

## LATE-BREAKING TRIAL SUMMARIES

## PRESENTATION HIGHLIGHTS FROM WEDNESDAY MORNING

**Utility of Sirolimus Drug-Eluting Balloons in the Treatment of Complex Below-the-Knee Atherosclerotic Disease in Patients With Chronic Limb-Threatening Ischemia—24-Month Results From the PRESTIGE Study**  
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The use of sirolimus-eluting balloons (SEBs) to improve long-term tibial artery patency in chronic limb-threatening ischemia (CLTI) is novel. The PRESTIGE study investigated performance outcomes and safety of the Selution sustained limus release (SLR) SEB (MedAlliance SA) for treatment of TASC II C and D tibial occlusive lesions in patients with CLTI from Singapore. We report 24-month results.

PRESTIGE was a prospective, nonrandomized, single-arm, multi-investigator, single-center clinical pilot study. 25 patients (25 limbs; 33 lesions) with Rutherford class 5 wound severity were originally included, and 18/25 (72%) patients were

available for 24-month analysis. Collected data included clinically driven target lesion revascularization (CD-TLR), amputation-free survival (AFS), change in Rutherford class, wound status, EQ-5D quality-of-life survey, and Walking Impairment Questionnaire (WIQ).

Baseline demographics included 17 (68.0%) males; mean age was  $63.7 \pm 9.7$  years. Significant comorbidities included diabetes mellitus ( $n = 22$ ; 88.0%) and end-stage renal failure ( $n = 11$ ; 44.0%). Fifteen (45.5%) patients had TASC II D lesions, and mean lesion length treated was  $19 \pm 11$  cm. At 24 months, AFS was 75.0% (18/24 patients; 4 deaths and 2 major lower extremity amputations), and freedom from CD-TLR was 87.0%. Mean Rutherford class improved from 5.00 at baseline to  $0.44 \pm 1.33$  ( $P < .05$ ) at 24 months. The wound healing rate was 94.4% (17/18). Mean EQ-5D visual analogue scale improved from  $58.0 \pm 9.57$  at baseline to  $76.7 \pm 11.1$  ( $P < .001$ ) at

**The PRESTIGE Trial – 24-Month Data Summary**

- Use of **Selution SLR™ SCB** in **CLTI patients** from Singapore - remains positive
- Frail & challenging population of patients reflecting everyday practice in Singapore
- **Safe device** - No serious adverse events using the balloon catheter
- **24-month data** – medium term **sustained efficacy and safety**
  - *Freedom from Target Lesion Revascularization (TLR)* : **87.0%**
  - *Amputation Free Survival (AFS)*: **75%**; **4 deaths and 2 LEA**
  - *Wound healing* : **94%!**
- **QoL measures** maintained and significant improvement from baseline
- Natural progression and recurrence of atherosclerotic disease as reflected by poorer WIQ scores
- **Minimal slow flow phenomenon** noted after treating BTK lesions
- **Selution the solution for BTK disease?**
- Await **Selution4BTK** RCT which has started recruiting

24 months. WIQ (distance) and WIQ (stairs) generally decreased, albeit insignificant from baseline to 24 months.

The Selution SLR SEB remains safe and efficacious in treating complex tibial arterial occlusive lesions in this frail cohort of CLTI patients with a high prevalence of diabe-

tes and end-stage renal failure. However, medium-term outcomes demonstrate a trend of disease progression or recurrence as reflected by worsening of the WIQ.