The REMEDEE trial: a randomized comparison of a combination sirolimus-eluting endothelial progenitor cell capture stent with a paclitaxel-eluting stent.

Haude M, Lee SW, Worthley SG, Silber S, Verheye S, Erbs S, Rosli MA, Botelho R, Meredith I, Sim KH, Stella PR, Tan HC, Whitbourn R, Thambar S, Abizaid A, Koh TH, Den Heijer P, Parise H, Cristea E, Maehara A, Mehran R.

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Source

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Abstract

OBJECTIVES:

This study sought to compare the efficacy and safety results after coronary implantation of a combined sirolimus-eluting CD34 antibody coated Combo stent (OrbusNeich Medical, Ft. Lauderdale, Florida) with the paclitaxel-eluting Taxus Liberté stent (PES) (Boston Scientific, Natick, Massachusetts). This report summarizes the first-in-man randomized, controlled multicenter REMEDEE trial (Randomized study to Evaluate the safety and effectiveness of an abluMinal sirolimus coatED bio-Engineered StEnt) angiographic, intravascular ultrasound, and clinical results up to 12 months.

BACKGROUND:

Drug-eluting stents have limited restenosis and reintervention but are complicated by especially late and very late stent thrombosis and accelerated neoatherosclerosis. Alternative or adjunct technologies should address these limitations.

METHODS:

One hundred eighty-three patients with de novo native coronary artery stenoses were randomized 2:1 to Combo stent or PES implantation. The primary endpoint is the angiographic in-stent late lumen loss at 9 months, which was tested for noninferiority between the 2 stent groups. Secondary endpoints include the occurrence of major adverse cardiac events.

RESULTS:

The Combo stent was found to be noninferior to the PES in 9-month angiographic in-stent late lumen loss with 0.39 ± 0.45 mm versus 0.44 ± 0.56 mm (pnoninferiority = 0.0012). At 12 months, the occurrence of major adverse cardiac events was 8.9% in the Combo group and 10.2% in the PES group (p = 0.80) with no difference in mortality, occurrence of myocardial infarction, or target lesion revascularization. No stent thrombosis was reported in either group.

CONCLUSIONS:

In the REMEDEE trial the Combo stent has shown to be effective by meeting the primary noninferiority angiographic endpoint and safe, with an overall low rate of clinical events in both stent groups, including no stent thrombosis up to 12 months.

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