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IMPACT OF CLINICAL PHARMACIST MEDIATED PATIENT COUNSELING IN DYS-LIPIDEMIA PATIENTS BY USING LIPID LOWERING AGENTS

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ABSTRACT: **Aim:** To estimate the impact of clinical pharmacist mediated patient counseling in dyslipidemia patients in RIMS hospital, Kadapa. **Objectives:** To conduct a randomized study on patients. To categorize patients on demographic basis, comorbidities. To compare the lipid levels based on 20 mg and 40 mg doses of atorvastatin, the outcome based on lipid profile. **Methodology:** It is a prospective observational, comparative type of study. Conducted in the department of general medicine, Rajiv Gandhi institute of medical sciences at Kadapa with a period of Six months (July 2018 to December 2018), and the sample size was 72 subjects. **Results:** A total of 72 patients were included in the study 86.11% were male, and 13.88% were female. Average age was found to be 57.11 years. Average BMI of males is 25.4 and females is 27.17. 36 patients included in group A (statin therapy) and 36 patients included in group B (statin + patient counseling). The P value of lipid levels in group A, and group B with two different doses of atorvastatin was found to be 0.7439. Baseline average lipids of both groups compared with follow up final average lipid levels, and the P-value was found to be 0.2427. **Conclusion:** The findings in our study conclude that males are having a high risk of dyslipidemia, commonly obtained comorbidity is HTN, and there is no significant difference between the patients of group A and B.

INTRODUCTION: Dyslipidemia can be defined as elevated total cholesterol, LDL-C, or triglycerides level, low HDL-C concentration, or some combination of these abnormalities. Hyper-lipoproteinemia refers to an increased concentration of the lipoprotein macromolecules that transport lipids in the plasma.

Abnormalities of plasma lipids can result in a predisposition to coronary, cerebrovascular, and peripheral vascular arterial disease^{1, 2}. Based on etiology it is classified into two types; Primary dyslipidemia: Up to 60% of the cholesterol variability may be genetically determined and is often influenced by interaction with environmental factors.

And Secondary dyslipidemia: that occur secondary to a number of disorders, dietary discretion, or as a side effect of drug therapy accounts for up to 40% of all dyslipidemias³. Statins are the most effective agents for treating dyslipidemia. Statins exhibit an effect by reduction of LDL levels through a

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mevalonic acid-like moiety that competitively inhibits HMG-CoA reductase. By reducing the conversion of HMG-CoA to mevalonate, statins inhibit an early and rate-limiting step in cholesterol biosynthesis. Statins affect blood cholesterol levels by inhibiting hepatic cholesterol synthesis⁴.

Patient counseling is the process of providing information, advice, and assistance to help patients use their medications appropriately. The information and advice is given by the pharmacist directly to the patient or patient's representative and may also include information about the patient's illness or recommended lifestyle changes. The information is provided verbally and or maybe supplemented with written material. There are four steps in patient counseling include Preparing for the session, Opening the session, Counseling content, closing the session⁵.

Aim and Objectives: The aim of the study is to estimate the impact of clinical pharmacist-mediated patient counseling in dyslipidemia patients.

Objectives:

The key objectives of the study include;

- To conduct a randomized study on patients.
- To categorize patients on a demographic basis [Age, BMI, Gender].
- To categorize patients based on comorbidities.
- To compare the lipid levels based on 20 mg and 40 mg doses of atorvastatin.
- To compare the outcome based on lipid profile.

MATERIALS AND METHODS:

Study Design: A prospective observational, comparative type of study.

Study Area: Study Conducted in the department of general medicine, Rajiv Gandhi institute of medical sciences, Kadapa.

Study Period: Six months (July 2018 to December 2018)

Sample Size: 72 subjects.

Source of Data:

- Patient case sheet.
- Patient prescriptions.
- Subjects included in the study

Inclusion Criteria: All adult patient of either sex with dyslipidemia patient with other comorbidities.

Exclusion Criteria:

- Pregnant women, lactating women and pediatrics.
- Patients with impaired liver function.
- Patients with ALD, involved with immune suppressant therapy.
- Patient intolerant or allergic to atorvastatin.
- Patients who dropout are excluded from the study.

Statistical Analysis: Microsoft excel spread sheet was used to record the data of recruited subjects. In the excel spreadsheet we calculated simple statistics like mean, percentage standard deviation for patient demographics (age, BMI, gender), and comorbidities. Two-way ANOVA techniques were used to calculate P-value to compare the difference between two groups with two different doses of atorvastatin and to compare the difference in lipid levels between two groups from baseline to follow up by using graph pad prism version 8.0.

Institutional Ethical Committee: Ethical committee approval was taken before initiating the study under Re. No.3298 / Acad. / 2018. Informed written consent & assent obtained after explaining the risks, benefits of the study from participants.

Results: Among the 72 subjects, males are 62 (86.11%) and females are 10 (13.88%). The majority of them belonged to the age group of 60–70(31.94%) years, followed by the age group of 50–60 years (30.55%), 40–50 years (19.44%), 30–40 years (9.72%). The average age of the subjects was 57.11. Average BMI of subjects was males (25.4) and females (27.17).

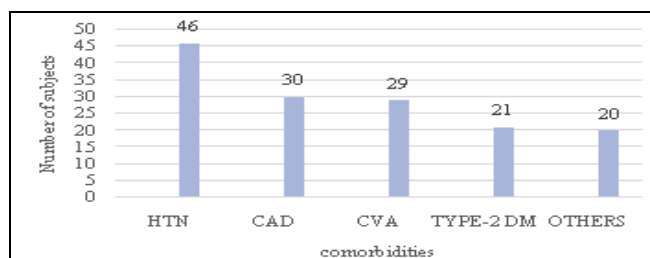


FIG. 1: DIFFERENTIATION OF DYSLIPIDEMIA SUBJECTS ACCORDING TO COMORBIDITIES

Fig. 1 shows Hypertension (46) was the most common comorbidity observed, followed by CAD (30), CVA (29), Type II DM (21), and other diseases (20).

Comparison of Lipid Levels Among Group A & B with Two Different doses of Atorvastatin: All the subjects were divided into two equal groups in which each group comprises of 36 members. Group A (statin), Group B (statin +patient counseling).

Both groups were given two different doses of atorvastatin 20 mg and 40 mg, respectively. We calculated the difference in average lipid levels with the two different doses, but there was no

significant difference in the decrease of lipid levels with a p-value of 0.7439 **Table 1**.

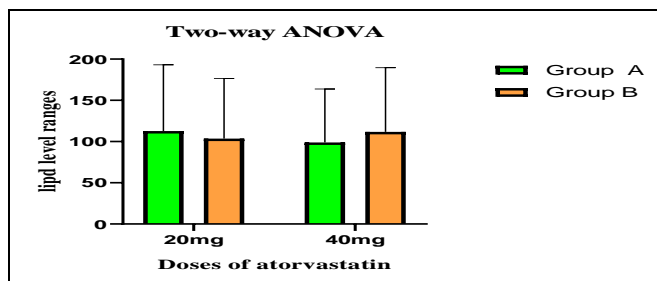


FIG. 2: P -VALUE ESTIMATION COMPARISON OF LIPID LEVELS AMONG GROUP A & B WITH TWO DIFFERENT DOSES OF ATORVASTATIN Probability of lipid levels were calculated by using graph pad prism version A.(P-Value is 0.7439.)

TABLE 1: COMPARISON OF LIPID LEVELS AMONG GROUP A & B WITH TWO DIFFERENT DOSES OF ATORVASTATIN

	Dose	Male	Female	Total	Lipid levels					P-value
					HDL	LDL	VLDL	TG	TC	
Group A (STATIN)	20 mg	13	0	13	40.38	101.69	31.69	182.23	207.69	0.7439
	40 mg	19	4	23	43.73	86.56	32	156	175.95	
Group B (Statin +Patient Counseling)	20 mg	12	1	13	39.615	91.769	30.153	163.07	193.38	
	40 mg	18	5	23	44.173	99.556	36.965	157.95	220.17	

Comparison of BMI and Lipid Levels Among Group A & B from Base Line To Final Follow Up: **Table 2** shows baseline lipid levels of all subjects present in both groups (Group A and Group B) are compared to the lipid level ranges

after final follow up (6 months) and calculated the difference in average lipid levels of both groups, but there was no significant difference in the decrease of lipid levels with a p-value of 0.2427 **Table 2**.

TABLE 2: COMPARISON OF BMI AND LIPID LEVELS AMONG GROUP A&B FROM BASELINE TO FINAL FOLLOW UP

Group	BMI Avg. + SD	BASELINE					FOLLOW UP					P-Value
		HDL	LDL	VLDL	TG	TC	HDL	LDL	VLDL	TG	TC	
Group A (statins)	25.43 ±3.21	42.52 ±8.2	92.02 ±30.59	31.88 ±12.71	165.47 ±64.49	187.41 ±54.66	40.69 ±6.97	102.36 ±29.15	33.19 ±9.59	163.58 ±50.43	193.02 ±51.31	0.2427
Group B (Statin+patient counseling)	25.0 ±3.34	42.52 ±6.59	96.74 ±32.56	34.5 ±13.96	167.9 ±66.1	204.3 ±69.53	42.72 ±5.28	100.4 ±18.98	29.58 ±9.73	153.3 ±35.79	189.97 ±46.66	

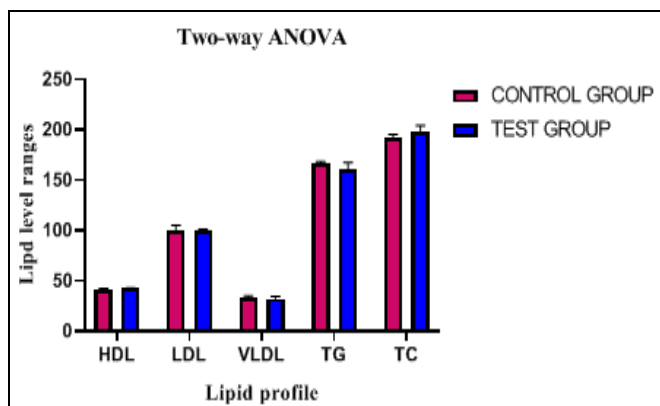


FIG. 3: OUTCOMES BASED ON FINAL LIPID LEVELS By using two way ANOVA in prism 8 software, P-Value is calculated (P-Value is 0.2427)

DISCUSSION: In our study, more number of males was affected with dyslipidemia when compared with females. The most affected age group is 60-70 years which was similar to the study done by Anil Babu A, Rani S, et al. Where the number of patients having hyperlipidemia is more in male population than in female population⁵. In our study, the baseline BMI was found to be 25.53 in group A and 25.76 in group B, and after the second follow up the BMI levels was found to be 25.43 in group A and 25.0 in group B.

The results were related to Jean Ferrières et al, BMI seems to have a direct influence on the

decision of statin⁷. In our study, we evaluated the effect of 20 mg and 40 mg dose of atorvastatin in subjects with proportionate changes in lipid levels among subjects, but there was no significant association between atorvastatin dose and reduction in lipid level changes likely to the previous study done by Hashem M. Mansour *et al.*, in which their study results revealed that there is no significant difference between high and low dose of atorvastatin⁸. Most of the patients have a comorbidity of HTN, followed by CAD, CVA, TYPE 2 DM, others. The results were similar to the study done by Juhwan Noh *et al.*, in which their study showed hypertension patients had a 1.51 times higher occurrence of dyslipidemia than an adult with normal BP⁹.

CONCLUSION: The present study concluded that more male patients were affected with dyslipidemia when compared with females. Commonly identified comorbidity along with dyslipidemia was HTN. There was no significant difference in the decrease of lipid levels in patients treated either with 20 mg or 40 mg of atorvastatin. There is no significant difference in patients who are exclusively using drugs or drugs along with patient counseling. Further, long-term studies on large populations are to be performed in patients with dyslipidemia to assess the effect of patient counseling.

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