



Evaluation of Quality of Life and Medication Adherence in Type-II Diabetic Patients

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ABSTRACT

Diabetes mellitus is the most common metabolic disorder in the world. In India, the prevalence rates of diabetes has increased dramatically since the first national survey was undertaken (1971). At that time the prevalence was 2.3% in ur an areas and 1.2% in rural areas. The most recent studies suggest prevalence rates between 15 to 20% in urban areas and around 5% in rural areas. Acute and long term complications of T2DM has effect on health related quality of life. Thus Quality of Life (QoL) has emerged as an important factor for assessing severity of chronic diabetes. Symptoms like dragging limbs, weakness, burning feet among individuals with chronic and uncontrolled diabetes provides valuable information about their medication adherence status and blood sugar levels. Variables such as HbA1c, diet adherence, self-care activities give an insight on medication adherence. Counselling patients regarding awareness and lifestyle modifications among diabetic and non-diabetic can reduce the prevalence of this chronic disease. The present study was conducted in care diabetes centre, Warangal region for 6 months period with a study population of 300. Patient's response against the pre-framed questionnaire was noted with an informed consent. The QoL was assessed by World Health Organization BREF instrument and medication adherence was calculated by Moriskyscale. QoL of 59.09% diabetics were found to be under average category and 62.3% diabetics were in high adherence category, reason being they were on fixed dose combinations.

Keywords: Type-2 diabetes, Quality of Life, WHO QoL-BREF, medication adherence, morisky scale, HbA1C.

Introduction

Diabetes Mellitus (DM) has become a pandemic endocrine disorder globally, especially in Indians due to sedentary lifestyle, lack of exercise, improper diet and obesity. It is a chronic condition, characterized by hyperglycemia due to

impaired insulin secretion with or without insulin resistance¹. The prevalence of adults with T2DM is estimated to be 4.0% (135 million) worldwide and by 2025 this figure is expected to increase to 5.4% (300 million). The increase in the prevalence of type-2 diabetes in the developing countries is

170%, whereas 42% increase in the developed countries. By 2025, countries such India, China, and the United States will be with largest number of people suffering with T2DM². Worldwide prevalence of DM has risen dramatically over the past two decades. Although the prevalence of both type 1 and type-2 diabetes is increasing worldwide, the prevalence of type-2 diabetes is expected to rise more rapidly in the future because of increasing obesity and reduced physical activity. DM increases with aging. In 2000, the prevalence of DM was estimated to be 0.19% in people <20 years old and 8.6% in people >20 years old. In individuals >65 years the prevalence of DM was 20.1%. The prevalence is similar in men and women throughout most age ranges but is slightly greater in men >60 years³. India has 69.2 million people (8.7%) living with diabetes as per the 2015. Of which 36 million people remained undiagnosed⁴. The metabolic dysregulation associated with DM causes secondary pathophysiological changes in multiple organ systems that impose a tremendous burden on the individual with diabetes and on the health care system. With an increasing incidence worldwide, DM will be a leading cause of morbidity and mortality for the future. India leads the world with the largest number of diabetes subjects earning the dubious distinction of being the term the "Diabetes Capital of the world"⁵.

The quality of life (QoL) is defined as individuals' perceptions of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns. It reflects the view that quality of life refers to a subjective evaluation which is embedded in a cultural, social and environmental context. Because it focuses on respondents' "perceived" quality of life, it is not expected to provide a means of measuring in any detailed fashion symptoms, diseases or conditions, but rather the effects of disease and health interventions on quality of life⁶. T2DM inflicts a significant burden in terms of disability and impaired QoL⁷. Health related QoL is an

important outcome for persons with type-2 diabetes and has been used to evaluate the impact of the disease and its treatment on individuals and health care costs⁸. QoL was significantly impaired in uncontrolled diabetic patients compared to controlled diabetes. Age, duration of diabetes, symptoms, comorbidities, symptoms, blood glucose level and the number of non-pharmacological measures were important predictors of QoL⁹. It is important to improve the quality of life among diabetics with proper treatment regimens ensuring good glycemic control¹⁰. Medication adherence is one of the most important factors that determine therapeutic outcomes, especially in patients suffering from chronic illnesses. Medication adherence is defined as the extent to which a patient's medication-taking behavior coincides with the intention of the health advice he or she has been given. Adherence to treatment is the key link between treatment outcome in medical care¹¹. Poor adherence to medication regimens is common, contributing to substantial worsening of disease, death and increased health-care costs¹². Low medication adherence is a serious problem in adult patients with type-2 diabetes, and its downstream effects will be multiplied by increased complication rates, psychological burden, and health care cost if left unaddressed¹³.

Methodology

A Descriptive, observational study was done for period of 6 months in a diabetic centre. Institutional Research Board approval was obtained prior to commencement of the study.

Study Population: All the patients visiting diabetic centre were screened for study after obtaining consent from the patient. Patients who are diagnosed with T2DM and on anti-diabetic therapy at least for a period of 6 months with an age of 18 years and above and willing to participate in the study were selected. Newly diagnosed individual diabetics (i.e. \leq 3 months), pregnant women and cognitive impaired patients were excluded from the study. Socio-demographic

details and relevant clinical data of participants was obtained through direct communication with the patients or care takers. Socio-demographic details such as age, gender, occupational status and clinical data such as symptoms, co-morbidities, complications, duration of diabetes, drugs prescribed, and laboratory details such as fasting blood glucose levels, HbA1C, post-prandial blood glucose levels and also non-pharmacological measures were collected from every participant. Then the participants were interviewed with WHOQOL-BREF questionnaire and 8-Item MORISKY scale, to obtain QoL and medication adherence status respectively.

WHOQOL-BREF instrument

The questionnaire has been extricated from the programme on mental health, World Health Organisation, GENEVA. It is a 26 item generic questionnaire, which is a brief version of the WHOQOL-100 questionnaire. All the items can be classified into five domains: global-overall general health (two items), physical health (seven items), psychological (six items), and social relationships (three items) and environment (eight items) on a five-point scale. The response options range from 1 (very dissatisfied) to 5 (very

satisfied), which focus on subjective response rather than objective life conditions.

8-Item Morisky Scale for Medication Adherence

Morisky scale includes 8 items, in which each item is in Yes (or) No format and medication adherence was determined by the score obtained.

Table 1: 8-point Morisky scale score was categorized as follows:

Score	Adherence
≥ 3	Low
1-2	Medium
0	High

Statistical Analysis: All the results were analyzed using Graph Pad Prism software version 7.01 and chi-square test.

Results

A total of 300 patients were interviewed during the study period. Among them 80 (26.67%) patients were of controlled diabetes and 220 (73.3%) were uncontrolled diabetes. Of 300 patients in both controlled and uncontrolled group, female were predominant compared to male i.e. 63% and 37% respectively.

Table 2: Age wise distribution of data

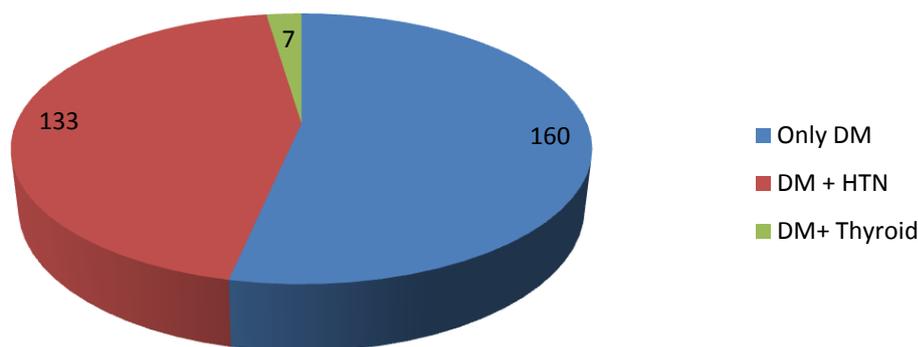
Age (in years)	Group (n=300)		Statistics
	Controlled DM (n=80)	Uncontrolled DM (n=220)	
25-35	4 (5%)	14 (6.3%)	$X^2 = 1.277^*$ P>0.05 Df = 3**
36-45	14 (17.5%)	37 (16.8%)	
46-55	39 (48.7%)	106 (48.1%)	
56-65	18 (22.5%)	55 (25%)	
66-75	5 (6.25%)	8 (3.6%)	
Total	80	220	300

*Chi square, ** Degree of freedom

40.6% of the patients were diagnosed with T2DM <5 years ago, whereas 13.3% were suffering with T2DM for more than 10 years. Hypertension (53.3%) is predominantly seen as a co-morbid condition in the study, followed by hyperlipidaemia (3.3%), asthma (2.6%), neuropathy (2.6%), CAD (2.3%), Chronic Kidney

Disease (2%), hydronephrosis (1.3%), cataract (1.6%), Left Ventricular-dysfunction (1.3%) and Coronary Artery Bypass Graft (1.3%) conditions. In present study patients were on statin therapy, that might be the reason for less percentile of hyperlipidemia.

Figure 1: Endocrine Disorders Observed in Patients



During the study period, most of the patients complained about dragging limb pains (20.3%) followed by general weakness (10.3%), burning foot (8%), giddiness (7.6%), indigestion (4.3%), insomnia (2.3%) and polyuria (2%).

Assessment of QoL in study participants

Response of all the patients to WHOQOL-BREF questionnaire was evaluated and the results were as shown below in various domains.

Table 3:

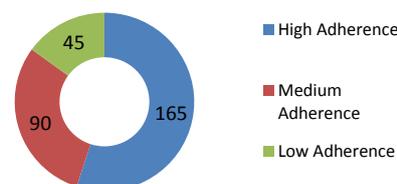
QoL Category	Group (n=300)		Statistics
	Controlled DM (n=80)	Uncontrolled DM (n=220)	
Physical domain			
Worst	3 (3.7%)	4 (1.8%)	$X^2 = 3.87^*$
Average	44 (55%)	130 (59.0%)	$P = 0.2759$
Good	32 (40%)	86 (39.0%)	$Df = 3^*$
Best	1 (1.2%)	0 (0%)	
Psychological domain			
Worst	5 (6.2%)	2 (0.9%)	$X^2 = 8.698^*$
Average	29 (36.2%)	75 (34.0%)	$P < 0.05$
Good	46 (57.5%)	140 (63.6%)	$Df = 3^{**}$
Best	0 (0%)	3 (1.3%)	
Social domain			
Worst	12 (15%)	9 (4.0%)	$X^2 = 14.08^*$
Average	31 (38.7%)	120 (54.5%)	$P < 0.05$
Good	37 (46.2%)	89 (40.4%)	$Df = 3^{**}$
Best	0 (0%)	2 (0.9%)	
Environmental domain			
Worst	0 (0%)	1 (0.4%)	$X^2 = 2.182^*$
Average	32 (40%)	67 (30.4%)	$P < 0.139$
Good	48 (60%)	150 (68.1%)	$Df = 1^{**}$
Best	0 (0%)	2 (0.9%)	

*Chi square, ** Degree of freedom

Assessment of Medication Adherence

Medication adherence was assessed using 8-item Morisky scale and the results are depicted as below.

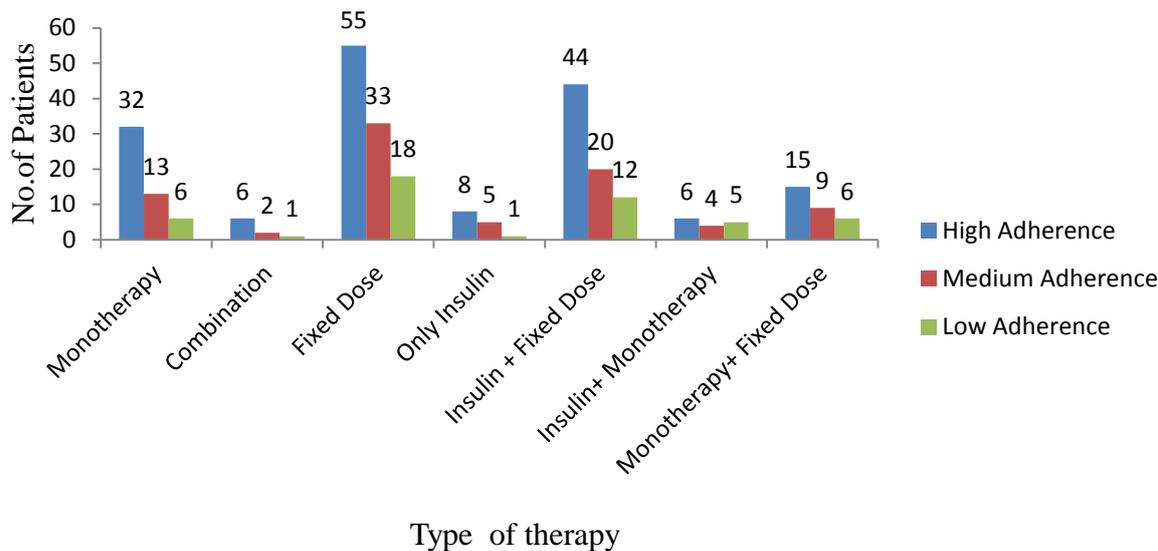
Figure 2: Distribution of Medication Adherence



In the study population, it has been observed that females (62.3%) were predominantly adhered to

medications rather than male (37.6%).

Figure 3: Medication Adherence based on type of therapy

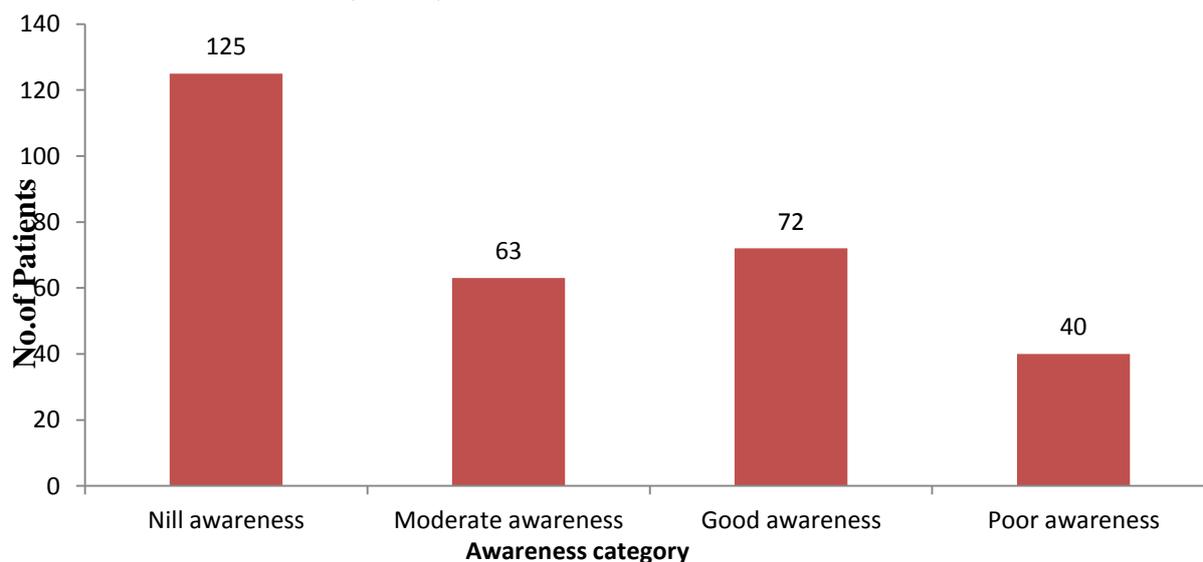


Type of treatment regimen had greater influence on the patient medication adherence and on QoL. In our study, subjects with age (>45 years), and longer duration of diabetes (>5years) were more likely to have low and medium adherence. Subjects with low and medium medication adherence (71.8%) have shown HbA1C ≥ 7 i.e. uncontrolled diabetes. In the present study, good

dietary adherence (67.3%) is predominantly seen followed by moderate adherence (29.6%) and poor adherence (3%).

Risk and prevalence of T2DM can be decreased by creating awareness among patients. The DM awareness among the study participants is as shown below.

Figure 4: Awareness of Diabetes (n=300)



Discussion

As there is insufficiency of traditional endpoints (which are mainly focused on the biologic and

physiologic outcomes) in capturing the effects of interventions on patients’ health-related quality of life (HRQoL), a growing interest has emerged

during the past decades for assessing determinant factors of patients' HRQoL, especially in chronic diseases. Diabetes mellitus is one of the chronic diseases that involve people of all ages and races. It is considered as one of the most common chronic diseases in approximately all countries, and its prevalence continues to increase mainly due to the sedentary lifestyles resulting in physical inactivity, improper diet and increased obesity.¹⁴

A structured questionnaire was used to obtain the information on socio-demographic profile and diabetic history. The quality of life was assessed by WHOQOL-BREF scale, which is a validated tool to assess QoL in people with type 2-diabetes, across different nationalities. The four domains measured in the study were: physical, psychological, social and environmental, through a set of 26 items. Overall general health domain result was insignificant in study patients. Scoring of the responses was done using 5-point Likert scale, enquiring 'how much', 'how satisfied' or 'how completely' the respondent felt in relation to the domain was investigated. It is crucial to ensure patient's adherence to the prescribed medication in type 2 DM because of strong co-relation between adherence, treatment costs, and patient outcomes. A patient with type-2 diabetes medication adherence is a key ingredient of self-management.¹⁵

Adherence to treatment has been assessed during a personal interview with each patient using 8-item Morisky Medication Adherence Scale (MMAS) questionnaire. Response category include yes/no for each item with a dichotomous response, except for the last item where in 5-point Likert scale was included.

Of 300 patients in the study, only 27% (n=80) were under diabetic control and remaining 73% (n=220) of the subjects had uncontrolled diabetes. Mean age in both the groups was found to be 51.1 (SD±9). Out of 300 patients, 109 (36%) patients had a family history of diabetes compared to 35% patients with past family history of diabetes and with mean age of 56.8 in the study conducted by BelaPatel et al.⁹

In our study patients, female 63% (n=189) were predominant over male 37% (n=111) and diabetes was more controlled in female than male. Gender-based classification in this study is in contrast to the study done by M.H.Kazemi-Galougahiet al¹⁶ 68.3% were male and 31.7% were female but it is comparable with the study done by Cheah WL et al¹⁷ where 81.7% of the study populations were women. 80% of the patient population had past history of diabetes of 5-10 years compared >10 years is just 19% population. In the present study, hypertension (53.3%) was most common co-morbid illness followed by hyperlipidemia (3.3%). Cardiovascular events are seen more in number. Atherosclerosis is the cause of a majority of cardiovascular events, and atherosclerosis is accelerated by diabetes and the metabolic syndrome. Many risk factors are associated with the metabolic syndrome and help explain the increased cardiovascular disease (CVD) in that condition. Because the metabolic syndrome occurs in most people with type-2 diabetes, its presence likely accounts for most of the increased incidence of CVD in type-2 diabetes. High glucose conditions may enhance activation of NFkB, which leads to the expression of several inflammatory genes, including adhesion molecules that facilitate monocyte adhesion to endothelial cells. Monocytes then differentiate into intimal macrophages, which take up lipids (thereby becoming foam cells) and accumulate in the artery wall in diabetes, resulting in accelerated fatty streak formation. With time, these early fatty streak lesions are believed to develop into advanced lesions, characterized by smooth muscle cell accumulation, necrotic core formation, and lipid accumulation. Some of these advanced lesions eventually become unstable and rupture, resulting in the clinical manifestations of CVD.¹⁸ These results are consistent with study done by Belapatel, et al.⁹

Patients with controlled and uncontrolled diabetes did not differ much in the physical domain. Both the groups scored the 'average' quality of life followed by 'good'. 'Best' quality of life score

(1.2%) has been noted in the controlled group but it is not that significant. In uncontrolled diabetic subjects, 'average' scoring in physical domain is predominantly seen (59.09%) followed by 'good' (39.09%). Good awareness regarding their clinical condition i.e. diabetes, is seen more in 'good' scored subjects (15.1%) whereas in 'average' score subjects it is 11% and subjects who doesn't have any idea of diabetes were more in 'average' scored group (51%) rather than 'good' scored group (43%). In addition to this co-morbid conditions are seen to be less in a best-scored group i.e. 53% whereas in an uncontrolled group it is 61%. Good diabetic diet adherence is seen to be good in 'good' scored subjects (70%) rather than 'average' scored group (59%). The physical domain in this study population is found to be insignificant as obtained p- value is >0.05. This result is in contrast when compared to another study from Belapatel, et al.⁹ Whereas this result is consistent with the study done by Bani-Issa W. et.al¹⁹ The above differences in the mean score of health related QoL and its domains in the diabetic subjects are strong proof that the health-related QoL is a subjective concept and is perceived differently by each individual in a different culture. Good awareness of diabetes, diet adherence, and less co-morbid conditions contributed patients to score 'good' in the physical domain, whereas these aspects lack in patients who scored 'average' in this domain in the uncontrolled diabetic group. Medication adherence and significant social habits didn't differ much in 'average' and 'good' scored subjects.

In the present study population, the psychological domain was found to be significant. This result is consistent with another study from Cheah WL et.al¹⁷ where Malay respondents were reported to have significantly higher adjusted mean score in emotional health component (81.3, CI=77.5 to 85.2) compared with Chinese (68.8, CI=63.4 to 74.3) (p=0.002) in their study population. Cultural background and health beliefs might have affected the perception of the emotional health of different

ethnic groups. Psychological and environmental domains were scored high mean score and the reason behind this might be the counseling provided to the patients in the clinic. Diabetes is associated with increased risk of psychological disturbance,¹⁶ especially for those with diabetes-related complications. Counseling these patients will have significant impact leading to positive health outcome. Respondents of both the groups scored 'good' QoL in this domain i.e. 57.5% and 63.6% respectively followed by 'average' QoL category of this domain. The mean score of this domain based on 4-20 scoring process is 13.51 (SD±1.99). Multiple co-morbid conditions (61%), nil awareness regarding diabetes (49.3%), less diet adherence (50%) and also medication adherence (48%) led to score 'average' QoL score; whereas these aspects are observed to be within normal limits in 'good' QoL categorized subjects of uncontrolled diabetic group.

The social domain was found to be significant in the present study group with a mean score of 12.13 (SD± 2.5). In our study for, WHOQOL-BREF, social domain scored lowest which is consistent with the study done in Belapatel, et al⁹ whereas these results are in contrast to Bani-Issa W. et.al¹⁹. Where social and environmental scored highest. These differences depict socio-cultural differences between two countries. The reason behind these differences might be that other country people enjoy social relationships more than what Indian's do. It has been practically noticed that subjects hesitated to answer when questioned about their sex life, social life and exercise. In the present study (n=300), 30.3% of the subjects response to sex life was 'very poor' and 1.3% was 'very good'. This signifies the effect of DM on personal relationship in the study group. Damage to the blood vessels and nerves due to diabetes lead to sexual and urologic problems in both the gender, which might be the reason for dissatisfied sexual life in diabetic patients. Personal relations and practical social support in these subjects were average. More co-morbid conditions nil awareness of diabetes

(55%), and poor compliance to the diet might have led most of the subjects to score 'average' QoL rather than to score 'good' QoL in uncontrolled diabetic subjects.

The environmental domain was found to be insignificant. The mean score of this domain in the study was found to be 13 (SD±9.0), which slightly differ in single point when compared to a study from BA Kolawole et.al²⁰ where the mean score was found to be 13.5(SD±1.7). As both the countries are still developing, the financial resources may vary from each individual subject. That might be the cause which led to an average score in this domain. More co-morbid conditions, less diet adherence and low medication adherence might have led the subjects to score 'average' QoL rather than to score good QoL in uncontrolled diabetic subjects. In India, diabetes is considered as a endpoint disorder where patients assume that there is no chance of leading normal life. Hence patients feel depressed, incompetent and non-enthusiastic. Some patients take it as part of life, follow strict medication adherence, diet restrictions, regular exercises whereas others give up easily, leading to various complications. Such trends are not observed in countries like USA and UK. This might be the reason for such varied scores in QoL.

Most of the patients had high adherence (55%, n=165) to medications, followed by 'medium adherence' 30% (n=90) and 'low adherence' 15% (n=45). These results are in contrast with a study done in Arulmozhi's et.al²¹, where only 49.3% of the subjects had high medication adherence followed by low adherence 26% and medium adherence 24.7%. These differences might be due to different sample size in both the studies. Age, duration of disease since diagnosis are been included as independent variables in the study are found to be insignificant. This result is consistent with a study done by Arulmohzi's et al.²¹ In this study, it has been noticed that female are more adhered to medications than male, and the difference may be due to the occupation of the individuals. It has been stated so because during

interview with each individual, subjects who were employed complained lack of time to take medicines on time and majority of the study population were female, who were housewives rather than employed subjects. This might be the reason for more compliance in female compared to male.

It has been observed that fixed-dose therapy is predominantly prescribed followed by insulin with fixed dose, monotherapy, monotherapy with fixed dose, insulin with monotherapy, only insulin, and combination therapy. High medication adherence is seen in the subjects who were on fixed-dose therapy (35%), followed by insulin with fixed dose (25.3%), monotherapy (17%), monotherapy with fixed dose (10%), insulin with monotherapy (5%), only insulin (4.6%), and combination therapy (3%). Sajith et al⁽³⁾ found that better percentage of adherence with combination therapy 43.9% was observed compared to monotherapy 18.9%. The differences might be due to variations in prescribing pattern, in different states or by individual physician choice.

HbA1C ≥ 7 is seen predominantly more in subject with low and medium medication adherence (71.8%) i.e. uncontrolled diabetic subjects. This implies that high medication adherence will led to good glycemic control. Hence each individual should be counselled regarding medication adherence and its importance in early effective treatment of any chronic illness.

Conclusions

QoL is an important aspect in T2DM patients, especially who are diagnosed long time ago. Impaired social, psychological and sexual life is observed in the study patients, reflecting the significance of controlling their glucose levels under check. Non-compliance to medications, presence of co-morbid conditions, irregular diabetic diet and poor awareness of diabetes were predictors of impaired QoL in the study. The significance of medication adherence in treatment of chronic diseases is established. Good medication adherence is seen in the subjects

prescribed with fixed dose therapy. Hence fixed dose therapy can be recommended to increase medication adherence. Poor medication adherence and less awareness of diabetes among type-2 diabetic subjects demonstrate the need to focus on this group of patients in order to improve treatment and general QoL. In our study, patients with longer duration of DM and elderly patients had low medication adherence. Hence patients with longer duration of diabetes, elderly patients and even younger patients with early onset of diabetes must be counselled about diabetes, its progression and importance of diabetic diet and strict medication adherence, so that patient develops self-discipline leading to good QoL. Interventions such as good communication between physician, pharmacist and patient, effective patient education and medication counseling, encouraging patients to monitor their blood glucose levels and simplifying drug regimen can improve the patient compliance and medication adherence.

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