Analysis of Two Randomized Clinical Trials Identify No Cases of Longitudinal Stent Deformation With Boston Scientific Platinum Chromium Stents

Quantitative Coronary Angiographic outcomes from PERSEUS and PLATINUM clinical trials presented at ACC 2012

Boston Scientific Corporation (NYSE: BSX) announces results from a quantitative coronary angiographic (QCA) analysis of the incidence of longitudinal stent deformation in the PERSEUS and PLATINUM randomized clinical trials, comprising more than 2,400 patients across three distinct coronary stent platforms: the Platinum Chromium Element™ platform (ION™ Paclitaxel-Eluting Stent System (TAXUS® Element™) and PROMUS Element™ Everolimus-Eluting Stent System), the Xience V®/PROMUS® Everolimus-Eluting Stent System, and the TAXUS Express® Paclitaxel-Eluting Stent System. This study represents the largest, systematic, independent core lab analysis to assess longitudinal stent deformation across multiple drug-eluting stent platforms and provides the first and only reported clinical data to evaluate longitudinal stent deformation based on prospective QCA measurements from randomized trials. Results were presented at the American College of Cardiology Annual Scientific Sessions by Dean Kereiakes, M.D., Medical Director at The Christ Hospital Heart and Vascular Center and The Lindner Research Center, Cincinnati. Results will be published concurrently online in EuroIntervention.

"In this large, systematic, angiographic analysis by an independent core laboratory, the data suggest that previously reported cases of longitudinal stent deformation are a rare occurrence among the stent platforms studied and across the spectrum of target lesion complexity evaluated," said Dr. Kereiakes. "This analysis and methodology may provide useful insights for future studies evaluating the incidence and clinical implications of longitudinal stent deformation."

The post hoc analysis included QCA data from 2,403 patients who received a single stent in the PERSEUS and PLATINUM Workhorse trials. Stent length, as prospectively measured by QCA during the trials, was compared to the nominal length of the implanted stent. A ratio of 1.0 indicates equivalent measured and nominal stent lengths while a ratio less than 1.0 suggests possible stent shortening and a ratio greater than 1.0 suggests possible stent lengthening. Distributions of the mean QCA-measured versus nominal stent length ratios were compared in the randomized test and control arms of each trial.

In the PERSEUS trial, the cumulative distribution of measured to nominal stent length ratios showed the difference in the mean values to be similar between the ION Stent and the TAXUS Express Stent platforms (respective mean ratios, 0.94 vs. 0.95, p=0.16). Minimum ratio values were also similar in the ION Stent and TAXUS Express Stent arms (0.594 vs. 0.612). In patients where post-dilatation was performed, the difference in mean values remained similar between the ION and TAXUS Express Stents (0.94 vs. 0.95, p=0.10) suggesting that post-dilatation did not cause longitudinal stent deformation in these patients.

In the PLATINUM trial, the cumulative distribution of measured to nominal stent length ratios showed the difference in the mean values to be slightly but significantly lower for the Xience V/PROMUS Stent compared to the PROMUS Element Stent (0.92 vs. 0.94, p=0.004). While the clinical relevance of this finding is uncertain given potential measurement variability caused by differences in stent visibility, foreshortening and calibration, it argues against an increased incidence of longitudinal stent shortening with the PROMUS Element platform. Minimum ratio values were also slightly lower for the Xience V/PROMUS Stent compared to the PROMUS Element Stent (0.426 vs. 0.559). In patients who received post-dilatation, the difference in mean values remained slightly lower for the Xience V/PROMUS Stent compared to the PROMUS Element Stent (0.93 vs. 0.94, p=0.04) indicating that post-dilatation had no effect on the potential for longitudinal stent deformation in these patients.

"Longitudinal stent deformation has been shown to be a rare event that can occur with many coronary stents, regardless of manufacturer, strut thickness, number of connectors or alloy composition," said Keith D. Dawkins, M.D., Global Chief Medical Officer for Boston Scientific. "The excellent radiopacity of the platinum chromium (PtCr) stent series can help physicians identify and treat longitudinal stent deformation in the rare cases when it does occur as well as facilitate accurate stent placement and complete stent expansion during all implantations."

In the U.S., the ION™ Paclitaxel-Eluting Stent System and the PROMUS Element Plus Everolimus-Eluting Stent System were approved by the Food and Drug Administration in 2011.

Xience V is a trademark of the Abbott Laboratories group of companies. The PROMUS Stent is a private-labeled Xience V Stent manufactured by Abbott and distributed by Boston Scientific.

About the PERSEUS and PLATINUM trials
The prospective, randomized PERSEUS Workhorse trial evaluated the safety and effectiveness of the ION Paclitaxel-Eluting Platinum Chromium Stent System (TAXUS Element) compared to the TAXUS Express Paclitaxel-Eluting Stent System in 1,262 patients. The prospective, randomized PLATINUM Workhorse trial compared the safety and effectiveness of the PROMUS Element Everolimus-Eluting Platinum Chromium Stent System to the Xience V/PROMUS Everolimus-Eluting Stent System in 1,530 patients. Both trials met the primary endpoint of non-inferiority for target lesion failure at 12 months.

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