



Received on 24 November, 2017; received in revised form, 29 January, 2018; accepted, 06 February, 2018; published 01 August, 2018

MEDICATION ADHERENCE AND HEALTH RELATED QUALITY OF LIFE IN ADULT PATIENTS SUFFERING FROM DIABETES MELLITUS TYPE 2 AND ITS ASSOCIATION WITH GLYCOSYLATED HEMOGLOBIN AND LIPIDS - A PROSPECTIVE STUDY AT TERTIARY CARE HOSPITAL

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Keywords:

Quality of life,
Type 2 DM, WHOQOL-BREF

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ABSTRACT: A prospective, cross sectional questionnaire-based study was carried out over a period of six months. All the diabetic patients aged 18 to 60 years in the Medicine department and diabetes clinic who are eligible for study were enrolled. In addition to a questionnaire on demography, exercise, and smoking status, we used a structured case record form to capture diabetes-related complications, duration of diabetes, glycemic status and lipid control, along with number and types of medication used. Also, their glycosylated hemoglobin, lipid profile was recorded. The Quality of life (QOL) was assessed by WHOQOL-BREF questionnaire and adherence to treatment was measured by using Modified Morisky Medication Adherence Scale (MMAS-8). Association between QOL and glycosylated hemoglobin, and lipids was established using pearson correlation coefficient. About 50% patients had poor glycemic control with the HbA1c value of 7.1-9.0. A Total of 215 drugs were given to total 100 patients with the average of 2.17 ± 0.682 per prescription. The mean score for questions related to the physical domain was 19.86 ± 11.61 and psychological domain was 44.73 ± 13.26 . As far as medication adherence was concerned, 84% showed medium adherence to medications. In the study, it was noted that increase in number of drugs decreases medication adherence which directly affects quality of life of the patients, the Pearson's correlation with drugs and adherence value of R is: 0.3998. QOL in type 2 diabetes was affected in physical domain. Medication adherence correlated with QOL ($P < 0.05$). There was an association between QOL and glycosylated hemoglobin and total cholesterol.

INTRODUCTION: The number of people with diabetes is increasing due to population growth, aging, urbanization, and increasing prevalence of obesity and physical inactivity¹. Diabetes is broadly of two types Type 1 and Type 2 Diabetes mellitus (DM) with also some new variants like LADA (Latent Autoimmune Diabetes of adulthood) / Type 1.5, Gestational and secondary diabetes.

The growing global epidemic of type 2 diabetes mellitus (T2DM) is expected to increase from 171 million cases in 2000 to 366 million in 2030, along with its associated morbidities, including microvascular damage, ischemic heart diseases and stroke².

T2DM was the fourth leading cause of death globally based on the report by the International Diabetes Federation³. The prevalence of diabetes is increasing worldwide, and most people with diabetes will die or be disabled as a consequence of vascular complications. Prospective studies have shown continuous associations of blood glucose and glycated hemoglobin levels with the risks of major vascular events^{4,5}.

<p>QUICK RESPONSE CODE</p> 	<p>DOI: 10.13040/IJPSR.0975-8232.9(8).3347-54</p> <hr/> <p>Article can be accessed online on: www.ijpsr.com</p> <hr/> <p>DOI link: http://dx.doi.org/10.13040/IJPSR.0975-8232.9(8).3347-54</p>
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Diabetes being a chronic disease requires patients to take drug therapy for long periods of time. The treatment endpoints which measure the success of therapies are basically focused on biological and physiological outcomes. Patients' health-related quality of life (HRQoL) is a growing area of interest and has emerged as a one of the outcomes especially in chronic diseases⁶.

High prevalence of diabetes and its related complications have attracted the research and policy concern in the country over last few years. In response to this policy concern, a considerable body of literature has been emerged to evaluate QOL and its determinants in diabetic patients⁷. Studies related to QOL in resource limited country like ours is lacking.

QOL assessment can also be used to identify unobserved need for rehabilitation for patients already undergoing treatment. With this knowledge the allocation of health resources can be revised and reallocate accordingly⁸.

The literature has shown that better medication adherence (MA) is associated with improved disease control (glycated hemoglobin [HbA1c], blood pressure, and lipid profile) and decreased health care resource utilization in patients with T2DM⁹.

Medication Adherence(MA) is usually defined as the extent to which patients follow the instructions given for prescribed medications¹⁰.

A study done by Vanelli *et al.*, showed that the discontinuation rates of the medication on the 30 days of treatment reached 42% and non-oral treatment of DM had the high risk of discontinuation¹¹.

According to the World Health Organization (WHO) report in 2003, average patient adherence in long-term therapy for chronic diseases in developed countries is only 50%, while in developing countries, it is even lower¹². The other previous study showed that nonadherence in oral antidiabetic treatment was associated with the incidence of end-stage renal disease, and the effect was more significant in the polytherapy of oral antidiabetic treatment and under the metformin polytherapy, besides other risk factors¹³.

Medication adherence being the most important factor, since it's influences the outcome of disease. Increased complication arising out of non-adherence can alter quality of life with the effect in all the important dimensions like physical, psychological and social.

Hence this study was planned to evaluate the current therapies used for the treatment of Type 2 DM, to evaluate QOL in such patients and the extent of MA.

Objectives of the Study:

1. Assessing the pattern of use of anti-diabetic drugs in the specified patient population.
2. Evaluate the extent of adherence to the medications prescribed and the effects of the disease per say on quality of life. (QOL)
3. Exploring association between QOL if any with glycosylated hemoglobin and lipids.

Methodology: A prospective, cross sectional questionnaire based study was conducted over a period of six months after approval by institutional ethics committee. All the diabetic patients aged 18 to 60 years in the outpatient department of Medicine and diabetes clinic who were eligible for study were enrolled in the study after explaining the aim of the study and obtaining a written consent. Patients with some other major illness other than mild/moderate hypertension, newly diagnosed or patients suffering from diabetes less than 6 months were excluded.

Sociodemographic data and prescription given to the patient including the drug prescribed, dose, frequency and duration of the treatment were noted on the case record form along with the Lab parameters of Blood Glucose and Lipids. Quality of life in elderly diabetic patient was assessed by WHOQOL-BREF questionnaire and adherence to treatment was evaluated by using Modified Morisky Medication adherence scale (MMAS-8). Glycosylated Haemoglobin values was converted to estimated average Glucose (eAG).

WHOQOL BREF: It contains 26 Question regarding quality of life which contains four subdivisions in the four domains: Physical, Psychological, Social and Environmental. The four domain scores denote an individual perception of

quality of life in each domain. Domain scores are scaled in a positive direction (*i.e.* higher scores denote higher quality of life). The mean score of items within each domain is used to calculate the domain score¹⁴.

Morisky Medication Adherence Scale (MMAS-8): MMAS-8 contains 8 questionnaires, which are answerable in the form of YES/NO related with adherence, total score of all items were calculated with a sum score ranging from 0 to 8 The MMAS scores were trichotomized previously into the following 3 levels of adherence: high adherence (score, 0), medium adherence (score, 1 - 2), and low adherence (score, 3-8)

Estimated average glucose (eAG): American Diabetes Association recommends the use of a new term in diabetes management, estimated average glucose, or eAG. Health care providers can now report A1C results to patients using the same units (mg/dl or mmol/l) that patients see routinely in blood glucose measurements, which can be used to help improve the discussion of glucose control with patients¹⁵.

The relationship between A1C and eAG is described by the formula:

$$28.7 \times A1C - 46.7 = eAG$$

Statistical Analysis: Data was entered in Microsoft Excel 2016®. SPSS® software (version. 21.0 IBM Corporation, California,) which was used for statistical analyses. The descriptive analysis was presented in tables as mean and SD for numeric data and frequency (n) and percentage (%) for categorical data the statistical correlations between QOL and MMAS 8 instruments, different domains of QOL and clinical parameters was analysed using Pearson correlation coefficient test. Odds Ratio and Risk ratio were calculated and P value was kept significant at the level of <0.05 for all the parameters. A total of one hundred patients were enrolled in the study, out of which majority of the patients (44 %) belonged to the group from 41 - 50 yrs. Male patients dominated the study. In relation to weight, 28% patients were weighing above 80 Kgs. Average duration of the DM ranged from 6 - 10 yrs. Most common co morbid illness was hypertension in (20%) followed by hypercholesterolemia (18%). Gestation diabetes

was observed in 9% **Table 1. Table 2** shows laboratory parameters in relation to Glucose and Lipid parameters.

TABLE 1: SOCIO DEMOGRAPHIC AND CLINICAL CHARACTERISTICS OF PARTICIPANTS (N=100)

Para Meters (Range)	Values N (%)
Age (years) [31– 60]	
<50	68%
>50	32%
Mean ± SD	47.15 ± 7.05
Gender	
Male: Female	3:2
Weight (Kg) [range 40-101]	
<80	72%
>80	28%
Mean ± SD	72.02 ± 12.32
Duration of Disease (years)	8.5 ± 4.36 (Mean ± SD)
<10	74%
>10	26%
Number of co-morbidities	41%
Addiction	10%
Family History	30%

TABLE 2: LABORATORY PARAMETERS OF PATIENTS IN STUDY (N=100)

Parameters	Numbers (%)
RBS(mg/dl)	
<200	52
>200	48
Mean ± SD	215.55±57.77
FBS(mg/dl)	
<126	11
>126	89
Mean ± SD	169.28±44.63
PPBS(mg/dl)	
<200	13
>200	87
Mean ± SD	266.21±68.31
Total cholesterol(mg/dl)	
<200	50
200 - 239	50
Mean ± SD	196.47±27.25
LDL(mg/dl)	
<159	96
>159	4
Mean ± SD	116.30±17.05
VLDL(mg/dl)	
2.0 - 30	97
>30	3
Mean ± SD	146.35±8.17
Triglycerides(mg/dl)	
<150	44
150 - 199	37
200 - 399	19
Mean ± SD	161.1±47.15
HDL(mg/dl)	
<40	50
40 - 59	26
Mean ± SD	44.06±10.92

TABLE 3: GLYCOSYLATED Hb (HBA1C) CONVERTED TO ESTIMATED AVERAGE GLUCOSE (eAG)

A1C	Percentage(n=100)	eAG	
%	(n)	mg/dl	mmol/l
<6	9	<126	<7.0
6.1 - 10.0	74	128 - 240	7.1 - 13.3
>10.1	13	>243	>13.5

As far as the glucose parameters were concerned more than 50% patients showed higher range in all the parameters. Hba1c, results were around the range 7.1 - 8.0 in about 37 patients. Mean SD of HBA1c was 8.38 ± 1.86 . **Table 3** also shows the conversion of HBA1c into estimated eAG. Only 18 patients were having HDL above 60, only 30 % patients were having LDL to HDL ratio below 2.5.

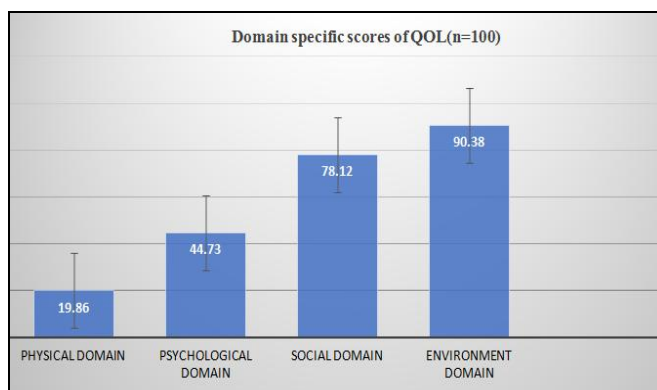
Patients' Prescription Pattern: A Total of 215 drugs were prescribed to 100 patients with the average of 2.17 ± 0.682 drugs per prescription. Metformin was prescribed to all patients of type 2 diabetes. Among sulfonylureas, Glimepride was prescribed in 27% followed by Glipizide in 17%. Metformin along with Glipizide was the most common fixed dose combination prescribed in 26% of the patients. DPP IV inhibitors and alpha glucosidase inhibitors was given along with Metformin in 28% and 12% respectively. They were not prescribed as monotherapy **Table 4**. Around 39% of the patients received insulin therapy. Long acting Inj. Glargine was the most commonly prescribed insulin (20%).

TABLE 4: DRUG PRESCRIPTION PATTERN IN T2DM (N=100)

Drugs	Numbers
Tab. Metformin (1gm)	8
Tab. Metformin + Tab. Glimepride (2mg)	14
Tab. Metformin + Tab. Glimepride (1mg)	4
Tab. Metformin + Tab. Glipizide	26
Tab. Metformin + Tab. Sitagliptin	14
Tab. Metformin + Tab. Vidagliptin	5
Tab. Metformin + Tab. Teneligliptin	4
Tab. Metformin + Tab. Voglibose	2

Analysis of Health related QOL: Analysis of health related QOL was performed using WHOQOL BREF. **Fig. 1**, highlights the scores in different domains. Higher scores corresponded to a better QOL. Physical domain was affected the most followed by psychological domain corresponding to lower score. Environment and social domain were least affected as they showed higher scores. 63% were satisfied with their health status. 33%

felt that physical pain prevented them from daily work. 14% felt they don't enjoy life because of the disease. About 33% resonance reported to have negative feelings like despair, anxiety and depression frequently.

**FIG. 1: DOMAIN SPECIFIC SCORES OF QOL ACCORDING TO WHOQOLBREF**

Analysis of Medication Adherence: Medication adherence were analyzed using MMAS 8. About 84% showed medium adherence to medications and 16% were not adherent **Table 5**.

TABLE 5: MMAS 8 SCORE IN PATIENT OF T2DM

Adherence	Total
High Adherence (0)	0
Medium Adherence (1-2)	84
Low Adherence (3-8)	16

In the study, it was noted that duration of disease correlated with social relationship domain ($r = 0.212$) Medication adherence positively correlated with psychological domain ($r = .959$) of QOL. HBA1C values correlated with psychological domain ($r = .959$) Total cholesterol was also positively correlated with psychological domain ($r = .935$). Increase in number of drugs decreases medication adherence of the patients which directly affects quality of life of the patients, the Pearson's correlation with number of drugs and medication adherence showed R value as: 0.3998 which was statistically significant ($P < 0.05$) and showed negative correlation **Table 6**.

It was found that RBS value less than 200 compared to above 200 (OR = 0.29, 95% CI: 0.093 - 0.92, RR = 0.35, 95% CI: 0.134 - 0.952) strongly related to low adherence ($p = 0.02$), and patients with duration of disease less than 10 with more than 10 (OR = 0.52, 95% CI: 0.16-1.61, RR = 0.58, 95% CI: 0.23 - 1.45) and male and female patients

(OR = 2.57, 95% CI: 0.85 - 7.75, RR = 2.20, 95% CI: 0.87-5.60) weakly related to low adherence respectively p = 0.34 and 0.08 **Table 7.**

TABLE 6: CORRELATIONS WITH QUALITY OF LIFE DOMAINS(WHOQOLBREF)

	Physical Domain	Psychological Domain	Social Domain	Environmental Domain	RBS	PPBS	HBA1C	Total Cholesterol	LDL
Age	.977	.922	.695	.830	.253*	.221*	.145	.262**	.276**
Weight	.053	.182	.078	.122	.000	.054	.044	.156	.423**
Duration	.007	.115	.205*	.087	.068	.208*	.157	.075	.175
HBA1C	.446	.959	.408	.856	-	-	-	-	-
RBS	.093	.586	.451	.808	-	-	-	-	-
LDL	.431	.536	.291	.909	.310**	.280**	.295**	.376**	

TABLE 7: MEDIUM Vs LOW ADHERENCE LEVEL BY SOCIODEMOGRAPHIC VARIABLES, DISEASE-RELATED VARIABLES AND CLINICAL PARAMETER

	Adherence level				
	Odds ratio	% 95 CI	Risk Ratio	% 95 CI	P value
RBS	0.29	0.093- 0.92	0.35	0.134-0.952	0.02
<200					
>200					
Duration of disease	0.52	0.16-1.61	0.58	0.23-1.45	0.34
<10yrs					
>10 yrs					
Gender	2.57	0.85-7.75	2.20	0.87-5.60	0.08
Male					
Female					

DISCUSSION: In this study, we have attempted to compare type 2 diabetes with the two important disease status variables HbA1c and lipids in a single setting along with its effect on quality of life and association with medication adherence. There have been very few studies that have tried to correlate all these outcomes in adults with T2DM.

In this study patients till the age of 60 years were only included, the reason was that patients over the 60 yrs. of age were referred to Geriatric OPD in the same hospital. As far as other sociodemographic characteristics were concerned like, gender, male patients were more affected. Similar findings have been observed in other studies pertaining to Indian population^{16, 17, 18}. This may be due to the fact that ours is a male dominated society they are more concerned regarding their health status and may report for consultations more in comparison to their female partner. In study done by Mohammadi *et al.*,¹⁹ showed female preponderance. According to WHO statement in 2008 the lifetime risk of developing diabetes is expected to be 39% for females and 33% for males. In the study, there were 53% patients who were having a duration range of 6 -10 yrs. This observation contrasted with

the observation made by Upadhyay *et al.*, which showed majority of less than 5 yrs. duration²⁰ similar with the study of Yolanda *et al.*, showing median duration of diabetes of 6 years²¹. Over the years, target HbA1C levels have been the subject of much debate, but until recently, it has been accepted that HbA1C should be as low as is realistically achievable. The strategy of 'the lower, the better' was reinforced by data from the UK Prospective Diabetes Study (UKPDS) that showed that any reduction in HbA1C in patients with type 2 diabetes is likely to reduce the risk of complications, with the lowest risk being in those with HbA1C values < 6%²².

For several years, the related phenomena of daily plasma glucose variability and postprandial glucose levels have been under scrutiny, particularly in relation to HbA1C and fasting plasma glucose^{23, 24}. Although their position in the so-called glucose triad is gaining acceptance so we have collected all three values in our study for every individual and they are highly co related in our study also like previous studies showing 200 - 299 PPBS (56%), HbA1C range 7.1 - 8.0 (37%) and FBS 126 - 200 (71%)²⁵.

And one metanalysis also conclude that PPBS has a closer association with HbA1c than FBS. Hence, PPBS is better in predicting overall glycemic control in the absence of HbA1c²⁶.

Postprandial glucose as a surrogate marker for other cardiovascular risk factors, serum lipids and triglycerides in particular; and direct toxicity of elevated glucose levels attributed to "spikes" in glucose concentration following caloric ingestion. That's why we have also try to correlate it by collecting the Lipid profile²⁷ which is also highly co related as per the previous studies which was also carried out in Indian population showing results of higher levels of LDL (116.30±17.05), HDL (44.06±10.92), TC (196.47±27.25) and TG (161.1±47.15) significantly higher in type 2 diabetics²⁸.

Glucose-triggered generation of diacylglycerol activates protein kinase C and thereby triggers recruitment of cellular stress signaling pathways; the polyol pathway generates reactive oxygen species (ROS), especially in the mitochondria, and leads to enhanced production of advanced glycation end-products and leads to many micro and macro vascular complication, most commonly "cindrella complication"²⁹.

So, it should be treated accurately. Treatment of diabetes mellitus type 2 has become very complex and controversial at some extent, because of availability of widening array of pharmacological agents. According to 'Standards of Medical Care in diabetes' of American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) said that it should be 'individualize' as per medical anthropology³⁰.

In Our Study Metformin alone and Metformin in combination with other drugs was most commonly prescribed. Sulfonylureas (glimipride most common) and DPP4 inhibitors and alpha-glucosidase inhibitor were most commonly prescribed. Patient with uncontrolled hyperglycemia with oral hypoglycemic agents were prescribed (39%) Insulin, in which long acting insulin glargine injection was most common. 92% drugs were prescribed in combination. As far as the prescribing pattern in our study was concern metformin was prescribed in all the cases of T2DM

which is according to the American Diabetes Association guideline. The result of our study shows same result as Premlata Das *et al.*, in drug utilization pattern showing metformin the most commonly prescribed drug alone and in combination³¹.

QOL Analysis: The WHOQOL-BREF which is short version of WHOQOL 100 and it is one of the cross cultural and widely used measures for assessing health-related quality of life³².

The QOL was measured with generic WHOQOL BREF instrument. In our study the physical and psychological domain was affected the most in comparison to environment and social domain. BA Issa and Bela *et al.*, has also used WHOQOL BREF to measure QOL showing same results of physical domain being most commonly affected followed by psychological domain. Environmental and social domain was least affected because of the disease. Patients were more concern for their physical pain which affect their physical life. Significant number of patients also reported negative feelings despair, anxiety and depression in relation to the disease. and poor QOL associated with some of the physical complication of DM^{33, 34}.

The MMAS was used because it comprehensively addressed all issues of medication adherence in 8 easily understandable questions. Evaluation of medication adherence is important in chronic disease like T2DM where regular medication also influences the outcome of disease. Good medication adherence not only ensures good glycemic control but also retards the long-term complications of T2DM. In our study majority of the patients reported medium to low adherence. Compliance to prescribed therapy can further be enhanced by securing a good doctor patient relationship and adequate counselling to the patient regarding the chronic nature of disease.

Yolanda *et al.*, using the same tool of WHOQOLBREF found that there was no association between quality of life and treatment adherence behaviour²¹. However, our study founds a positive correlation between psychological domain of WHOBREF and Medication adherence. A study by Chew *et al.* also supports a similar

finding³⁵. In our study lower adherence to medication adversely affected HBA1C(eAG) levels which was similar to study same as Manel Pladevall *et al.*, 2004³⁶.

As shown in our study, increased number of drugs prescribed showed significant negative correlation with physical and social domains of WHOQOL-BREF scale. This suggests that more number of drug prescribed may influence QOL adversely this could be due to adverse effect of the drug experienced by the patients although polytherapy may be indicated in diabetic patients to reach at goal blood sugar level.

Hence prescriber should start with monotherapy with one single antidiabetic agent but can consider addition of other drugs as need be. It has been shown that more the blood sugar levels remain in the target range lesser the long term irreversible complications of the disease. Hence impairment in quality of life in few domains is acceptable.

Medication adherence showed negative correlation with numbers of drugs which was statistically significant and it is similar review literature of Karen S. Ingersoll *et al.*, conclude the same for any chronic disease³⁷.

As far as individual questions majority of the patients rated their QOL as good and were satisfied with their health Status. About 1/3rd of the patients reported negative feeling regarding physical wellbeing. This signifies that patients who are diabetic and taking medication for the same do not demonstrate much impairment in QOL. Data of our study was taken from relatively young patients presented to OPD of tertiary care hospital who were managed effectively. We expect significant impairment of in QOL in inpatients.

CONCLUSION: Patients with type 2 diabetes are increasing day by day. Being a chronic disease, medication adherence plays an important role in type 2 Diabetes. Quality of life of the patients in our study was most affected in physical domain. It was also noted that poor medication adherence is negatively correlated with quality of life. Patient should be educated regarding the importance of adherence to medication and also its effect on their quality of life.

ACKNOWLEDGEMENT: The authors would like to thank superintendant of Jivaraj Mehta Hospital, Ahmadabad, Gujarat, India.

CONFLICT OF INTEREST: Nil

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How to cite this article:

Rajgadhi H, Patel V, Sabu B and Malhotra S: Medication adherence and health related quality of life in adult patients suffering from diabetes mellitus type 2 and its association with glycosylated hemoglobin and lipids - a prospective study at tertiary care hospital. Int J Pharm Sci Res 2018; 9(8): 3347-54. doi: 10.13040/IJPSR.0975-8232.9(8).3347-54.

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