Results of the REMEDEE trial reported at TCT 2011

November 11 2011

A randomized comparison of a dual therapy stent – which combines low-dose sirolimus delivery from an abluminal biodegradable polymer matrix with a covalently bound anti-CD34 antibody layer – with a paclitaxel-eluting stent showed that the dual therapy stent effectively controls neointimal proliferation and was shown to be safe and effective. Results of the REMEDEE trial were presented today at the 23rd annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium, sponsored by the Cardiovascular Research Foundation.

The REMEDEE trial was designed to demonstrate the safety and effectiveness of the new dual therapy stent compared to a clinically proven paclitaxel-eluting stent. The new stent is designed for control of neointimal proliferation as well as accelerated vessel healing. The trial was conducted among patients with symptomatic, ischemic heart disease due to a stenotic lesion located in a single native coronary artery.

In the study, 183 patients were randomized at 17 sites in Australia (4), Belgium (2), Brazil (2), Germany (2), Hong Kong (1), Malaysia (2), Netherlands (2), and Singapore (2). Of all subjects enrolled, 124 subjects were placed in the dual therapy group and 59 in the paclitaxel-eluting group.

Major inclusion criteria included single de-novo lesions in native coronary arteries, lesion length ≤ 20 mm and a diameter of 2.5 mm to 3.5. Major exclusion criteria were acute myocardial infarction, ostial lesions and unprotected left main with ≥ 50% stenosis. Baseline patient

characteristics included a mean age of 64.2 in the dual therapy group and 64.0 in the paclitaxel-eluting group; 71.8% male in the dual therapy group and 71.2% in the paclitaxel-eluting group. The mean number of lesions treated per patients was 1.1 in both groups.

The primary endpoint was angiographic in-stent late lumen loss at nine months post-procedure.

Secondary endpoints include the occurrence of death, myocardial infarction, stent thrombosis and clinically-driven revascularization reported as individual events and composites at the time of the procedure and post-procedure at 30 days, nine months, 12 months, and annually to five years.

In-stent late lumen loss at nine months for the dual therapy stent was a mean of .39 ± 0.45 mm and .44 ± 0.56 mm in the paclitaxel-eluting stent. At nine months, there were 1% deaths in the combo group, and 0% in the paclitaxel group. The rate of myocardial infarction at nine months was 2.4% in the combo group and 1.7% in the paclitaxel group. And, the rate of major adverse cardiac events (MACE) at nine months was 8.7% in the combo group and 11.0% in the paclitaxel group. Both groups had 0% stent thrombosis at nine months.

"In this first-in-man study, the dual therapy stent effectively controls neointimal proliferation," said lead researcher Michael Haude, MD. Dr Haude is Professor of Internal Medicine at Lukaskrankenhaus Neuss in Germany.

"There was an overall low rate of clinical events in both study groups, including no stent thrombosis. In-stent and in-segment late loss and binary restenosis rates are accordingly low and comparable to the paclitaxel-eluting stent. The dual therapy stent was shown to be safe and effective, as well as non-inferior to the paclitaxel-eluting stent," Dr.

Haude said.

Provided by Cardiovascular Research Foundation