

TAXUS II 3-Year Clinical Follow-Up: Long-Term Safety and Efficacy Post Polymer-Based Paclitaxel-Eluting Stent Implantation for De Novo Coronary Artery Lesions

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Background: TAXUS II showed that both slow-release (SR) and moderate-release (MR) formulations of polymer-based paclitaxel-eluting stents reduce restenosis versus bare metal stents. Clinical benefits of TAXUS were maintained at 2 years as shown by low target lesion revascularization (TLR) rates. A 2-year QCA and IVUS substudy demonstrated that the reduction in % net volume obstruction was preserved and that QCA-determined minimum lumen diameter and late loss were durable between 6 months and 2 years. The purpose of the present study is to evaluate 3-year clinical follow-up of TAXUS II patients.

Methods: TAXUS II is a randomized, double-blind clinical trial conducted at 38 sites comparing TAXUS SR (n=131) and TAXUS MR (n=135) stents to bare metal control stents (BMS, n=270) in patients with focal, de novo lesions. Clinical follow-up is being conducted annually for 5 years to assess the stability of TAXUS benefits over time. **Results:** The 3-year follow-up adjudicated by an independent Clinical Events Committee is currently being analyzed to further evaluate long-term clinical profiles of both drug-eluting and bare metal stents. Overall, 94.2% of patients have completed the 3-year follow-up, and the results will be finalized by the time of presentation. At 2 years, the safety and efficacy of both stent formulations were maintained with only 1 new TLR in TAXUS from 1 to 2 years, compared to 8 TLRs during the same period for BMS. Accordingly, TAXUS groups had significantly lower TLR (5.5% SR and 3.9% MR vs. 15.5% BMS, $p=0.0002$) and MACE rates (14.2% both SR and MR vs. 24.6% BMS, $p=0.0178$) than BMS at 2 years. Out of hospital stent thrombosis (ST) rates through 2 years were low and comparable (1.5% both SR and MR vs. 0.0% BMS, $p=0.06$). At 3 years, overall MACE rates remained low in TAXUS versus BMS (15.7% SR and 16.4% MR vs. 27.3% BMS, $p=0.0096$). There were no new TLRs or STs in TAXUS from 2 to 3 years, while there were 3 TLRs and 1 ST in BMS. **Conclusions:** TAXUS II has suggested that TAXUS stents inhibit, rather than delay, restenosis as shown by profound reductions in TLR rates out to 2 years. This benefit is accompanied by an excellent safety profile similar to that seen in BMS. The 3-year analysis will be the first to evaluate late clinical safety and efficacy outcomes of both SR and MR TAXUS stents.