Prognostic Role of High Dose Rosuvastatin Pre-Loading in Anterior STEMI Patients Undergoing Primary PCI

Thesis

Submitted for Partial Fulfillment of Master Degree in Cardiology

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Ahmed Mamdouh Mohammed Al-Siwi

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Abb.	Full term
AKI	Acute kidney injury.
AMI	Acute myocardial infarction.
CABG	Coronary artery bypass grafting.
CHD	Coronary heart disease.
CI-AKI	Contrast induced acute kidney injury.
CRP	C reactive protein.
CTO	Chronic total occlusion
CVD	Cardio vascular disease.
DES	Drug-Eluting stents.
ECG	Electrocardiogram.
FFR	Fractional flow reserve
HsCRP	Highly sensitive C reactive protein.
ICD	Implantable cardioverter-defibrillators.
IVUS	Intravascular ultrasonography.
LBBB	Left bundle branch block.
LMWH	Low molecular weight heparin.
LVH	Left ventricular hypertrophy.
MACCE	Major adverse cardiac and cerebrovascular events
MI	Myocardial infarction.
MPS	Myocardial perfusion scintigraphy
NCEP	National Cholesterol Education Program.
NSTE-ACS	Non ST elevation acute coronary syndrome.
OCT	Optical coherence tomography.
PCI	Percutaneous coronary intervention.
PET	Positron emission tomography
PPCI	Primary Percutaneous coronary intervention.

List of Abbreviations cont…

Abb.	Full term

PTCA..... Percutaneous transluminal coronary angioplasty

SPECT ..... Single photon emission computed tomography.

STEMI..... ST elevation myocardial infarction.

UFH..... Unfractionated heparin.

Abstract

Background: Percutaneous coronary intervention (PCI) is extensively used as a reperfusion strategy for coronary artery disease. Although this procedure is relatively safe and the procedure-related complications have markedly decreased over the years and with increased experience, myocardial injury can still occur. Recently it was found that pretreatment with statins may significantly reduce major adverse cardiac events (MACE) in patients undergoing PCI.

Methods: The study includes a total of 40 patients will be randomly assigned to Group A of 20 patients which received 40 mg Rosuvastatin high dose-loading before PCI or Group B which received no statin pretreatment (Control group). Detailed clinical and laboratoty history of the patients were carried out. High sensitivity C-reactive protein (hs-CRP) level will be withdrawn from both groups Post-PCI (24h after PCI) and compared to pre-PCI results. Follow up of major adverse cardiac events (MACE) including primary and secondary end-point of non fatal MI, cardiovascular mortality, stroke, major bleeding, & need for revascularization that occurred during in-hospital stay and within 30 days after PCI**.**

Results: There were no statistically significant differences between the 2 study groups as regards the demographic findings. Numerically, procedural characteristics appear to be similar and therefore there was no statistical significance to report. Some results were notable especially post-procedural serum Creatinine, the pre and post procedural Hs-CRP and the MACCE. Post-procedural serum Creatinine was significantly lower in the Rosuvastatin Group (A). This had a statistical significance with a *P* value of 0.055 proving that Rosuvastatin high dose pre-loading before PCI had renal protective effects and helped prevent Contrast Induced Acute Kidney Injury (CI-AKI). Considering Hs-CRP numerical values, in Group A they were significantly lower hinting the role of Rosuvastatin as an anti-inflammatory agent. However, the percentage change in comparison to Group B's numbers were not statistically significant. Finally, a total MACCE of four cases or 20% in Group B in comparison to 0% among Rosuvastatin Group A. However, this numerical significance failed to translate into a significant statistical result with a *P* value of 0.147 and so no positive conclusion could be drawn from this data to formulate a sound recommendation.

Conclusion: High dose Rosuvastatin pre-loading in patients undergoing PPCI, resulted in a numerical reduction in MACCE and lower percentage elevation of hs-CRP but with no statistical significance. However it did confirm the efficacy of statin pre-treatment for the prevention of Contrast-Induced Acute Kidney Injury in patients undergoing Percutaneous Coronary Intervention.

Keywords: Rosuvastatin, Anterior STEMI and Primary PCI.

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1- *Introduction*

Percutaneous coronary intervention (PCI) is the Gold Standard in treatment of acute coronary syndrome (ACS), especially in patients presented with ST Segment Elevation Myocardial Infarction (STEMI). The role of statins in patients undergoing percutaneous coronary intervention (PCI) has been clarified. However, most of these studies were retrospective analysis of patients who underwent chronic statin administration.

In patients undergoing PCI, the levels of inflammatory cytokines and markers increased rapidly, such as vascular cell adhesion molecule-1 (VCAM-1), matrix metalloproteinase-9 (MMP-9) [1,2]. PCI-induced myocardial damage does not result in clear clinical symptoms, changes in electrocardiogram readings or effects on cardiac functions; instead, such damage may only appear as an increase in myocardial marker levels.

Abundant data have elucidated clearly the anti-inflammatory effects of statins, which show prompt effects in the therapy of patients with ACS [3,4]. Some

reports suggested that statin therapy prior to PCI is associated with reduced mortality and the reduction of peri-procedural myocardial injury after PCI in patients with or without acute myocardial infarction (MI) [5–7]

So far studies and trials tested the efficacy of high loading dose atorvastatin therapy before PCI in patients with ACS but there were only few trials about rosuvastatin effects.

2- *Aim of the Study*

The aim of the study proposed is to determine the Prognostic Role of High Dose Rosuvastatin Pre-Loading in Anterior STEMI Pateints Undergoing Primary PCI

3- ***Patients & Methods***

- The study will include 40 (Diabetic) patients presented to *National Heart Institute* (Cardiology Department) & *Ain Shams University Hospitals* with the first attack of Ischaemic Heart Disease in the form of Anterior *STEMI* that are eligible for Primary PCI.
- All patients will be scheduled to undergo PCI within 90 minutes to a maximum 12 hours from ER admission.

Exclusion Criteria:

- Patients already on statin therapy.
- Patients in Cardiogenic Shock.
- Patients with known history of IHD or Myocardial disorder pre-infarction
- Patients with Hepatic insufficiency.
- Patients with Renal Impairment.
- Patients with Muscular disorders.
- Patients with other contraindications to statin therapy.
- Patients with Other Causes of Increased level of (hs-CRP) (inflammatory conditions e.g. Lupus,

Rheumatoid Arthritis or Infection e.g Osteomyelitis or Neoplasm e.g Lymphoma)

Methods:

After written informed consent Eligible patients will be randomly assigned to Either:

- **Group A:**

20 patients will receive 40 mg Rosuvastatin High dose-loading before PCI or

- **Group B:**

The Other 20 patients will receive No statin pretreatment (Control group)

Randomization is performed on a 1:1 ratio

The following measures will be taken:

1- Pre-Procedural Management: (ER Anti-Ischaemic measures & PCI Preparation Steps):

- Thorough history taking including:

(i)- Baseline demographic data (will be unified in both groups regarding age & gender)

(ii)- Risk factors for CAD:

- Hypertension
- Dyslipidemia
- Smoking