

Evaluating the Effect of Pharmacist's Delivered Counseling on Medication Adherence and Glycemic Control in Patients with Diabetes Mellitus

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Abstract

Introduction: Diabetes mellitus is a metabolic disorder leading to significant morbidity and mortality and negatively affects patient quality of life. Lifestyle modifications and patient medication adherence are the most important factor that contributes to effective management.

Objectives: To assess the impact of pharmacist delivered counseling on medication adherence and glycemic control in patients with diabetes mellitus.

Method: It was a prospective, interventional study carried over a period of 12 months from October 2014 – September 2015 in general medicine outpatient department of a tertiary care teaching hospital. A total of 106 Patients who fulfilled the study criteria were randomized into intervention group (55 patients) and usual care groups (51 patients) were completed the study. Patient information leaflet and medication counseling was provided to intervention group by the clinical pharmacist. Adherence to the treatment has been assessed during a personal interview with each patient in both the groups by using Morisky Medication Adherence Scale at base line and final follow up. In a group of 30 patients in the intervention group glycosylated hemoglobin was recorded at baseline and final follow up. These adherence scores and glycemic levels (fasting plasma glucose and post prandial plasma glucose) were obtained and compared between both groups at the end of the study.

Results: At the baseline, there was no significant difference in medication adherence scores and glycemic levels between the usual care and intervention groups ($p > 0.005$). However, statistically significant differences in glycemic levels (fasting plasma glucose and post prandial plasma glucose) and medication adherence scores was observed in the final follow up in intervention group as compared to the usual care group ($p < 0.005$).

Conclusion: The study suggests that clinical pharmacist intervention through patient education and medication counseling made a significant influence for improvement in medication adherence and glycemic control in patients with diabetes mellitus.

Keywords: Medication adherence; Diabetes mellitus; Patient counseling; Glycemic control; Clinical pharmacist

Introduction

Diabetes mellitus is a lifelong chronic disease requiring continuous medical care and significant effort by the individuals regarding self-care practices for its prevention. Globally, the number of patients with diabetes mellitus has risen sharply world-wide [1]. The sedentary life style as well as ageing of our population is found to be the major causative factors for the diabetes mellitus. Poor glycemic control in the long term leads to several health complications with increased hospitalization, morbidity and mortality [1]. Lifestyle modifications and medication adherence are the most important factors that contribute in the effective management of diabetes mellitus [2]. Researchers have found a significant association between medication adherence and optimal glycemic control. Studies have shown that growing age, memory impairment, social deprivation, co-morbidities and complex treatment regimen might present hurdles in adhering to drug therapy [2-4].

Medication adherence is defined as the extent to which patients take medications as prescribed by their healthcare providers. Patient education about the disease and medication counseling has been regarded as the effective method to improve adherence to the therapy. Educational interventions involving patient and family members and enhancing communication between the physician and patient is a

key and effective strategy in boosting the patient's ability to follow a prescribed medication regimen [5]. Multidisciplinary approaches can support adherence success and enable a more effective management of diabetes care. One approach in diabetes care is the involvement of pharmacist as a member of healthcare team which has been shown to improve patient outcomes in various healthcare settings across the world. Pharmacists are uniquely positioned to educate patients and can improve the adherence by counseling the patient regarding the knowledge about disease and the need of appropriate medical therapy by providing information leaflets and medication alert cards which help to minimize medication non-adherence [6]. Hence the present study aims to assess the impact of pharmacist counseling on medication adherence in patients with type 2 diabetes mellitus.

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Received February 07, 2016; **Accepted** March 07, 2016; **Published** March 12, 2016

Citation: Shareef J, Fernandes J, Samaga L, Bhat ML (2016) Evaluating the Effect of Pharmacist's Delivered Counseling on Medication Adherence and Glycemic Control in Patients with Diabetes Mellitus. J Diabetes Metab 7: 654. doi:10.4172/2155-6156.1000654

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Materials and Methods

A prospective interventional study was carried out in the outpatient general medicine department of 1200 bedded tertiary care teaching hospital with various specialty departments. The study was carried out for a period of twelve months from October 2014 – September 2015. Ethical clearance was obtained from the institutional central ethical committee before the initiation of the study. Patients with diabetic mellitus (type 1 or type 2 DM) with or without co-morbidities visiting the outpatient general medicine department were included in the study. Pregnant women, mentally challenged patients and critically ill patients were excluded from the study.

Patients who met the study criteria were enrolled and randomized into usual care group and interventional group after obtaining informed consent. Patient's demographic details including past medical and medication history, current drug treatment and laboratory values were collected in the data sheet designed as per the need of the study. Educational materials (validated patient information leaflets) and medication counseling was given to interventional group by the study pharmacist during various follow up visits. The counseling program included knowledge on diabetes, self monitoring of blood glucose, diet, exercise therapy, importance of medication adherence in patients with diabetes mellitus, tips to carry medicines while traveling, early recognition of the symptoms of hypoglycemia and its management. Patients in the intervention group were also educated on diabetic complications such as micro vascular, macro vascular and diabetic foot ulcers. A total of three follow ups were made from the baseline with an interval of two months in each follow up visits.

A Morisky medication adherence scale (MMAS-8) was used to assess the patient medication adherence behavior; license agreement was made before initiating the study. It is self-report adherence measure with eight questions and is one of the most frequently used to assess patients adherence to prescribed medicines in an outpatient setting. It was assessed at baseline and at the final follow up visits for both the groups by using the 8-item scale. Score was given based on the scheme of “yes”=0 and “No”=1. Fasting and post prandial blood glucose values for both the groups were recorded at baseline and during each follow up visits. Glycosylated hemoglobin (HbA1c) was recorded in 30 patients from intervention group at baseline and final follow up.

The data was analyzed by using descriptive statistics. Paired ‘t’ test was used to compare the medication adherence total scores within groups. Chi-square and Fischer's exact tests were used to assess the differences between the adherence levels of intervention and usual care groups. Repeated measures of ANOVA were used to compare the blood glycemic levels among patients with diabetes mellitus between the groups.

Results

A total of 147 patients who met the study criteria were enrolled into the study. Out of them 106 patients completed the study (three follow ups of three month interval each) with 55 patients in the intervention group and 51 patients in the usual care group. Forty one patients had lost follow up due to unknown reasons. Among the 106 patients, it was found that 58 patients were males (49.07%) and 48 were females (50.92%). The age range of the participants in both the groups was between 33 to 79 years old. The mean age of the study population in both intervention and usual care groups was found to be 58.38 ± 10.43 and 55.37 ± 9.88 (Mean \pm SD) years respectively. The demographic details of the study population were presented in Table 1.

Medication adherence of the study populations

The medication adherence scores were significantly improved from the baseline to final follow up within the intervention group of patients with diabetes mellitus when compared with usual care group. In the paired ‘t’ test, a significant difference in the intervention group was observed between the mean baseline test score and final follow up test score at 5% level of significance ($p < 0.005$). Morisky adherence scores significantly increased from 5.16 to 7.20 ($P < 0.001$) within the intervention group when compared to the usual care group (5.56 - 5.78, $p = 0.403$) indicates that the patients in the interventional group achieved more adherence and better glycemic control as compared to the usual care group (Table 2).

The level of adherence before and after pharmacist interventions between the intervention and usual care groups was carried out by using Fischer's exact test. A statistically significant difference was observed between the baseline test and final follow up test level of adherence at 5% level of significance ($p < 0.005$). The scores of adherence level was significantly improved in the intervention group at 20% ($n = 11$), 50.90% ($n = 28$) and 29.09% for high, medium and low adherence respectively

Sl no	Demographic details	Intervention group (n)	Control group(n)
1	Gender		
	Male	31 (56.4%)	27 (52.9%)
	Female	24 (43.6%)	24 (47.1%)
2	Age (in years)		
	31 - 40	3 (5.45%)	5 (9.80%)
	41 - 50	8 (14.54%)	9 (17.64%)
	51 - 60	20 (36.36%)	22 (43.13%)
	61 - 70	16 (29.09%)	13 (25.48%)
	71 - 80	8 (14.54%)	2 (3.92%)
3	Duration of diabetes mellitus (in years)		
	≤ 1	5 (5.05%)	5 (9.80%)
	1 - 5	6 (6.06%)	19 (37.25%)
	6 - 10	31 (31.31%)	19 (37.25%)
	11 - 15	33 (33.33%)	3 (5.88%)
	16 - 20	21 (21.21%)	3 (5.88%)
	≥ 21	3 (3.03%)	2 (3.92%)
4	Family history of diabetes mellitus		
	Yes	24 (43.6%)	19 (37.3%)
	No	31 (56.4%)	32 (62.7%)
5	Co-morbidities		
	0	5 (9.1%)	18 (35.3%)
	1	30 (54.5%)	16 (31.4%)
	2	13 (23.6%)	12 (23.5%)
	3	4 (7.3%)	4 (7.8%)
	4	2 (3.6%)	1 (2.0%)
	5	1 (1.8%)	0 (0%)
6	Marital status		
	Married	54 (98.2%)	50 (98.0%)
	Unmarried	1 (1.8%)	1 (2.0%)
7	Mother tongue		
	Malayalam	25 (45.5%)	29 (56.9%)
	Kannada	30 (54.5%)	22 (43.1%)
8	Educational qualifications		
	Illiterate	16 (29.1%)	7 (13.7%)
	Primary school	30 (54.5%)	36 (70.6%)
	Secondary school	7 (12.7%)	5 (9.8%)
	Graduate & above	2 (3.6%)	3 (5.9%)

Table 1: Baseline demographic details of the study populations.

Groups	Evaluation	N	Mean	Std. deviation	t	p
Test	Pre	55	5.16	0.93	10.88	<0.001
	Post	55	7.2	1.17		
Control	Pre	51	5.56	1.38	0.844	0.403
	Post	51	5.78	1.13		

Table 2: Comparison of medication adherence scores within groups (pre & post test) by using paired 't' test.

Evaluation	Level of adherence	Frequency		p
		Intervention group (n=55) (%)	Control group (n=51) (%)	
Baseline	Low adherence	50 (90.9)	43 (84.3)	0.416
	Medium adherence	5 (9.09)	6 (11.7)	
	High adherence	0(0.0)	2 (3.92)	
Final follow up	Low adherence	16 (29.0)	40 (78.4)	<0.001
	Medium adherence	28 (50.9)	11 (21.5)	
	High adherence	11 (20.0)	0 (0.0)	

Table 3: Difference in the level of adherence before and after interventions between the groups by using Fischer's exact test.

as compared to the usual care group [0% (n=0), 21.56% (n=11) & 78.43 (n=40)] (Table 3).

Blood glucose levels

The results of glycemic control parameters which have been monitored at baseline and final visit shows that there is a significant variation between the intervention and usual care group. There was significant decline in fasting blood glucose from 163.45 ± 56.03 mg/dl to 114.45 ± 18.87 mg/dl ($p < 0.001$) and the post prandial glucose levels also decreased from 146.48 ± 45.73 mg/dl to 162.52 ± 28.27 mg/dl ($p < 0.001$) in the intervention group (Tables 4 and 5).

Glycosylated hemoglobin (HbA1c) is the internationally accepted test for glycemic control. It was carried out in 30 patients in the intervention group (small number was taken due to financial constraints). A significant reduction in the HbA1c level in the intervention group was observed from 9.15 ± 1.37 % to 7.21 ± 0.844 % between the baseline and the final follow up ($p < 0.001$) (Table 6).

Discussion

Medication adherence is the act of filling new prescriptions or refilling prescriptions on time and one of the most key components in the management of health conditions in achieving better therapeutic outcomes. Medication non-adherence can lead to therapy failure, increase risk of hospitalization and has a significant negative economic impact. Medication nonadherence is most simply defined as the number of doses not taken or taken incorrectly that jeopardizes the patient's therapeutic outcome. It also includes delaying prescription fills, failing to fill prescriptions, cutting dosages, and reducing the frequency of administration. It is estimated that improved adherence to treatment could prevent premature deaths in the United States annually. Furthermore, 33-69% of all medicated related hospital admissions stem from poor medication adherence [7,8]. The healthcare professional across various countries accept patient education and medication counseling as one of the most important tools in improving medication adherence. Patient education and counseling is defined as a combination of teaching activities that focus on keeping patients informed about their health condition, treatment plans, medication therapy and self care management to facilitate changes in behavior for improvement and maintenance of health. Pharmacist, thus providing the information on prescribed drugs to patients and stressing the

importance of following the prescribed regimen, plays a central role in combating patient non-compliance [9-11]. Diabetes is one such disease where pharmacist has a major role in improving the patient medication adherence and thereby achieving better therapeutic outcomes and quality of life.

Influence of counseling and education on medication adherence

Health education and counseling plays a very important role in influencing patient medication adherence behavior. The medication adherence behavior was assessed by using the MMAS-8 scale. The baseline score of the patients in the interventional group and the control group shows that the patients were non-adherent to the therapy. But the scores of the patients in the final follow up in interventional group showed significant improvement ($p < 0.005$) when compared with the usual care group. This could be largely due to structured education, counseling, reinforcement and motivation offered by the pharmacist. The study results observed were similar to the study conducted by the Morisky et al. [12-14]. The study highlights the need for a periodic interaction between pharmacist and patient which will helps in improving patient medication adherence behavior.

Assessment of level of adherence

Medication adherence of the enrolled patients were assessed by using MMAS-8 adherence scale consists of 8 questions with score based on the scheme of "yes" = 0 and "No" = 1. The 8th item score ranged from 1 to 4. In MMAS-8 scale, score <6 is considered as low adherence, between 6- <8 as medium adherence and equal to 8 considered as high adherence. Our study found that the follow up visit level of adherence score was significantly improved in the intervention group at 20% (n=11), 50.90% (n=28) and 29.09% (n=16) for high, medium and low

Group	Evaluation	Mean	Std. deviation	p
Intervention group	Baseline	163.45	56.03	<0.001 Greenhouse Geisser
	1 st follow up	149.04	41.96	
	2 nd follow up	127.57	33.26	
	Final follow up	114.45	18.87	
Control group	Baseline	146.48	45.73	0.280 Greenhouse Geisser
	1 st follow up	153.12	43.82	
	2 nd follow up	147.24	43.54	
	Final follow up	162.52	28.27	

Table 4: Comparison of fasting blood sugar levels among patients with diabetes mellitus between the groups by using repeated measures of ANOVA.

Group	Evaluation	Mean	Std. deviation	p
Intervention group	Baseline	260.30	93.43	<0.001 Greenhouse Geisser
	1 st follow up	230.89	74.04	
	2 nd follow up	207.57	57.26	
	Final follow up	165.19	33.44	
Control group	Baseline	264.88	104.05	0.408 Greenhouse Geisser
	1 st follow up	250.04	89.31	
	2 nd follow up	238.20	79.97	
	Final follow up	262.92	57.31	

Table 5: Comparison of post prandial blood sugar levels among patients with diabetes mellitus between the groups by using repeated measures of ANOVA.

Group	Evaluation	N	Mean	Std. deviation	p
Intervention group	Baseline	30	9.15	1.37	<0.001
	Final follow up	30	7.21	0.844	

Table 6: Comparison of HbA1c values among the groups in the intervention group by using paired 't' test.

adherence respectively as compared to the control group [0% (n=0), 21.56% (n=11) and 78.43 (n=40). This suggest that the counseling and motivation given by the clinical pharmacist to the patients regarding the appropriate use of medications has led to increased level of adherence and statistically significant improvement in the intervention group in the follow up visit. This finding is in line with the findings of studies carried out by Chung et al. [14], Binila et al. [15] and Manan et al. [16].

Outcome of glycemic levels

Statistically significant improvement ($p < 0.005$) in blood glucose levels of both fasting and post prandial levels and HbA1c levels were observed from the baseline and sustained until the end of the study period. HbA1c was measured in a group of 30 patients in the intervention group due to financial constraints. The study shows that the pharmacist education sessions, follow up calls and appointment with the interventional group proved beneficial in reducing the mean blood glucose levels significantly. The pharmacist continuous follow up and advice for their glycemic control in the intervention group can develop a trustable close professional relationship between the pharmacist and patients as a part of the educational program might has contributed to a better glycemic control in this study. These findings are similar to those of other studies conducted in other countries which show that the pharmacist led patient education and medication counseling was effective in improving medication adherence and glycemic levels in patients with type 2 diabetes mellitus [17-26].

Conclusion

Improving the patient's knowledge about their disease, diet control, life style modification and appropriate use of medications through education and medication counseling by a clinical pharmacist will have positive effects on patient medication adherence behavior and glycemic control in patients with diabetes mellitus. So the present study emphasizes on the unconditional role of pharmacist as a patient medication counselor and educator who can significantly contribute in the management of health conditions and thereby improving therapeutic outcomes and reduces healthcare costs.

Acknowledgement

Authors are thankful to Principal Dr C.S Shastri, NGSM Institute of Pharmaceutical Sciences for providing necessary support to the study. Secondly we would like to thank Department of General Medicine, Justice K. S. Hegde charitable Hospital, Mangalore for permitting to conduct the study in the hospital. The authors acknowledge the help of Mr. Sanal T S, Biostatistician, KSHEMA with the statistical calculation. We express special thanks to Dr. Karuna Ramesh Kumar, Medical Superintendent for providing us special concession for carrying out glycarted haemoglobin in selected patients of our study. Authors would like to express their great appreciation to Dr. Morisky DE for giving written permission to use the MMAS-8 questionnaires in the study.

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