

Study in European Heart Journal Favors TAXUS® Stent Over Cypher® Stent and Bare-Metal Stents in Diabetic Patients

Lower rates of re-intervention and major adverse events reported for the TAXUS Stent in study of diabetic patients

NATICK, Mass., Jan. 12 [PRNewswire-FirstCall](#)/ -- Boston Scientific Corporation (NYSE: BSX) today welcomed the results of an independent study demonstrating that Boston Scientific's TAXUS® paclitaxel-eluting stent (PES) exhibited a lower re-intervention rate and equal or lower instances of death or heart attack than the Cypher® sirolimus-eluting stent (SES) and bare-metal stents (BMS). The results of the study were published in the January 1 edition of the European Heart Journal.

The study, conducted at the Thoraxcenter, Erasmus University Medical Center in Rotterdam, The Netherlands, compared two-year clinical outcomes for 708 consecutive diabetic patients treated from April 2002 to April 2004 with either a TAXUS Stent (n=250) or Cypher Stent (n=206) as part of the RESEARCH and T-SEARCH real-world registries. A group of 252 consecutive diabetic patients treated with a BMS prior to April 2002 was retrospectively selected as a control group. Eligible patients were undergoing pharmacological treatment with either insulin or hypoglycaemic agents at the time of the index procedure.

The results showed favorable rates of re-intervention for the TAXUS Stent compared to the Cypher Stent and BMS. Target lesion revascularization (TLR) occurred in a significantly lower percentage of TAXUS Stent patients (5.3 percent) when compared with Cypher Stent (13.2 percent) and BMS (15.6 percent) patients ($p=0.0037$ PES vs. SES; $p=0.0004$ PES vs. BMS). Target vessel revascularization (TVR), another measure of re-intervention, showed similar positive trends for the TAXUS Stent, which reported a TVR rate of 9.7 percent compared to 15.3 percent for the Cypher Stent ($p=0.06$) and 19.5 percent for BMS ($p=0.0034$).

The study's primary endpoint of major adverse cardiac events (MACE) was also lower for the TAXUS Stent arm at 21.2 percent compared to 28.9 percent for the Cypher Stent arm ($p=0.057$ PES vs. SES) and 29.7 percent for the BMS arm ($p=0.04$ PES vs. BMS). Both MACE and TVR data demonstrated strong trends in favor of the TAXUS Stent over the Cypher Stent while showing significant benefits for the TAXUS Stent compared to BMS. Additionally, rates of MACE and TVR for the Cypher Stent and BMS were comparable ($p=0.97$ and $p=0.35$ respectively).

Two-year cumulative incidence of mortality was comparable among the three stent groups, with rates of 11.5 percent for the TAXUS Stent, 13.3 percent for the Cypher Stent and 9.8 percent for BMS. Myocardial infarction (MI or heart attack) was 5.1 percent in the Cypher Stent group compared to 3.4 percent in the TAXUS Stent group. MI was significantly more frequent in the BMS group (7.7 percent) compared to the TAXUS Stent group ($p=0.048$ PES vs. BMS). The stent thrombosis rate for the TAXUS Stent was lower at two years than that of the Cypher Stent (2.4 percent versus 4.4 percent), however, the difference was not statistically significant ($p=0.29$). Stent thrombosis for BMS at two years was 0.8 percent, which was a statistically significant difference from the Cypher Stent ($p=0.015$) but not from the TAXUS Stent ($p=0.18$).

"We are pleased that this real-world study reconfirms the strong safety and efficacy profile of paclitaxel-eluting stent systems we have seen across our broad range of clinical trials as well as in the millions of TAXUS Stent systems implanted to date," said Hank Kucheman, Senior Vice President and Group President of Boston Scientific's Interventional Cardiology business. "The favorable results for the TAXUS Stent are particularly impressive given the high degree of complex patients and lesions."

Diabetic patients generally have more long-term complications than interventional cardiology patients as a whole, making results in diabetic patients with heart disease worthy of note when evaluating overall stent performance. The important and growing diabetic patient subset accounts for more than one-quarter of all coronary interventional procedures in the United States.

The Company is currently sponsoring the collection of clinical data to support an application to the U.S. Food and Drug Administration to expand the TAXUS Stent's labeled indications for use in the United States to include diabetic patients. The safety and effectiveness of the TAXUS Express™ Stent have not been established in patients with diabetes.

Boston Scientific is a worldwide developer, manufacturer and marketer of medical devices whose products are used in a broad range of interventional medical specialties. For more information, please visit: <http://www.bostonscientific.com/>.

This press release contains forward-looking statements. Boston Scientific wishes to caution the reader of this press release that actual results may differ from those discussed in the forward-looking statements and may be adversely affected by, among other things, risks associated with new product development and commercialization, clinical trials, intellectual property, regulatory approvals, competitive offerings, Boston Scientific's overall business strategy, and other factors described in Boston Scientific's filings with the Securities and Exchange Commission.

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