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Post-approval TAVI registry shows high rates of device success at one year

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One-year results from SOURCE XT – one of the largest, post-approval transcatheter aortic valve implantation (TAVI) registries to-date – reported today at EuroPCR 2013 show good clinical outcomes in routine clinical practice, with high rates of device success for all access approaches, valve sizes and delivery systems.

The SOURCE XT Post-Approval Study followed up 2688 consecutively enrolled patients (mean age 81.5 years) undergoing TAVI with the Sapien XT heart valve at 93 centres in 17 countries between July 2010 and October 2011. Access was transfemoral, transapical, transaortic or transsubclavian. Events were adjudicated by an independent clinical event committee.

"Results for one-year outcomes showed a large treatment effect in terms of symptom relief and improved quality of life," reported Stephan Windecker, Professor and Chief of Cardiology, Swiss Cardiovascular Center and Clinical Trials Unit Bern, Bern University Hospital, Switzerland. Patients showed sustained improvement in effective orifice area, with low rates of moderate or severe aortic regurgitation.

"One-year mortality and stroke rates were low in this elderly population," Windecker said. The all-cause mortality rate was 19.5% and the stroke rate 6.3% overall. But he noted that one-year survival associated with all-cause mortality was higher in women (90.6%) than in men (87.6%; p=0.0075) and survival associated with cardiac mortality was also higher.

Windecker concluded, "SOURCE XT showed high rates of device success for all access approaches, valve sizes and delivery systems."

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