Comparison of the incidence of contrast-induced nephropathy after primary PCI in patients receiving high-dose rosuvastatin and atorvastatin

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Introduction: Contrast-induced nephropathy (CIN) is associated with increased disability and death. Randomized clinical trial studies have shown that short-term treatment with statins prior to cardiac intervention was capable of reducing the incidence of CIN. Therefore, the aim of this study was to compare the incidence of CIN after primary PCI in patients receiving high-dose rosuvastatin and atorvastatin. Methods: This clinical trial was performed in Mazandaran Heart Center Hospital on patients referred to the emergency department who underwent primary PCI with a diagnosis of STEMI. Patients received 1 cc/kg/h normal saline from PCI for up to 12 hours. Patients with EF less than or equal to 35% received intravenous normal saline at half the usual dose. SPSS software version 24 was used for data analysis. P value less than 0.05 was considered to be statistically significant. Results: 206 patients were included in the study that the most underlying diseases of patients (79, 38.3%) were hypertension, followed by anemia (76, 36.9%) and diabetes mellitus (52, 25.2%). Among these, in the first criterion, 10 (8.1%) and 4 patients (4.8%) were in the atorvastatin and rosuvastatin groups, respectively, which did not have a statistically significant difference (P = 0.264). Examination of GFR subgroups also showed that GFR above 30 had significant differences between the two groups. Conclusion: The use of different statins has had similar results in the prevention of CIN in patients undergoing primary PCI. Rosuvastatin has no special advantage over atorvastatin, showing that the use of any of these drugs can be useful in patients requiring angiography.

Keywords: Atorvastatin, contrast-induced nephropathy, myocardial infarction, rosuvastatin

Abstract

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coronary angiography have shown that the incidence of CIN is less than 2% in patients with no risk factor for CIN. However, its incidence has been reported up to 90% in patients with high risk for CIN.[6,9] The treatment strategies proposed for CIN are limited to supportive care and dialysis. Therefore, screening high-risk patients and using appropriate preventive regimens play an important role in reducing the incidence of CIN. Previous studies have suggested that some CIN drugs and prophylactic measures are appropriate, including sodium bicarbonate, acetylcysteine (NAC), calcium channel blockers, diuretics, dopamine, endothelin antagonists, atrial natriuretic peptide, ascorbic acid, and hemodialysis after or during administration of contrast material.

Among these strategies, increasing extracellular volume using intravascular saline or sodium bicarbonate, reducing the dose of contrast agent, using low osmolarity non-ionic contrast agents instead of high osmotic agents, discontinuing nephrotoxic drugs and drugs such as NAC, theophylline and statins have been shown to be more effective in preventing CIN.[7] Statins, in addition to regulating lipid profile, have anti-inflammatory and antioxidant properties that can be effective in preventing CIN.[10] Statins may play a Renoprotective role by reducing the inflammatory process of the tubulointerstitial fibrosis. By reducing endocytosis, they are capable of reducing inflammation, endothelial dysfunction and tubulointerstitial fibrosis.[11] Inhibition of tubular reabsorption of contrast, which in turn reduces inflammation, oxidative damage, and the apoptotic process.[12] Recent studies have evaluated the effectiveness of statins in preventing CIN, but the results of these studies have been controversial. The meta-analyses of available clinical trials have concluded that short-term treatment with high-dose statins were capable of preventing CIN, but the quality of the data is still unsatisfactory and further studies are needed.[13,14] Therefore, the aim of this study was to compare the incidence of CIN after primary PCI in patients receiving high-dose rosuvastatin and atorvastatin.

Materials and Methods

This double-blind clinical trial was performed on patients referred to Mazandaran Heart Hospital who underwent Primary Percutaneous Coronary Intervention (PCI) with STEMI diagnosis and patients who met the inclusion and exclusion criteria were included in the study.

Inclusion criteria include: 1- Patients with STEMI diagnosis requiring primary PCI. Exclusion criteria were: 1- Patients with cardiogenic shock, acute pulmonary edema, and bleeding complications, 2- Patients in need of emergency CABG, IABP or ESRD, 3- Patients who have received intravenous contrast in the last week, 4- Patients who have already been treated with statins.

Sample size

Due to the limitations of studies on the prevalence of CIN after PCI priming in patients receiving rosuvastatin, a pilot study was performed on 206 eligible patients.

Procedure

After informed consent, all patients admitted to the study received ASA, Plavix, Nitrate, ACEI/ARB. Patients received 1 cc/kg normal saline from PCI for up to 12 hours. Patients with EF less than or equal to 35% received intravenous normal saline at half the usual dose (half a cc/kg/hr). Patient baseline creatinine measured. Serum creatinine was measured again 48 hours after angioplasty. According to the first criterion, CIN was defined as an increase of more than 0.3 mg/dL or more than 50% of baseline creatinine. The second criterion for CIN was defined as an increase of more than 0.5 mg/dL or more than 25% of baseline creatinine. Baseline and subsequent eGFR (48 hours later) were calculated based on the formula [(140 - age) * weight/(72 Cr *)], which in women was multiplied by 0.85. The randomized distribution was that patients received atorvastatin (80 mg at baseline and daily) or rosuvastatin (40 mg at baseline and daily) using random numbers based on the day of admission. In this study, ST-Elevation Myocardial Infarction (STEMI) was diagnosed based on the presence of symptoms of acute myocardial ischemia and ST segment elevation in the ECG. The elevation of ST segment was considered at least 1 mm in two adjacent leads (except for V2, V3, and posterior). A minimum of 2 mm was considered for V2 and V3 leads and a minimum of 0.5 mm for posterior leads.

Data analysis

Central indicators (mean and standard deviation) were used for descriptive reporting. The frequency of CIN was reported as number and percentage. To compare the variables in the two groups, t-test was used for quantitative variables and Chi-square was used for qualitative variables. Then, data analysis was performed using SPSS software, version 24. A significance level of 0.05 was considered to be statistically significant.

Ethical considerations

A written letter of introduction was received from university officials. The purpose of the study was described for the research units and written consent was obtained from them. The information of all patients was kept confidential by the project manager. In all stages of the research, all ethical declarations of Helsinki and ethical principles of research committees of the University of Medical Sciences were considered.

Results

A total of 206 patients were enrolled in the study. Table 1 shows the demographic characteristics between the two groups of atorvastatin and rosuvastatin, of which 171 were male (83%) and 35 were female (17%). Furthermore, 123 patients (59.7%) were in the atorvastatin group and 83 patients (40.3%) were in the rosuvastatin group. The age range of patients was between 27-84 years with a mean of 58.47 ± 11.05 years and also the weight of patients was between 45-120 kg with a mean of 74.87 ± 14.14. The results showed that the patients’ hemoglobin level was between 8.8-18.3 (mean 13.09 ± 1.69) g/dl. Comparison of sociodemographic characteristics between the two groups.
showed that the two groups were identical for all of these variables and were not statistically different (P > 0.05).

Figure 1 examined the underlying diseases and risk factors in patients. In the atherosclerotic group, hypertension (49 patients, 39.8%) was observed, followed by diabetes mellitus (32 patients, 26%), anemia (48 patients, 39%) and smoking (40 people, 32.5%). In the rosuvastatin group, 30 patients (36.1%) showed hypertension, followed by diabetes mellitus (20 patients, 24.1%), anemia (28 patients, 33.7%) and smoking (26 patients, 31.3%). None of the variables are statistically significant (P > 0.05).

The study of paraclinical variables between the two groups is shown in Table 2. According to the results, none of the variables is statistically significant (P > 0.05), but the creatinine level in patients taking atorvastatin is equal to 1.16 ± 0.23 after Primary PCI. In the rosuvastatin group, it was equal to 1.09 ± 0.2, which was statistically significant (P = 0.02).

CIN was evaluated based on two criteria in GFR subgroups, atorvastatin and rosuvastatin groups [Table 3]. The results showed that any of the subgroups there was no statistically significant difference.

Among all patients with myocardial infarction, 106 (51.7%) had anterior infarction and the rest had other infarcts. The highest consumption of contrast material is in the category 201‑300 (106 cases, 51.5%) followed by the category 101‑200 (86 cases, 41.7%). Also, the glomerular filtration rate of most patients (152 patients) was in the range above 60. According to the information obtained, there was no statistically significant difference between the two groups in terms of other clinical factors (P > 0.05) Table 4.

The incidence of CIN based on whether patients are diabetic or non-diabetic in the two groups of atorvastatin and rosuvastatin is shown in Table 5. No statistically significant difference was obtained based on both criteria (P > 0.05). Also, there was no statistically significant difference between anemic and non-anemic patients in terms of the incidence of CIN based on both criteria (P > 0.05).

Changes in plasma creatinine and glomerular filtration rate based on GFR classification between atorvastatin and rosuvastatin are listed in Table 6. The results show that changes in creatinine and glomerular filtration rate in GFR above 30 were significantly different between the two groups.

**Discussion**

CIN is associated with increased disability and death. Randomized clinical trial studies have shown that short-term treatment with statins before cardiac interventions reduces the incidence of CNI. Therefore, the aim of this study was to compare the incidence of CNI after primary PCI in patients receiving high-dose rosuvastatin and atorvastatin.
The reasons for the comparison of atorvastatin and rosuvastatin their inherent differences, so that rosuvastatin causes a further decrease in LDL levels than other statins and its plasma level reaches its peak effect within 3-5 hours and its plasma half-life is more and has more anti-inflammatory properties than atorvastatin. Our findings showed that the incidence of CIN was 6.8% according to the first criterion and 11.7% according to the second criterion. Regarding the second criterion assessment by studies, we also evaluated the results based on the second criterion. The study by Patti et al. examined the effect of high-dose statins before intervention to prevent CIN in 566 patients with acute coronary syndrome undergoing PCI.

In the present study, the incidence of CIN and glomerular filtration rate were not statistically significant in the groups and subgroups. In the atorvastatin and rosuvastatin groups and subgroups. In the study of Liu et al. the use of high-dose rosuvastatin had no advantage over high-dose atorvastatin and the same results were obtained. The results confirm the same effect of the two drugs in patients with any amount of glomerular filtration. In addition, Kaya et al. investigated the prophylactic effects of different statins on CIN in patients with myocardial infarction, elevated ST segment and glomerular filtration rate above 60 who underwent a primary PCI. Their results showed no significant difference between the atorvastatin and rosuvastatin groups, which is consistent with the results of our study.

In the study of demographic characteristics, patients ranged in age from 27-84 years with a mean of 58.47 ± 11.05 years (atorvastatin group: 58.65 ± 11.05 years and rosuvastatin group: 58.19 ± 11.11 years). Out of 206 patients, 171 (83%) were male (103 [83.7%] in the atorvastatin group, and 68 [81.9%] in the rosuvastatin group, and the rest were female. The most common underlying diseases were hypertension (79 cases), followed by anemia (76 cases) and diabetes mellitus (52 cases). Also, 66 (32%) of the patients were smokers. The left ventricular ejection fraction in the atorvastatin and rosuvastatin groups had an average of 39.74 ± 7.8 and 39.37 ± 6.67, respectively, but this difference was not statistically significant (P = 0.725). The baseline creatinine of the patients in the atorvastatin group was 1.11 ± 0.23, while this level was 1.09 ± 0.31 for the rosuvastatin group. Also, the baseline creatinine of the patients in the atorvastatin group was 1.11 ± 0.23, while this level was 1.09 ± 0.31 for the rosuvastatin group and 8.6% in the rosuvastatin group, which is consistent with the results of our study. But Liu et al. in a study investigated the effects of rosuvastatin and atorvastatin in the prevention of CIN in patients with chronic kidney disease under PCI intervention, where the overall incidence of CIN was reported to be 5.4%. This discrepancy with the present study may be due to the specific population being studied including patients with myocardial infarction who underwent a primary PCI.

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### Table 4: Clinical factors of patients in atorvastatin and rosuvastatin groups

| Variable                        | Frequency (%) | P     |
|---------------------------------|---------------|-------|
| The amount of contrast material |               |       |
| ≤100                            | 2 (1.6%)      | 1 (1.2%) | 0.827 |
| 101-200                         | 54 (43.9%)    | 32 (26.6%) |
| 201-300                         | 60 (48.8%)    | 46 (35.4%) |
| 301-400                         | 7 (5.7%)      | 4 (3.2%) |
| Glomerular filtration rate      |               |       |
| <30                             | 3 (2.4%)      | 1 (1.2%) | 0.54  |
| 30-59                           | 32 (26%)      | 17 (26%) |
| ≥60                             | 88 (71.5%)    | 64 (78%) |
| Myocardial infarction           |               |       |
| Anterior                        | 60 (49.2%)    | 46 (55.4%) | 0.38  |
| Other                           | 62 (50.8%)    | 37 (44.6%) |

### Table 5: Distribution of CIN based on diabetes and anemia among the two groups

| Contrast-induced nephropathy | Frequency (%) | P     |
|------------------------------|---------------|-------|
| According to the first criterion |               |       |
| Non-diabetic                  | 9 (9.9%)      | 3 (4.7%) | 0.243 |
| Diabetic                      | 1 (3.1%)      | 1 (5%)  | 0.732 |
| Non-anemic                    | 7 (9.3%)      | 3 (5.5%) | 0.412 |
| Anemic                        | 3 (6.3%)      | 1 (3.6%) | 0.614 |
| According to the second criterion |           |       |
| Non-diabetic                  | 15 (16.5%)    | 4 (6.3%) | 0.06  |
| Diabetic                      | 3 (9.4%)      | 2 (10%)  | 0.941 |
| Non-anemic                    | 10 (13.3%)    | 5 (9.1%) | 0.454 |
| Anemic                        | 8 (16.7%)     | 1 (3.6%) | 0.088 |

### Table 6: Changes in creatinine and glomerular filtration rate based on GFR classification between the two groups

| Variable                        | Category       | Atorvastatin | Rosuvastatin | P     |
|---------------------------------|----------------|--------------|--------------|-------|
|                                | Number         | Mean±SD      | Number       | Mean±SD |       |
| Creatinine changes              | GFR <30        | 3            | -0.03±0.53   | 1      | -1.72±0.0 | 0.5  |
|                                | GFR between 30-60 | 32          | -0.03±0.21   | 17     | 0.04±0.15  | 0.043 |
|                                | GFR >60        | 88           | 0.08±0.17    | 64     | 0.02±0.16  | 0.008 |
| Glomerular filtration changes   | GFR <30        | 3            | 2.27±5.76    | 1      | 27.54±0.0  | 0.5  |
|                                | GFR between 30-60 | 32          | 1.85±8.69    | 17     | -1.59±5.49 | 0.036 |
|                                | GFR >60        | 88           | -6.41±15.38  | 64     | -1.35±16.47| 0.013 |
In the study of Liu et al.,[20] 1078 patients participated in the study with a mean age of 65.2 ± 10.1 years (atorvastatin group: 65.79 ± 10.28 years and rosuvastatin group: 65.28 ± 9.89 years). Also, out of 1078 patients, 834 (77.4%) were male (618 in atorvastatin group [67.7%] and 216 in rosuvastatin [79.1%]) and the rest were female. The highest prevalence of underlying diseases was related to hypertension (682 cases, 63.3%), followed by anemia (375 cases, 34.8%) and diabetes mellitus (262 cases, 24.3%). Also, 409 patients were smokers. The left ventricular ejection fraction in the atorvastatin and rosuvastatin groups had a mean of 59.96 ± 11.18 and 59.05 ± 11.77, respectively, but this difference was not statistically significant (P = 0.029). The baseline creatinine in the patients of the atorvastatin group was 1.11 ± 0.26 and in the rosuvastatin group was 1.12 ± 0.28 which was not statistically significant (P = 0.495). These findings were consistent with our study.

In the study of Kaya et al.[18] out of 192 patients participating in the study, the mean age was 62.6 ± 10.5 years (Atorvastatin group: 61.5 ± 11.6 years and rosuvastatin group: 63.8 ± 9.4 years). Out of 192 patients, 143 (74.4%) were male (72 [3.5%] and rosuvastatin group: 70 [75.5%]) and the remaining were female. The highest prevalence of underlying diseases was related to hypertension (61 cases [31.7%]), followed by diabetes mellitus (38 cases). Moreover, 46 patients were smokers. The mean left ventricular ejection fraction in the atorvastatin and rosuvastatin groups was 46.2 ± 8.2 and 48.1 ± 9.3, respectively, which was not statistically significant (P = 0.11). The baseline creatinine of the patients in the atorvastatin group was 0.88 ± 0.22 and in the rosuvastatin group was 0.88 ± 0.21 which was not statistically significant (P = 0.8). These are consistent with the findings of the present study.

**Conclusion**

The use of different statins has had similar results in preventing CIN in patients undergoing primary PCI. Rosuvastatin has no particular advantage over atorvastatin, indicating that the use of any of these drugs may be useful in patients requiring angiography.

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**Conflicts of interest**

There are no conflicts of interest.

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