

Contact:
Dr. Michael Boxberger
michael.boxberger@bbraun.com
Phone +49 30 68989724
Fax +49 30 68989730

Every day, some 43,000 B. Braun employees in over 55 countries share their knowledge with colleagues and customers. The innovations developed in this way help to improve working processes in hospitals and medical practices and to enhance safety for patients, doctors and nurses. In 2010, the Group generated sales of approximately €4.4 billion.

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Safety and Efficacy: Paclitaxel-Eluting Balloon SeQuent® Please Shows Positive Results in Largest Real World International Registry

The results of the largest registry about treatment with Drug Eluting Balloons (DEB) were presented last week during the Transcatheter Cardiovascular Therapeutics conference (TCT) in San Francisco. Primary investigator Prof. Dr. Jochen Woehrle from the University of Ulm explained: "The aim of the SeQuent Please World Wide Registry is to assess the safety and efficacy of the paclitaxel-coated SeQuent Please treatment of patients under so called real world conditions for multiple indications."

About the Registry

The total enrolled population included 2,095 patients with a total of 2,348 treated lesions in different subgroup cohorts. 1,187 patients were treated because of ISR after BMS and DES, 388 patients were treated in De-novo lesions with DEB only (avoiding the implantation of a stent) strategy.

Prior clinical studies have already demonstrated the clinical benefit of the drug eluting balloon SeQuent Please for the treatment of different subgroups of patients, mainly for restenosed lesions (in-stent restenosis - ISR) and for certain newly developed (de-novo) lesions. The International SeQuent Please Registry is a multi-center, all comer trial with virtually no patient exclusion criteria, except those patients with contraindications for anti-platelet therapy. The SeQuent Please World Wide Registry is the largest registry with a drug-coated balloon

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including the following indications: DES or BMS In-Stent restenosis, De-novo lesions and ACS patients. Primary endpoint is clinically driven TLR at 9 months, secondary endpoint is MACE at 9 and 24 months. MACE was defined per protocol as cardiac death, MI due to target vessel involvement and ischemia driven TLR.

About the Results

The 9 months follow-up shows very promising results in safety with a low total MACE rate among all patients (6.7%). The total Myocardial Infarction (0.8%) and Cardiac Death rate (1.8%) was low considering the “real world” patient enrollment. The target lesion revascularization rate after 9 months underlines the efficacy of SeQuent Please with a TLR rate of 5.2% for all patients enrolled, 9.6% for the critical subgroup of patients with ISR from drug eluting stents and 3.8% for patients with ISR from bare metal stents. The clinical results for patients with de-novo lesions will be reported later.

“SeQuent Please is a very exciting development for the cardiological community” said the Vice President of B. Braun Vascular Systems Gerd Wacker. “With the current clinical evidence, SeQuent Please can be considered as a reasonable alternative to drug-eluting stents for selected patients with coronary artery disease; it is the most advanced solution for the treatment of patients with ISR and it represents currently the most promising therapeutic alternative to reduce the number of unnecessary stent implantations.”

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