National Journal of Physiology, Pharmacy and Pharmacology

RESEARCH ARTICLE

Comparative assessment of glycemic control in hypertensive patients treated with or without statins

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Received: August 02, 2016; **Accepted:** August 19, 2016

ABSTRACT

Background: It has been a matter of recent concern whether statins deteriorates diabetes mellitus or glycemic control. This association is worrying because diabetes doubles the risk of cardiovascular diseases and deaths, which accounts for about 50% of deaths in diabetes. **Aims and Objectives:** Comparison of the hemoglobin A1c (HbA1c) levels in hypertensive patients with or without atorvastatin was done to study the effects of atorvastatin at therapeutic doses on glycemic control. Statins association with blood glucose levels and their impacts in the management of patients are the focus of our study. **Materials and Methods:** A cross-sectional, prospective, hospital-based, observational study was conducted at Father Muller Medical College Hospital, 60 eligible patients included were randomized into 2 groups. Group A included 30 patients taking tablet atorvastatin 10mg once daily since 3 or more months. Group B, and Group B included 30 patients, not taking any statin therapy. Further in each group of 30 patients, 15 patients with hypertension only and remaining 15 patients with hypertension and diabetes both were included. Patients demographic profile, status of disease, treatment history, and HbA1c were recorded. Comparison of glycemic control was done using suitable statistical methods. **Results:** There was no statistically significant difference between two groups in terms of HbA1c levels. However, the patients on atorvastatin were found to have higher HbA1c levels compared to patients not on atorvastatin therapy. **Conclusion:** According to our study, atorvastatin had no significant impact on glycemic control; further larger trials are needed in this regard.

KEY WORDS: Atorvastatin; Poor Glycemic Control; Hyperglycemia

INTRODUCTION

Statins are presently considered first line drugs in treating Hyperlipidemia.[1] Statins have the general reputation as very effective and safe cholesterol-lowering drugs, with some known adverse effects such as elevation of liver enzymes and rhabdomyolysis.[2] It has been a matter of recent concern whether statins deteriorates diabetes mellitus or glycemic control. This association is worrying because diabetes doubles the risk of cardiovascular diseases and deaths, which accounts for about 50% of deaths in diabetes.[3] Many case reports, clinical trials, and meta-analysis have indicated the association of statins and poor glycemic control. With this evidence in February 2012, the US Food and Drug Administration revised the labels of statins in the US to include the information that the increases in fasting serum glucose and glycated hemoglobin levels have been reported with use of statins. Many studies have also ruled out this association and claimed the advantages in the prevention of cardiovascular events.[4,5] Various mechanism for the

Access this article online	
Website: www.njppp.com	Quick Response code
DOI: 10.5455/njppp.2017.7.0824719082016	

association of hyperglycemia with statins have been proposed, down regulation of glucose transporters on the cell appears to be, one of the important cause.[6] Generally in geriatric patients with metabolic syndrome statins should be cautiously used and regular monitoring of blood glucose levels are advised[6-7] Comparison of the average blood glucose levels in hypertensive patients with or without atorvastatin was done to study the effects of atorvastatin at therapeutic doses on glycemic control. Statins association with blood glucose levels and their impacts in the management of patients are the focus of our study.

Primary Objective

To determine the effects of the atorvastatin on glycemic control in hypertensive patients.

Secondary Objective

To compare the association of atorvastatin and glycemic control in patients with hypertension and patients having both hypertension and diabetes.

MATERIALS AND METHODS

The cross-sectional, hospital-based observational study was initiated after approval by institutional ethics committee, written informed consent was taken from all the participants before taking the data of patients. It was conducted at Father Muller Medical College Hospital, Mangaluru, in 2014.

60 eligible hypertensive patients were included, and they were divided into 2 groups by depending on the use of atorvastatin for past 3 months or not. Group A including 30 patients on tablet atorvastatin 10 mg once daily for at least 3 months and Group B including 30 patients without any statin therapy. Further in each group of 30 patients, 15 patients with hypertension only and remaining 15 patients with hypertension and diabetes both were included (Figure 1). Patients demographic profile, status of disease, treatment history, and hemoglobin A1c (HbA1c) were recorded. Comparison of glycemic control was done using suitable statistical method**s**. SPSS software was used for the analysis of the data.

Inclusion Criteria

- Patients of 18-80 years age
- Patients on regular treatment for hypertension, diabetes, or both.
- Hypertensive patients with or without atorvastatin therapy
- Diabetic patients with or without atorvastatin therapy
- Hypertension + diabetic patients with or without atorvastatin therapy.

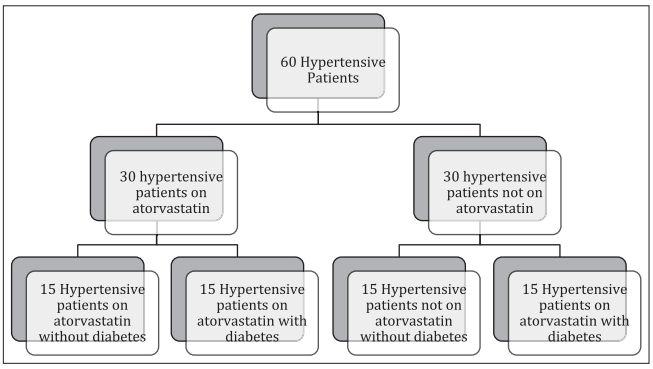

Figure 1: Patient recruitment

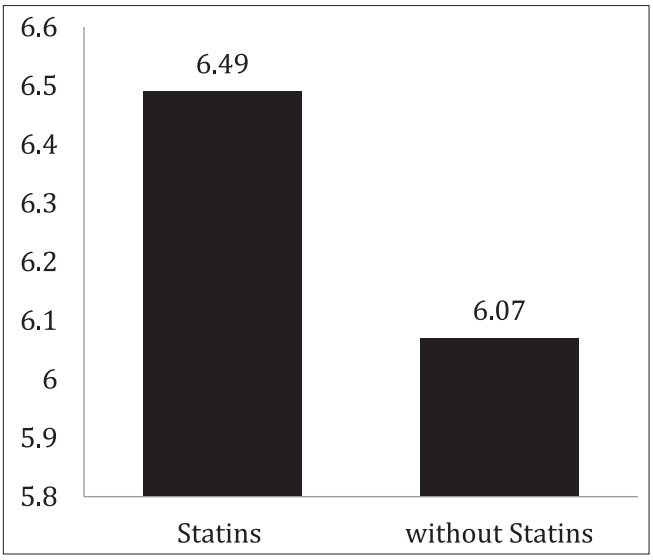

Figure 2: Hypertensive average hemoglobin A1c comparison

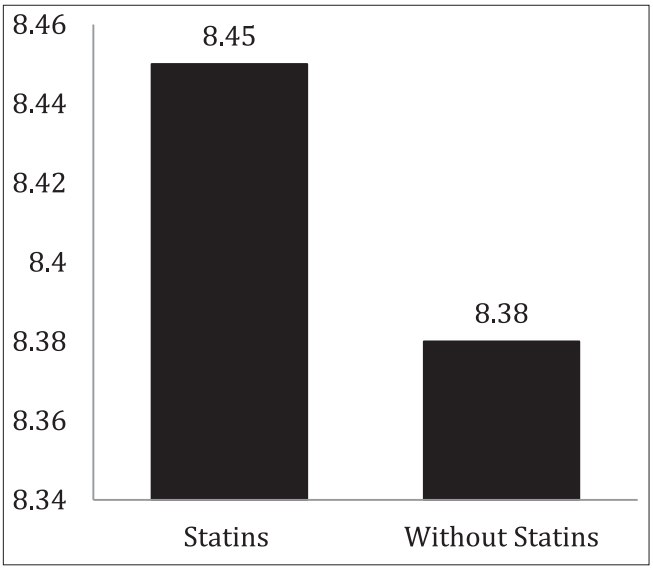

Figure 3: Hypertensive diabetic average hemoglobin A1c comparison

Exclusion Criteria

- Patients with dual statin therapy
- Patients with known insulin resistance

Table 1: Comparison of HbA1c levels with different groups

Depending on HbA1c levels	HTN statin	HTN+DM statin	HTN without statin	HTN+DM without statin
Normal (<5.7)	4	0	3	1
Prediabetes (5.7-6.4)	8	3	9	6
Good control (6.5-7.5)	1	2	3	1
Average control (7.5-9.5)	0	6	0	2
Bad control (9.5-11.5)	2	2	0	2
Worst control (>11.5)	0	2	0	3

HbA1c: Hemoglobin A1c

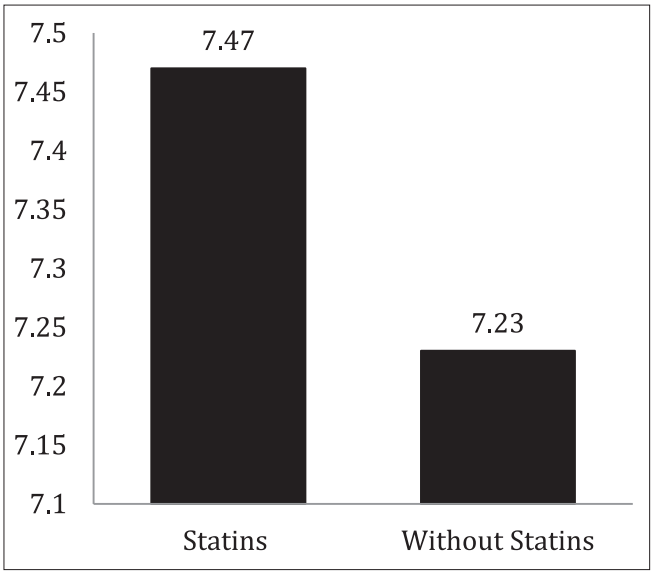

Figure 4: Overall average hemoglobin A1c comparison

- Patients on steroid therapy
- Patients with severe systemic infections
- Patients on drugs known to cause hyperglycemia.

The patient was given all rights to know the results of the study and confidentiality of the information collected is maintained throughout.

RESULTS

Most of the patients enrolled in the study were females 53%, with average age of 65 years. All baseline characteristics such as age and gender were matched between the groups.

Study of average HbA1c levels in hypertensive groups revealed that statin users had an average of 6.49 and patients not on statin had 6.07 (Figure 2).

The difference was statistically insignificant $P = 0.36$ ($P > 0.05$).

Study of average HbA1c levels in hypertensive diabetic groups revealed that statin users had an average of 8.45 and patients not on statin had 8.38 (Figure 3). The difference was statistically insignificant $P = 0.943$ ($P > 0.05$).

Overall average HbA1c comparison between statin users and non-users revealed that statin users had 7.47 and non-users had 7.23 HbA1c levels (Figure 4). The difference was statistically insignificant $P = 0.674$ ($P > 0.05$).

Glycemic control appears to be same in both comparative groups, and no significant variation in HbA1c could be established. However, most of the patients on atorvastatin tend to have higher HbA1c levels compared to patients not on atorvastatin therapy (Table 1).

DISCUSSION

Atorvastatin is widely used drug, and confusions prevailing its association with hyperglycemia, poor glycemic control, and early onset of diabetes mellitus among statin users have urged us to explore this association by our comparative study. It is a simple cross-sectional survey where we have collected HbA1C values at the clinic in statin users and non-user hypertensive patients. Although the method is simple, it gives immense details regarding the glycemic controls. On context to various reports for pro and contrast association between statins and poor glycemic control, our study fails to demonstrate significant differences between the groups.

Glycemic control appears to be same in both comparative groups, and no significant variation in HbA1c could be established. However, most of the patients on atorvastatin tend to have higher HbA1c levels compared to patients not on atorvastatin therapy.

It would be inappropriate to comment the association with cross-sectional studies as ours, ideally a randomized control trial with large sample size, monitoring various glycemic indicators, with matched groups in terms of the disease condition, co-administered drugs, and baseline characteristics would have been better.

However, strength of our study is that it is simple, informative with adequate sampling. We consider it as a beginning for our future studies in this regard.

Hence, the association of statins with poor glycemic control lacks proper evidence and needs further probe with well-designed studies.

CONCLUSION

Although the results have not established the association in our study, further larger trials are needed in this regard.

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How to cite this article: Kumar BP, Scandashree K, Udaykumar P. Comparative assessment of glycemic control in hypertensive patients treated with or without statins. Natl J Physiol Pharm Pharmacol 2017;7(2):155-158.

Source of Support: Nil, **Conflict of Interest:** None declared.