Correlation observation between HbA₁C and Lipid profile in Type II Diabetes Mellitus Out-Patients

N. Senthilkumar*1, Anandhasayanam A1, A. S. Senthilvelu2, Rasheed M.1

1. JKKMMRFs AJKK SA College of Pharmacy, Ethirmedu, Vattamalai, B. Komarapalayam, Namakkal Dist. TN. 638183, India.
2. Consultant Physician & Diabetologist, Maaruthi Medical Centre & Hospitals, Perundurai road, Erode Dist., TN, India.

ABSTRACT

Diabetes mellitus the ticking bomb has multifaceted impact on the lifestyle of a patient. Apart from physical limitations and stress, Diabetes adds to economic burden for the patients. Diagnosis of diabetes mostly do not happen at the right time and many live with it till it was explored through the lab tests done when the patient goes for the treatment of some other ailment. This study was intended to look into the correlation between HbA1c and Lipid profile, so as if any correlation exists the same can lead to a decrease in the economic burden as well as can save many punctures done to the body of the already suffering patient using correlation coefficient. Many studies in the past had been done with the same objective and there are mixed results. In this southern part of India, where people are still not so cohesive with the health advisory of going for regular health check-ups after one reaches the age of 40 yrs., it was necessary to understand the correlation between HbA1c and the lipid profile parameters. Also with this correlation the impact of the pharmacists counselling on medication adherence and other drug & disease related information was also to be observed using chi square test. Except for HDL & TG, All other clinical parameters like FBG, PPBG, HbA1c, LDL, VLDL & TC showed significant positive changes in 4th visit compared to baseline. There was no correlation between HbA1C and Lipid values both at the baseline (except some small association in TGL values) and that too at the fourth visit. The limitation of high drop-out rates in the study should not be ignored while interpreting the results of this study.

*Address for correspondence:
N. Senthilkumar,
Principal, JKKMMRFs AJKK SA College of Pharmacy, Ethirmedu, Vattamalai, B. Komarapalayam, Namakkal, India.
E-mail: senthilkumarjkkm@gmail.com, jkkmanandha@gmail.com
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INTRODUCTION

Diabetes mellitus, the most insidious disease and the lifestyle disorder which is haunting India with growing number of cases and the vast spectrum of the co-morbidities it leads to needs a great attention from all healthcare workers. The irony of the situation is that many are not aware that they are suffering from Diabetes – the undiagnosed disease. Pharmacists have been of great impact in controlling the co-morbidity progression and the disease progression delaying too. Now with the given economic conditions in India whether the burden on the patient can be brought down by decreasing the number of laboratory tests he/she undergoes was our search. The major expenditure happens in the diagnosis and the medicine part of healthcare in India in outpatients. If the diabetes marker HbA1C can be used also as a marker for Lipid profile that would decrease the physical and economic burden on the already burdened Diabetic patients.

As per WHO, **Diabetes Mellitus (DM)** is a group of metabolic disorders characterized by hyperglycemia and abnormalities in carbohydrate, fat, and protein metabolism. It results from defects in insulin secretion, insulin sensitivity, or both. Chronic micro vascular, macro vascular, and neuropathic complications may ensue.

STATISTICS OF DIABETES MELLITUS [1]

One in every 12 across the globe is diabetic. One in two people who are diabetic do not

know they have it. Every 7 seconds a person dies from diabetes. Diabetes has caused 2.9 million deaths in 2014. 8.3% people in south east Asia suffer from Diabetes amounting to about 75 million. 387 million people live with diabetes and approximately 46.3% is undiagnosed. Additions of about 205 million people are expected to suffer from diabetes by 2035 over and above the current diabetic population.

Current state of diabetes mellitus in India [2-26]

Diabetes is a fast gaining potential epidemic in India with more than 62 million diabetic individuals currently diagnosed with the disease. [27] In 2010, India (31.7 million) topped the world with the highest number of people with the diabetes mellitus followed by China (20.8 million) with the united states (17.7 million) in second and third place respectively. It is predicted that by 2030, diabetes mellitus may afflict up to 79.4 million individuals in India, while China (42.3 million) and the United States (30.3 million) will also see significant increase in the number of people affected by the disease. [28]

The aetiology of diabetes in India is multi factorial and includes genetic factors coupled with the environmental influences such as obesity associated with rising living standards, steady urban migration and life style changes. There are, however, patterns of diabetes incidence that are related to the geographical distribution of diabetes in India. Rough estimates that the prevalence of diabetes in rural population is one quarter that of urban population for India.

Preliminary results from a large community study conducted by the Indian Council of Medical Research (ICMR) revealed that a lower proportion of the population is affected in states of Northern India (Chandigarh 0.12 million, Jharkhand 0.96 million) as compared to Maharashtra (9.2 million) and Tamil Nadu (4.8 million). [29]

DIABETIC COMPLICATIONS

This includes two types, the micro- vascular and the macro- vascular complications, broadly apart from the co-morbidities and the details are as follows

MICROVASCULAR COMPLICATIONS OF DIABETES [30,31]

DIABETIC RETINOPATHY

Diabetic retinopathy (DR) is a micro vascular complication that can affect the peripheral retina, the macula, or both and is a leading cause of visual disability and blindness in people with diabetes. Diabetic retinopathy also recently was seen in approximately 10% of people with insulin resistance (pre-diabetes) and was associated with the presence of hypertension and a higher body mass index. [31]

DIABETIC NEUROPATHY

Approximately one half of the people with diabetes have some form of peripheral neuropathy (PN), either poly diabetic or mono diabetic neuropathy. Diabetes related cardiac autonomic neuropathy is frequently under diagnosed and can include clinical abnormalities such as resting tachycardia, exercise intolerance, resting HR variability, slow HR recovery after exercise, ortho stasis, "silent" myocardial infarction and increased risk of mortality. [32]

The prevalence of diabetes related cardiac autonomic neuropathy is unclear and has been reported to range from 1% to 90%, depending on the outcome variable. [33] Risk factors for diabetes associated cardiac neuropathy include age, obesity, smoking, poor glycemic control and hypertension.

DIABETIC NEPHROPATHY

Diabetic nephropathy (DN) is a serious and progressive complication of both type1 and type 2 DM. The first manifestation of DN is typically micro albuminuria, which progresses to over albuminuria (ie, increased albumin levels in the urine, indicating more severe renal dysfunction) and eventually to renal failure and is the leading cause of end stage renal disease (ESRD). [34]

MACRO VASCULAR COMPLICATIONS
CARDIO VASUCULAR DISEASE (CVD)

Cardiovascular disease is the leading cause (70%) death in people with type 2 diabetes. people with diabetes has a 4 fold greater risk for having CVD, such as age, obesity, tobacco use, dyslipidemia and hypertension. These CVD factors are common in diabetes, but data suggests that diabetes is an independent factor for CVD. People with diabetes also have a 5 fold greater risk for a first myocardial infarction (MI) and a 2 fold

greater risk for a recurrent MI than people who previously had an MI but do not have diabetes. Further people with diabetes have a poorer long term prognosis after MI, including an increased risk of congestive heart failure and death. [35] However, recent evidence suggest that these conditions are rapidly emerging in resource limited region of the world and estimates indicates that 80% of people with diabetes worldwide will die from CVD. [36]

CEREBRO VASCULAR DISEASE

Stroke is the third leading cause of death in the united states, after CVD and cancer and is an event very familiar to physical therapists. Diabetes is an independent risk factor across all ages for stroke; [37] the risk in people with diabetes is -4 fold greater, more so in white people and in women. Diabetes is also a sudden and eventual death from stroke and people who have diabetes and who have a stroke have more severe neurological deficits and disability, a proper long term prognosis and a higher incidence of stroke recurrence than people without diabetes.

PEREPHERAL ARTERY DISEASE (PAD)

Hyperglycemia, specifically, glycation haemoglobin, has been shown to be an independent risk factor for PAD. [38] In addition to diabetes, other risk factors for PAD include hypertension, tobacco use, obesity (ie, waist to hip ratio), elevated serum fibrinogen levels, dyslipidemia, a history of CVD and physical activity.

HBA$_1$C AND LIPID PROFILE RELATIONSHIP

There are several studies done to understand the relationship between HbA1C and lipid profile. HbA1C can also be used as a predictor of dyslipidemia in type 2 diabetes mellitus in addition to as a glycemic control parameter and the study also said that, early diagnosis of dyslilpidemia can be used as a preventive measure for the development of cardio vascular disease in type 2 diabetes. [39] There certainly exists an association between plasma glucose and HBA$_1$C to lipid profile tests and   all established diabetic patients should be screened for cardiac related problems. [40] The lipid changes as a result of improved glycemic control are not uniform findings

associated with anti diabetic therapy and also the study was concluded that, OHA's like metformin, acarbose, voglibose, rosaglitazone and pioglitazones only had a significant effect on the lipid profile. [41] The mean values of fasting blood sugar, total cholesterol, triglycerides and LDL cholesterol for diabetic males and females were higher than their non-diabetic counterparts, and HDL cholesterol values were found to be lower than the non-diabetics.

The glycemic control of the patient has got a strong impact on serum lipid profile levels and atherosclerosis, CVD and CHD including heart attack and stroke. Patients should be educated about regular monitoring of profiles and if found to be abnormal, should control blood glucose and cholesterol very effectively. [42, 47,48]

PHARMACIST INTERVENTION IN DIABETES MANAGEMENT

Moreover the risk of complications and the burden of disease on the patient, the cost associated with diabetes is a major economic burden. Medical expenses for people living with diabetes are over 2 times higher than for people living without diabetes, and inpatient care continues to be the largest expenditure (43% of total cost). Previous studies have shown that patients with diabetes who receive clinical pharmacist interventions demonstrate significantly improved haemoglobin HbA1c. Besides, the data have shown that increased HbA1c is associated with increased costs per hospitalization. In fact, patients with a mean A1c of at least 10% or greater have significantly higher rates of diabetes-related hospital utilization, compared with patients with a mean HbA1c of < 7%.13 However, there is a lack of data for clinical pharmacist's impact on inpatient utilization, especially in underserved populations.

There have been a large number of clinical trials evaluating pharmacists interventions in diabetes mellitus (DM). However, the outcomes of these studies remain controversial. [43]

Pharmacist management of patients with diabetes significantly reduces HbA1C and allows more patients to meet ADA treatment goals, a clinical pharmacist-run

diabetes clinic can provide numerous clinical benefits to patient. [44]

AIM AND OBJECTIVES

Aim of the study:

To understand the lipid profile changes while moving towards target blood glucose levels.

Objectives:

1. Change in HbA1c levels with pharmacist intervention

2. Correlation between changes in HbA1c & changes in TC, LDL, HDL, VLDL & TG

METHODOLOGY

Study design:- A 11 month prospective open label study in Diabetes Mellitus out patients who visited the diabetic clinic in a tertiary care hospital.

Study criteria:-

Inclusion criteria

• Type 2 DM patients.

• Both male and female

• The patient must have been on drug treatment for upward of 6 months

• Diabetes Mellitus patients who have been on drug treatment with OHA with/without insulin were added.

Exclusion criteria

• Inpatients

• Patients on dietary modification and/or exercise alone.

• Patients with BMI <18.

Data collection

Randomly sampled out patients with type 2 DM those visited the consultant outpatient clinic , over a period of 11 months were interviewed using a pre tested, structured data collection form to collect the demographic profile and present illness/complaints of patients along with the laboratory parameters of the patients in Base line,V1,V2,V3 & V4. Laboratory parameters like FPG, PPG, HBA1C, Total Cholesterol, HDL, LDL, VLDL & TG were asked for and noted down from the lab reports. Informed consent was taken prior to data collection.

STATISTICAL ANALYSIS

STATISTICAL TOOLS:

The information collected regarding all the selected cases were recorded in a Master Chart. Data analysis was done with the help of computer using **SPSS statistical package- Version 17.**

Using this software range, frequencies, percentages, means, standard deviations, chi square and 'p' valueswere calculated. Student's 't' test or ANOVA was used to test the significance of difference between quantitative variables and Yate's and Fisher's chi square tests for qualitative variables. A 'p' value less than 0.05 denotes significant relationship. ROC analysis was also done using this software. Correlation was tested using correlation co-efficient in the same software.

RESULTS AND DISCUSSION

1. Profile of Cases Studied

Table 1: Age Distribution (N=162)

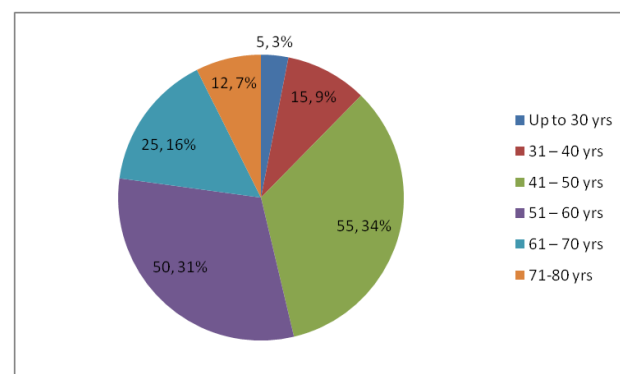| Age Distribution	Cases	
	No. of Patients	%
Up to 30 yrs	5	3.1
31 – 40 yrs	15	9.3
41 – 50 yrs	55	34.0
51 – 60 yrs	50	30.9
61 – 70 yrs	25	15.4
71-80 yrs	12	7.4
Total	162	100
Range	29 – 80 yrs	
Mean	52.6 yrs	
S.D.	11.2 yrs	

Figure 1: Age Distribution (N=162)

A total of 162 sample subjects participated in the study with age range from 29 yrs to 80 yrs range and a mean of 52.6 years.

Highest no of patients 34% were from the age group 41-50 year followed by 51-60 years with 31% and the least was from the upto 30 yrs, ie 3%.

111 patients (68.5%) were male and 51 patients (31.5%) were female. Maximum male patients as double as the females were part of the study.

Table 2: Sex Distribution (N=162)

Sex	Cases	
	No	%
Male	111	68.5
Female	51	31.5
Total	**162**	**100.0**

Table 3: Body Mass Index (BMI) (N=162)

Parameter	BMI Values
Range	18.01 – 28.8
Mean	23.77
SD	2.14

The mean BMI of the sample was 23.77 – borderline normal – but still diabetic – goes with some observations seen in other studies where the population in normal BMI was also diabetic.

Table 4: Body Mass Index (BMI) (N=162)

BMI	Total No. of Patients (N=162)	% Total
18.6-24.9 (Normal)	116	71.6
25-29.9 (Over weight)	42	26
<18.5 (under weight)	4	2.4
>30 (Obese)	0	0
TOTAL	162	100

In this study group 71.6% patients were in the category of normal weight followed by 26% patients were in over weight and finally about 4% patients were in the category of underweight. No patients were included in the category of obese patients.

Table 5: Family History of Diabetes (N=162)

Family History of Diabetes in	Family History of Diabetes			
	Present		Absent	
	No	%	No	%
Children	8	4.9	154	95.1
Mother	71	43.8	91	56.2
Father	74	45.7	88	54.3
Siblings	122	75.3	40	24.7

Most diabetic patients in the study had either had a diabetic mother or father (individually 43.8% & 45.7%). Most patients Siblings (75.3%) suffered from diabetes followed by the children of these patients with up-to 4.9%.

Table 6: Personal Habits (N=162)

Personal Habits	Yes		No	
	No.	%	No.	%
Smoking	49	30.2	113	69.8
Tobacco use	28	17.3	134	82.7
Alcohol	17	10.5	145	89.5

49 patients were smokers (30.2%) followed by 28 patients (17.3%) with the habit of tobacco use and 17 patients (10.5%) with the habit of alcohol consumption.

Table 7: Educational Status (N=162)

Educational Status	Cases	
	No	%
Primary (1 -5)	60	37.0
High school (9 – 12)	41	25.3
Middle school (6 – 8)	37	22.8
Illiterate	12	7.4
Degree	12	7.4
Total	**162**	**100.0**

7.4% were illiterate & 7.4% were degree holders and the remaining 85.2% had done their schooling only. Levels of education can have an impact on the levels of self health consciousness and the same is to be understood with the increasing amounts of diabetic population in this part of the country.

Table 8: Present Illness (N=162)

Present Illness	Cases	
	No	%
Type 2 DM	91	56.2
Fever	29	17.9
Fatigue	25	15.4
Cold	10	6.2
Hypertension	8	4.9
Chest Discomfort	3	1.9
Breathlessness	2	1.2
Diarrhoea	2	1.2
Head ache	2	1.2
Body Pain	1	0.6
COPD with fever	1	0.6
Cough	1	0.6
Gastric problem	1	0.6
Knee pain	1	0.6
Stomach upset	1	0.6
Thyroid problem	1	0.6
Weakness	1	0.6
Total	**162***	**100.0**

*Many cases had more than one illness.

The present complaints / illness data shows that, 91 patients (51%) were follow up patients for type 2 DM. Then, 29 patients (16%) were with the complaints of fever followed by 25 patients (14%) with the complaints of fatigue followed by 10 patients (6%) with the complaints of cold. Rest of the patients was with the complaints of Cardiovascular, respiratory and gastrointestinal tract complaints etc. In that many patients were with more than one complaint.

Table 9: Past Medical History (N=162)

Past Medical History	Cases	
	No. of Patients	%
Nil	66	40.7
Hypertension	62	38.3
Dyslipidemia	35	21.6
C A D	5	3.1
Hyperlipidemia	3	1.9
Jaundice	3	1.9
C OP D	2	1.2
Depression	2	1.2
Hyper urecamia	2	1.2
Thyroid disorder	2	1.2
Allergic Problem	1	0.6
Asthma	1	0.6
Coronary Angioplasty	1	0.6
Hypertriglyciridemia	1	0.6
Gastric problem	1	0.6
Knee pain	1	0.6
Rheumatic Arthritis	1	0.6
Sleep disorder	1	0.6
Total	**162***	**100.0**

*Many cases had more than one illness in the past.

The past medical history of study patients, 66 patients (35%) were with no past medical history at all in their life. 62 patients (33%) were with the past medical history of Hypertension in their life and followed by 35 patients (18%) were with the past medical history of dyslipidemia. Rests of the patients were with the past medical history of CAD, COPD, thyroid disorders Rheumatoid Arthritis and Gastro Intestinal issues and ortho problems etc.
The duration of diabetes ranged from 1 yrs to 30 yrs of sufferings and history with a mean of 6.6 years and SD of 5.2 years.

Table 10: Duration of Diabetes (N=162)

Parameter	Duration of Diabetes (years)
Range	1 – 30 yrs
Mean	6.6 yrs
S.D.	5.2 yrs

IMPACT OF PHARMACIST INTERVENTION ON BLOOD SUGAR VALUES
Table 11: Changes in Fasting Blood Sugar Values (N=162)

Period	Fasting Blood Sugar Values		'p' Value (Significance of difference from Baseline Values)
	Mean	SD	
Baseline	141.2	51.8	-
Visit 1	131.5	45.5	**0.003 significant**
Visit 2	131.8	47.0	**0.032 Significant**
Visit 3	134.9	52.8	0.153 Not Significant
Visit 4	121.1	20.7	**0.043 Significant**

Mean value of FBG in base line was 141.2 and SD was 51.8 and the mean values of FBG in visit4 were 121.1 and SD was 20.7.
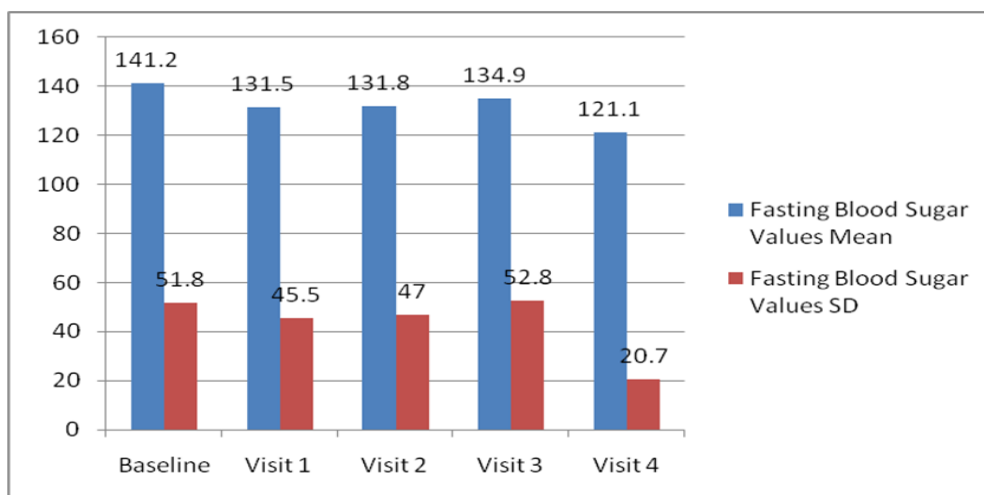

Figure 2: Changes In Fasting Blood Sugar Values (N=162)

"The P value indicates significant changes in visit1 (p=0.003), visit2 (p=0.032) and visit 4 (p=0.043) compared to base line". This shows that there is an impact of pharmacist intervention on changing the fasting blood sugar values. The patients in the study group attains good improvement in their blood sugar values during their 4th visit, regular follow up of patients to the doctor will improve the quality of health.

Table 12: Changes in Post Prandial Blood Sugar Values (N=162)

Period	Post Prandial Blood Sugar Values		'p' Value (Significance of difference from Baseline Values)
	Mean	SD	
Baseline	202.6	86.1	-
Visit 1	170.0	53.7	**< 0.0001 significant**
Visit 2	159.7	42.1	**< 0.0001 Significant**
Visit 3	177.7	66.0	0.179 Not Significant
Visit 4	150.3	21.9	**0.0062 Significant**

Mean value of PPBG in base line was 202.6 and the SD was 86.1 and the mean values of visit 4 were 150.3 and the SD were 21.9.
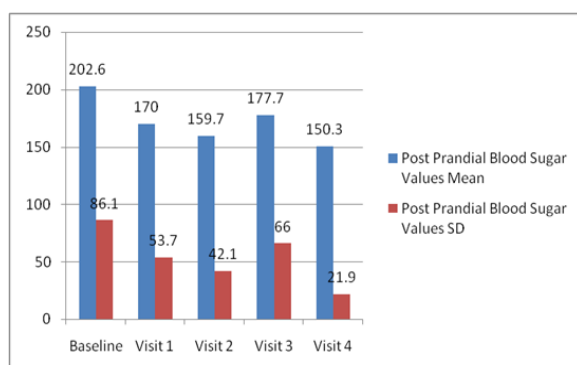

Figure 3: Changes in Post Prandial Blood Sugar Values (N=162)

The P value indicate significant changes in visit 1(p<0.001), visit 2(p<0.001) and visit4 (p=0.0062) compared to base line. This shows that there is an impact of pharmacist counselling on changing post prandial blood sugar values.

The P values indicate that, patients were getting good improvement with their regular follow up by the pharmacist & the doctor compared to the base line values (**Fig. 3**).

Mean value of HbA1C in base line was 7.51 and the SD was 1.1 and the mean value of HbA1C in visit 4 is 6.88 and the SD is 0.88.

The P value indicates significant changes in visit 4 (p=0.002) compared to base line. This shows that there is an impact of pharmacist counselling on changes in HbA1C values.

P value shows that, pharmacist counselling and regular follow up of the patient to doctor brings the HbA1C to the normal level compared with the base line HbA1C. So the doctor advice and medication adherence will give a better glycemic control to the patient (**Table 13**).

IMPACT OF PHARMACIST INTER-VENTION IN LIPID PROFILE

The mean value of total cholesterol in base line was 206.1 and the SD was 40 and the mean value of total cholesterol in visit 4 was 191.4 and the SD was 31.1(**Table 14**).

Though the P values were not significant in the first 3 visits, there was a significant P value in the 4th visit indicating a possible impact of the pharmacists intervention of the total cholesterol levels (**Fig. 4**).

Though there was an obvious improvement in the HDL levels of the samples, the P value was not significant in visit 1 (p=0.376), visit 2 (p=0.198), visit 3(p=0.34) and visit 4 (p=0.259) compared to base line. This shows that there is no impact of pharmacist counselling on changing HDL values. HDL values did not have any significant with the base line values (**Table 15 & Fig. 5**).

The P value indicates significant changes in visit 1(p=0.005), visit 3 (p=0.005) and visit 4(p=0.003) compared to base line. This shows that there is an impact of pharmacist counselling on changing the LDL values (**Table 16 & Fig. 6**).

The P value indicates significant changes in visit 2(p=0.013), visit 3(p=0.014) and visit 4(p =0.005) compared to base line. This shows there was an impact of pharmacist counselling on changing VLDL values (**Table 17 & Fig. 7**).

The P values in no visit were significant compared to base line. This shows there is no impact of pharmacist counselling on controlling the TG values (**Table 18 & Fig. 8**).

Except HDL & TG levels all other parameters like the FBG, PPBG, HbA1c, TC,

LDL & VLDL significantly reduced over four follow-ups by the pharmacist with significant P values (**Table 19**).

There is no correlation between HbA1C and Lipid values both at the baseline (except some small association in TGL values and fourth visit, unlike the results of a study done in this part of South India in 2014. [45] This coincides with results of a similarstudy, which states " The correlation was insignificant ('p' > 0.05) in Type 2 DM patients with good glycemic control (Arshiya Parveen et al)" The patients included in this Study had attained good glycemic control at the fourth visit (**Table 20**).

Table 13: Changes in HbA1 C Values (N=162)

Period	HbA1C Values		'p' Value (Significance of difference from Baseline Values)
	Mean	**SD**	
Baseline	7.51	1.1	-
Visit 1	No Cases Investigated -		
Visit 2	No cases Investigated -		
Visit 3	8.15	1.06	0.295 Not Significant
Visit 4	6.88	0.88	**0.002 Significant**

Table 14: Changes in Total Cholesterol (N=162)

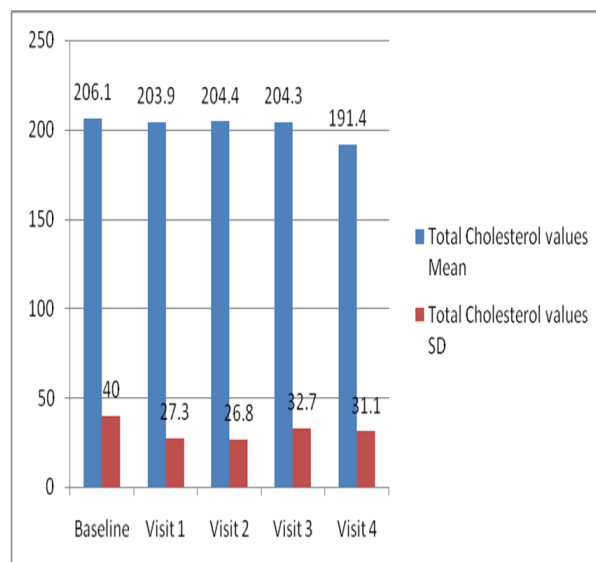| Period	Total Cholesterol values		'p' Value (Significance of difference from Baseline Values)
	Mean	**SD**	
Baseline	206.1	40.0	-
Visit 1	203.9	27.3	0.381 Not Significant
Visit 2	204.4	26.8	0.152 Not significant
Visit 3	204.3	32.7	0.098 Not significant
Visit 4	191.4	31.1	**0.017 Significant**

Figure 4: Changes in Total Cholesterol Values (N=162)

Table 15: Changes in HDL Values (N=162)

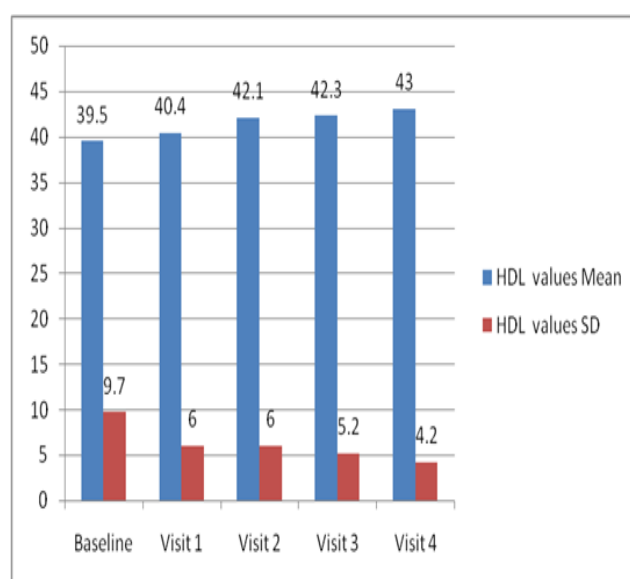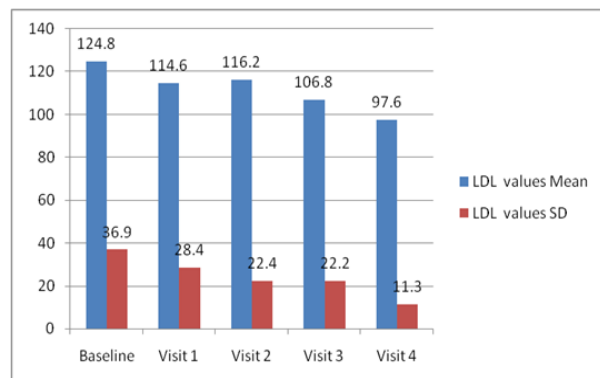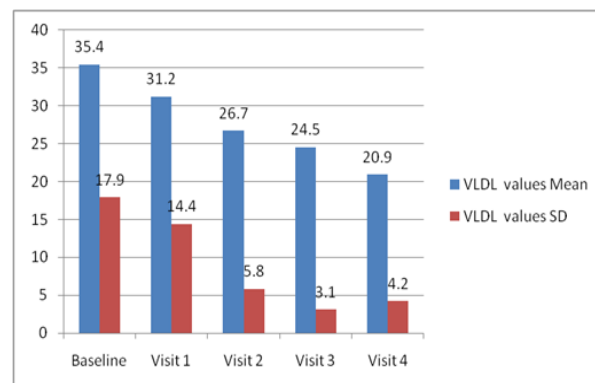| Period	HDL values		'p' Value (Significance of difference from Baseline Values)
	Mean	**SD**	
Baseline	39.5	9.7	-
Visit 1	40.4	6.0	0.376 Not Significant
Visit 2	42.1	6.0	0.198 Not significant
Visit 3	42.3	5.2	0.34 Not significant
Visit 4	43.0	4.2	0.259 Not Significant

Figure 5: Changes in HDL Values (N=162)
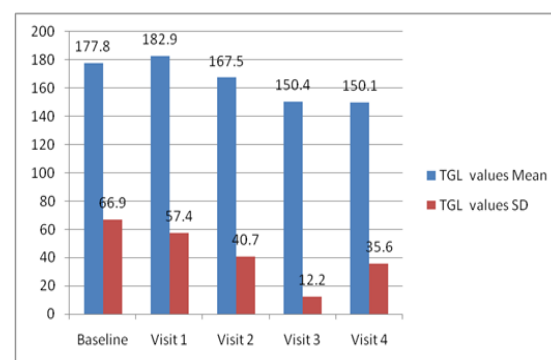
Table 16: Changes in LDL Values (N=162)

Period	LDL values		'p' Value (Significance of difference from Baseline Values)
	Mean	SD	
Baseline	124.8	36.9	-
Visit 1	114.6	28.4	**0.005 Significant**
Visit 2	116.2	22.4	0.071 Not significant
Visit 3	106.8	22.2	**0.005 Significant**
Visit 4	97.6	11.3	**0.003 Significant**

Figure 7: Changes in VLDL Values (N=162)

Figure 6: Changes in LDL Values (N=162)

Table 17: Changes in VLDL Values (N=162)

Period	VLDL values		'p' Value (Significance of difference from Baseline Values)
	Mean	SD	
Baseline	35.4	17.9	-
Visit 1	31.2	14.4	0.292 Not Significant
Visit 2	26.7	5.8	**0.013 significant**
Visit 3	24.5	3.1	**0.014 significant**
Visit 4	20.9	4.2	**0.005 Significant**

Table 18: Changes in TG Values (N=162)

Period	TGL values		'p' Value (Significance of difference from Baseline Values)
	Mean	SD	
Baseline	177.8	66.9	-
Visit 1	182.9	57.4	0.693 Not Significant
Visit 2	167.5	40.7	0.343 Not significant
Visit 3	150.4	12.2	0.122 Not significant
Visit 4	150.1	35.6	0.105 Not Significant

Figure 8: Changes in TG Values (N=162)

Table 19: Abstract of Significance of Changes in Mean Values (N=162)

PARAMETERS	BASE LINE MEAN	V1 MEAN	P VALUE	V2 MEAN	P VALUE	V3 MEAN	P VALUE	V4 MEAN	P VALUE
FBG	141.2	131.5	**0.003**	131.8	**0.032**	134.9	0.153	121.1	**0.043**
PPBG	202.6	170.0	**< 0.0001**	159.7	**< 0.0001**	177.7	0.179	150.3	**0.002**
HbA1C	7.51	N.A.	-	N.A	-	8.15	0.295	6.88	**0.002**
TC	206.1	203.9	0.381	204.4	0.152	204.3	0.098	191.4	**0.017**
HDL	39.5	40.4	0.376	42.1	0.198	42.3	0.34	43.0	0.259
LDL	124.8	114.6	**0.005**	116.2	0.071	106.8	**0.005**	97.6	**0.003**
VLDL	35.4	31.2	0.292	26.7	**0.013**	24.5	**0.014**	20.9	**0.005**
TG	177.8	182.9	0.693	167.5	0.343	150.4	0.122	150.1	0.105

Table 20: Correlation between HbA1c Values and Lipid Profile (N=162)

Correlation between HbA1C and lipid profile	Correlation coefficient at	
	Baseline	Visit 4
TC	-0.356	0.021
HDL	0.338	0.211
LDL	-0.379	0.185
VLDL	-0.446	0.231
TG	-0.583	0.047

CONCLUSION

The mean age of population in the study was 52.6years with majority are male population(68.5%), who had a mean BMI of 23.77- in the normal range, with most having family history of diabetes, 58% of the study population either smoked, consumed alcohol or tobacco use or one or more. 62.3% of the population were below high school education. All these explain the cause of disease and awareness about the same.

40.7% suffered from hypertension followed by dyslipidemia and coronary artery disease in 38.3% and 21.6% respectively. On an average 6.6 years was the duration of diabetes suffering as of the interview period with a range of 1-30 years.

There was significant impact with the pharmacist counselling in the following parameters.(base line compared to V4).($p<0.05$)

- FBS
- PPBS
- HbA1C
- TC
- LDL
- VLDL

There were no significant changes in the following

- HDL
- TG

With the correlation analysis, it was found that, there were no significant correlation in the changes between HbA1C and lipid profile except for TG in the 4th visit unlike some similar observations from India & abroad. [46-48]

FUTURE RECOMMENDATIONS

1. Larger sample size is to be ensured

2. Concurrent testing over a period of 18-36 months for both HbA1C and lipid profile is must owing to diabetes being a lifestyle disorder.
3. Drop out minimisation practices to ensure clinic regularity and lab parameter testing regularity is must.
4. A study involving cross reaction of populations with diabetes are to be studied for correlation with other parameters as there are many studies that proved either way on the correlation; that not giving the end were any clarity.

LIMITATIONS OF THE STUDY

- ❖ Visit irregularities of patients
- ❖ Drop out in between the study
- ❖ Concurrent testing of HbA1C and lipid profile in all patients was limited for economical reasons.
- ❖ Smaller sample size only could complete the study with both the laboratory parameters - HbA1C and lipid profile test.

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