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IMPACT OF CONTINUOUS PATIENT COUNSELLING ON KNOWLEDGE, ATTITUDE, AND PRACTICES AND MEDICATION ADHERENCE OF DIABETIC PATIENTS ATTENDING OUTPATIENT PHARMACY SERVICES

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ABSTRACT

Objective: The morbidity and morbidity associated with diabetes can be drastically reduced by the knowledge about diabetes mellitus and appropriate attitude toward the disease. A study was conducted to assess the level of knowledge, attitude, and practices (KAP) and medication adherence patterns of diabetic patients and effect of pharmacist-led patient education on KAP and medication adherence patterns in these patients.

Methods: 400 diabetic patients of either sex, aged above 18 years were divided randomly into two groups of 200 each as control and the intervention groups. At the baseline, patients in both the groups were assessed for KAP using KAP Questionnaire and medication adherence using Morisky Adherence Questionnaire. Patients in the intervention group were counseled both verbally and by distribution of a patient education leaflets at baseline and at three consecutive follow-ups (1st, 2nd, and 3rd months), and patients in the control group were counseled both verbally and by distribution of patient education leaflets at the baseline and then on the follow-up after 3 months. Both the groups were assessed repeatedly for KAP and medication adherence using same questionnaires after each counseling sessions. The mean scores of KAP and medication adherence, and the fasting blood sugar levels (FBS) at the baseline and on the follow-up for control and the intervention groups were analyzed statistically using independent sample *t*-test and Mann–Whitney U-test.

Results: Of 200 patients in each group, 178 females and 22 males in the intervention group (mean age 57.80±9.878 years) and 179 females and 21 males in the control group (mean age 57.57±9.438 years). A statistically significant improvement in the mean KAP and adherence scores was observed from the baseline to the final follow-up in both groups ($p \le 0.001$). The increase in the KAP and medication adherence scores from baseline to the follow-up in the intervention group was found to be significantly higher than the control group. There was a reduction in the mean FBS from baseline to the follow-up in both the groups but a statistically significant higher reduction in the mean FBS was found in the intervention group from baseline to the final follow-up when compared to the control group (p < 0.001).

Conclusion: A better KAP of diabetic patients about their disease can improve the medication adherence behavior which in turn can improve clinical outcomes. The patient education should be a continuous process, and patients should be assessed at every subsequent visit for medication adherence to achieve better health outcome.

Keywords: Diabetes, Adherence, Knowledge, attitude and practices, Patient education.

INTRODUCTION

Diabetes is a major disease with an alarmingly increasing prevalence for the past two decades and often both diabetes and hypertension co-exist, posing a major risk for cardiovascular complications. More than 170 million people worldwide have diabetes, and by the year 2030, this figure is proposed to be doubled with the greatest number of cases in China and India [1]. As per the prediction of International Diabetes Federation, the diabetic population will increase to 380 million in 2025 [2] with the prevalence of 4.2% in the general population, estimated to be 2.2% in the rural areas and as high as 12.2% in urban areas [3,4].

The diabetes atlas 2006 published by the International Diabetes Federation reported around 40.9 million people with diabetes in India which is expected to rise to 69.9 million by 2025 [5]. The World Health Organization states that currently India heads the world with over 32 million diabetic patients, and this number is projected to increase to 79.4 million by the year 2030 [1]. Recent surveys indicate that diabetes now affects a staggering 10-16% of urban population and 5-8% of rural population in India, making India the global diabetes capital by 2050 [6].

Adherence to drug therapy and lifestyle changes are key factors in the management of diabetes [7]. Poor compliance with drug therapy is a common and important problem in diabetes resulting in treatment failure and poor outcomes [8]. Possible reasons for the constant increase in the prevalence of diabetes mellitus (DM) may include lack of knowledge and unsatisfactory attitude and practices toward DM among diabetic patients and also in the general population.

Knowledge is the greatest weapon in the fight against DM and can help people assess their risk of diabetes, encourage them to take charge of their disease, and motivate them to seek proper treatment and care. Proper diagnosis, management, and treatment protocols are salient for people with diabetes [9].

The incidence and morbidity associated with DM can be drastically reduced by knowledge about DM, appropriate attitude toward the disease and there exists an apparent gap between knowledge and the attitude toward diabetes among diabetes patients [10]. Due to a lack of proper awareness and education, diabetics are particularly prone to complications and increased mortality. Inadequate awareness in the population and health professionals and less concern to initiate an appropriate preventive care plan is identified as a prime problem in the management of diabetes [11]. Self-management is the cornerstone for proper management of patients with diabetes, and patient education on diabetes plays a pivotal role in improving clinical outcomes [12].

Knowledge and attitude of the patients also have a significant impact on the adherence, making the patients feel that the consequences of the disease could have a serious impact on their well-being. Behavioral changes and adherence to pharmacological treatment are essential for improving the prognosis of DM. Patients with good adherence to diabetes management were reported to have positive health outcomes and lower mortality compared to those with poor adherence [13,14].

Patients with diabetes need to know a lot about their illness and awareness about the diseases, and their complication has become an integral and essential part of disease management. Hence, educational efforts to improve self-management are central components of an effective treatment plan. Studies have confirmed that knowledge and attitude of patients have a significant impact on the management of their illness, and improving knowledge is known to improve compliance to treatment in chronic diseases such as diabetes [15,16].

Pharmacists are in a unique position to play a vital role in helping patients to cope up with their disease and make informed decisions regarding management and medication by patient education [17]. A study was proposed to assess the level of knowledge, attitude, and practices (KAP) and medication adherence patterns of diabetic patients and to evaluate the influence of pharmacist-led patient education on KAP and medication adherence patterns in these patients.

METHODS

A study was conducted in the outpatient pharmacy of a tertiary care teaching hospital in South India, with the approval of the Institutional Ethics committee (CSP/13/OCT/31/163) and the consent of the study participants. The study population consisted of 400 diabetic patients of either sex, aged above 18 years, attending the outpatient pharmacy for filling and refilling of their prescriptions of diabetes medications once in a month. The study population was divided randomly into two groups as control and the intervention groups with each group consisting of 200 patients. Data including the patient demographics (age, sex, height, and weight) history of illness, past medication history, present medication history, family history, co-morbidities, and drug therapy were obtained for both the groups by patient medical history interview and from the medical records of the patients. At the baseline, patients in both the groups were assessed for KAP using KAP Questionnaire given by Palaian et al. [18] and medication adherence using Morisky Adherence Questionnaire [19]. Both the questionnaires were used after obtaining necessary permission from the concerned authors.

Patients in the intervention group were counseled both verbally and by the distribution of a patient education leaflet in English and Tamil at baseline and at three consecutive follow-ups (1st, 2nd, and 3rd month) and were assessed repeatedly for KAP and medication adherence using same questionnaires after each counseling sessions. Each counseling session lasted for about 30 minutes. Patients in the control group were counseled both verbally and by the distribution of patient education leaflets at the baseline and then on the follow-up after 3 months. They were also assessed again for KAP and medication adherence patterns at the end of the follow-up counseling session after 3 months.

The responses obtained from both the groups were scored as stated in the questionnaires and the mean scores of KAP and medication adherence at the baseline and on the follow-up were tabulated for the control group. The mean scores of KAP and medication adherence at baseline, on first, second, and third follow-ups were tabulated for the intervention group.

Questionnaires used

KAP questionnaire

The questionnaire has 25 questions (Knowledge - 18, Attitude - 4, and

Practice - 3 questions). For the knowledge questions, each question was scored as one (1) for a correct answer and as zero (0) for an incorrect answer. Knowledge was assessed using related questions on definitions, symptoms, causes, and complications of DM.

For the practice and attitude questions, adhering to the guidelines for disease management or instructions from the patient's health care provider merited a score of 1; non-adherence was given a score of 0. Attitudes were assessed using a series of questions that focused toward having the disease, the ability to self-manage diabetes and awareness of the importance of adherence to DM (self) care. Patients' practices were assessed using questions on self-care, dietary modification, compliance with medications, weight control, self-monitoring of blood sugar, and regular follow-up.

Morisky 8-item Medication Adherence Questionnaire

Medication adherence behavior of the patients was assessed at each follow-up for both the groups using a 8 item scale. Scoring was given based on the scheme of "Yes" = 1 and "No" = 0. A score of > 2 = low adherence, 1 or 2 = medium adherence, and 0 = high adherence.

Statistical analysis

The collected data were analyzed using SPSS 16.0 version. Descriptive statistics (frequency, percentage, mean, and standard deviation) was used to demonstrate baseline characteristics of the study population. Chi-square analysis was done to analyze the difference between the baseline characteristics of the two groups. The effect of patient counseling on the KAP and the medication adherence patterns from baseline to the three follow-ups in the intervention group and from baseline to one follow-up after 3 months in the control group was assessed using Independent sample *t*-test. The differences in the mean scores of KAP and medication adherence of the intervention and the control groups at the baseline and on the follow-ups were assessed using Mann–Whitney U-test. A p≤0.05 was considered to be statistically significant.

RESULTS

A total of 400 patients were enrolled and randomized equally into control and intervention group (200 each). All the patients in the intervention group completed three follow-ups successfully. Patients in the control group were counseled at the baseline and only on one follow-up after 3 months and then assessed for KAP and medication adherence patterns after follow-up counseling (3rd month). In the present study, all 200 patients in the control group completed their follow-up.

The intervention group consisted of 178 (89.0%) female patients and 22 (11.0%) male patients and control group had 179 (89.0%) female patients and 21 (11.0%) male patients, with no statistically significant difference in the gender distribution among both the groups (p=0.872). The mean age of intervention group was found to be 57.80 ± 9.878 years and control group was 57.57 ± 9.438 years. There was no statistically significant difference in the age range of the patients in both the groups (p=0.991). The age distribution of the intervention and the control group is explained in Table 1.

The educational level of the 200 patients in the intervention group was as follows: 41 (20.5%) were illiterates, 103 (51.5%) have done primary school and below, 53 (26.7%) have done up to secondary schooling, and 3 (1.5%) were graduates and above. Similarly, the educational level of the 200 in the control group was as follows: 27 (13.5%) were illiterates, 128 (64.0%) have done primary school and below, 45 (22.5%) have done up to secondary schooling, and there were no graduates in this group. There was a statistically significant difference in the educational status of the patients in the intervention and the control group (p=0.026). The diabetic medications prescribed in the study population were metformin at the dose of 500 mg to 1g twice daily for all the patients in both the groups and glipizide 5 mg twice daily

Characteristics	Intervention group (N=200)	Control group (N=200)	Significance	
	n (%)	n (%)	р	
Gender			0.872	
Female	178 (89.0)	179 (89.0)		
Male	22 (11.0)	21 (11.0)		
Age (years)			0.991	
≤35	1 (0.5)	1 (0.5)		
36-45	21 (10.5)	18 (9.0)		
46-55	63 (31.5)	65 (32.5)		
56-65	76 (38.0)	76 (38.0)		
≥65	39 (19.5)	40 (20.0)		
Mean±SD	57.80±9.9	57.57±9.4		
Educational status			0.026*	
Illiterates	41 (20.5)	27 (13.5)		
Primary school and below	103 (51.5)	128 (64.0)		
Up to secondary school	53 (26.5)	45 (22.5)		
Graduates	3 (1.5)	0		
Family history of diabetes			0.083	
Yes	19 (9.5)	10 (5.0)		
No	181 (90.5)	190 (95.0)		
Present medication			0.995	
Metformin	200 (100)	200 (100)		
Glipizide	192 (96.0)	199 (99.5)		
Co-morbidities			0.669	
Hypertension	133 (66.5)	137 (68.5)		
Duration of diabetes (years)			0.391	
≤1	17 (8.5)	16 (8.0)		
2-5	98 (49.0)	97 (48.5)		
6-10	62 (31.0)	65 (32.5)		
11-15	20 (10.0)	22 (11.0)		
≥16	3 (1.5)	0		
Mean±SD	6.11±4.2	5.79±3.4		

Table 1: Baseline characteristics of study population

*p<0.05 - significant. SD: Standard deviation

for 192 (96.0%) patients in the intervention group and 199 (99.5%) patients in the control group with no statistically significant difference between both the groups (p=0.995) (Table 1).

In the present study, the intervention group had 19 (9.5%) patients with family history of diabetes and 181 (90.5%) patients were not found to have a history of diabetes. Similarly, the control group had 10 (5.0%) patients with family history of diabetes and 190 (95.0%) patients were not found to have a family history of diabetes. Of the study patients, 133 (66.5%) patients in intervention group and 137 (68.5%) patients in the control group had hypertension as co-morbidity. There was no statistically significant difference in the family history of diabetes (p=0.083) and the co-morbidity (p=0.669) between the intervention and the control group (Table 1).

The duration of DM was found to be ≤ 1 year for 17 (8.5%) patients, 2-5 years for 98 (49.0%), 6-10 years for 62 (31.0%), 11-15 years for 20 (10.0%) patients, and \geq 16 years for 3 (1.5%) patients in the intervention group. Similarly, among patients in control group, the duration of diabetes was found to be ≤ 1 year for 16 (8.0%) patients, 2-5 years for 97 (48.5%), 6-10 years for 65 (32.5%), 11-15 years for 22 (11.0%) patients, and none of them had diabetes for \geq 16 years. The mean duration of DM for the intervention group was found to be 6.11±4.2 years and for the control group were 5.79±3.5 years. There was no statistically significant difference in the duration of diabetes between both the groups (p=0.391) (Table 1).

The mean KAP scores of intervention group at baseline was 10.84 \pm 1.651, at the first follow-up was 14.03 \pm 1.591, at the second and the third follow-ups were 17.68 \pm 1.431, 21.80 \pm 1.315, respectively. A statistically significant improvement in the mean scores was observed from the baseline to the third follow-up (p<0.001) (Table 2).

The mean KAP scores of patients in the control group was 10.57±1.558 at the baseline and 17.21±1.273 on follow-up after 3 months. There was

a statistically significant improvement in the mean scores from baseline to the follow-up after 3 months ($p \le 0.001$)[Table 3].

At the baseline, there was no significant difference in the mean KAP score of the intervention group and control group (p=0.087), but the score has significantly improved in both the groups after final follow-up, and there was a highly significant difference between the mean scores in both the groups after final follow-up. The increase in the mean KAP scores from the baseline to the third follow-up in the intervention group was found to be significantly higher than the increase in the mean KAP score from baseline to the follow-up after 3 months in control group patients (p<0.001)[Table 4]. This indicates the effectiveness of continuous patient counseling in the intervention group.

The medication adherence was assessed by Morisky 8-item Medication Adherence Questionnaire. In the intervention group, at baseline the medication adherence scores were found to be high for 20 (10%) patients, medium for 38 (19%) patients, and low for 142 (71%) patients, and at the 3^{rd} month follow-up, the scores were improved to high for 187 (93.5%) patients, medium for 13 (6.5%) patients, and no patients had low score [Table 5].

A statistically significant improvement in adherence was observed from the baseline to the third follow-up ($p \le 0.001$) in the intervention group. Similarly, in the control group, at baseline the medication adherence scores were found to be high for 18 (9%) patients, medium for 52 (26%) patients, and low for 130 (65%) patients, and on follow-up after 3 months, the scores were improved to high for 179 (89.5%) patients, medium for 21 (10.5%) patients, and no patients had low score [Table 6].

A statistically significant improvement in adherence was observed from the baseline to the follow-up after 3 months ($p \le 0.001$) in the control group. The increase in medication adherence assessment scores from baseline to the 3 months follow-up in intervention group patients was found to be significantly higher than the increase in score from baseline to the follow-up after 3 months in the control group. The adherence level was very high with the intervention group than the control group, indicating the effectiveness of continuous patient counseling in the intervention group [Table 7].

The mean fasting blood sugar (FBS) levels at baseline and at final follow-up of the intervention group were 225 ± 43.66 mg/dl and 160 ± 38.29 mg/dl, respectively, whereas in the control group the mean FBS level at the baseline was 219 ± 43.82 mg/dl and at the follow-up was 193 ± 40.31 mg/dl. There was a reduction in the mean FBS from baseline to the follow-up in both the groups but a statistically significant higher reduction in the mean FBS was found in the intervention group from baseline to the final follow-up when compared to the control group (p < 0.001)[Table 8].

DISCUSSION

This study was done to assess the effect of patient counseling on improving patients' KAP and medication adherence toward diabetes and its disease management. In this study, 400 patients diagnosed with type 2 DM were randomly divided into two equal groups as 200 in each.

Out of 400 patients, there were 178 (89.0%) females and 22 (11.0%) males in the intervention group and 179 (89.0%) females and 21 (11.0%) males in control group. The gender wise distribution of the study participants showed that majority of the patients were females. A similar study done by Hawal *et al.* [20] comprised of 56.85% of females.

Table 2: Assessment of mean KA	P scores in intervention group
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Follow-up	Intervention group (n=200)	Significance
		р
Baseline	10.84±1.651	0.001**
First follow-up	14.03±1.591	
Second follow-up	17.68±1.431	
Third follow-up	21.80±1.315	

**p<0.001 - highly significant. KAP: Knowledge, attitude, and practices

Table 3: Assessment of mean KAP scores in control group

Follow-up	Control group (n=200) Mean±SD	Significance p
Baseline Follow-up (after 3 months)	10.57±1.558 17.21±1.273	0.001**

**p<0.001 - highly significant. SD: Standard deviation, KAP: KAP: Knowledge, attitude, and practices

Table 4: Mean KAP score in both the groups

KAP score	Mean±SD (n=200)		Significance
	Intervention Control		р
	group	group	
Baseline	10.84±1.651	10.57±1.558	0.087
Final follow-up	21.80±1.315	17.21±1.273	0.001**
**n<0.001 - highly significant SD: Standard deviation KAP: KAP: Knowledge			

**p<0.001 - highly significant. SD: Standard deviation, KAP: KAP: Knowledge, attitude, and practices

The mean age of intervention group patients was 57.80 ± 9.878 years and control group was 57.57 ± 9.438 years. This observation was found to be similar to observations made by Hawal *et al.* [20] and Malathy *et al.* [21]. The mean duration of diabetes of intervention group patients was 6.11 ± 4.167 years and control group was 5.79 ± 3.427 years. The baseline characteristics were found to be similar for the patients in the intervention and the control groups. A similar study done by Ramanath *et al.* [22] also observed there was no significant difference between the two groups.

In the present study, patients in both the groups were assessed for the KAP and medication adherence behavior and improve the patient education. Then, the patients in the intervention group were continuously educated and counseled during each follow-up (every month), and patients in the control group were counseled only at baseline and at the end of 3rd month. Apart from verbal counseling, patient information leaflets in English or in the local language (Tamil) were provided to patients. At baseline, only a few patients were aware of the cause of disease, sign and symptoms, complications, and management of diabetes in both the groups. However, on the last follow-up, the KAP scores were increased for both the groups but the improvement was significantly higher for the intervention group patients when compared to the control group due to continuous patient counseling.

The highly significant increase in the mean KAP scores from the baseline to the third follow-up in intervention group indicate the positive impact of continuous patient education given by the clinical pharmacist on the management of the disease. A similar study done by Al-Maskari *et al.* [23] had shown that patient education adds value to diabetes management and that specific interventions aimed at improving patient knowledge, attitude, and practices can improve diabetes control. It is well understood that diabetes management requires patient involvement for a better disease control.

The study done by Malathy *et al.* [21] found a significant improvement in the test group, whereas no significant changes were observed in control group patients. This study reveals that pharmacist counseling might be an important element in diabetes management. Then, a similar study done by Al-Maskari *et al.* [23] also observed a significant increase in KAP in intervention group when compared to control group. This study also concluded that pharmacist plays an important role in educating the patients.

Medication adherence scores of both the groups showed that at baseline most of the patients in both intervention and control group were non-adherent to their treatment mainly due to lack of knowledge and awareness about the consequences of the uncontrolled disease. After

Table 6: Medication adherence scores of control group (n=200)

Adherence scores	Baseline n (%)	Follow-up (after 3 months) n (%)	Significance p
Low	130 (65)	0 (0)	0.001**
Medium	52 (26)	21 (10.5)	
High	18 (9)	179 (89.5)	
**p<0.001 - highly significant			

Adherence scores	Baseline n (%)	First follow-up n (%)	Second follow-up n (%)	Third follow-up n (%)	Significance p
Low	142 (71)	28 (14)	11 (5.5)	0 (0)	0.001**
Medium	38 (19)	114 (57)	17 (8.5)	13 (6.5)	
High	20 (10)	58 (29)	172 (86)	187 (93.5)	

**p<0.001 - highly significant

Adherence scores	Intervention	Intervention group (n=200) n (%)		Control group (n=200) n (%)	
	Baseline	Third follow-up	Baseline	Final follow-up (after 3 months)	р
Low High	142 (71) 20 (10)	0 187 (93.5)	130 (65) 18 (9)	0 179 (89.5)	0.001**

Table 7: Adherence scores in both the groups

**p<0.001 - highly significant

FBS	Intervention	Control group	Significance
	group (n=200)	(n=200)	p
Baseline	225±43.66	219±43.82	0.852
Final follow-up	160±38.29	193±40.31	0.01**

**p<0.001 - highly significant, FBS: Fasting blood sugar

being educated at the final follow-up, there was an increase in the level of adherence and a statistically significant improvement was observed in intervention group and control group but much higher in the intervention group which could be due to the influence of pharmacist-led continuous education on disease and medication when compared to the control group. These findings suggest that educating patients about their medications and their role in the management of disease helped them to improve the adherence levels, which in turn improved the health outcomes. A similar finding was also noted by Adepu *et al.* [24] which stated that there was a significant improvement in adherence level on continuous patient counseling. Another similar study done by Ramanath *et al.* [22] also showed a significant increase in adherence scores in intervention group when compared to control group.

In this study, a significant reduction in the FBS level was observed from the baseline to the final follow-up in intervention group indicating the positive impact of continuous patient education on the management of diabetes. A study was conducted by Malathy *et al.* [21] and they reported a significant reduction in the PPBG level in the test group while no significant reduction in the control group.

The present study revealed that KAP score of the patients were low in both the groups at baseline. Most of the patients in both the intervention and control group were non-adherent to their treatment. At the baseline, the majority of the patients in both the groups had no knowledge about the cause, the complications, the need for regular monitoring of therapy, the need for adhering to the therapy hypoglycemia, and lifestyle modifications needed for diabetes management. Even the patients with a family history of diabetes were also unaware. However, there was an incredible improvement in these areas post patient education in both the groups, especially a markedly higher improvement in the intervention group indicating the effect of continuous patient education which is a must for a chronic disease like diabetes.

The clinical pharmacist could play an important role in this area. To get these outcomes, patients must be educated regularly to improve their KAP. They must be made to understand the need for treatment, benefits, and risk associated with the prescribed medicines and impact of non-adherence to their medications [25]. The present study has shown the pharmacist's education improved the health outcomes in patients by improving their KAP and medication adherence behavior. By taking an active role in patient education and encouraging adherence based management guidelines, pharmacists can play a pivotal role in improving health outcomes of patients with diabetes.

CONCLUSION

This study reveals the positive impact of pharmacist provided education and counseling in improving the health outcomes such as KAP and medication adherence and the clinical outcome as shown by a reduction in the mean FBS levels in patients with DM. The study also confirmed that a better KAP of diabetic patients about their disease can improve the medication adherence behavior which in turn can improve clinical outcomes. The patient education should be a continuous process, and patients should be assessed during every subsequent visit for medication adherence to achieve the better clinical outcome.

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