

Serum MMP-9 increases statistically significantly ($p < 0.001$) with the increase of the severity of the stenosis and the number of the affected arteries: no severe stenosis ($<75\%$ stenosis) (0.245 ± 0.086 ng/ml); 1 vessel severe ($>75\%$ stenosis) (0.317 ± 0.132 ng/ml), 2 vessel severe stenosis (0.348 ± 0.157 ng/ml), 3 vessel severe stenosis (0.422 ± 0.112 ng/ml).

Furthermore, serum MMP-9 enzyme increases with accordance of severity of the myocardium injury with the statistical significance ($p < 0.01$): the borderline abnormality group (CIIS < 10 , 0.227 ± 0.099 ng/ml), possible injury (CIIS 10–15, 0.317 ± 0.132 ng/ml), probable injury (CIIS > 15 , 0.376 ± 0.132 ng/ml) group. MMP-9 levels were significantly higher in the probable injury (CIIS > 15) patients compared to the possible injury (CIIS 10–15) patients ($p < 0.001$).

Conclusion: An increase in serum MMP-9 enzyme levels is a risk factor of the coronary atherosclerotic plaque rupture (OR = 0.001, $p < 0.001$).

Impact of monitoring of Cath lab quality indicators



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Background: Cardiovascular disease (CVD) is an important cause of mortality and morbidity in India. Mortality statistics and morbidity surveys indicate substantial regional variations in CVD prevalence and mortality rates. WHO has predicted that from years 2000 to 2020 disability-adjusted life years lost from coronary heart disease in India shall double in both men and women from 7.7 and 5.5 million, respectively. This health scenario will therefore demand a robust healthcare infrastructure and integrated approach of CVD prevention and management.

Aim: To study impact on patient & procedure outcomes of Cath lab by monitoring of Cath lab quality indicators.

Objectives: (a) To maintain a dedicated database of Cath lab quality indicators (CQI) as a continuous improvement initiative. (b) Benchmarking Cath lab procedural outcomes against current standards of Cath lab quality for future improvisation.

Methodology: This study was carried out from February 2013 to February 2015 & involved 2000 cases. 3 duration groups of 8 months each were considered with 650, 800, 550 patients in 1st eight month group, 800 patients in 2nd eight month group & 550 patients in 3rd eight month group respectively.

Inclusion criteria: Patients above 18 years of age, admitted for diagnostic coronary angiograms and/or PCI procedures who have given written informed consent for above procedures.

Exclusion criteria: Post-operative CABG patients, Patients studied for non-coronary issues, such as pulmonary hypertension, cardiomyopathy, valvular disease, or adult congenital heart disease who did not undergo PCI.

Data collection technique & tools: Documentation of Cath lab quality indicators was done on basis of GUIDELINES as laid down by "Quality Assessment and Improvement in Interventional Cardiology: 2011 Statement of the Society of Cardiovascular Angiography and Intervention (SCAI) & 2012 ACCF & SCAI Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update.

Salient results: (a) The mean door-to-balloon time (DTB) improved significantly from 84 min in 1st group to 79 min in 2nd group to 73 min in last group. The average DTB in all the 3 groups were found to be well within the recommended timeframe of 90 min as per AHA guidelines.

(b) For the patients who underwent elective PCI or PAMI, 75.2% of the procedures done were appropriately indicated as per the appropriate use criteria of AHA. 23.5% of the PCI procedures were

moderately appropriate & only 1.3% of the procedures performed had rarely appropriate indications. Also a positive trend was noted for use of appropriate indications from 1st group towards the last group. On the other hand, use of rarely appropriate indication for PCI showed statistically significant decline from 1.6% to 1.3% to 1.1% from 1st to 3rd group respectively; reflecting the trend towards guideline-based practice.

(c) Access site complications showed a declining trend with 26 complications in 1st group, 10 complications in 2nd group & 4 in last group.

(d) Amongst other vascular complications, a total, 0.2% of abrupt coronary vessel closure with slow flow, 0.4% coronary perforations, 0.8% coronary dissections, 0.5% cardiac tamponade were noted with declining trend from 1st group to 3rd group.

(e) Re-infarctions were noted as 0.3% on-table, 1% during hospital stay. Only 1 case of subacute stent thrombosis was seen & no cases requiring emergency CABG were seen during study period. There were 0.3% (5) cases of pulmonary edema, 0.2% (4) cases of stroke but none of them observed in 3rd eight month group. Morbidity owing to above complications in our study is well within the standard reported data.

(f) Overall incidence of death was noted as (0.00%) on table, (0.10%) in hospital & (0.05%) after 30 days with all of these events encountered in primary PCI (PAMI) cases while the survival rate was overall 99.85%. Considering the American heart association guidelines on mortality to be below 1% for CAG $< 2\%$ for PTCA, $< 5\%$ for PAMI, observations in above study are in accordance with the guidelines.

(g) The use of mean contrast volume & Radiation was in accordance with the "ALARA" principle (as low as reasonably achievable) of AHA and the recent SIR (Society of Interventional Radiology) guidelines reflecting institutional trend towards practising safety standards for Radiation.

Conclusions: This study has allowed collection of data pertaining 2000 patients undergoing coronary angiography and/or angioplasty, analysis of their demographic, epidemiologic, clinical variables with comparison amongst 3 duration-based groups & also contemporary international studies & the ACC/AHA guidelines revealing mortality & morbidity parameters as well within the framework of standard guidelines. It thus reflects upon use of standard practices in Interventional cardiovascular care, culminating into favorable patient outcomes. The study has shown a positive impact on patient & procedure outcomes by monitoring of Cath lab quality indicators. It has helped establish a continuous care initiative in Cath lab by maintaining a dedicated database of Cath lab quality indicators allowing for future benchmarking of procedural outcomes against standard practices in cardiovascular care thus achieving all aims and objectives it had set out with. The study emphatically recommends monitoring of Cath lab quality indicators as a routine practice in Cath labs everywhere. Inputs from cardiac catheterization laboratories from all around our country into a common National Registry will go a long way in assessing current trends in patient presentation, patient management, improve patient outcomes, also help modulate cardiovascular guidelines as per national scenario, aid in formulating newer benchmarks and probably contribute to the next wave of evolution in Interventional cardiology.

Efficiency and safety of thrombolysis with tenecteplase in acute ST elevation myocardial infarction



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Background: Thrombolysis in ST elevation MI (STEMI) continues to be life saving means of reperfusion therapy in our country specially

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