Treatment of Coronary Drug-Eluting Stent Restenosis by a Sirolimus- or Paclitaxel-Coated Balloon

Rosi Mohd Ali, MD,* Muhamad Ali S.K. Abdul Kader, MD,† Wan Azman Wan Ahmad, MD,‡ Tiong Kiam Ong, MD,§ Houng Bang Liew, MD,∥ Al-Fazir Omar, MD,¶ Ahmad Syadi Mahmood Zuhdi, MD,‡ Amin Ariff Nuruddin, MD,¶ Beatriz Schorr, PhD,∥ Bruno Scheller, MD∥

ABSTRACT

OBJECTIVES The aim of this randomized controlled trial was to investigate a novel sirolimus-coated balloon (SCB) compared with the best investigated paclitaxel-coated balloon (PCB).

BACKGROUND Treatment of coronary in-stent restenosis (ISR) remains challenging. PCBs are an established treatment option outside the United States with a Class I, Level of Evidence: A recommendation in the European guidelines. However, their efficacy is better in bare-metal stent (BMS) ISR compared with drug-eluting stent (DES) ISR.

METHODS Fifty patients with DES ISR were enrolled in a randomized, multicenter trial to compare a novel SCB (SeQuent SCB, 4 μg/mm²) with a clinically proven PCB (SeQuent Please Neo, 3 μg/mm²) in coronary DES ISR. The primary endpoint was angiographic late lumen loss at 6 months. Secondary endpoints included procedural success, major adverse cardiovascular events, and individual clinical endpoints such as stent thrombosis, cardiac death, target lesion myocardial infarction, clinically driven target lesion revascularization, and binary restenosis.

RESULTS Quantitative coronary angiography revealed no differences in baseline parameters. After 6 months, in-segment late lumen loss was 0.21 ± 0.54 mm in the PCB group versus 0.17 ± 0.55 mm in the SCB group (p = NS; per-protocol analysis). Clinical events up to 12 months also did not differ between the groups.

CONCLUSIONS This first-in-man comparison of a novel SCB with a crystalline coating shows similar angiographic outcomes in the treatment of coronary DES ISR compared with a clinically proven PCB. (Treatment of Coronary In-Stent Restenosis by a Sirolimus [Rapamycin] Coated Balloon or a Paclitaxel Coated Balloon [FIM LIMUS DCB]; NCT02996318) (J Am Coll Cardiol Intv 2019;12:558-66) © 2019 by the American College of Cardiology Foundation.

Restenosis after coronary stent implantation remains a clinically relevant scenario, even in the era of newer-generation drug-eluting stents (DES). The occurrence of in-stent restenosis (ISR) is associated with worsened clinical outcomes (1). Two endovascular treatment options for ISR have been identified as clinically relevant: the implantation of another DES or the use of a drug-coated balloon (DCB) (2), both with a Class I, Level of Evidence: A recommendation in the 2018 European guidelines for revascularization (3). Even small randomized trials showed superiority of paclitaxel-coated balloons (PCBs) over conventional angioplasty in bare-metal stent (BMS) ISR (4) and DES ISR (5). Compared with first-generation DES, DCB treatment of ISR was similar in angiographic outcomes (6-8) and superior in hard clinical endpoints on longer-term follow-up (9,10). However, as other

From the *Cardiac Vascular Sentral Kuala Lumpur, Kuala Lumpur, Malaysia; †Cardiology Department, Hospital Pulau Pinang, George Town, Malaysia; ‡Cardiology Department, University Malaya Medical Center, Kuala Lumpur, Malaysia; †Cardiology Department, Sarawak Heart Centre, Kota Samarahan, Malaysia; ¶Cardiology Department and Clinical Research Center, Queen Elizabeth Hospital II, Kota Kinabalu, Malaysia; ¶Cardiology Department, National Heart Institute Malaysia, Kuala Lumpur, Malaysia; ∥Experimental Radiology, Charité, Berlin, Germany; and the *Cardiology Department, University Hospital of Saarland, Homburg/Saar, Germany. Dr. Scheller owns stock in InnoBla GmbH, Berlin, Germany. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

Manuscript received September 17, 2018; revised manuscript received November 18, 2018, accepted November 27, 2018.

ISSN 1936-8796/$36.00
https://doi.org/10.1016/j.jcin.2018.11.040