

Presentation 1038-36

Number:

Abstract TAXUS II: Prolonged Clinical Follow-Up After Thienopyridine Withdrawal
Title:

Presentation Sunday, Mar 06, 2005, 3:30 PM - 4:30 PM

Start:

Topic: Percutaneous Interventions--Coronary Stents

Author Sigmund Silber, Antonio Colombo, Adrian Banning, Karl E. Hauptmann, Janusz Drzewiecki,

Block: Eberhard Grube, Joerg Koglin, Mary E. Russell, Internistische Klinik Dr. Muller, Munchen, Germany

Background: TAXUS II mandated the use of clopidogrel for 6 months and aspirin (ASA) for 12 months post-procedure. Stents with polymer-based elution of paclitaxel provide an effective way to prevent restenosis as shown by low rates of target lesion revascularization (TLR) with no identified safety concerns up to 1 year. It is unclear whether these benefits are due to a sustained inhibition of restenosis or just a timely delay. Protocol mandated double antiplatelet therapy could suppress major adverse cardiac events (MACE) for up to 1 year in the absence of complete vascular healing; however, this benefit would disappear after therapy withdrawal. TAXUS II 2-year clinical follow-up addresses these issues.

Methods: TAXUS II is a randomized, double-blind clinical trial conducted at 38 sites comparing the safety and efficacy of the TAXUS slow-release (SR, n = 131) and TAXUS moderate-release (MR, n = 135) stents to bare control stents (BMS, n = 270) in patients with focal, de novo lesions. Clinical follow-up, including use of antiplatelet and cardiac medications, is being conducted annually for 5 years.

Results: Six months post-procedure, there were significant reductions in MACE for TAXUS compared to BMS, mainly due to a decrease of TLR. These benefits, along with an absence of late stent thrombosis, were preserved at 1 year when 10.2% of patients were on double antiplatelet therapy and 94.4% were on ASA only. The 2-year clinical follow-up rate was 97.2% with 92.7% patients still on ASA and 7.7% on ASA and clopidogrel. Within the TAXUS groups, there was only 1 new TLR, associated with a late stent thrombosis, while 8 new TLRs were reported for BMS. As seen at 6 months and 1 year, TAXUS groups had significantly lower MACE rates (14.2% for both SR and MR vs. 24.6% BMS, P=0.0178) and TLR rates (5.5% SR and 3.9% MR vs. 15.5% BMS, P=0.0002) than BMS.

Conclusions: The reduction of restenosis in TAXUS, as evidenced by lower TLR rates, is maintained over time, confirming that paclitaxel-eluting stents inhibit rather than delay restenosis. Withdrawal of double antiplatelet therapy did not result in increased incidence of MACE or stent thrombosis, demonstrating stability of the TAXUS safety profile, and indicating complete healing.

Commercial S. Silber, None; A. Colombo, None; A. Banning, None; K.E. Hauptmann, None; J. Drzewiecki,
Relationship: None; E. Grube, None; J. Koglin, Boston Scientific Corp. C; M.E. Russell, Boston Scientific Corp. C.