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COMPARATIVE STUDY OF ROSUVASTATINE WITH ATROVASTATINE IN POOL NST ACS PATIENTS FOR PREVENTION OF MYOCARDIAL ISCHEMIC EVENTS.

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ABSTRACT

Introduction: Now a day coronary artery disease is one of major cause of death & dyslipidemia is an important factor for CAD. Dyslipidemia cause atherosclerotic cardiovascular disease which is now a modern epidemic. As Hyperlipidemia is a mostly important for revention of CAD.

Aims: Compare the efficiency of Rosuvastatin & Atorvastatin in reducing the further Ischemic events in post ACS patients, both status in equivalent dose and monitoring the tolerance of side effects of long term statine use.

Materials and method: This was a prospective & comparative study performed in 100 patients admitted in our hospital B.S.M.C. Bankura at Cardiology Department. Both men and women aged between 35 – 70 years with previous history of acute Coronary Syndrom (UA, NSTMI were recruited every patient under follow up from the date of discharge from hospital after the index event. Out of 100 patients 94 patients were ultimately participated upto end of the study.

Result: In our study, Group A was significantly higher in mean Changes % in CRP levels (mg/L) [56.2±4.1] compared to CRP levels at baseline [37.4±10.2.] and CRP levels at two years [17.6±5.23]. ($p<0.0001$). we found that, Group B was significantly higher in CRP levels at baseline [38.1±12.4] compared to mean Changes % in CRP levels [36.04±3.9] and CRP levels at two years [24.1±7.23] ($p<0.0001$). It was found that, Group A was significantly more in mean ESR levels at baseline [26.4±12.5] compared to mean ESR levels at two years [20.1±11.52] and mean Changes % in ESR levels [16.7±1.38] ($p=0.031$). In our study, Group B was significantly higher in mean ESR levels at baseline [23.46±13.1] compared to mean ESR levels at two years [21.86±12.4] and mean Changes % in ESR levels [14.62±0.93] ($p=0.043$).

Conclusion: we concluded that trial recommended to follow the ACS patients until LS CRP level return to normal and to assess the important of statin choice in of mortality cardiac mortality & new MACES.

Keywords: Rosuvastatine, Atrovastatine, Myocardial Ischemic Events and ACS.

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INTRODUCTION:

Now a day coronary artery disease is one of major cause of death & dyslipidemia is an important factor for CAD. Dyslipidemia cause atherosclerotic cardiovascular disease which is now a modern epidemic. As Hyperlipidemia is a mostly important for revention of CAD. Compared to Europeans, Americans & other Asian population prevalence incidents, hospitalization and mortality from coronary artery diseases in India is 2 – 4 fold higher at all ages, 5 – 10 fold higher is those less than 40 years age. Indians are unique in having an atherogenic lipid profile & hipoprotein treatment of strain for Prevention of Recurrent MI & ischemia has been demonstrated in several Randomized Controlled Trials. Statine is an inhibitor of HMG COA reductive and it is identified to have Pleotropic effect such as anti-inflammatory & anti thrombotic properties & antioxidant effects. Therefore statins are regarded as an important agent for prevention of MI & Atorvastatin & Rosuvastatin are two important statine used at present age. In our study we compare the efficiency of Atorvastatin e & Rosuvastatin post ACS for prevention of future myocardial ischemic events.

AIMS & OBJECTIVES:

This present study was conducted to –

i) Compare the efficiency of Rosuvastatin & Atorvastatin in reducing the further Ischemic events in post ACS patients.

ii) Compare the efficiency of Both status in equivalent dose.

iii) Monitoring the tolerance of side effects of long term statine use.

MATERIALS & METHODS:

This was a prospective & comparative study performed in 100 patients admitted in our hospital B.S.M.C. Bankura at Cardiology Department. Both men and women aged between 35 – 70 years with previous history of acute Coronary Syndrom (UA, NSTMI were recruited every patient under follow up from the date of discharge from hospital after the index event. During discharge the patients had no signs of Ischemia. consent were taken from patients & their relatives. As most of the patients weight were < 70 kg the dose selected from Atorvastatin was 20 mg & Rosuvastatin 10 mg respectively. Our patients were selected & placed into two groups, one group was given Atorvastatin 20 mg & another group Rosuvastatin 10 mg at HS. Population were derived into equal halt.

Out of 100 patients 94 patients were ultimately participated upto end of the study.

Following inclusion and Exclusion criteria was used to recruitment of population:

Inclusion criteria

Age – 35 – 70 years

Sex – Male, Female

ACS – UA, NSTMI

LDL - □ 100 mg

Serum creatinine □ 1.2 mg/dl

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Normal Liver Function Test

Exclusion Criteria

i) High risk population with
ii) patient undergone
iii) Renal failure
iv) Hepatic dysfunction
v) any other major systemic illness.

Study Periods starts during discharge of every individual patient. Every patient posted in a protocol and risk factors like smoking, HIV, dyslipidemia, glycemic states, Family History of CAD & Typo of ACS (UA/ NSTMI) are taken into account.

Among 100 patients 64 patients were Hypertensive, 47 patients were either smoker or any other form of tobacco user. 64 patients were male, 36 patients were female. Every patients had dyslipidemia suggested by LDL>100 mg/dl. 23 patients were hyperglycemic with HbAlc>7%. Among the population, 17 patients had family of CVD eight cardiovascular cerebrovascular insult. Out of 100 patients popular 68 patients had unstable anging & 32 patients had NSTMI.

Diagosis of ACS done by Protocol proposed by ACC, AHA Every patient undergone basic investigation for Protocol in TropT, ECG & Echocardiography. During discharge every patient should be pain free without any sign of residual ischemic and asymptomic cardiovas strain. Medical treat given to every patient as per guideline & with instruction for strict adhere to protocol treatment.

Patient were advised to come for follow ups at least once in a month. 50 patients were given Rosuvastatine 10 mg at HS with other supportive medicine. 50 patients were given Atorvastatin. During follow up study patient were asked about chest pain, SOB, unusual discomfort in chest during that eriod. ECG done in every routine visit. Any unusual symptoms namely muscle crap, unexplained muscle weakness also taken into consideration.

Lipid profile, LFT & Echocardiography done at 6 months intervals and for diabetic patients HBACL done 3 months interval. Othalmological check-up done for every diabetic patient. Serum creatinine Phosphorus level check-up in every patient at 6 months intervals to detect any acute myopathy with statine use.

Seral LSCRP level checked in every patient at baseline & 3 months intervals.

Future id chance events was guided by hospital admission due. during the period study. For every patient it was 2 years from index hospitalization for the first event.

RESULT:

Both Rosuvastatine & Atorvastatin is well tolareted but rosuvastatin is more effective for reduction of CRP Level & Lipid profile during our follow up study.

Out of patients Rosuvastatin 20 mg doses 81% means reduction in HSCRP level in our follow up. With one year treatment. Both Rosuvastatin & Atorvastatin shown a significant in LS CRP level ($P< 0.0001$) there was 35% decrease in LSCRP with one year follow up treatment. With one year treatment both Rosuvasatin & Atorvastatin group showed a static fall in ESR level

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($P < 0.05$). In Rosuvastatin there was main reducting of ESR 18% & Atorvastatin group it was 13%. This difference was statistically significant.

In comparison for lipid profile both Rosuvastatin & Atorvastatin shows significant reduction in all unfavourable lipid marks. When inter group comparison was done main change in was statistically ($P < 0.05$).

Considering the post AMI hard & soft cardiac events namely (i) Post infection anging, hospital admitting, (ii) Re in (iii) Revas (iv) Suuden cardiac death both grous show statistically insignificant difference outcome in one year study.

CRP levels (mg/L) during the study period

Group A (Rosuvastatin 20 mg daily)

In Group A, the mean CRP levels at baseline (mean± s.d.) of patients was 37.4±10.2. In Group A, the mean CRP levels at two years (mean± s.d.) of patients was 17.6±5.23. In Group A, the CRP levels mean Changes % (mean± s.d.) of patients was 56.2±4.1. Distribution of mean CRP levels with Groups A was statistically significant ($p<0.0001$).

Group B (Atorvastatin 40 mg daily)

In Group B, the mean CRP levels at baseline (mean± s.d.) of patients was 38.1±12.4 In Group B, the mean CRP levels at two years (mean± s.d.) of patients was 24.1±7.23. In Group B, the CRP levels mean Changes % (mean± s.d.) of patients was 36.04±3.9. Distribution of mean CRP levels with Groups B was statistically significant ($p<0.0001$).

ESR levels (mm/) during the study period

Group A (Rosuvastatin 20 mg daily)

In Group A, the mean ESR levels at baseline (mean± s.d.) of patients was 26.4±12.5. In Group A, the mean ESR levels at two years (mean± s.d.) of patients was 20.1±11.52. In Group A, the ESR levels mean Changes % (mean± s.d.) of patients was 16.7±1.38. Distribution of mean ESR levels with Groups A was statistically significant ($p=0.031$).

Group B (Atorvastatin 40 mg daily)

In Group B, the mean ESR levels at baseline (mean± s.d.) of patients was 23.46±13.1In Group B, the mean ESR levels at two years (mean± s.d.) of patients was 21.86±12.4. In Group B, the ESR levels mean Changes % (mean± s.d.) of patients was 14.62±0.93. Distribution of mean ESR levels with Groups B was statistically significant ($p=0.043$).

Total cholesterol and LDL during the study period

Group A (Rosuvastatin 20 mg daily) in Total cholesterol

In Group A, the mean Total cholesterol at baseline (mean± s.d.) of patients was 218.4±34.1. In Group A, the mean Total cholesterol at two years (mean± s.d.) of patients was 147.3±26.2. In Group A, the Total cholesterol mean Changes % (mean± s.d.) of patients was 71.8±16.4. Distribution of mean Total cholesterol with Groups A was statistically significant ($p<0.0001$).

Group A (Rosuvastatin 20 mg daily) in LDL

In Group A, the mean LDL at baseline (mean± s.d.) of patients was 189.4±56.2. In Group A, the mean LDL at two years (mean± s.d.) of patients was 68.41±24.2. In Group A, the LDL mean

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Changes % (mean± s.d.) of patients was 64.4±5.81. Distribution of mean LDL with Groups A was statistically significant (p<0.0001).

Group B (Atorvastatin 40 mg daily) in Total cholesterol

In Group B, the mean Total cholesterol at baseline (mean± s.d.) of patients was 221.11±38.4. In Group B, the mean Total cholesterol at two years (mean± s.d.) of patients was 154.26±22.1. In Group B, the Total cholesterol mean Changes % (mean± s.d.) of patients was 34.38±2.84. Distribution of mean Total cholesterol with Groups B was statistically significant (p<0.0001).

Group B (Atorvastatin 40 mg daily) in LDL

In Group B, the mean LDL at baseline (mean± s.d.) of patients was 206.4±56.2 In Group B, the mean LDL at two years (mean± s.d.) of patients was 74.2±34.81. In Group B, the LDL mean Changes % (mean± s.d.) of patients was 66.72±3.18. Distribution of mean LDL with Groups B was statistically significant (p<0.0001).

DISCUSSION:

In this study we want to established the relation between reduction of inflammatory vs MACE in post ACS patients with two lipid lowering effect of. In this open level trial, it was shown that LS CRP, ESR & Lipid Profile were significantly decrease after 1 year treatment in both Rosuvastatin & Atorvastatin group (P < 0.001) between the groups the test revealed that rosuvastatin group show significant lower LS CRP level as compared to the Atorvastatin group. The mean decrease in LS CRP after 1 year of treatment was 51% in Rosuvastatin group & 35% in Atorvastatin group. But if we considered the clinical the beneficial effect of Rosuvastatin over Atorvastatin is not considered. In our study Rosuvastatin group shown only little insignificant in total MACE, so the Biomarker profile could not be the actual future predictor of cardiovascular event though they are important rough guide. The also regarding the superiorly or either stain in reduction of is not. in a open level randomized trial with diabetic patients only atorvastatin significantly reduces LS CRP level while Rosavastatin did not. Jupiter trial has been a land mark trial in establishing the role of rosavastatin in anti-inflammatory affect or risk but it did not compare with other states. In another meta-analysis rosuvastatin displayed liid reduction mainly LDL but in consideration LS CRP reduction that at, So the effect of Rosuvastatin & Atorvastatin in cardiovascular system is diverse.

CRP levels (mg/L) during the study period with Group A and Group B

Jiang F et al[1] (2014) Statins reduce the incidence of cardiovascular events after percutaneous coronary intervention (PCI), but no clinical studies have investigated the role of statins in ischemia- reperfusion injury after PCI. Rosuvastatin could reduce ischemia- reperfusion injury in patients with acute coronary syndrome treated with PCI. hs- CRP levels in the rosuvastatin-treated group were lower than that of the control group. Four weeks after PCI, the left ventricular ejection fraction in the treatment group was higher than that of the control group, and the left ventricular end- diastolic volume was lower.

Roy D et al [2](2020) Atorvastatin-80mg/day and Rosuvastatin-40mg/day are the commonest high-dose statin (3-hydroxy-3-methylglutaryl coenzyme-A reductase inhibitors) regimes for

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post-PCI (Percutaneous Coronary Interventions) patients to lower (by ≥50%) blood low-density-lipoprotein cholesterol (LDL-C). Groups varied minimally regarding distribution of age/gender/tobaccouse/medication/comorbidity/baseline (pre-PCI) LDL and hs-CRP level. At three-months follow up uncontrolled hs-CRP (22.74% vs 31.08%) Rosuvastatin-40mg regime had poorer control of hs-CRP (A3OR = 1.45,p = 0.0202), Patients treated with Atrovastatin had significantly lower number of patients with hs-CRP (high-sensitivity C-reactive protein)/C-reactive protein (CRP) level beyond comparable safe limit and relatively better tolerated as opposed to Rosuvastatin-40mg.

Kumar B et al [3](2019) High-sensitivity C-reactive protein (hs-CRP) has emerged to be a very useful and reliable clinical marker of primary as well as secondary cardiovascular morbidity and mortality. Elevated hs-CRP contributes to underlying atherogenesis and worsens disease prognosis. With four weeks of treatment, both group A and B showed statistically significant reduction in serum hs-CRP levels ($p<0.0001$). In group A, there was a mean 51% decrease in hs-CRP levels, and in group B, a 35% reduction was seen. Group A showed markedly low hs-CRP levels than group B after four weeks of therapy (18.46 ± 6.35 vs. 24.67 ± 8.45) ($p<0.0001$). Rosuvastatin showed a 50% decrease and atorvastatin showed a 35% reduction in serum hs-CRP levels in statin-naive ACS patients. Rosuvastatin has a more effective role in reducing micro-inflammation in ACS patients.

In our study, Group A was significantly higher in **mean Changes % in CRP levels (mg/L)** [56.2±4.1] compared to CRP levels at baseline [37.4±10.2.] and CRP levels at two years [17.6±5.23]. ($p<0.0001$). we found that, Group B was significantly higher in CRP levels at baseline [38.1±12.4] compared to mean Changes % in CRP levels [36.04±3.9] and CRP levels at two years [24.1±7.23] ($p<0.0001$).

ESR levels (mm/) during the study period with Group A and Group B

Kumar B et al (2019) High-sensitivity C-reactive protein (hs-CRP) has emerged to be a very useful and reliable clinical marker of primary as well as secondary cardiovascular morbidity and mortality. Elevated hs-CRP contributes to underlying atherogenesis and worsens disease prognosis. Group A showed mean 16% decrease in ESR levels as compared to 14% decrease in group B. Group A showed lower ESR levels than group B after four weeks of therapy (19.59 ± 11.83 vs. 20.52 ± 12.13) ($p<0.0001$).

It was found that, Group A was significantly more in mean ESR levels at baseline [26.4±12.5] compared to mean ESR levels at two years [20.1±11.52] and mean Changes % in ESR levels [16.7±1.38] ($p=0.031$). In our study, Group B was significantly higher in mean ESR levels at baseline [23.46±13.1] compared to mean ESR levels at two years [21.86±12.4] and mean Changes % in ESR levels [14.62±0.93] ($p=0.043$).

Total cholesterol and LDL during the study period with Group A and Group B

Roy D et al (2020) Atorvastatin-80mg/day and Rosuvastatin-40mg/day are the commonest high-dose statin (3-hydroxy-3-methylglutaryl coenzyme-A reductase inhibitors) regimes for post-PCI (Percutaneous Coronary Interventions) patients to lower (by ≥50%) blood low-density-

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lipoprotein cholesterol (LDL-C). Groups varied minimally regarding distribution of age/gender/tobaccouse/medication/comorbidity/baseline (pre-PCI) LDL.

In our study, Group A was significantly higher in Total cholesterol at baseline [218.4±34.1] compared to Total cholesterol at two years [147.3±26.2] and mean Changes % in Total cholesterol [71.8±16.4]. We observed that, Group A was significantly higher in LDL at baseline [189.4±56.2] compared to LDL at two years [68.41±24.2] and mean Changes % in LDL [64.4±5.81] ($p<0.0001$).

We found that, Group B was significantly higher in Total cholesterol at baseline [221.11±38.4] compared to Total cholesterol at two years [154.26±22.1] and mean Changes % in Total cholesterol [34.38±2.84]. We observed that, Group B was significantly higher in LDL at baseline [206.4±56.2] compared to LDL at two years [74.2±34.81] and mean Changes % in LDL [66.72±3.18] ($p<0.0001$).

CONCLUTION:

In statin naïve patients with acute coronary syndrome the current choice of statin is controversial. Both statin can achieve the goal of optimizing lipid profile, statistically significant reduction in inflammatory Biomarker namely LS CRP & ESR. Rosuvastatin show 51% reduction in LS CRP & Atorvastatin show 35% reduction in LS CRP level. Though Rosuvastatin better control the statistically biomarker level over Atorvastatin but could not reduction of total MACE rate over the one year period where is statistically.

trial recommended to follow the ACS patients until LS CRP level return to normal and to assess the important of statin choice in of mortality cardiac mortality & new MACES.

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Table 1: Mean Changes in CRP levels (mg/L) during the study period

Groups	At baseline	At two years	Mean Changes %	P-Value
Group A (Rosuvastatin 20 mg daily)	37.4±10.2	17.6±5.23	56.2±4.1	<0.0001
Group B (Atorvastatin 40 mg daily)	38.1±12.4	24.1±7.23	36.04±3.9	<0.0001

Table 2: Mean Changes in ESR levels (mm/) during the study period

Groups	At baseline	At two years	Mean Changes %	P-Value
Group A (Rosuvastatin 20 mg daily)	26.4±12.5	20.1±11.52	16.7±1.38	0.031
Group B (Atorvastatin 40 mg daily)	23.46±13.1	21.86±12.4	14.62±0.93	0.043

Table 3: Mean Changes in total cholesterol and LDL during the study period

Groups		At baseline	At two years	Mean Changes %	P-Value
Group A (Rosuvastatin 20 mg daily)	**Total cholesterol**	218.4±34.1	147.3±26.2	71.8±16.4	<0.0001
	LDL	189.4±56.2	68.41±24.2	64.4±5.81	<0.0001
Group B (Atorvastatin 40 mg daily)	**Total cholesterol**	221.11±38.4	154.26±22.1	34.38±2.84	<0.0001
	LDL	206.4±56.2	74.2±34.81	66.72±3.18	<0.0001