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The effect of lipid lowering with atorvastatin and rosuvastatin in diabetic dyslipidaemic patients and assessment of cognitive impairment using AMTS scale

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Abstract
Background: The study aimed to compare the effect of lipid lowering with Atorvastatin and Rosuvastatin in diabetic dyslipidaemic patients and the assessment of cognitive impairment using AMTS scale.
Meterial and Methods: The study was conducted in a hospital at Elayampalayam for 6 months period in patients with Diabetic Dyslipidemia and having Atorvastatin or Rosuvastatin from 6 months to 3 years were included in the study. The data obtained was introduced to compare the most effective lipid lowering statin and to assess the cognitive impairment induced by both statins. To determine the significant difference between the reduction of lipid parameters, statistical test (Student t test) was introduced.
Results: A total of 86 patients were included in the study in which 62.8% accounts for males and 37.2% accounts for females, and most of the patients were in the age group of 61–70 years. Greater percentage reduction of TC, TG and LDL-C level was seen in 3 years history patients and it was found to be 25.01%, 29.6%, 38.5% with Rosuvastatin and 22.7%, 25.6%, 36.6% with Atorvastatin**.** In the total study population it was found to be 23.4%, 25.4%, 34.2% with Rosuvastatin and 19.8%, 20.1%, 30.6% with Atorvastatin**.** Rosuvastatin showed only 27.9% moderate impairment and no severe impairment but Atorvastatin showed 58.1% moderate impairment and 6.9% severe impairment in Diabetic Dyslipidaemic patients**.**
Conclusion: Rosuvastatin was found to be more effective in Diabetic Dyslipidaemic patients and showed only a less Cognitive impairment than Atorvastatin.

Keywords: Diabetic Dyslipidaemia, Atorvastatin, Rosuvastatin, Cognitive Impairment

1. Introduction
Dyslipidemia contributes to a major impairment to quality of life and an increase in cardiovascular mortality among diabetic patients [1, 2]. Diabetic dyslipidemia may cause marked elevation in VLDLs and low levels of HDL-C. Defects in insulin action and hyperglycemia are the major reasons of dyslipidemia in patients with diabetes. In the case of T2DM, the obesity/insulin-resistant state is the basis of development of this disease and can lead to lipid abnormalities independently of hyperglycemia [3, 4].
HMG-CoA reductase inhibitors or statins are the most widely used lipid-lowering medications and the first choice for the treatment of diabetic dyslipidemia [5, 6]. Like all drugs, some adverse effects cannot be identified in clinical trials but later become evident after use in large patient populations. Cholesterol is a key component of myelin and it is an integral part in controlling myelin membrane permeability and fluidity. Treatment with statins will thereby reduce de novo cholesterol synthesis and interfere with myelin formation. Impaired myelination may lead to neural conduction defects and cognitive impairment [7].
This study will provide more information regarding the safety and efficacy of statins inorder to decrease the cardiovascular mortality among diabetic dyslipidaemic patients and the importance of monitoring cognitive status in these statin consuming patients. So it's an attempt to improve quality of statin drug treatment among diabetic dyslipidaemic population.

2. Materials and Method
2.1 Study design
A Comparative Observational Study was conducted in General Medicine and Cardiology Department at Vivekanandha Medical Care Hospital, Elayampalayam, Tiruchengode. The study was carried out for 6 months (January 2016 – June 2016). The proposal was approved by Institutional Ethical Committee (IEC) and obtained informed consent from the selected patients

2.2 Study Population
Out of 153 patients interviewed, 86 were included in the study population based on inclusion and exclusion criteria. Both male and female patients (20–70 years old) having both diabetes and dyslipidaemia with atleast 6 months history of statin therapy are included in the study. Patients already having brain related diseases, greater than 70 years old, uncontrolled DM, history of diabetic dyslipidaemia ≥ 4 years was excluded from the study.

2.3 Study visits and follow up
In our study, lipid profile test values are monitored. It includes Low Density Lipoprotein (LDL), High Density Lipoprotein (HDL), Triglycerides (TG), and Total Cholesterol (TC). We are taking patients with history of 6 months, 1 year, 2 years and 3 years diabetic dyslipidemics with Atorvastatin (10mg) or Rosuvastatin (10mg). Then we are comparing the baseline values with the endpoint and identifying the most effective

statin for the treatment of diabetic dyslipidemic patients. Cognitive impairment was assessed using AMTS scale which is a 10-item scale derived to assesses orientation, registration, recall and concentration. Scores of 4 - 6 indicates moderate impairment and less than 3 shows severe impairment.

2.4 Statistical analysis

Student t test was used to analyze the statistical difference between two groups. Results were expressed as Mean ± SD. P < 0.05 was considered significant.

3. Results and Discussion

The study includes 86 patients with Diabetic Dyslipidaemia in which 62.8% accounts for males and 37.2% accounts for females, and most of the patients were in the age group of 61–70 years. Percentage reduction of TC, TG, LDL-C level in 6 months history patients was found to be 21.09%, 23.1%, 23.8% with Rosuvastatin and 17.6%, 16.8%, 20.7% with Atorvastatin**.** Percentage reduction of TC, TG and LDL-C level in 1 year history patients was found to be 20.4%, 20.1%, 31.7% with Rosuvastatin and 16.5%, 15.9%, 30.2% with Atorvastatin. (Table 1&2)

Table 1: Reduction of lipid parameters in different history of Rosuvastatin therapy Diabetic Dyslipidaemic patients (n = 43)

History of statin therapy	Baseline			End point		
	TC	TG	LDL-C	TC	TG	LDL-C
6 months (n = 8)	360 ± 41.7	315.7 ± 26.1	254 ± 50.5	285 ± 51.1$^{***\ \#}$	243 ± 26.9$^{***\ \#\#}$	193.7 ± 39.5$^{**\ \#}$
1 year (n = 8)	336 ± 48.8	376.1 ± 79.4	188.3 ± 23.4	267.8 ± 44.3$^{****\ \#}$	302.6 ± 81.4$^{****\ \#}$	129.9 ± 26.8$^{****\ ns}$
2 years (n = 10)	297.4 ± 48.1	313.6 ± 83.6	220.7 ± 53.9	225.8 ± 40.3 $^{****\ \#}$	242.3 ± 80.9$^{****\ \#}$	149.6 ± 52.5$^{****\ \#}$
3 years (n = 17)	275.4 ± 39.5	225.2 ± 35.6	191.6 ± 38.1	207.1 ± 37.02$^{****\ \#}$	159.7 ± 34.6 $^{****\ \#}$	118.5 ± 22.8$^{****\ \#}$

**** P< 0.0001, ***P=0.0001-0.001, **P=0.001-0.01 Basevalue Vs End point of Rosuvastatin.

Table 2: Reduction of lipid parameters in different history of Atorvastatin therapy Diabetic Dyslipidaemic patients (n = 43)

History of statin therapy	Baseline			End point		
	TC	TG	LDL-C	TC	TG	LDL-C
6 months(n = 8)	242.4± 45.5	179± 23.0	164.3± 38.4	201.3± 51.2****	151.5± 34.8***	130.6± 37.5***
1 year(n = 8)	257.8± 48.2	249.5± 142.6	160.1± 60.3	217.3± 55.4****	206.6± 105.4*	120.0± 55.1****
2 years(n = 10)	229.1± 32.1	204.2± 26.7	150.8± 24.6	187.4± 40.2****	171.7± 31.5****	106.5± 29.8****
3 years(n = 17)	222.8± 43.5	169.7± 50.5	144.2± 43.6	172.9± 46.5****	128.2± 54.7****	94.2± 42.8****

**** P < 0.0001, *** P = 0.0001 – 0.001, * P = 0.01 – 0.05 Baseline Vs Endpoint of atorvastatin

In patients with different history of Atorvastatin therapy, 3 year history patients showed 30.2% and 6.9% moderate and severe impairment. But in patients with Rosuvastatin therapy, 3 year history patients showed 13.9% moderate impairment and none of them showed severe impairment**.** Among the two statins Atorvastatin showed 58.1% moderate impairment and 6.9% severe impairment in Diabetic Dyslipidaemic patients and Rosuvastatin showed only 27.9% moderate impairment and no severe impairment in Diabetic Dyslipidaemic patients**.** (Table 3)

Table 3: Percentage comparison of AMTS scale score based on history of statin therapy in study population (N = 86)

History of statin therapy	Atorvastatin (%)			Rosuvastatin (%)		
	Normal	Moderate	Severe	Normal	Moderate	Severe
6 months	16.3	2.3	-	6.9	-	-
1 year	11.6	6.9	-	20.9	2.3	-
2 year	4.7	18.6	-	16.2	11.6	-
3 year	2.3	30.2	6.9	27.9	13.9	-

The present study was consistent with the study carried out by Abdulbari Bener *et al*. their study states that Rosuvastatin (10mg) was the most effective statin in reducing TC, TG and LDL in Diabetic Dyslipidaemic patients. And also consistent with the study carried out by Frances M Sahebzamani *et al*., and their reports states that lipophilic statin such as atorvastatin can cause greater proportion of cognitive impairment as compared to other less potent or less lipophilic statin.

4. Conclusion

Rosuvastatin more effectively reduces TC, TG and LDL-C as compared to Atorvastatin. Among this, Rosuvastatin shows greater reduction in 3 years history Diabetic Dyslipidaemic patients. Atorvastatin shows a greater percentage of moderate and severe cognitive impairment in Diabetic Dyslipidaemic patients as compared to Rosuvastatin.

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