

when primary PCI is not possible within recommended door to balloon time. Our objective was to conclude the efficacy and safety of tenecteplase in patients with STEMI.

**Method:** Data of 500 patients with STEMI who received tenecteplase in the last 1 year were analyzed.

**Result:** 90% patients had successful thrombolysis (SUCC.TH). Hypertensives, diabetics, smokers and dyslipidemic patients had SUCC.TH rates comparable to the general patient data. SUCC.TH rates were significantly lower in the elderly patients (>70 years, 86%,  $p < 0.0001$ ), patients with history of IHD (88%,  $p < 0.0004$ ) and in patients receiving tenecteplase >6 h after onset of chest pain (80%,  $p < 0.0001$ ). SUCC.TH was significantly higher in patients who received early thrombolysis (<3 h after onset of chest pain, 89%,  $p = 0.006$ ). Overall mortality was 1.5%. It was significantly higher in the elderly (4.5%), patients with history of IHD (3%), females (3%), with delayed thrombolysis (5%). Overall incidence of ICH 0.3%, other bleeds 2%, stroke 0.1% and ventricular tachyarrhythmias 2.5% were noted. Age >70 years, diabetes, dyslipidemia and history of IHD were associated with a higher incidence of heart failure, re infarction or ventricular tachyarrhythmias. Incidence of ICH and other bleeds were comparable amongst all patient subgroups. Ventricular arrhythmias were significantly higher in dyslipidemics, with history of IHD, Killip class III & IV.

**Conclusion:** The study confirmed the safety and efficacy of tenecteplase.

## Paclitaxel-eluting stent (PES) versus everolimus-eluting stent (EES) in insulin requiring diabetics – Are the results different?



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**Background:** Diabetes has been an Achilles heel of patients with limus eluting drug-eluting stents (DES). In SPIRIT sub studies PES had equivalent or better results than EES in Insulin requiring diabetics. Our objective was to analyze this factor in Tuxedo-India study, the largest ever DES study in patients with diabetes mellitus comparing PES with EES.

**Method:** TUXEDO is a prospective, randomized, multicentre clinical trial in patients with DM comparing the safety and efficacy outcomes of a PES with EES in a non-inferiority trial design.

We randomly assigned 1830 patients with diabetes mellitus to receive either PES (TAXUS Element™) or EES (XIENCE Prime™) in a non-inferiority trial design. Of these patients, 747 (40%) were insulin requiring diabetics; 365/914 (39.9%) in PES group and

382/916 (41.7%) in the EES group. In a subset analyses, we evaluated the 1-year rates of target-vessel failure (TVF), myocardial infarction (MI), stent thrombosis (ST), target-lesion revascularization (TLR), and target-vessel revascularization (TVR) with PES or EES in insulin requiring diabetics.

**Results:** The baseline characteristics of PES and EES groups in insulin requiring diabetics were comparable. In insulin requiring patients, there was a statistically significant higher 1-year rate of TVF in the PES group as compared to the EES group (7.9% vs. 3.4%,  $p = 0.006$ ). In addition, the rate of MI (4.4% vs. 1.3%,  $p = 0.01$ ), ST (3.0% vs. 0.5%,  $p = 0.009$ ), TLR (5.2% vs. 1.0%;  $p = 0.001$ ) and TVR (5.2% vs. 1.0%;  $p = 0.001$ ) was significantly higher in the PES group compared to the EES group over 1-year follow-up period.

**Conclusion:** PES, as compared to EES had higher rates of TVF, MI, ST, TVR, and TLR at 1-year follow-up. The superiority of EES, as compared to PES was maintained in insulin requiring diabetics.

## Paclitaxel-eluting versus everolimus-eluting stents in patients with diabetes mellitus and coronary artery disease (TUXEDO India Study)



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**Background:** Prior trials (such as the SPIRIT trials) have shown the superiority of EES over PES in general cohort. However, subgroup analyses from these trials have failed to consistently show a superiority of EES over PES in the diabetic cohort, leading to the general notion that a 'taxol' eluting stent (such as PES) works as well as a limus eluting stent (such as EES) in subjects with DM. Our objective was to conduct a sufficiently powered randomized trial comparing the efficacy and safety of PES with EES in a population of patients with DM on drug treatment.

**Method:** TUXEDO is a prospective, randomized, multicenter clinical trial in patients with DM comparing the safety and efficacy outcomes of a PES with EES in a non-inferiority trial design.

We randomly assigned a total of 1830 patients with DM, at 46 centers in India to receive either PES (TAXUS Element™ Boston scientific) or EES (Xiience Prime™ Abbott Vascular) without a routine angiographic follow up. The primary endpoint was target vessel failure defined as a composite of cardiac death, target vessel myocardial infarction or ischemia driven target vessel revascularization at 12 months follow up.

**Results:** The mean age of the patients included was 58.4 years, males 75.3% with the mean duration of DM being 6.5 years. Insulin