Randomized controlled trial for de-novo

Clinical evidence SeQuent® SCB
Preclinical work and randomized controlled trials

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SHARING EXPERTISE

Randomized controlled trial for de-novo

Treatment of coronary de novo lesions by a sirolimus- or paclitaxel-coated balloon

First in Man Trials in Malaysia

Ahmad WAW et al. Cardiovascular Interventions 15.7 (2022): 770-779.

Overview

- First in Man RCT in de-novo lesions in 70 patients (35 in PCB, 35 in SCB)
- 1:1 Randomization of SeQuent® Please NEO vs. SeQuent® SCB
- Major inclusion criteria: 70% diameter of stenosis or more or intermediate between 50% to 70% diameter stenosis with positive functional test or symptom of ischemia
- Major exclusion criteria: Myocardial infarction within the past 72 hours, reference vessel diameter (RVD) <2.5 mm
- Primary endpoint @ 6 months: In segment late lumen loss (LLL)
- Secondary endpoints @ 12 months: TLR, ST, Death, Target Vessel MI, MACE

Results

Primary endpoints:

- SCB is non-inferior to PCB in terms of LLL after 6 months
- LLL was 0.01 +/- 0.33 mm in the PCB group versus 0.10 +/- 0.32 mm in the SCB group (p=0.08)

Secondary endpoints:

	PCB (n=35)	SCB (n=35)	P value
TLR	0	0	1.000
Stent thrombosis	0	0	1.000
Death	2 (6)	0	0.493
TV MI	0	0	1.000
Unscheduled angiography	2 (6)	3 (9)	1.000
MACE	2 (6)	0	0.493

No difference in clinical endpoints after 12 months.
Not any event of TLR, Stent thrombosis, TV-MI.

Conclusion

This first-in-human **comparison of a novel SCB** with a crystalline coating showed **similar angiographic outcomes** in the treatment of coronary **de novo disease compared with a clinically proven PCB**. However, late luminal enlargement was more frequently observed **after PCB** treatment.

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