

Catheterization and Cardiovascular Interventions (CCI) Journal Publishes Sahajanand Medical Technologies PAINT trial 1 year results

“The 74th issue of prestigious international journal Catheterization and Cardiovascular Interventions published an article of Sahajanand Medical Technologies PAINT (**P**ercut**A**neous **I**NTervention) Trial - A randomized evaluation of two drug-eluting stents with identical metallic platform and biodegradable polymer but different agents (Paclitaxel or Sirolimus) compared against Bare stents: 1-year result.”

Surat, India —October 30, 2009 – Sahajanand Medical Technologies, a leading developer and manufacturer of Drug Eluting Stents, announced that the Journal of the WILEY inter science - Catheterization and Cardiovascular Interventions (CCI) has published 1 year results from the PAINT trial (ClinicalTrials.gov ID: NCT00752362). The article entitled “Randomized evaluation of two drug-eluting stents with identical metallic platform and biodegradable polymer but different agents (Paclitaxel or Sirolimus) compared against Bare stents: 1-year results of the PAINT trial” is published in the November 74th issue of CCI journal and available online at <http://www3.interscience.wiley.com/cgi-bin/fulltext/122445261/PDFSTART>. The CCI Journal is published by WILEY inter science to focused on material that will be of immediate practical value to physicians providing patient care in the clinical laboratory setting.

The article, authored by Dr. Pedro A. Lemos, MD, PhD at Dr. Eneas de Carvalho Aguiar, Sao Paulo Brazil, describes the positive results from the 1-year follow-up of a multicenter, 274 patients (Sirolimus=106, Paclitaxel=111, Bare Metal Stent=57), Phase IV study headed by Dr. Pedro A. Lemos himself. The Sirolimus drug-eluting Stents, Paclitaxel drug eluting Stents and Bare metal Stents were successfully implanted in a (2:2:1) randomization.

According to Dr. Atul Abhyankar, Medical Director- Sahajanand Medical Technologies, “Both Paclitaxel and Sirolimus stents reduce the 9-month in-stent late loss to 0.54 ± 0.44 mm, 0.32 ± 0.43 mm, vs. 0.90 ± 0.45 mm for Bare metal stent respectively, and 1-year risk of target vessel revascularization and combined major adverse cardiac event is reduced for both DES in all comparisons which proves the efficacy of Drug Eluting Stents against Bare Metal Stents.”

The PAINT TRIAL nine months angiographic results analyzed by Cardialysis (Rotterdam, Netherlands) showed that the head-to-head comparison between two novel DES (Paclitaxel & Sirolimus), both the novel DES were effective in reducing neointimal hyperplasia, late lumen loss, 1-year re-intervention and adverse cardiac event during first year compared to Bare metal stent. Sirolimus Stents had lower late loss than Paclitaxel stents (less than 0.01) but similar 1-year clinical outcomes.

Mr. J P Dutta, SMT’s Chief Operating Officer shared the significance by citing “The article discusses about the result and conclusion of PAINT trial which eventually reveal the benefit and safety of usage of biodegradable polymer as a vehicle for DES irrespective of drugs.”

“Results of PAINT trial reinforce the fact that our proprietary blend of biodegradable polymers is effective as a carrier for DES technology and also this proprietary blend of polymers seems to work very effectively in both the different kind of drugs,” said Mr. Rahul Gaywala, SMT’s Executive Director. “It has been fundamental policy of SMT to promote evidence based medicine and in the past many of the trials conducted have been presented and published in index journals. The current publication too is in keeping with the underlying fundamental principle. We are happy that we have contributed positively to the interventional community.”

The Founder and Chairman of SMT Mr. Dhirajlal Kotadia said, "Sahajanand Medical Technologies always stand in front to support this and other large clinical trials that present the medical community with important scientific data that can be used to provide optimal treatment approach for complex patient subset."

About PAINT Trial:

PAINT study was a unique 3-arm format designed with following two objectives,
1) To test two novel drug-eluting stents (DES) covered with a biodegradable-polymer carrier and releasing Paclitaxel or Sirolimus, which were compared against a Bare metal stent.
2) DES differed by the drugs, but was identical otherwise, allowing comparing the anti-restenosis effects of Sirolimus versus Paclitaxel.
Angiographic follow-up was obtained at 9 months and major cardiac adverse events up to 12 months.

About CCI Journal:

Catheterization and Cardiovascular Interventions is an international journal and an official publication of the society for cardiac angiography & interventions. The journal focuses on material that will be of immediate practical value to physicians providing patient care in the field of interventional cardiology. Articles are subject to double-blind peer review and complete editorial evaluation prior to any decision regarding acceptability

About Sahajanand Medical Technologies:

Established in the year 1998, SMTPL became the first Indigenous Stent Manufacturer in world to have two DES systems in its product portfolio. SMTPL is the first company to get CE approval for DES with Biodegradable Polymers. All the DESs are made with proprietary blend of Biodegradable Polymers. The company has both Stainless Steel & Cobalt Chromium platforms. It is India's largest manufacturing company based for Evidence Based Implantable Medical Devices and Medical Equipments. The products are manufactured conforming to the international quality standards and are offered at the most competitive prices. The Company is ISO 9001 and ISO 13485 certified & also obtained CE certification for its advanced range of products. This gives assurance of company's quality consciousness. For more information log on to: www.smtpl.com.