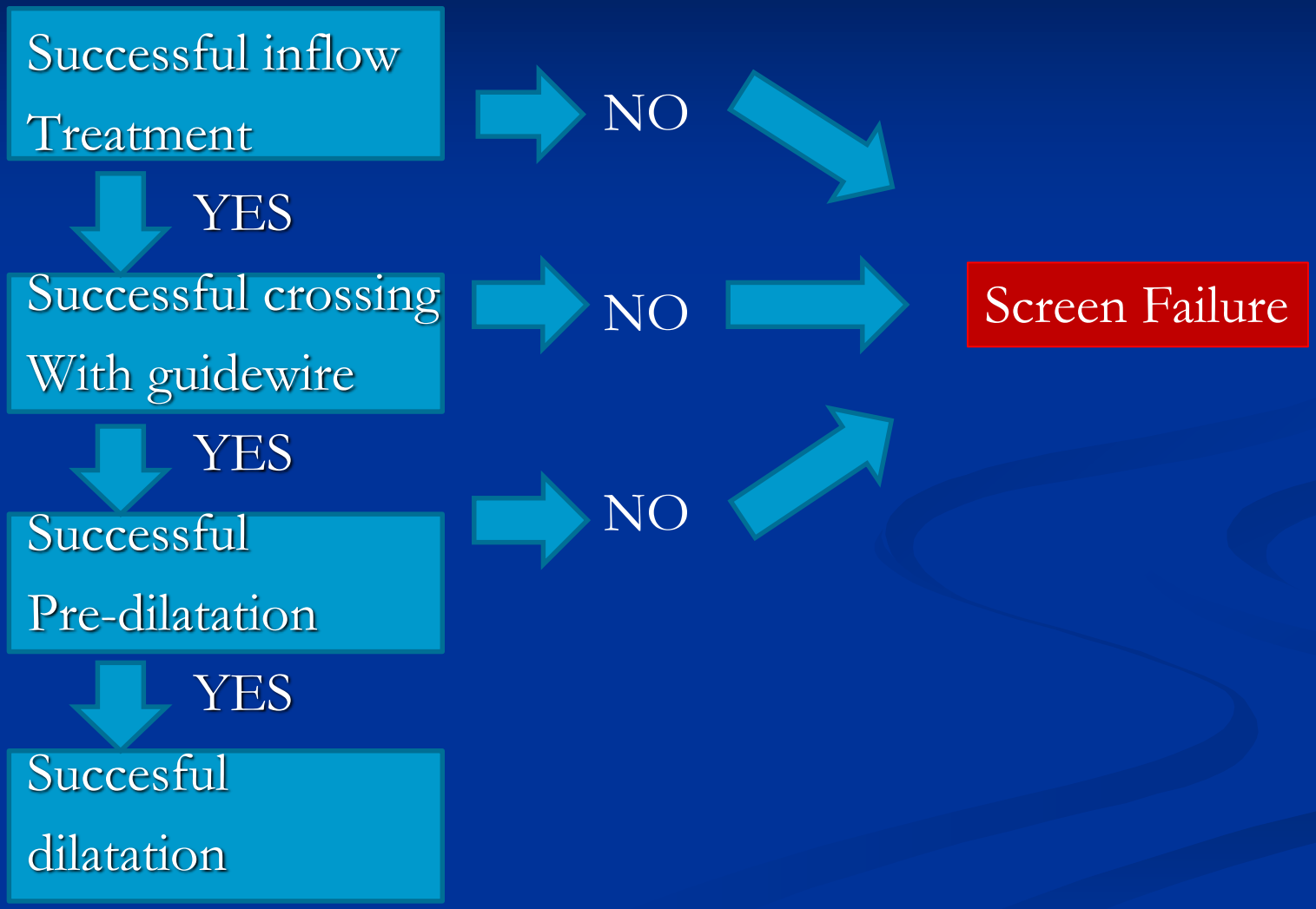
General inclusion



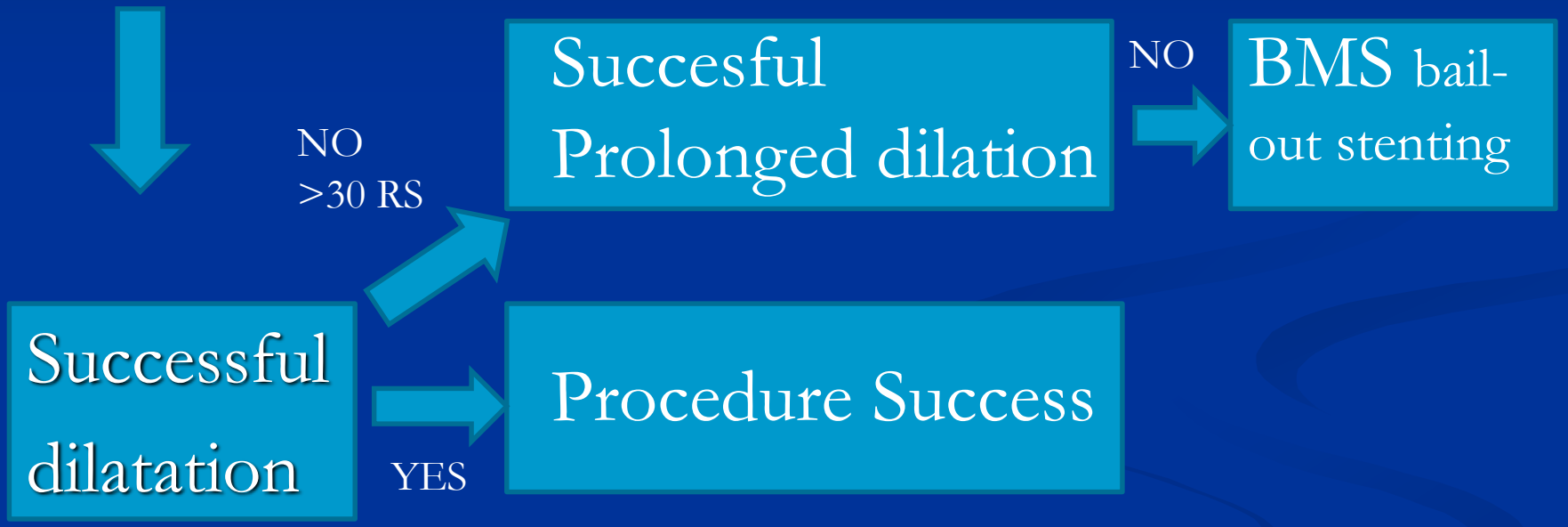
Procedure (before treating target lesion)

- Contralateral treatment; allowed
- Inflow lesion treatment: allowed
- Endovascular or surgical procedure 30 days after procedure in target limb: not allowed
- Vascular access : site standard of care
- Inflow limiting lesion (>50% stenosis)
  - Must be treated succesfully (<30% stenosis)
  - Standard of care (if DCB: only Luminor)
- If multiple BTK arteries → 1study lesion !
  - Non-target lesions : per standard of care (no drug eluting technologies)

Procedure overview



Procedure overview



DCB Balloon = longer than lesion 5mm healthy vessel
If more DCB's overlap mandatory = overlap of 1cm

Biblios study
Luminor 14 Paclitaxel coated in BTK vessel i-vascular

- Start inclusions january 2019
- Hope to End inclusions january 2020
- Hope to Report results january 2021

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