

Presentation Time: 11/8/2004 2:00:00 PM

Title: **3-Year Follow-Up of TAXUS I: A Randomized, Controlled Study with Polymer-Based Paclitaxel-Eluting Stents for Coronary Artery Lesions**

Keywords: Stent, Coronary artery disease, Clinical trials, Follow-up studies, Restenosis

Author Block: Eberhard Grube, Heart Ctr Siegburg, Siegburg, Germany; Sigmund Silber, Internistische Klinik Dr. Mueller, Munchen, Germany; Karl E. Hauptmann, Krankenhaus der Barmherzigen Bruder, Trier, Germany; Mary E. Russell for the TAXUS I Investigators, Boston Scientific Corp, Natick, MA

Disclosure Block: **E. Grube**, None; **S. Silber**, None; **K.E. Hauptmann**, None; **M.E. Russell for the TAXUS I Investigators**, Boston Scientific Corp. C. Employment (full or part-time).

Unlabeled/unapproved: There are no unlabeled/unapproved uses of drugs or products

Background: TAXUS I is the first human experience evaluating safety and feasibility of the paclitaxel-eluting TAXUS stent compared to an uncoated control stent in a multi-center, prospective, randomized study. As presented earlier, the 6-month follow-up demonstrated an excellent safety profile and reductions in target lesion revascularizations and restenosis. The excellent clinical outcomes were maintained at 12 and 24 months. We now report the first 3-year experience with the TAXUS SR stent.

Methods: Between October 2000 and March 2001, 61 patients with single de novo or restenotic coronary lesions were enrolled in the study, 31 in the TAXUS group and 30 in the Control group. Angiographic inclusion criteria were lesion length ≤12 mm, 50% to 99% diameter stenosis, and vessel diameter between 3.0 mm and 3.5 mm. The 3 year follow-up included a history, physical exam and record of adverse events.

Results: The cumulative MACE rate at 2 years was 3% in TAXUS (1/31) versus 10% (3/30) for the Controls. The only MACE in TAXUS was due to a target vessel revascularisation outside the target lesion 200 days after the index procedure. Between years 2 and 3, there were no additional MACE events. Hence, the difference between TAXUS (3.0%) and Control (10%) was maintained. Additionally, no stent thromboses were reported in either group out to 3-years (See Table).

Clinical Event:	Control	TAXUS
3-year results:		
Any MACE (no. of events)	4	1
TVR (no. of events)	4	1
TVR (% of patients)	10.0	3.2
Cardiac death	0	0
Stent thrombosis	0	0
Time course:		
Any MACE (% of patients) (6mo/12mo/24mo/36mo)	7/10/10/10	0/3/3/3
TVR (% of patients) (6mo/12mo/24mo/36mo)	7/10/10/10	0/3/3/3

Conclusion: To date, this study provides the first 3-year clinical follow-up and the first human experience with the Paclitaxel-eluting TAXUS SR stent. The present data demonstrates continued safety without any stent thrombosis out to 3-years. Furthermore, these results suggest that TAXUS might be effective in inhibiting rather than just delaying restenosis after stent implantation.