DIABETES MELLITUS;

CORRELATION OF TREATMENT SATISFACTION PARAMETERS, EDUCATIONAL STATUS AND THERAPY TYPE WITH ADHERENCE IN TYPE-II DIABETES MELLITUS.

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ABSTRACT... Objectives: Diabetes Mellitus being a major issue faced by developing countries like Pakistan. Non-adherence is a major issue in achieving a desired therapeutic goal. This study aims at determining relation with the drug non-adherence associated with the treatment regime, treatment satisfaction and educational status of the person. Study Design: This was a cross sectional study. Place and Duration: This study was done at the Diabetes clinic, Nishtar hospital, Multan. Total 242 diabetic patients were studied over a period of 10 months. Methodology: The inclusion criteria was set as patients who have been diagnosed with Diabetes Type II and had been on oral hypoglycemic medications for about last 5 months or more. Those patients who were diagnosed with Type I diabetes and Type II diabetes less than 5 months were not included in the study. Also those patients who were on Insulin therapy were also excluded. Socio-demographic data was obtained along with therapy type and educational status. Drug adherence level was studied with the 8-item Morisky (MMAS-8). Treatment satisfaction was studied with the help of treatment satisfaction questionnaire for medication. The data was analyzed on the SPSS version 23 with significant p-value <0.05. Results: Among 242 patients 152(62.81%) were females and 90(37.19%) were males. Mean age of the patients were 47.68 ± 15.13 years. Patients on combination therapy were (n=134, 55.3%) and on monotherapy were (n=108, 44.6%). Mean adherence score was 5.4 ± 1.1 . The mean for four domains of Treatment Satisfaction Questionnaire for Medication(TSQM) were: effectiveness = 66.93 ± 15.27 , side effects = 32.09 ± 26.91 , convenience = 62.59 ± 14.49 and satisfaction = 65.49 ± 16.13 . Non-adherence was found to be associated with age, illiteracy, side-effects, satisfaction and convenience (p<0.05). Conclusion: Non-adherence must be overcome in patients to achieve appropriate glucose levels. Significant factors affecting the adherence levels were Illiteracy, Side effects, convenience and satisfaction of the patient. Public awareness campaigns and regular clinic visits should be encouraged. Drugs having lower sideeffects, higher satisfaction levels and combined generics for once daily dosing having greater convenience should be used.

Key words: Adherence, Diabetes Mellitus, Diabetes Type I, Pakistan, Satisfaction.

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INTRODUCTION

Diabetes Mellitus (DM) is a metabolic disorder characterized by the episodes of hyperglycemia and glucose intolerance.¹ 85% to 95% of patients are of Type II DM and 5 % to 15% are of Type I DM.² It was estimated that in year 2000 171 million people were suffering from DM and it will rise up to 366 million by 2030.³ The occurrence of diabetes mellitus in Pakistan is 8.6% with 11.1% in Balochistan and KPK and 13.9% in Sindh.⁴ Diabetes Mellitus is a chronic disease and appropriate glycemic control along with dietary modifications and lifestyle changes is necessary to beat this condition.⁵ Adherence is a key factor in achieving therapeutic success.^{6,7} Adherence refers to as an extent patient takes the medication being prescribed by the health care provider.⁸ Primary non adherence, Nonpersistence and non-compliance are some of the patterns of Non-adherence.⁹ Adherence can be measured by the direct and indirect methods. Direct methods include measuring the level of drug or its metabolites in blood or urine. While indirect methods include prescription refills, self-

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Article received on: 19/04/2017 Accepted for publication: 25/08/2017 Received after proof reading: 03/11/2017 reports, electronic monitors etc.¹⁰ In this study we evaluated the patients for non-adherence and their satisfaction with ongoing treatment. We also evaluated factors affecting the non-adherence and global satisfaction as well as their mutual association affecting each other. This study will help in achieving better levels of adherence as well as better treatment satisfaction regimes.

METHODS

This Cross-sectional study was conducted at Diabetes Clinic Nishtar Medical College and Hospital, Multan, Pakistan over a period of 10 months from November 2015 to August 2016. The approval was obtained from the institutional review board and ethical committee. Total 242 patients with 90 males and 152 females of diabetes type Il were selected for the study after obtaining an informed consent. The inclusion criteria was set as patients who have been diagnosed with Diabetes Type II and had been on oral hypoglycemic medications for about last 5 months or more. Those patients who were diagnosed with Type I diabetes and Type II diabetes less than 5 months were not included in the study. Also those patients who were on Insulin therapy were also excluded.

The primary objective was to measure the adherence and Treatment Satisfaction in patients taking oral hypoglycemic medications. Secondary aim was to study different factors affecting adherence and satisfaction levels. The Morisky Medication Adherence Scale (MMAS-8) was used for measuring the adherence.¹¹ The Morisky (MMAS-8) is an eight item questionnaire, based on the scoring system of MMAS-8 adherence was rated as follows: High adherence=8, Medium adherence 6 to < 8 and Low adherence < 6. The persons having medium or low adherence is considered as non-adherent. Treatment Satisfaction Questionnaire for Medication (TSQM) was used to measure Treatment Satisfaction in patients. TSQM scale is 11 item questionnaire with score ranging from 0-100 along with four domains: Effectiveness. Side Effects. Convenience and Global Satisfaction.¹² Sociodemographic, clinical and medication data was obtained separately. After obtaining an informed consent the patients were interviewed about 8

item MMAS-8, 11 item TSQM, sociodemographic, clinical and medication data.

The analysis was carried out with SPSS version 23.0. Frequencies and percentages was calculated for the descriptive variables. Continuous variables were expressed as means \pm SD. The correlation between continuous variables and adherence score was assessed by Pearson correlation. Independent sample T test was used to compares means of continuous variables of two groups.

Analysis of the correlations showed that age was strongly and positively correlated with the Adherence tested as continuous variables r=214, P=0.001 (Pearson correlation). There was no significant correlation found between the gender and adherence P=0.409, mean difference =-0.0733, 95% CI= -0.101 to -0.248 (Independent sample T test). Similarly no significant differences were found in the adherence scores of patients on monotherapy or combination therapy and no significant relation was found P=0.170, mean difference = -0.065 to -0.309, 95% CI = -0.122 (Independent sample T test).

RESULTS

Total 242 patients diagnosed with DM Type II included in this research out of these 152 (62.81%) were females and 90 (37.19%) were males. Mean age of the patient was 47.68 \pm 15.13 years (Range 25-85). Majority of the patients were on Combination therapy (n=134, 55.3%) while number of patients receiving monotherapy (n=108, 44.6%) was small. According to study 118(48.8%) were illiterate, 48(19.8%) were having Primary education, persons having secondary education 56(23.1%) and university education or Diploma were 20 (8.3%). Details regardingage, gender, therapy and educational status type is given in Table-I.

According to MMAS-8, The Mean adherence score was 5.4 ± 1.1 . Among total 134(55.4%) patients have low adherence, 84(34.7%) patients have medium adherence and 24(9.9%) patients have high adherence.

		Low Adherence	Medium Adherence	High Adherence	p-Value
		Mean ± SD	Mean ± SD	Mean ± SD	
Age		44.86 ± 15.10	50.47 ± 14.05	53.66 ± 16.05	P=0.001
Treatment Satisfaction Questionnaire for Medication (TSQM) Domains	Effectiveness	65.36 ± 13.12	68.29 ± 16.43	71.00 ± 20.88	P=0.52
	Side Effects	39.25 ± 28.13	19.52 ± 21.19	36.17 ± 22.42	P=0.002
	Convenience	60.93 ± 14.42	60.45 ± 14.50	66.83 ± 14.11	P=0.03
	Satisfaction	63.39 ± 14.71	67.00 ± 18.65	72.00 ± 11.90	P=0.009
		Count (%)	Count (%)	Count (%)	
Gender	Male	50 (55.6%)	40 (26.7%)	16 (17.8%)	P=0.409
	Female	84 (55.3%)	60 (39.5%)	08 (5.3%)	
Education	Illiterate	62 (52.5%)	48 (40.7%)	08 (6.8%)	
	Primary	28 (58.3%)	16 (33.3%)	04 (8.3%)	
	Secondary	36 (64.3%)	16 (28.6%)	04 (7.1%)	
	University or Diploma	08 (40.0%)	04 (20.0%)	08 (40.0%)	
Therapy	Monotherapy	83 (55.3%)	48 (32.0%)	19 (12.7%)	P=0.170
	Combination Therapy	51 (55.4%)	36 (39.1%)	05 (5.4%)	
		Table-I			

This means that total 218(90.1%) patients were nonadherent. 38.4% patients said that they sometimes forget to take their medicines, 9.5% patients stopped taking their medications due to worsening of symptoms, 7.4% patients forgot to take their medicines with them during travelling, 14.9% patients stopped taking medicines when they started feeling better and 27.6% patients felt dissatisfaction or resentment or confusion due to the daily medication plan.

According to the TSQM mean for effectiveness domain among the diabetic patient was 66.93±15.27, mean for side effects domain was 32.09±26.19, mean for convenience domain was 62.59±14.49 and mean for global satisfaction domain was 65.49±16.13 as shown by Table-I.

The means ± SD for four domains of TSQM was: Effectiveness (EFF) = 66.93 ± 15.27 , Side Effects (SE) = 32.09 ± 26.91 , Convenience $=62.59\pm14.49$ and Satisfaction = 65.49 ± 16.13 (as given in Table-I).

Analysis of the correlations showed that age was strongly and positively correlated with the Adherence tested as continuous variables r=214, P=0.001 (Pearson correlation). There was no significant correlation found between the gender and adherence P=0.409, mean difference =-0.0733, 95% CI= -0.101 to -0.248 (Independent sample T test). Similarly no significant differences

were found in the adherence scores of patients on monotherapy or combination therapy and no significant relation was found P=0.170, mean difference = -0.065 to -0.309, 95% CI = -0.122(Independent sample T test).

Strong negative correlation was found between the adherence and SE domain P=0.002(Pearson correlation). The adherence was also significantly and positively correlated with the Satisfaction domain P=0.009 (Pearson correlation). Similar correlation was also found between Convenience domain and adherence P=0.03 (Pearson correlation). No significant correlation was found between the Effectiveness domain and adherence scores of the patients P=0.52 (Pearson).







DISCUSSION

In this study we aimed to investigate the correlations of effectiveness, side effects. Convenience, Satisfaction, Educational status and therapy type with adherence. In our study we found that 90.1% type II DM patients were non -adherent. There are few studies on regional basis which showed different adherence levels. Similar study conducted in Multan by Imtiaz et al on indoor diabetics shows 36% patients to be non-compliant.13 Another study conducted by Riaz et al shows very high level of nonadherence in 88% patients.14 In Egypt Shams and Barkat also reported good adherence in 40% of patients. A systematic review of adherence showed an average adherence from 36% to 93% different regions.15

Total 242 patients participated in this study and among these 37.2% were males and 62.8% were females. No significant relation was found between gender and adherence levels. Imtiaz et al also found no significant adherence in gender and diabetes.¹³ In an Egyptian study researchers found that age and Satisfaction domain was significantly correlated.¹⁶ A Nigerian study shows gender was significantly related to the adherence levels with males being less adherent.¹⁷

In our study we found slight higher adherence levels in the patients having monotherapy than combination therapy patients but no significant relation was found between the Therapy type and adherence. Similar results were reported by the Sweilehet al where they found weak association between polypharmacy and drug nonadherence.¹⁸

In this study University or Diploma patients have significantly higher levels of adherence this may be associated with higher level of Knowledge of diabetes. A study conducted by Nadia S. at Rawal Institute of Health Sciences showed that better knowledge about diabetes and blood glycemic levels results in increased level of adherence.¹⁹ Imtiaz et al also found relation between Illiteracy and drug non adherence.¹³

In this study we found no significant association between effectiveness of the medication and adherence levels. A study conducted in Palestine by Raniah M. found effectiveness to be strongly related with the effectiveness of the drugs.²⁰

Our results also showed significant negative relation with the Side effects experienced by the patients with their adherence levels. This may be due to stoppage of medication in relation to their adverse effects. Morello CM research also shows that increasing patients knowledge about managing adverse effects with medications results in increased adherence levels.²¹ Study by Raniah M. showed no significant relation with the adherence and side effects.²⁰

Convenience levels of patients was also found weakly associated with adherence levels in

our study. This may be due to due to usage of medications with longer half-lives and combination of two generic drugs in one pill form which is easy to remember and results in increased adherence levels. In our study we also found 38.4 % response to forgetfulness to take their medication (Question #1) in MMAS-8 scale. Similar results were also reported by Raniah M. in which authors found 37.7% patients who forget to take their medicines.²⁰ A study conducted by Nadia S. at Rawal Institute of medical sciences showed high response of 51% to question about forgetfulness to take their medication.¹⁹

Our study also showed that Satisfaction domain was strongly correlated with the adherence of patients. Raniah M. also found similar correlation between satisfaction and adherence levels of the patients. They also found significant positive relation of age with the satisfaction of the patients.²⁰ improving patient satisfaction about the efficacy of treatment and higher knowledge of patient blood glycemic control will result in increased adherence levels.

CONCLUSION

Non-adherence in patients with Type II DM is a serious issue as daily blood glucose levels must be appropriately maintained in these patients. Significant factors affecting the adherence levels of the of the patients with type II DM were found out to be Illiteracy, Side effects associated with the medications and satisfaction of the patient with ongoing treatment. Convenience was also found to be weak factor affecting the adherence levels. Improving the knowledge about disease and managing appropriate glycemic control can result in higher adherence levels. Public awareness campaigns, self-glucose monitoring and regular clinic visits should be encouraged to improve patient adherence. Drugs having lower side effects and higher satisfaction rates should be used to improve adherence. Drugs having once daily dosing and with combined generics should be used as they have better convenience levels which may results in higher adherence levels.

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