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OrbusNeich’s Scoreflex™ Coronary Dilatation Catheter Associated with Less In-Stent Late Loss Versus a Non-Compliant Balloon for Pre-Dilation Prior to Drug Eluting Stent Implantation

Study Published in World Journal of Cardiovascular Diseases

HONG KONG, Oct. 18, 2013 – OrbusNeich today announced the publication of a study demonstrating that lesion preparation with the company’s Scoreflex™ coronary dilatation catheter prior to drug eluting stent (DES) implantation is associated with equivalent acute stent expansion and less in-stent late loss versus a non-compliant balloon. The study was published in the *World Journal of Cardiovascular Diseases*.

In-stent late loss as determined by quantitative coronary angiography for patients pre-dilated with a dual wire scoring balloon (Scoreflex) was $0.23 \pm 0.52$ mm versus $0.71 \pm 0.63$ mm for patients treated with a non-compliant balloon ($p = 0.03$). Follow-up angiography was performed at nine months following initial coronary intervention in 17 patients from the Scoreflex group and in 16 patients from the non-compliant balloon group.
No significant differences in stent expansion between the two groups were observed, although the balloon size was larger (3.33 ± 0.28 versus 3.09 ± 0.33 mm, p = 0.01) and the maximal dilation pressure for pre-dilation was higher (11.6 ± 3.2 versus 8.6 ± 2.7 atm, p < 0.01) for the non-compliant balloon group. Two patients pre-dilated with a non-compliant balloon required target lesion revascularization (TLR) whereas there was no TLR in the Scoreflex group. In general, no significant difference in major adverse cardiac event rates was observed.

“Pre-dilation with Scoreflex prior to DES implantation may be a more feasible strategy than conventional ballooning because it is less traumatic while associated with equivalent stent expansion,” said Kenji Sadamatsu, M.D., of the Saga-ken Medical Centre Koseikan, Saga, Japan, corresponding author of the publication. “The observed reduction in late loss for the Scoreflex group suggests that this novel semi-compliant balloon may have additional long-term advantages, particularly for severely stenotic lesions.”

The study included 46 consecutive patients with *de novo* lesions in native coronary arteries ≥ 2.5 mm in angiographic diameter who underwent elective DES implantation under intravascular ultrasound guidance. The patients were equally and randomly assigned to pre-dilation with a non-compliant balloon (Hiryu®, Terumo, Tokyo) or to pre-dilation with Scoreflex. Major adverse cardiac events were defined as a composite of cardiac death, non-fatal myocardial infarction, TLR and stent thrombosis.

**About OrbusNeich**

OrbusNeich is a global company that designs, develops, manufactures and markets innovative medical devices for the treatment of vascular diseases. Current products are the world’s first dual therapy stent, the COMBO™ Dual Therapy Stent, and the world’s first pro-healing stent, the Genous™ Stent. Other products include stents and balloons marketed under the names of Azule™, R stent, Scoreflex, Sapphire™, Sapphire II and Sapphire NC. OrbusNeich is headquartered in Hong Kong and has operations in Shenzhen, China; Fort Lauderdale, Fla.; Hoevelaken, The Netherlands;
and Tokyo, Japan. OrbusNeich supplies medical devices to interventional cardiologists in more than 60 countries. For more information, visit www.OrbusNeich.com.

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