Journal of Cardiovascular Disease Research
ISSN: 0975-3583, 0976-2833 VOL13, ISSUE 08, 2022

ASSESSING THE LIPID PROFILE AND EFFECT OF THE THERAPEUTIC INTERVENTION IN SUBJECTS WITH DIABETES: A CLINICAL STUDY

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Conflict of Interest: None
Type of study: Original Research Paper
Date of submission: 22 November 2022
Date of acceptance: 30 November 2022
Date of publication: 15 December 2022

ABSTRACT

Background: Most common metabolic disorder affecting the human population is diabetes mellitus with increasing prevalence globally including in India. Various cardiovascular complications and lipid disorders have been found to have an association with diabetes mellitus.

Aim: The present clinical study was conducted to assess the lipid profile and effect of the therapeutic intervention in subjects with diabetes mellitus.

Materials and Methods: The present case-control clinical study included 120 subjects having diabetes mellitus and 12 subjects as controls well-matched for gender and age. In fasting blood samples of study subjects, HDL Cholesterol (HDL-C), LDL Cholesterol (LDL-C), Triglycerides (TG), and Total Cholesterol (TC) levels were assessed using a spectrophotometer by liquid chemistry, and results were assessed.

Results: The study results showed that total cholesterol, triglycerides, and LDL cholesterol levels were higher in subjects in a study group with cases compared to the controls. Also, a significant correlation was seen in fasting blood sugar (FBS) and LDL-cholesterol, triglycerides, and total cholesterol in subjects with type-2 diabetes mellitus, and no correlation in Type-2 diabetes mellitus and HDL levels.

Conclusion: The present study concludes that increased levels of LDL cholesterol, triglycerides, and total cholesterol lead to higher blood glucose levels in subjects with diabetes mellitus, and no correlation exists between HDL levels and type-2 diabetes mellitus.

Keywords: Cholesterol, Diabetes mellitus, diet, lipid profile, triglycerides

INTRODUCTION

The most common metabolic disorder seen globally is Diabetes mellitus (DM). Diabetes mellitus also pose a high burden on the healthcare sector in India. Although diabetes mellitus is a disorder known since ancient times, it's only in the recent past that attempts have been made via newer research to reduce mortality and morbidity associated with Diabetes Mellitus. With a high increase in the prevalence of diabetes mellitus, it is still considered that one undiagnosed diabetes case exists for each diagnosed case. Various complications are associated with diabetes mellitus, however, one of the major fatal diabetes complications is diabetic ketoacidosis, the incidence of which has drastically reduced after the discovery of Insulin. The presence of chronic hyperglycemia in diabetics can affect various organs in long-term concerning disturbance, dysfunction, and damage including blood vessels, heart, nerves, kidneys, and eyes.[1]

Increased cardiovascular disease risk in subjects of diabetes mellitus is reported and correlated with dyslipidemia and atherogenic abnormalities. Myocardial infarction, one of the coronary artery diseases, is the main cause of mortality and morbidity globally along with atherosclerosis and hyperglycemia as being related in subjects with type-2 diabetes mellitus. As of 2014 data, nearly 422 million adults have diabetes mellitus compared to 1980 data where only 108 million subjects were reported to have diabetes mellitus. The age-standardized global prevalence for diabetes mellitus has doubled from 1980 from nearly 4.7% to 8.5% in the adult subjects with the most strongly associated risk factors being obesity and overweight.[2] In the recent past, compared to the high-income countries, the prevalence of diabetes mellitus has markedly increased in low and middle-income countries like India.[2]

Cholesterol and Fatty acid triglycerides constitute the blood lipids. High blood cholesterol is usually reflected by high levels of triglycerides. There are various types of cholesterols which are alcoholic steroids with advantages of fat including HDL (high-density lipoprotein) also known as good cholesterol and LDL (low-density lipoprotein) known as bad cholesterol. In assessing the total blood cholesterol being protective or harming, determining the total cholesterol proportion to high-density lipoprotein is a vital determining factor for human health.[3]

Various cardiovascular complications and lipid disorders have been found to have an association with diabetes mellitus. Hence, maintaining balanced levels of lipids and cholesterol in subjects with diabetes mellitus is vital to prevent cardiovascular diseases. Subjects with diabetes mellitus are usually managed with either diet modification alone or diet modification combined with glucose-lowering drugs or insulin with lifestyle modifications. Despite the availability of various drugs and insulin for maintaining blood glucose levels, diet modification has shown promising results in maintaining glycemic control in subjects with diabetes mellitus. This nutrition and diet therapy can lead to delayed progression of diabetic complications.[4]

The present clinical study was conducted to assess the lipid profile, fat status, and biochemical changes along with the effect of the therapeutic nutritional intervention in subjects with diabetes mellitus.

MATERIALS AND METHODS

The present case-control clinical study was conducted to assess the lipid profile, fat status, and biochemical changes along with the effect of the therapeutic nutritional intervention in subjects with diabetes mellitus. The study was conducted at Department Biochemistry, Darbhanga Medical College and Hospital, Darbhanga, Bihar

The study population was comprised of the subjects visiting the Outpatient Department of the Institute.

The study screened 200 subjects with diabetes mellitus visiting the institute. The inclusion criteria for the study were subjects with a confirmed diagnosis of diabetes mellitus, diabetes managed with diet and lifestyle modifications, oral hypoglycemic drugs, and an impaired glucose tolerance test. The exclusion criteria for the study were subjects on drugs affecting lipid profile, corticosteroids, life-threatening drugs, nephropathy, vascular diseases, angina history, medications for hypertension or cardiovascular diseases, and subjects on insulin for diabetes control. After explaining the detailed study design, informed consent was taken from all the subjects in both written and verbal form.

After final inclusion of the study subjects based on inclusion and exclusion criteria, they were divided into 4 groups based on the diabetes duration where Group I had subjects of diabetes duration of 1-2 years, Group II of 2-4 years, Group III of 4-6 years, and Group IV of 6-8 years. For all the subjects, detailed history was recorded followed by a general examination. The variables assessed were familial history including diabetes, menstrual history, smoking history, exercise status, nutrition status, eating habits, personal history, gender, and age.

Serum glucose estimation for study subjects was estimated using the Lopez method,[5] LDL-Cholesterol by Fried Wald's Formula, HDL-Cholesterol by Watson method,[6,] and total cholesterol determination by Watson method.[7]

The collected data were subjected to the statistical evaluation using SPSS software version 21 (Chicago, IL, USA) and one-way ANOVA and t-test for results formulation. The data were expressed in percentage and number, and mean and standard deviation. The level of significance was kept at $p<0.05$.

RESULTS

The present case-control clinical study was conducted to assess the lipid profile, fat status, and biochemical changes along with the effect of the therapeutic nutritional intervention in subjects with diabetes mellitus. The present case-control clinical study included 120 subjects having diabetes mellitus and 12 subjects as controls well-matched for gender and age. In fasting blood samples of study subjects, HDL Cholesterol (HDL-C), LDL Cholesterol (LDL-C), Triglycerides (TG), and Total Cholesterol (TC) levels were assessed using a spectrophotometer by liquid chemistry were assessed. LDL in the study group was 130.2±18.2 which was significantly higher in the study group compared to the control group where LDL was 95.5±14.2 mg/dl with $p<0.01$. For HDL, the values were higher in controls with 61.2±20.4mg/dl compared to the study group with 59.7±14.6mg/dl. This was statistically non-significant with $p=.68$. Triglycerides and total cholesterol levels were 181.4±31.5 and 230.3±20.4mg/dl in the study group which were significantly higher compared to controls with 133.4±11.5 and 160.2±13.3mg/dl with a p-value of <.001. Fasting

blood glucose in the study group was also significantly higher in the study group of 233.4±16.2mg/dl compared to controls with 100.3±10.2 mg/dl with p<0.001 (Table 1).

On assessing and comparing the lipid variables and fasting blood glucose values in the test group before and after the intervention, it was seen that baseline FBS was 190.06±53.23mg/dl which after 2-week intervention decreased significantly to 109.82±38.71mg/dl (p=0.001) which further reduced significantly at 3 weeks to 52.32±22.07 mg/dl (p=0.000). However, at 4 weeks it showed a non-significance increase to 134.44±50.26 mg/dl (p=0.07). Total cholesterol value at baseline was 240.51±83.05mg/dl which reduced non-significantly to 219.44±61.77 (p=0.355) at week 2 following the intervention, to 196.36±53.04 at week 3 (p=0.108), and to 200.32±41.13 at week 4 (p=0.151). At baseline, triglycerides were 179.32±75.27mg/dl which reduced significantly at week 2, 4 to 92.02±32.36 and 114.67±54.51 with respective p-values of 0.003 and 0.004 (Table 2). For the control group, all these parameters showed a non-significant change from baseline to weeks 2, 3, and 4 for FBS, total cholesterol, and triglycerides (Table 2).

Concerning fasting blood glucose, at baseline statistically significant difference was seen between the experimental and control group with respective values of 190.06±53.23 and 106.82±31.36mg/dl (p=0.005). This difference at weeks 2 and 3 was also statistically significant between the experimental and control group with p=-.005 and 0.000 respectively. At week 4, FBS was higher in controls compared to the experimental group. However, the difference was statistically non-significant with p=0.705. Total cholesterol values were the statistically non-significant difference in the experiment and control group at baseline, week 2, 3, and 4 with respective p-values of 0.666, 0.426, 0.856, and 0.785. For triglycerides, values were the statistically non-significant difference in experiment and control group at baseline, week 2, 3, and 4 with p-values of 0.85, 0.13, 0.19, and 0.35 respectively (Table 3).

DISCUSSION

The present case-control clinical study was conducted to assess the lipid profile, fat status, and biochemical changes along with the effect of the therapeutic nutritional intervention in subjects with diabetes mellitus. LDL in the study group was 130.2±18.2 which was significantly higher in the study group compared to the control group where LDL was 95.5±14.2 mg/dl with p<0.01. For HDL, the values were higher in controls with 61.2±20.4mg/dl compared to the study group with 59.7±14.6mg/dl. This was statistically non-significant with p=.68. Triglycerides and total cholesterol levels were 181.4±31.5 and 230.3±20.4mg/dl in the study group which were significantly higher compared to controls with 133.4±11.5 and 160.2±13.3mg/dl with a p-value of <.001. Fasting blood glucose in the study group was also significantly higher in the study group of 233.4±16.2mg/dl compared to controls with 100.3±10.2 mg/dl with p<0.001. These results were consistent with the findings of Di Tocco A et al[8] in 2018 and Tiwari U et al[9] in 2011 where authors reported similar triglycerides, total cholesterol, and lipid parameters levels in their study.

Concerning the assessment and comparison of the lipid variables and fasting blood glucose values in the test group before and after the intervention, it was seen that baseline FBS was 190.06±53.23mg/dl which after 2-week intervention decreased significantly to

109.82±38.71mg/dl (p=0.001) which further reduced significantly at 3 weeks to 52.32±22.07 mg/dl (p=0.000). However, at 4 weeks it showed a non-significance increase to 134.44±50.26 mg/dl (p=0.07). Total cholesterol value at baseline was 240.51±83.05mg/dl which reduced non-significantly to 219.44±61.77 (p=0.355) at week 2 following the intervention, to 196.36±53.04 at week 3 (p=0.108), and to 200.32±41.13 at week 4 (p=0.151). At baseline, triglycerides were 179.32±75.27mg/dl which reduced significantly at week 2, 4 to 92.02±32.36 and 114.67±54.51 with respective p-values of 0.003 and 0.004. For the control group, all these parameters showed a non-significant change from baseline to week 2, 3, and 4 for FBS, total cholesterol, and triglycerides. These results were in agreement with the studies of Ho HV et al[10] in 2016 and Bhagyashree B et al[11] in 2017 where authors also depicted significant reduction following intervention in lipid parameters in their data.

On assessing the fasting blood glucose, at baseline statistically significant difference was seen between the experimental and control group with respective values of 190.06±53.23 and 106.82±31.36mg/dl (p=0.005). This difference at weeks 2 and 3 was also statistically significant between the experimental and control group with p=-.005 and 0.000 respectively. At week 4, FBS was higher in controls compared to the experimental group. However, the difference was statistically non-significant with p=0.705. Total cholesterol values were the statistically non-significant difference in the experiment and control group at baseline, week 2, 3, and 4 with respective p-values of 0.666, 0.426, 0.856, and 0.785. For triglycerides, values were the statistically non-significant difference in experiment and control group at baseline, week 2, 3, and 4 with p-values of 0.85, 0.13, 0.19, and 0.35 respectively. These results were comparable to the results of Arokiraj S[12] in 2016 and Holleander EL et al[13] in 2015 where subjects with diabetes showed significant improvement in various parameters after the intervention.

CONCLUSION

Within its limitations, the present study concludes that increased levels of LDL cholesterol, triglycerides, and total cholesterol lead to higher blood glucose levels in subjects with diabetes mellitus, and no correlation exists between HDL levels and type-2 diabetes mellitus. Diet therapy also has a protective and positive role in subjects with diabetes mellitus.

REFERENCES

1. American Diabetes Association. Diabetic retinopathy (Position Statement), Diabetes Care., 2014;27:584.
2. World Health Organization. Diabetic nephropathy (Position Statement), Diabetes Care, 2005;27:579.
3. International Diabetic Federation. (2019) IDF MENA Members. https://www.idf.org/our-network/regions-members/middle-east-andnorth-africa/members/50-yemen.htmi
4. Wang Q, Xia W, Zhao Z, et al. Effects comparison between low glycemic index diets and high glycemic index diets on HbA1c and fructosamine for patients with diabetes: A systematic review and meta-analysis. Prim Care Diabetes, 2015;9:362–9.

5. Lopez, Joseph. "Carl A. Burtis, Edward R. Ashwood and David E. Bruns (eds): Tietz Textbook of Clinical Chemistry and Molecular Diagnosis." 2013; 104.
6. Assmann G, Jabs HU, Kohnert U, Nolte W, Schriewer H. LDL-cholesterol determination in blood serum following precipitation of LDL with polyvinyl sulfate. Clinica Chimica Acta, Jun 27, 1984;140:77-83.
7. Aggarwal V, Malik J, Prashant A, Jaiwal PK, Pundir CS. Amperometric determination of serum total cholesterol with nanoparticles of cholesterol esterase and cholesterol oxidase. Analytical Biochemistry, May 1, 2016;500:6-11.
8. Di Tocco A, Robledo SN, Osuna Y, Sandoval-Cortez J, Granero AM, Vettorazzi NR. Development of an electrochemical biosensor for the determination of triglycerides in serum samples based on a lipase/magnetite-chitosan/copper oxide nanoparticles/multiwalled carbon nanotubes/pectin composite. Talanta. Dec 1, 2018; 190: 30-7.
9. Tiwari U, Cummins E. Meta-analysis of the effect of beta-glucan intake on blood cholesterol and glucose levels. Nutrition, 2011;27:1008–16.
10. Ho HV, Sievenpiper JL, Zurbau A, et al. A systematic review and meta-analysis of randomized controlled trials of the effect of barley beta-glucan on LDL-C, non-HDL-C, and apoB for cardiovascular disease risk reduction i-iv. Eur J Clin Nutr, 2016;70:1239–45.
11. Bhuyar Bhagyashree. Lipid profile in Diabetes Mellitus. International Journal of Biotechnology and Biochemistry, 2017;13:123131.
12. Arokiaraj S. Blood Sugar, Lipid Profile And Their Correlation: A Pilot Study In Puducherry. International journal of applied pure science an agriculture, 2016;142:605-007.
13. Hollænder PL, Ross AB, Kristensen M. Whole-grain and blood lipid changes in apparently healthy adults: A systematic review and meta-analysis of randomized controlled studies. Am J Clin Nutr, 2015;102:556–72.

TABLES

Groups	LDL mg/dl	HDL mg/dl	Triglycerides mg/dl	Total cholesterol mg/dl	Fasting blood glucose mg/dl
Study	130.2±18.2	59.7±14.6	181.4±31.5	230.3±20.4	233.4±16.2
Control	95.5±14.2	61.2±20.4	133.4±11.5	160.2±13.3	100.3±10.2
p-value	<0.01	0.68	<0.001	<0.001	<0.001

Table 1: Comparison of Lipid parameters and blood glucose in study and control groups

Test	Comparison	Mean ± S. D (Test group)	p-value	Mean ± S. D (Control group)	P Value
Fasting blood glucose	**0 week**	190.06±53.23	0.001	106.82±31.36	0.56
	2 weeks	109.82±38.71		180.02±56.34	
	0 week	190.06±53.23	0.000	106.82±31.36	.792
	3 weeks	52.32±22.07		110.82±21.63	
	0 week	190.06±53.23	0.07	106.82±31.36	0.043

	4 weeks	134.44±50.26		144.82±51.39	
Total cholesterol	**0 week**	240.51±83.05	0.355	223.22±45.12	0.617
	2 weeks	219.44±61.77		249.62±89.81	
	0 week	240.51±83.05	0.108	223.22±45.12	0.628
	3 weeks	196.36±53.04		202.02±67.12	
	0 week	240.51±83.05	0.151	223.22±45.12	0.613
	4 weeks	200.32±41.13		206.42±41.90	
Triglycerides	**0 week**	179.32±75.27	0.003	281.62±168.85	0.145
	2 weeks	92.02±32.36		159.82±69.47	
	0 week	179.32±75.27	0.26	281.62±168.85	0.749
	3 weeks	123.48±44.26		264.02±184.67	
	0 week	179.32±75.27	0.004	281.62±168.85	0.08
	4 weeks	114.67±54.51		192.02±87.85	

Table 2: Comparison of Lipid variables and blood glucose in test and control groups of study subjects

Parameter	Group	Mean ± S. D	p-value
Fasting blood glucose 0 week	**Experimental**	190.06±53.23	0.005
	Control	106.82±31.36	
Fasting blood glucose 2 week	**Experimental**	109.82±38.71	0.005
	Control	180.02±56.34	
Fasting blood glucose 3 week	**Experimental**	52.32±22.07	0.000
	Control	110.82±21.63	
Fasting blood glucose 4 week	**Experimental**	134.44±50.26	0.705
	Control	144.82±51.39	
Total cholesterol 0 week	**Experimental**	240.51±83.05	0.666
	Control	223.22±45.12	
Total cholesterol 2 week	**Experimental**	219.44±61.77	0.426
	Control	249.62±89.81	
Total cholesterol 3 week	**Experimental**	196.36±53.04	0.856
	Control	202.02±67.12	
Total cholesterol 4 week	**Experimental**	200.32±41.13	0.785
	Control	206.42±41.90	
Triglycerides 0 week	**Experimental**	179.32±75.27	0.85
	Control	281.62±168.85	
Triglycerides 2 week	**Experimental**	92.02±32.36	0.13
	Control	159.82±69.47	
Triglycerides 3 week	**Experimental**	123.48±44.26	0.19
	Control	264.02±184.67	
Triglycerides 4 week	**Experimental**	114.67±54.51	0.35
	Control	192.02±87.85	

Table 3: Comparison of blood glucose, total cholesterol, and triglycerides in test and control groups of study subjects