

STUDY OF LIPID PROFILE IN DIABETIC PATIENTS AND THE EFFECT OF THERAPEUTIC INTERVENTION

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ABSTRACT

Diabetes mellitus is the most common metabolic disorder affecting the people all over the world. Diabetes mellitus has been known to be associated with lipid disorders and cardiovascular complications. This study is planned to assess the lipaemic changes in diabetes mellitus patients attending the out-patient center of Diabetic in Al-Gumhoria Hospital, Aden, Yemen. Total Cholesterol (TC), Triglycerides (TG), LDL Cholesterol (LDL-C), HDL Cholesterol (HDL-C) levels were studied in serum of diabetes patients. This is a case control study which included 100 patients of diabetes as cases and 10 controls of the same age group and sex. All the samples were taken from subjects who fasted for at least 12 hours before the blood collection. The parameters were determined by manual method using spectrophotometer by liquid chemistry. The Triglycerides, Total cholesterol, LDL Cholesterol were

higher in cases as compared to controls in Type-2 diabetes (T2D). There was significant correlation between FBS and TC, TG and LDL-C in T2D patients in addition to there was no correlation between HDL and T2D.

KEYWORDS: Cholesterol, Diabetes mellitus, Lipid profile, Diet Therapy.

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INTRODUCTION

Diabetes mellitus (DM) is the most common metabolic disorder affecting the people worldwide. Even though diabetes has been known since antiquity, only in the last few decades new discoveries have provided great hopes to minimize morbidity and mortality. It is estimated that for one diagnosed diabetes there is undetected diabetes. The diabetic ketoacidosis was major fatal complication of diabetes has virtually come down with advent of insulin (**American Diabetes Association, 2014**). The chronic hyperglycemia of diabetes is associated with long-term damage, dysfunction and disturbance in failure of various organs, especially the eyes, kidneys, nerves, heart and blood vessels (**World Health Organization, 2005**). Patients with type-2 diabetes have increased risk of cardiovascular disease associated with atherogenic abnormalities and dyslipidemia. Coronary artery disease, especially myocardial infarction is the leading cause of morbidity and mortality worldwide as well as hyperglycemia and atherosclerosis are related in type-2 diabetes (**Vries et al., 2014**). Globally, an estimated 422 million adults were living with diabetes in 2014, compared to 108 million in 1980. The global prevalence (age-standardized) of diabetes has nearly doubled since 1980, rising from 4.7% to 8.5% in the adult population. This reflects an increase in associated risk factors such as being overweight or obese. Over the past decade, diabetes prevalence has risen faster in low and middle-income countries than in high-income countries (**World Health Organization, 2016**). Very few studies had been done in Yemen on diabetes duration and lipid profile in type 2 diabetes mellitus patients of age range of 30-65 years old (**Zaid, 2015**). Blood lipids are mainly (fatty acids Triglycerides and cholesterol). High TG are usually accompanied by high total cholesterol (**Andrew, 2004**). Cholesterol is an alcoholic steroid that has the advantages of fat, there are several types of cholesterol, the most important: low- density lipoprotein (LDL), which is called bad cholesterol, and high-density lipoprotein (HDL), which is called good cholesterol, the proportion of high-density cholesterol to the total number of cholesterol is the decisive factor In determining the seriousness of total cholesterol in the body to human health.

Treatment can be by diet alone or by a diet combined with insulin or an oral glucose-lowering medication plus regulated exercise and the regular monitoring of the client's blood glucose levels (**Reeves et al, 1993**). Diet plays an important role in achieving and maintaining good glycolic control in diabetic patients (**Perez-Diaz et al, 2013**). Nutrition therapy can improve both blood glucose levels is slow the progression of diabetic complication (**Rolfes sharon et al, 2012**).

The Objectives of this study was Study the biochemical changes and fat status of diabetics and know the effect of nutritional intervention on blood sugar and blood lipid.

MATERIAL AND METHODS

This study was conducted in Clinical Nutrition and Dietetics Department of Medical Health College in University of Science and Technology, Aden, Yemen.

One hundred and fifty type 2 diabetic patients were selected from diabetic center, Gommhoria Hospital in Aden city, Yemen From October 2018 to March 2019.

Patients with impaired glucose tolerance test, or known diabetics taking oral hypoglycemic drugs, or managed with diet for the control of diabetes, were included in the study.

Patients using insulin, using cardiovascular and hypertension medication, having previous history of angina, severe vascular disease, nephropathy or other life threatening disease, and patients taking corticosteroids or any drug affecting lipid profile or diabetic status, were excluded from the study.

Participants of the study were divided into four groups according to the duration of diabetes mellitus. In the first group patients with 1-2 years, second group 2-4 years, third group 4-6 years and in the fourth group 6-8 years duration were included.

The patient underwent a clinical assessment, which included history (a questionnaire) and clinical examination. The variables of questionnaire were age, sex, marital status, personal history (occupation, education, socio-economic status) eating pattern, nutritional status, exercise history, smoking status, menstrual history and family history (including family history of diabetes

Serum glucose was estimation by Lopez method (**Lopez, J. 2013**), total cholesterol determination by Watson method (**Aggarwal, V., et al,2016**), triglycerides determination by kit method (triglycerides escape), HDL-Cholesterol determination by Watson method (**Hirowatari, Y., et al, 2003**) and LDL-Cholesterol was calculated by Fried Wald's Formula (**Assmann, G., et a, 1984**).

Statistical Analysis

For both parts, data were processed by the SPSS program (Version 20 (Statistical Package for the Social Sciences)). The differences between the groups were tested for significance by t-test and chi-square test. Data were expressed as *P*-values < 0.05 are considered statistically significant. Also, correlations were considered significant at $p < 0.05$.

RESULTS

Table 1: Showing Comparison of FBG, TC, TG, HDL, LDL Between Insulin Treated Diabetic subjects (2DM) and Control Subjects.

Groups	FB Glucose mg/dl	TC mg/dl	TG mg/dl	HDL mg/dl	LDL mg/dl
Control	100.1±10.0	160.0±13.1	133.2±11.3	61.0±20.2	95.3±14.0
T2D Subjects	233.2±16.0	230.1±20.2	181.2±31.3	59.5±14.4	130.0±18.0
p-value	<.001	<.001	<.001	>.05	>.01
Statistical Significance	H.S	H.S	H.S	N.S	S.S

Table No 1. Shows the comparison between the estimated levels of FBG, TC, TG, HDL and LDL, in healthy controls and in type 2 DM subjects. It is evident from the table that there are increased levels of FBG, TC, TG, HDL and LDL in type 2DM subjects as compared to controls. The "p" value is highly significant for FBG, TC and TG statistically significant for LDL and not significant for HDL.

Table 4: Correlation between blood sugar and different lipid profile parameter in diabetic patients.

		FBS	TC	TG	HDL	LDL
FBS	Pearson Correlation	1	0.090	0.034	0.051	0.113
	p- value		0.373	0.733	0.614	0.263
TC	Pearson Correlation	0.090	1	0.293**	0.269**	0.823**
	p- value	0.373		0.003	0.007	0.000
TG	Pearson Correlation	0.034	0.293**	1	-.256*	0.106
	p- value	.733	.003		0.010	0.292
HDL	Pearson Correlation	0.051	0.051	0.269**	1	0.230*
	p- value	0.614	0.007	0.007		0.021
LDL	Pearson Correlation	0.113	0.823**	0.106	0.230*	1
	p- value	0.263	0.000	0.292	0.021	

** . Correlation is significant at the 0.01 level (2-tailed).

* . Correlation is significant at the 0.05 level (2-tailed).

Table 4. Showed the correlation between fasting blood sugar and different lipid profile parameter all. The correlation results indicates that no connection could be noticed between fasting blood sugar and total cholesterol, triglyceride, LDL and HDL ($p > 0.05$) p -value = .733 -.733 -.614 -.263 -.733 respectively. Whereas correlation was observed between the various lipid profiles, A high correlation existed between total cholesterol with TG, LDL and HDL p -value = (.003 -.007 -.000) respectively.

There are another correlation found between TG with TC & HDL with TG. In addition to we observed also high correlation between HDL and TG and LDL $p < 0.05$ = (.007 -.021).

Table 5: Comparison of TC, TG, HDL and LDL levels among diabetic patients.

			Sex		Total
			Female	Male	
TC	Normal	Count % Within TC	25 (25%) 39.1%	39 (39%) 60.9%	64 (64%) 100.0%
	High	Count % Within TC	18 (18%) 50.0%	18 (18%) 50.0%	36 (36%) 100.0%
TG	Normal	Count % Within TG	26 (26%) 41.9%	36 (36%) 58.1%	62 (62%) 100%
	High	Count % Within TG	17 (17%) 44.7%	21 (21%) 55.3%	38 (38%) 100%
HDL	Normal	Count % Within HDL	25 (25%) 55.6%	20 (20%) 44.4%	45 (45%) 100%
	High	Count % Within HDL	18 (18%) 32.8%	37 (37%) 67.2%	55 (55%) 100%
LDL	Normal	Count % Within LDL	12 (12%) 38.7%	19 (19%) 61.3%	31 (31%) 100.0%
	High	Count % Within LDL	31 (31%) 44.9%	38 (38%) 55.1%	69 (69%) 100.0%

Table 5. Showed the analysis of distribution of lipid profile among diabetic patients, these showed that hypertriglyceridemia ($TG \geq 150$ mg/dl) was present in 38%. Low HDL ($HDL \leq 40$ mg/dl) was present 55%. The highest level was observed in LDL ($LDL \geq 100$ mg/dl) it represents 69% and lowest level was observed in TC ($TC \geq 200$ mg/dl) 36% ($LDL > HDL > TG > TC$ respectively).

In comparison with sex the level of high lipid profile is slightly higher in male than female, knowing that all these disparities did not showed statistical significant differences.

Table 6: Showed the distribution of diabetic patient based on sex.

		Sex		Total
		Female	Male	
High blood sugar >120 mg/dl	Count	25	34	59
	% Within high blood sugar	42.4%	57.6%	100%
	% Within sex	58.1%	59.6%	59.0%
	Of Total%	25.0%	34.0%	59.0%
Very High blood sugar >270 mg/dl	Count	18	23	41
	% Within high blood sugar	43.9%	56.1%	100%
	% Within sex	41.9%	40.4%	41%
	Of Total%	18.0%	23.0%	41%

Table 6. Showed the distribution of diabetic patient based on sex, the distribution of patients were according to the degree of diabetes high blood sugar (120-270 mg/dl) and very high blood sugar (more than 270 mg/dcl). Among diabetic patients, males had higher level of glucose 57 (57%) and 43 (43%) were female. patients who have higher blood sugar were more than patients who have very high.

Table 7: Comparison between mean of tests results of FBS, TC and TG in experimental group before and during experiment.

Name of test	Compare	mean	Std. Deviation	T-test	P-value
FBS	Before experiment (0) during experiment (1)	190.08 109.84	53.21 38.69	4.527	.001
	Before experiment (0) during experiment (2)	190.08 52.30	53.21 22.09	7.528	.000
	Before experiment (0) during experiment (3)	190.08 134.46	53.21 50.24	3.358	.006
TC	Before experiment (0) during experiment (1)	240.53 219.46	83.03 61.75	.966	.353
	Before experiment (0) during experiment (2)	240.53 196.38	83.03 53.02	1.733	.109
	Before experiment (0) during experiment (3)	240.53 200.30	83.03 41.11	1.541	.149
TG	Before experiment (0) during experiment (1)	179.30 92.00	75.29 32.38	3.831	.002
	Before experiment (0) during experiment (2)	179.30 123.46	75.29 44.28	2.573	.024
	Before experiment (0) during experiment (3)	179.30 114.69	75.29 54.49	3.451	.005

*Experimental group (exposure nutrition intervention during mouth)

Table 7. showed the mean value of three tests results of blood had been performed fast blood sugar (FBS), triglyceride (TG) and total cholesterol (TC) in four times during experiment

period 'one month'. First one was before experimentation start (**time 0**), second one was after 2nd weeks from experimentation start (**time 1**), third one in 3rd week during experimentation start (**time 2**) and last one during 4th week (**time 3**) from experimentation start. The p- value is highly significant ($p < 0.05$) in FBS and TG, while the p-value show no significant for TC.

Table 8: Comparison between mean of tests results of FBS, TC and TG in control group before and during experiment.

Name of test	Compare	mean	Std. Deviation	T-test	P-value
FBS	Before experiment	106.80	31.38	2.702	.054
	during experiment (1)	180.00	56.36		
	Before experiment	106.80	31.38	.285	.790
	during experiment (2)	110.80	21.65		
TC	Before experiment	106.80	31.38	2.966	.041
	during experiment (3)	144.80	51.41		
	Before experiment	223.20	45.14	.545	.615
during experiment (1)	249.60	89.83			
TG	Before experiment	223.20	45.14	.526	.626
	during experiment (2)	202.00	67.14		
	Before experiment	223.20	45.14	.551	.611
during experiment (3)	206.40	41.92			
TG	Before experiment	281.60	168.87	1.820	.143
	during experiment (1)	159.80	69.49		
	Before experiment	281.60	168.87	.346	.747
during experiment (2)	264.00	184.69			
	Before experiment	281.60	168.87	2.452	.070
	during experiment (3)	192.00	87.87		

*control group (without any intervention diet)

Table 8. Showed the mean value of three tests results of blood had been performed (fast blood sugar - triglyceride - total cholesterol) in four times during experimentation period 'one month'. First one was before experimentation start (**time 0**), second one was after two weeks during experimentation (**time 1**), third one during 3ed week (**2 time**) from experimentation start and last one during 4th week (**time 3**) from experimentation start. The "p" value is significant in third (**time 2**) compared of FBS only, while there were no significant for first (**time 0**) and second (**time 1**) compare of FBS.

Table 9: Comparison between experimental group (EXP) and control group (CON) in mean of tests results of FBS, TC and TG of before experiment (Time 0) and during experiment (1, 2 and 3 times).

Test	Group	Mean	Std. Deviation	T-test	P. V
FBS 0	EXP	190.08	53.21	3.251	.005
	CON	106.80	31.38		
FBS 1	EXP	109.85	38.69	3.045	.005
	CON	180.00	56.36		
FBS 2	EXP	52.31	22.09	5.056	.000
	CON	110.80	21.65		
FBS 3	EXP	134.46	50.24	.389	.703
	CON	144.80	51.42		
TC 0	EXP	240.54	83.02	.437	.668
	CON	223.20	45.14		
TC 1	EXP	219.46	61.75	.820	.424
	CON	249.60	89.83		
TC 2	EXP	196.38	53.01	.188	.854
	CON	202.00	67.13		
TC 3	EXP	200.30	41.11	280	.783
	CON	206.40	41.92		
TG 0	EXP	179.31	75.29	1.822	.087
	CON	281.60	168.87		
TG 1	EXP	92.00	32.38	2.886	.011
	CON	159.80	69.49		
TG 2	EXP	123.46	44.28	2.671	.017
	CON	264.00	184.69		
TG 3	EXP	114.69	54.49	2.278	.037
	CON	192.00	87.87		

Table 9. Showed comparison between experimental group and control group in mean value of tests results of FBS, TC and TG in one time before experiment (time 0) and in 2nd, 3rd and 4th weeks during experiment (1,2 and 3 times) respectively. The "p" value is highly <0.05 in FBS (1 and 2 times) and TG (1, 2 and 3 times), it is not significant in TC.

DISCUSSIONS

Yemen is one of the 19 countries and territories of the Middle East and North Africa Diabetes (MENA) region. 425 million people have diabetes in the world and more than 39 million people in the MENA Region: by 2045 this will rise to 67 million. There were 530.500 cases of diabetes in Yemen in 2017 (*IDF, 2019*). The data in **Table (4)** showed that there is no statistically significant relationship between fasting blood sugar and lipid profile (TG, TC, LDL and LDL) all ($P>0.05$). This study is in agreement with the previous study done in Puducherry, showed that no correlation noticed could be between fasting blood sugar and

other lipid profiles (*Arokiaraj, 2016*). The same in (*Vijayaraghavan, 2010*) showed levels of TC, TG, HDL and LDL were significantly low in diabetics. **Table (5)** showed significant increased levels of TC, TG, LDL and HDL in diabetic patients as this study is in agreement with the previous studies have shown that impaired insulin efficiency and high blood sugar are among the most common causes of abnormal changes in the levels of protein fat in people with diabetes, especially type 2 diabetes (*Decode study group, 1999*). Cardiovascular disease commonly occurs first type I type II diabetes and it is one of the most causes leading to death in the world, have found that the most serious factors that lead to the development of heart disease are dyslipidemia (*Goldberg, 2001*). In another study found in Nepal, the result is the same our result with correlation between blood sugar with HDL ($P=0.596$), But it shows there is correlation between blood sugar and TC ($P=0.017$) and blood sugar with LDL ($P=0.015$) (*Vinod at el, 2011*).

In our study we got reverse result comparison with another study done in India, it show highly significant between blood glucose with TC, LDL, TG and HDL which p

$<.001$ (*Bhuyar, 2017*). The difference in result in our study may due to the patient in this study do not have long term in medical history with diabetes. This agreement with the reports of the United Kingdom Prospective Diabetes Study (UKPDS) demonstrated conclusively that elevated blood glucose levels cause long-term complications in type 2 diabetes, just as in type 1 diabetes (United Kingdom Prospective Diabetes Study Group) (*UKPD, 1998*). The current study in **Table (6)** showed the distribution of diabetic patient based on sex. The males had slightly higher level of glucose, TG, LDL and HDL, the same level of cholesterol as compared to females. This differences were statistically not significant ($p>0.05$). This result is in agreement with the previous studies done by (*Naway, 2003*) in Sudan and by (*Arokiaraj, 2016*). The most common dyslipidemia was high TG and least was high LDL among diabetic patients in study obtained by (*Onkar, 2015*), while in our result most common dyslipidemia was high LDL and least was high TC among diabetic patients. Correlation studies within the lipid groups also showed interesting results. As cholesterol increased, it was accompanied with increase in triglyceride, LDL and a while HDL decreased. This is in agreement with reports of (*EL-Hazmy, 1994; Naway, 2003*). The different between our studies that they found the triglyceride levels correlated positively with LDL, but negatively with HDL. While we found correlated positively with TC and HDL, but negatively with LDL.

Result of the present study revealed significant high between total cholesterol with TG, LDL and HDL it was the same what (Arokiaraj, 2016). Has been observed.

In two part of study, we got three type of result, comparison between blood test in first group (experiment) before and during experiment, comparison between blood test in the second group and comparison between the two groups in blood test at third group. **The table 7** showed reduction in FBS and TG in three times test during experiment, the mean of (FBS0) (190-53) and (FBS4) (134-50) and value of mean (TG0) = (179-75) and (TG4) = (114-54) this reduction highly statically significant <0.05 in mean of all number the group. This agreement with previous studies done by (Tiwari, 2011; Hollaender, 2015) which base on whole grain shown reduction in FBG. In a Systematic reviews and meta-analyses of randomized trials and large individual randomized trials of interventions replacing high-glycemic index (GI) foods with low-GI foods have shown clinically significant improvements in glycemic control over 2weeks to 6 months in people with type1 or type2 diabetes (Jenkins *at el.*, 2008; Wang *at el.*, 2015). Another Systematic reviews, meta-analyses of randomized controlled trials and individual randomized controlled trials have shown that different sources of viscous soluble fiber result in improvements in glycemic control assessed as fasting blood sugar (FBS) (Post *at el.*, 2012) and blood lipids (HoHV *at el.*, 2016).

Prevent added sugar into diet with replace it by complex carbohydrate (CHO) as in our study, it effects in lower TG. In a systematic review and meta-analysis of randomized controlled trials ≥ 2 weeks duration showed that added sugars from sucrose, fructose and honey in is caloric substitution for starch have a modest fasting TG-raising effect in people with diabetes, which was not seen at doses $\leq 10\%$ of total energy (Morenga *at el.*, 2014). **The eighths table** showed comparison in control group all test FBS, TC and TG and observed did not show any significant >0.05 .

The eighths table showed comparison between two study group, experiment and control; it was show highly significant <0.05 in FBS and TG and not significant in TC, this result show positive effect nutritional intervention on diabetes patients in our study compatibility with a many previous studies. Similar our study but use FBS in measure outcome. It was done by (Kirsten, 2010) in New Zealand and it show highly significant <0.05 . There were associations between dietary patterns and type2 diabetes (**Figure 1**), many studies show that dietary patterns characterized by high whole grain fruit/vegetable and low fat dairy intake are

inversely associated with type 2 diabetes risk. (*Gittelsohn et al., 1998; Hodge et al., 2007*). Analogously dietary patterns characterized by high intake of red or processed meats; refined grains, fried foods and foods containing high amounts of added sugars are associated with greater type2 diabetes risk (*Halton et al., 2006*).

In our study we got reverse result of TC comparison with another Previous study dependent on the diet therapy, it showed improve total cholesterol TC over 2 to 24 weeks in people with diabetes (**Opperman at el., 2004**).

Interpretation of result total cholesterol TC in our study may due to lower TC need statins (drug) combination with nutritional intervention according report of association Diabetes American ADA (**American Diabetes Association, 2006**).

In seventh **table**, the results showed a marked improvement in blood sugar levels, TC and TG in-group that underwent food intervention compared with control, with an improvement in symptoms associated with diabetes (**Table 7**).

CONCLUSIONS

There is a statistically significant large effect in FBS, TG and HDL levels of cases compared with controls, whereas LDL and total cholesterol levels are no significant. Increased cholesterol/HDL ratio is well-known risk factors of coronary artery disease. As well as, there are effect of diet therapy with type 2 diabetes of some people employed at the University of Science and Technology and other institutions in Aden, Yemen.

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