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IJPBS |Volume 3| Issue 4 |OCT-DEC|2013|361-368

Research Article
Pharmaceutical Sciences

PROSPECTIVE ASSESSMENT OF MEDICATION ADHERANCE AND ITS IMPACT ON TREATMENT OUTCOMES IN DIABETICS OF NORTHEN TELANGANA

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ABSTRACT

***Background**: Non-compliance to oral hypoglycemic medication is one the major reason for poor control of complications of diabetic patients worldwide. Study was conducted to evaluate medication adherence impact of patient education on behaviour and treatment outcomes in diabetes patients. **Methodology**: Three hundred outpatients were interviewed randomized into test and control by convenient sample technique. Total patients were interviewed using a pre-tested, structured, mostly closed ended Brief Medication Questionnaire (BMQ), screening tool to assess medication adherence behaviour. Test population was educated at each follow up and control group was educated at end of study. Fasting blood sugar was determined at each follow up. **Results**: By the end of study, good compliance was observed in test population when compared to control group reporting poor compliance. In test group Intervention reduced beliefs barrier from 19% to 0.4% and recall barrier from 30% to 21% in test group. In control group Intervention reduced beliefs barrier from 17% to 0.5% and access barrier from 30% to 4% in control group. Poor compliance was found to be mainly due to ignorance on need for regular treatment, lack of funds to purchase drugs. **Conclusion**: Based on the findings of this study, there is a need for launching a comprehensive approach involving health care providers, patients and the general public to educating patients on the need to take their drugs regularly and in the manner prescribed. Doctors should consider the financial status of their patients in prescribing oral hypoglycaemic drugs to enable affordability.*

KEY WORDS

Hypoglycaemic, Test population, comprehensive approach.

INTRODUCTION

Diabetes is a heterogeneous spectrum of metabolic disorders characterized by hyperglycaemia as a common finding. It is a multisystem disease with both biochemical and anatomical / structural consequences[1]. WHO defines diabetes as follows ‘‘The term diabetes mellitus describes a metabolic disorder of multiple etiologies characterized by chronic hyperglycaemia with disturbances of carbohydrate, fat, and protein metabolism resulting from defects in insulin secretion ,insulin action, or both[2]. India leads the world with largest number of diabetic subjects earning the dubious distinction of being termed the “*diabetes capital of the world*”. According to the Diabetes Atlas 2006 published by the International Diabetes Federation, the number of people with diabetes in India currently around 40.9 million is expected to rise to 69.9 million by 2025 unless urgent preventive steps are taken[3].Adherencehas becomes the preferred term management of chronic disease like diabetes mellitus and hypertension. Adherence defined by the World Health Organization as **“**the extent to which a person’s behaviour in taking medication corresponds with agreed recommendations from a health care provider[4, 5]**.** The word “adherence” is preferred by

many health care providers, because "compliance" suggests that the patient is passively following the doctor's orders and that the treatment plan is not based on a therapeutic alliance or contract established between the patient and the physician[6]. Accurate assessment of adherence behaviour is necessary for effective and efficient treatment planning, and for ensuring that changes in health outcomes can be attributed to the recommended regimen.[7] Diabetes mellitus has become an international healthcare crisis that requires new approaches to prevent and treat it[8].It also affects psychoemotional functioning and consequently, the quality of life (QOL) of patients Patient literacy affects many aspects of medication use and may influence the measurement of adherence[9].The current study reinforces the importance of preventing diabetes complications by assessing and improving medication adherence behaviour of patients.

MATERIALS AND METHODS

This is a prospective study conducted for a period of nine months from March 2012-to November -2012. The patients from various places visit this clinic regularly for treatment of many diabetes and its related complications. The study was approved by the Institutional Human Ethical Committee of Talla Padmavathi College of Pharmacy, Warangal.

Sources of data:

A suitable data collection form was designed to collect, document and analyze the data. Informed consent section was also incorporated in the data collection form. Data collection form included the provision for collection of information related to demographic details of patients (name, age, sex, weight, contact details, address), diagnoses, medication usages and details pertaining to social habits like smoking etc.

The data including demographics, drug usage pattern of patients. All the relevant and necessary data was collected frompatients' case notes, treatment charts and interviewing patients or patients care takers.

Study procedure:

Patients visiting outpatient study site and with a diagnosis of Diabetes mellitus and who are on oral hypoglycemic agents with minimum disease duration of 1-10 years were included in this study. A duly filled inform consent from (ICF) was obtained from patient after getting permission from institutional ethical committee. Recruited patients were randomized into test and control group by selective sample technique. Both groups of patients had got a baseline patient counseling. The control group patients had only the baseline counseling and test group patients had patient counseling on monthly basis regarding the medications and there usage. Medication adherence questionnaire was administered at baseline and subsequent follow ups. The duration of each follow-up is 45 days with four follow-ups (six months). Medication adherence patterns was recorded and compared in between both the groups by using appropriate parametric and non-parametric statistical tests like ANOVA, Multiple Regression Analysis, Pearson's Correlation Analysis were done

Brief medication Questionnaire designed by ***Prof. Svastad*** was used to measure the adherence behavior in this study. The BMQ-ARS measures the number of adherence risk factors present and is constructed by adding the subtotals listed above (Subtotal A + Subtotal B + Subtotal C + Subtotal D = ARS). The ARS score ranges from 0 to 4, with "0" indicating no self-reported nonadherence or barriers to adherence and "4" indicating the presence of self-reported nonadherence and three types of barriers (belief or motivational barrier, recall barrier, and access barrier)

RESULTS

In the present study, a total number of 287 patients were enrolled and followed up who are receiving Oral hypoglycemic agents study site.287 patients were classified into 4 groups based on educational status. Patients were segregated, based on their education qualification into four groups. Uneducated (UE), Undergraduate (UG), Graduate (G), and Post Graduate (PG). Most of the study populations were found to be graduates. Results are displayed in **Table No. 1**

Table No.1 Patients Distribution Based on Educational Status

S.No	Educational Status	Males	Females	Percentage
1	UE(0)	14	18	11.15%
2	UG(1)	90	110	69.67%
3	G(2)	47	0	16.38%
4	PG(3)	6	2	2.79%
5	Total	157	130	100%

Patients who are mono therapy are included in the study. Generally three drugs metformin, glimepiride, pioglitazone are used by the patients enrolled in the study.

The drug distribution among the patients at baseline and at final follow up is given in **Figure1 and Figure 2** respectively.

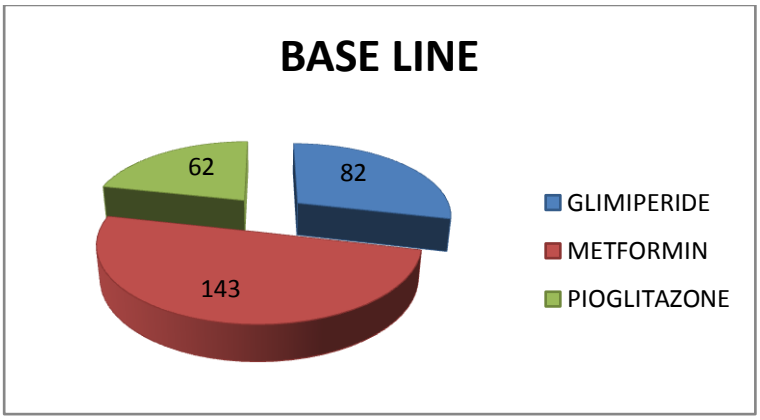

Figure 1 Distribution based on drug usage pattern in baseline follow up

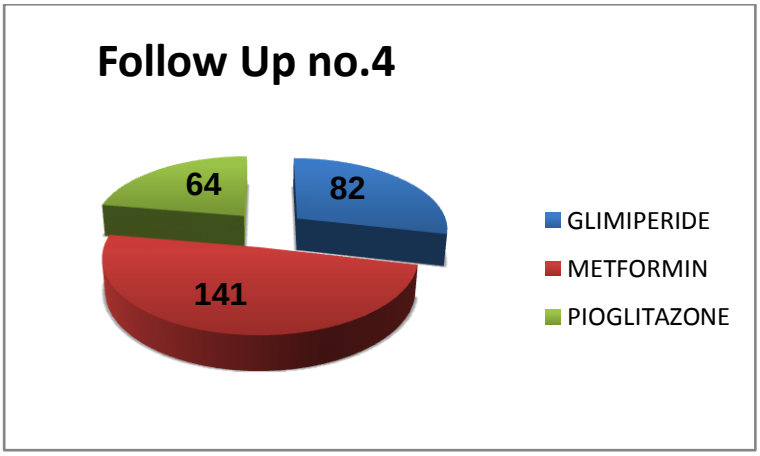

Figure 2 Distribution based on drug usage pattern in Final follow up

ANOVA of mean MA Scores of test group males and their respective P values are presented in **Table No: 2**.

Table 2.ANOVA of M.A of Test group males

S.No.	Age	Gender	Baseline	Follow Up No.1	Follow Up No.2	Follow Up No.3	Follow Up No.4	P Value
1	20-40	Male	1.857	2.857	2.857	0.7857	0.85714	P<0.0001
2	40-60	Male	1.607	2.666	2.647	1.0196	1	P<0.0001
3	60-80	Male	1.826	2.7826	2.7826	1.04347	1.13043	P<0.0001

ANOVA of mean MA Scores of test group females and their respective P values are presented in **Table No:3**

Table 3.ANOVA of M.A of Test group females

S.No.	Age	Gender	Baseline	Follow Up No.1	Follow Up No.2	Follow Up No.3	Follow Up No.4	P Value
1	20-40	Female	1.625	3	3	1.25	0.625	P<0.0001
2	40-60	Female	1.5227	2.727	2.727	1	1.2727	P<0.0001
3	60-80	Female	2	2.75	2.75	0.375	0.625	P<0.0001

ANOVA of mean MA Scores of control group males and their respective P values are presented in Table No:4

Table 4.ANOVA of M.A of Control group males

S.No.	Age	Gender	Baseline	Follow Up No.1	Follow Up No.2	Follow Up No.3	Follow Up No.4	P Value
1	20-40	Male	1.555	2.33	2.33	2.222	2.33	P<0.0001
2	40-60	Male	1.625	2.7	2.7	2.15	2.225	P<0.0001
3	60-80	Male	1.470588	2.70588	2.70588	2.11764	2.5294	P<0.0001

ANOVA of mean MA Scores of control group males and their respective P values are presented in **Table No: 5**.

Table 5.ANOVA of M.A of Control group females

S.No.	Age	Gender	Bs	Follow Up No.1	Follow Up No.2	Follow Up No.3	Follow Up No.4	P Value
1	20-40	F	1.85715	2.28571	2.28571	2.14287	2.4287	P<0.0001
2	40-60	F	1.96	2.52	2.52	2.3	2.3	P<0.0001
3	60-80	F	1.5	2.4375	2.4375	2	2.3125	P<0.0001

We have conducted multiple regressions before and after intervention including Total MA score as Y and individual domains of scale as four variables X_1, X_2, X_3, X_4respectively Respective R square values shows there is good improvement in the test group after intervention. Multiple regression analysis of total MA score and individual domains in control group before intervention is presented in **Table No.6**

Table:6 Multiple regression analysis of total MA score and individual domains in Control Group before intervention.

S.NO.	DOMAIN	R-SQUARE
1	DRB	0.51189
2	BLB	0.17423
3	RLB	0.30178
4	ASB	0.2985

Multiple regression analysis of total MA score and individual domains in test group before intervention is presented in **Table No.7**

Table: 7 Multiple regression analysis of total MA score and individual domains in Test Group before intervention.

S.No.	DOMAIN	R-SQUARE
1	DRB	0.3497
2	BLB	0.1971
3	RLB	0.3005
4	ASB	0.17878

A multiple regression analysis was performed between Medication adherence total score versus its individual domains for control group after intervention. Results are shown in **Fig 3**.

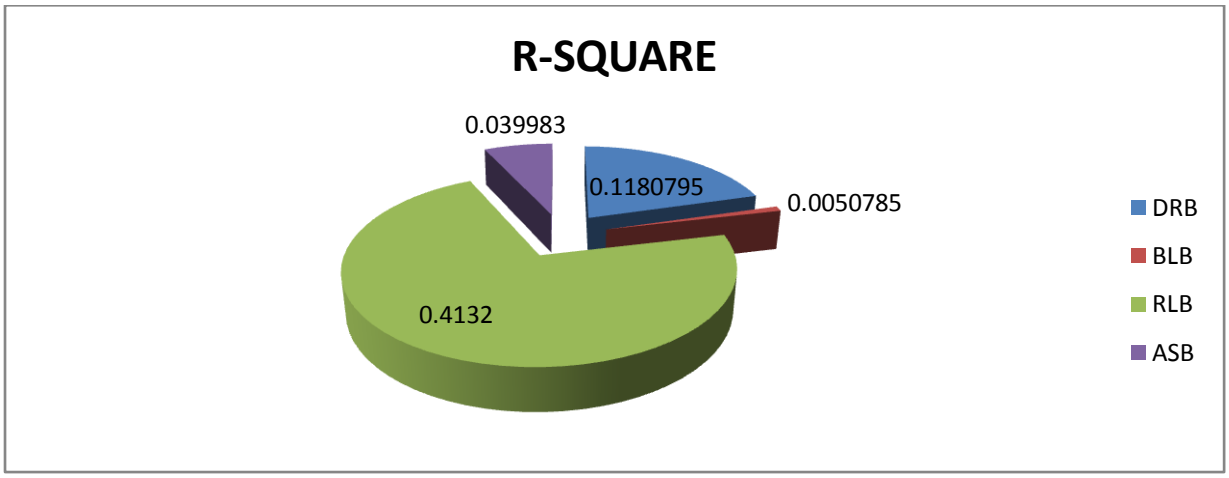

Figure 3: Multiple regression analysis of total MA score and **individual domains in Control Group**

A multiple regression analysis was performed MA total scores and its individual domains in test group following the intervention. The results an improved adherence in the test group in post intervention analysis. Results are presented in **Table NO.7**

Table: 7 multiple regression analysis of total MA score and individual domains in Test group after intervention

S.No.	Domain	R-Square
1	DRB	0.42635
2	BLB	0.004356
3	RLB	0.20827
4	ASB	0.339005

Treatment out comes were also assessed during the study. Mean medication adherence value and their corresponding mean Fasting blood glucouse levels were presented in the following table No: 08.

Table no 8: Mean medication adherence value and corresponding FBS follow-up wise.

S.No.	FOLLOW UP NO.	MA	FBS
1	1	2.536486	149.6216
2	2	1.662162	128.446
3	3	1.047297	120.1419
4	4	0.236500	109.6959

Pearson correlation analysis was performed between mean values of Fasting blood glucose and Medication adherence was performed in control population and results are depicted in **Figure No.4**

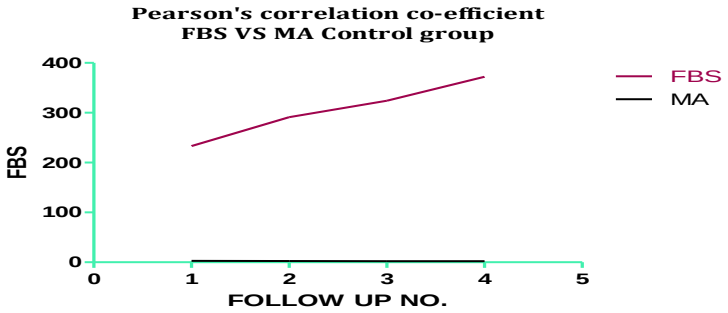

Figure No 4: Pearson correlation analysis between FBS and MA in control group Patients.

Pearson correlation analysis was performed between mean values of Fasting blood glucose and Medication adherence was performed in control population and results are depicted in **Figure No.5**

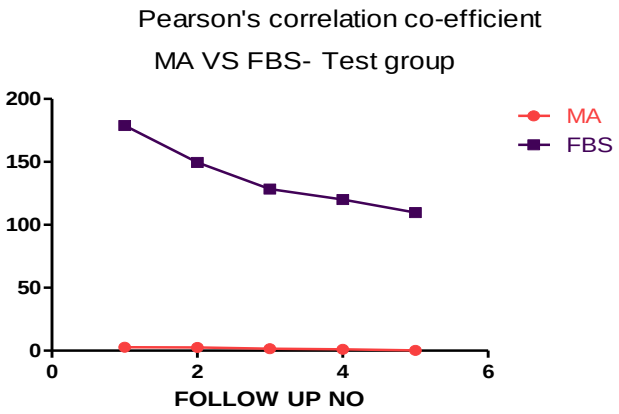

Figure No: 05 Pearson's correlation betweenFBS and MA in Test group

DISCUSSION

Patient non-compliance or lack of adherence with drug regimens continues to be a major problem in virtually all medical specialties, patient populations and health settings[10]. Studies show that approximately 25% of all prescribed doses are omitted by patients and that this non-adherence is a significant factor in cardiovascular morbidity and mortality, rejection of transplanted kidneys, leukemia relapse, vision loss in glaucoma, and other indicators of treatment failure[11]. Poor adherence also has been

implicated in unnecessary and costly procedures and hospitalization in asthma and other conditions[12]. Researchers have identified many determinants of non-adherence, specific ways in which communication between professionals and patients contributes to non-adherence, and effective interventions[13]. Patients also are reluctant to admit non-adherence unless clinicians make specific efforts to monitor the degree of adherence on a regular basis[14].

Pharmacy refill records and drug claims provide relatively objective, unobtrusive, and inexpensive estimates of adherence in large populations over extended periods of time[15]. However, these methods only provide a gross measure of adherence cannot be used for short-term regimens. Researchers also have used laboratory tests, blood readings, and other physiological measures for detecting non-adherence; however, these methods are not always available or feasible[16].

The mean values of Fasting Blood Sugar (FBS), a general and reliable biological indicator to known diabetes status, were calculated for test and control group separately and a line graph was plotted.

The plot depicts there was a sharp decline in FBS in test group when we compared to control group as we move from baseline period to final follow up period, i.e. subjects who have undergone intervention shown fruitful results when compared to control subjects

Patients are sorted in 3 classes based on the medication they used during follow up and baseline period. A pie chart was plotted based on no. of patients on each medication at baseline and at final follow up, signifies that majority of patients are on Metformin(about 50%), Glimepiride (28%) and finally Pioglitazone (about22%) A correlation analysis was done between demographics and medication adherence behaviour. When all the three variables are included, r^2 value was found to be 0.00038. That means it is explained the 0.038% of variance.

When all the two variables (age and gender) are included, r^2 value decreased to 0.00033. Thus explained the 0.033% of variance. When one variable (age) is included, r^2 value decreased to 0.000515. Thus explained the 0.051% of variance. When all the two variables (age and gender) are included, r^2 value decreased to 0.0014. Thus explained the 0.14% of variance. When one variable (age) is included, r^2 value decreased to 0.0017. Thus explained the 0.17% of variance. Obviously demographics have no significant impact on the MA profile of the patients. We have conducted multiple regressions before and after intervention including Total MA score as Y and individual domains of scale as four variables X_1, X_2, X_3, X_4 respectively. R squared values are obtained and from the values it was interpreted that: Current drug regimen (DRB) has major impact on MA profile of control patients. We conclude that Intervention *reduced beliefs barrier from 19% to 0.4% and recall barrier from 30% to 21% in test group. Intervention reduced beliefs barrier from 17% to 0.5% and access barrier from 30% to 4% in control group.* When we perform correlation analysis among MA profile and FBS, we observed that the raise in FBS in **control group**. The Pearson's correlation co-efficient was 0.9948 and p-value is 0.0052 and "R squared" value is 0.9897, the correlation was **very significant**. Concurrently we performed correlation analysis among **MA profile and FBS**; we observed that decline in FBS in **test group**. The Pearson's correlation co-efficient was -0.9868 and p-value is 0.0018 and "R squared" value is 0.9738, the correlation was **very significant.** From the above observations we conclude that in test group a significant correlation establishes between MA profile and FBS and FBS decreased very significantly in test group and FBS raised very significantly in control group. From all the findings, we conclude that our intervention i.e. patient education (post discharge counselling) has significantly increased. Medication compliance behavior.

CONCLUSION

The study could reflect a fair picture of agony of the most commonly prevailing disease i.e. diabetes. The study reveals that patient education and counselling the patients, providing him sufficient information, motivating the patients had improved Medication adherence of the patients. Realizing the patients, the importance of medication in disease mitigation has increased the medication compliance behaviour, which ultimately improved treatment outcomes, which was clarified by objective analysis by measure FBS value. The FBS values are again correlated to MA

scores and correlation signifies improvement in MA behavior. The study corroborates contribution of patient educating or counseling has improved MA behavior. However, a prospective study taking a larger sample is necessary to arrive at a definite conclusion.

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