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ORIGINAL RESEARCH

Effect of statin use on status of diabetic retinopathy/diabetic macular edema in patients of type 2 diabetes mellitus

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ABSTRACT

Background: Diabetic retinopathy is common complaint for visual disturbances in patients with Diabetes mellitus. Statins can effectively decrease the lipid parameters along with improvement in visual acuity. This study was undertaken in order to assess effect of use of statins on diabetic retinopathy/ diabetic macular edema in patients with type 2 diabetes mellitus. **Methodology:** A prospective study was undertaken in 100 patients in Basaveshwara Medical College and Hospital, Chitradurga. The patients undergone examination for visual acuity, fundoscopic examination for progression of diabetic retinopathy and macular edema, total cholesterol, LDL Cholesterol and Triglycerides. The patients were followed for 12 months and same readings were obtained at the follow up. **Results:** This study had shown that, majority of the cases were aged more than 60 years and were males. The mean duration of the diabetes mellitus was 15.9 years. The visual acuity in this study was improved as per Logmar vision. The CSME was present in 10.0% of the left eye and 13.0% of the right eye of the patients. The use of statins on the patients have significantly reduced the severity of diabetic retinopathy in both left and right eyes in this study. The lipid profile of the patients had shown significant decrease in Total cholesterol, Triglycerides and LDL cholesterol levels after use of statins. **Conclusion:** This study had shown the improvement of visual acuity, decrease in severity of CSME and diabetic retinopathy along with decrease in lipid parameters.

Key words: Statins, visual acuity, CSME, total cholesterol, diabetic retinopathy

INTRODUCTION

Diabetes mellitus is a complex metabolic disease and is often characterized by chronic hyperglycaemia. The disease carries high mortality and morbidity with variety of complications which are known to worsen over a period of time. Diabetes mellitus (DM) is characterized by abnormal insulin secretion, high levels of blood glucose and variety of complications including retinopathy, nephropathy, neuropathy and atherosclerosis[1, 2].

Diabetic retinopathy is the most frequently occurring chronic micro vascular complication in patients with diabetes resulting from hyperglycemia, glucose related hyperosmolarity, and DME is a leading cause of severe vision loss in patients with diabetic retinopathy[3].

FIELD study had shown the benefit of fenofibrate intervention in the form of reduction in need for laser treatment in diabetic retinopathy[4]. ACCROD - EYE study had shown that,fenofibrate with simvastatin decreased the progression of diabetic retinopathy compared with simvastatin alone which itself shown no improvement in this trial vs placebo.' The statin therapy alone was associated with reduced risk of development of diabetic macular edema and progression of diabetic retinopathy[6].

But the results of many studies have not demonstrated any beneficial effects of lipid lowering agents such as statins. Hence it was decided to take up this study to ascertain effect of statin use on status of diabetic retinopathy and diabetic macular edema.

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MATERIAL AND METHODS

A prospective study was conducted in the OPD of upgraded department of ophthalmology at Basaveshwara Medical College and hospital, Chitradurga over the duration of from July 2021 to June 2022. The proposed study was in association of status use and hyper triglyceridemia with diabetes macular edema in patients with type-2 diabetes and diabetic retinopathy. Clearance from institution ethics committee was obtained before the study was started. An informed consent was obtained from all the patients before including them in to the study.

The calculated sample size worked out be 100 as the prevalence of diabetic retinopathy reported in India by Gadkari*et al*.

The patients attending the OPD of department of medicine and ophthalmology during were enrolled. The patients with Type-2 DM patient with DR with or without DME of either sex were included. The patients with no DR, Use of any other lipid lowering agent other than statins, Follow of less than 1 year, Hypertension retinopathy patient, Sickle cell disease patient, Mature cataract & hazy media, Vitrectomy and Other retinal diseases were excluded.

Patient were selected from OPD, the baseline characteristics were obtained. A detailed history regarding the systemic symptoms of DM, onset and progression of decrease of vision, distortion of vision, difficulty in colour perception, seeing spot (floaters) was elicited from the patients. Duration of disease, History of type-2 DM in any one of the parents or both the parents and in siblings and also history of hypertension was taken. A detailed Ocular examination was performed including Visual acuity assessed as per log MAR chart, BCVA, Amsler grid test, Retinoscopy and OCT (OPTIVUE) done to measure retinal thickness wherever required. All the patients were subjected for blood investigation including Blood Sugar, HA,C, Lipid profile, a complete general examination is done. Only DR patients were followed up on every 3 months till 12 months after giving treatment (statins) to check the effect of statins on DR and then repeat the fundus photography to see any changes and also repeat the OCT to look the changes of retinal thickness and FFA done wherever required to know the baseline status of retina and macular ischemia.

RESULTS

Table 1: Distribution of the study group according to socio demographic characteristics

		Frequency	Present
Age group	31-40 years	6	6.0
	41-50 years	17	17.0
	51-60 years	37	37.0
	More than 60 years	40	40.0
Sex	Male	70	70.0
	Female	30	30.0
Duration of diabetes mellitus	Mean, SD	15.87	7.15

About 40.0% of the cases in this study were aged more than 60 years and 70.0% werefemales. The mean duration of diabetes was 15.87 years in this study.

Table 2. Distribution of the study group according to Visual acuity

	Visual acuity	Baseline	Follow up	T Value	P Value,Sig.
Right eye	Mean ± SD	3.0 ± 0.94	2.9 ± 1.02	7.911	0.000, Sig
Left eye	Mean ± SD	2.95 ± 1.02	2.18 ± 0.73	6.436	0.000, Sig

The mean Logmar visual acuity in this study improved in both the eyes which was statistically significant. The mean Logar visual acuity of the right eye was 3.0 at the baseline and 2.9 at the time of follow up. The mean Logmar visual acuity of the left eye at the baseline was 2.95 and improved to 2.18 at the time of follow up.

Table 3: Distribution of the study group according to CSME

CSME	Left eye		Right eye	
	Baselinen (%)	Follow upn (%)	Baselinen (%)	Follow upn (%)
Absent	76 (76.0)	90 (90.0)	64 (64.0)	87 (87.0)
Present	24 (24.0)	10 (10.0)	36 (36.0)	13 (13.0)
Total	100 (100)	100 (100)	100 (100)	100 (100)

Left eye: x2 Value=6.945,DF=1, p value, sig=0.008, Sig
Right eye: x2 Value=14.299, DF=1, p value, sig=0.000, Sig

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Clinically significant macular edema was present in 24.0% of the cases at the baseline in left eye and 10.0% during follow up which was statistically significant. In right eye, clinically significant macular edema was present in 36.0% of the cases during baseline and 13.0% of the cases during follow up this was also statistically significant.

Table 3: Distribution of the study group according to severity of diabetic retinopathy

DiabeticRetinopathy	Left eye		Right eye	
	Baselinen (%)	Follow upn (%)	Baselinen (%)	Follow upn (%)
Mild NPDR	44 (76.0)	77 (77.0)	55(55.0)	87 (87.0)
Moderate NPDR	42 (42.0)	22 (22.0)	35 (35.0)	13 (13.0)
Severe NPDR	14 (14.0)	1 (1.0)	10 (10.0)	0
Total	100 (100)	100 (100)	100 (100)	100 (100)

Left eye: x2 Value=26.517,DF=2, p value, sig=0.000, Sig
Right eye: x2 Value=28.871,DF=2, p value, sig=0.000, Sig

Severe non-progressive diabetic retinopathy was present in 14.0% of the cases in left eye during baseline and 1.0% during follow up. In the right eye, 10.0% had NPDR during baseline and no cases during follow up. This difference was statistically significant in both right and left eyes.

Table 4: Distribution of the study group according to lipid parameters

Mean ± SD	Baseline	Follow up	T value	P value, Sig.
Total Cholesterol	154.0 ± 32.2	139.3 ± 22.4	6.42	0.000, Sig.
Triglycerides	178.0 ± 30.9	155.6± 23.7	12.21	0.000, Sig.
LDL Cholesterol	95.4 ± 26.9	59.8± 16.5	16.293	0.000, Sig.

The mean total cholesterol at the baseline was 154.0 mg /đl and 139.3% during the follow up. This difference was statistically significant. The mean triglycerides and LDL cholesterol levels also significantly decreased between baseline and during follow up.

DISCUSSION

This study was mainly undertaken to study the effect of statin use on status of diabetic retinopathy / diabetic macular edema. Diabetic retinopathy happens to be the most commonly occurring microvascular complication of diabetes mellitus resulting mainly due to hyperglycaemia, glucose related hyperosmolarity. This study had shown that, majority of the cases were aged more than 60 years and were males. The mean duration of the diabetes mellitus was 15.9 years.

The visual acuity in this study was improved as per Logmar vision. In a study by Shi *et al*., there no significant difference in worsening of vision acuity between the lipid lowering drugs and the placebo groups." In a study by Sen*et al*., VA improved in four patients using simvastatin, and worsening of VA occurred in seven patients in the placebo group." The CSME was present in 10.0% of the left eye and 13.0% of the right eye of the patients. In a study by Kang *et al*., in the statin group macular edema was significantly lower than the no statin group. 2 In a study by Chung *et al*., macular edema was present in 23% of the statin group and 18% of the no statin group had diabetic macular edema[13].

The use of statins on the patients have significantly reduced the severity of diabetic retinopathy in both left and right eyes in this study. A study by Shi *et al*. had shown that, the lipid lowering drugs were associated with reduced risk in DR progression. In a study by Chung *et al*., the number of moderate NPDR cases were higher in statin and no statin

Group. * Al - Janabi*et al*. reported that, simvastatin 20 mg delayed the progression of DR compared with placebo treated controls[14].

The lipid profile of the patients had shown significant decrease in Total cholesterol, Triglycerides and LDL cholesterol levels after use of statins. Sen*et al*. and Chung *et al*. had also reported similar results[11, 13].

Conclusion

This study had shown significant improvement in visual acuity, decrease in macular edema and progression of diabetic retinopathy. The statins were effective in reduction of total cholesterol, LDL cholesterol and triglycerides.

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