3097 : Final 5-year clinical follow-up of TAXUS II: long-term anti-restenotic efficacy and safety for both slow- and moderate-release polymer-based, paclitaxel-eluting TAXUS stents

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Topic(s):
PCI: longterm outcome

Citation:
European Heart Journal (2007) 28 (Abstract Supplement), 509

Purpose: TAXUS II, the phase II, randomized, controlled trial evaluating two different dose formulations of the polymer-based, paclitaxel-eluting TAXUS stent is now in its final year of follow-up. Out to 4 years, TAXUS II demonstrated that both slow-release (SR) and moderate-release (MR) TAXUS stents reduce restenosis versus bare metal stents (BMS) in focal, de novo lesions while not posing any significant safety concerns. TAXUS II, which was used as the basis for EU approval of the TAXUS stent, helped to identify the SR dose formulation as the minimum effective dose. We now present the final, 5-year, safety and efficacy data of TAXUS II.

Methods: TAXUS II is a randomized, double-blind clinical trial conducted at 38 sites comparing the safety and efficacy of TAXUS SR (N=131) and TAXUS MR (N=135) versus BMS (N=270) in the final year of its total 5-year follow-up.

Results: Through 4 years, the risk to benefit profile of TAXUS has been favorable. The TAXUS groups have demonstrated sustained efficacy with significant reductions in target lesion revascularizations (TLR) for TAXUS versus BMS (7.2% SR, 3.7% MR, 15.7% BMS, p=0.0004), while cardiac death (1.6% SR, 1.6% MR, and 1.5% BMS, p=1.00), total death (5.5% SR, 4.6% MR, and 3.7% BMS, p=0.74), and myocardial infarction (4.7% SR, 5.3% MR, and 6.7% BMS, p=0.67) rates remained comparable across groups. From 2 to 4 years, there were no new late stent thromboses in either TAXUS group versus 1 in BMS, and the overall ST rates through 4 years were comparable (2.3%, n=3, SR; 1.5%, n=2, MR; and 0.4%, n=1, BMS; p=0.20). No statistically significant differences between the SR and MR cohorts have been noted for any parameter analyzed. The 5-year clinical follow-up is currently being conducted, and the data will be available for presentation in September 2007.

Conclusions: The benefit of the TAXUS SR and MR stents has been demonstrated with continued safety and efficacy firmly established through 4 years. The present analysis will evaluate the long-term clinical profile for both SR and MR TAXUS stents by providing final 5-year outcomes. This analysis will focus on late safety parameters for the largest patient population with the TAXUS stent followed for this duration to date.

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