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Post-reteplase evaluation of clinical safety & efficacy in Indian patients (precise-in study)

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Background: ST elevated myocardial infarction is a serious and life threatening condition. In patients suitable for thrombolytic treatment, time is critical and reperfusion should be initiated as soon as possible. Reteplase is commonly used in the management of ST elevated myocardial infarction.

Objective: To assess the safety and efficacy of intravenous Retelex (Reteplase) injection in management of patients with ST elevated myocardial infarction in clinical practice

Material and methods: An open label, non-comparative, multicentric, post marketing observational study was conducted in >18 years of patients with ST elevated myocardial infarction (STEMI) receiving Retelex. All patients received 20 units Retelex within 6 hours after the onset of acute myocardial infarction (AMI) symptoms. The dose was given as two 10 unit Intravenous injections each over two minutes 30 minutes apart.

Evaluation criteria: Patients were followed on day 1, 3, 5/7 and 30. The primary evaluation criteria was total number of patients showing clinically successful thrombolysis based on 50% resolution of ST-elevation in the maximum affected (adjacent) leads within 90-120 minutes of initiation of Reteplase and resolution of chest pain. Secondary evaluation criteria included percentage of patient requiring rescue percutaneous coronary intervention (PCI), percentage of patient underwent angioplasty or CABG after thrombolysis. Door to needle time was also recorded in patients receiving the study drug. Global assessment of efficacy and safety was done by patient as well as investigator. All adverse events were recorded for safety assessment.

Statistical analysis: Mean and percentage were calculated for primary efficacy parameters i.e. 50% resolution of ST elevation and resolution of chest pain. Chi square test was used for comparing the difference between diabetes versus non-diabetes patients for primary efficacy variables as well as for comparing the number of patients requiring rescue PCI, angioplasty and CABG between these two groups.

Results: A total of 228 patients were enrolled out of which 140 were having diabetes mellitus. Out of all patients, 68.9% had ST elevated anterior wall myocardial infarction. Resolution of 50% of ST elevation and resolution of chest pain was reported in 90.50% and 95.4% patients respectively.). No significant difference was seen in primary efficacy variables between diabetes versus non-diabetes patients (p=0.1538 for 50% ST elevation resolution, p=0.4031 resolution of chest pain). Rescue PCI was required by 7.6 % patients while angioplasty and CABG was done in 22% and 16.8% patients respectively. . No significant difference was seen in diabetes versus non-diabetes patients requiring rescue PCI (p=0.1059), angioplasty (p=0.2172) and CABG (p=0.9128). The incidence of adverse event in this study was 5.3%.

Conclusion: Reteplase IV Injection-recombinant plasminogen activator is effective and well tolerated in the management of ST elevated myocardial infarction (STEMI) in Indian patients including diabetes patients.

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