

SMT announces EverOCT study results in catheterization and cardiovascular intervention

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The study has been designed to assess immediate results and healing patterns in two different time frames of three and six months from implantation



Sahajanand Medical Technologies (SMT) announced the publication of EverOCT study in Catheterization and Cardiovascular Intervention (CCI) journal evaluating three and six months results of its EVERolimus-eluting Coronary Stent, Tetrilimus by OCT analysis. The study assesses the immediate results and healing pattern in two different time frames.

EverOCT was a prospective, multi-centre, single-arm, and investigator-initiated study performed at seven Indian sites between January 2017 and September 2018. OCT evaluations were done on 57 patients who underwent Tetrilimus stent implantation. Follow-up OCT was scheduled at three months for the first 16 patients and at six months for 41 patients. Primary outcomes included degree of strut coverage, malapposition and thickness of neointimal hyperplasia (NIH) over covered struts.

Presently there is no available data about the healing pattern of everolimus coated ultra-thin struts (60 μ m). This is the only study that documents the OCT healing parameters of ultra-thin strut stents larger than 3.00 mm. Tetrilimus has the ultra-thin strut thickness (60 μ m) for the entire size matrix (2.0 to 4.5 mm diameter).

EverOCT study was aimed to evaluate healing response at strut-level and cross-section level of the new everolimus-eluting ultra-thin stent (60 μ m) with a biodegradable polymer, using serial OCT analysis at three and six months after implantation.

61 Tetrilimus stents were implanted to treat 59 lesions in 57 patients. Paired (baseline and follow-up) OCT data were available for 12 patients and 30 patients at three and six months, respectively. At three months, rapid early healing was indicated by 95.48 per cent covered struts per lesion with very low (0.11 ± 0.06 mm) NIH. At six months, NIH accumulation was greater (0.21 ± 0.07 mm) as compared to three months. 99.77 per cent of struts per lesion were covered at 6 months.

Data regarding >3.00 mm diameter stents were unique as the comparative data showed that there was no significant difference in coverage of stents, eccentricity index and NIH thickness over the struts as compared to ?3.00 mm diameter stents. Tetrilimus portrays uniform expansion and concentric apposition over the vessel wall.