

*Original Article***Effect of pharmacist-led patient education on glycemic control of type 2 diabetics: a randomized controlled trial**

Shadi Farsaei^{*a}, Ali Mohammad Sabzghabae^b,
Amir Hooshang Zargarzadeh^a, Massoud Amini^c

Abstract

BACKGROUND: This study was conducted to evaluate the effect of a clinical pharmacist-led patient education program for type 2 diabetic patients at Isfahan Endocrine & Metabolism Research Center (IEMRC) from April 2008 to January 2009.

METHODS: In a randomized controlled clinical trial, a total of 172 patients with uncontrolled type 2 diabetes were selected and randomly allocated into control and intervention groups. After taking informed written consent, the intervention group received an educational program about oral anti-hyperglycemic medications, adherence, diabetes dairy log and pill box usage. Patient's glycemic control in the intervention group was followed for three months through either telephone or face to face interviews with the pharmacist. Fasting blood glucose and HbA1c were measured at the start and end of the pharmacist-led drug education program for both intervention and control groups.

RESULTS: After a three months follow-up, mean fasting blood glucose and HbA1c of the patients in the intervention group decreased significantly compared to control group ($p < 0.001$).

CONCLUSIONS: This study demonstrates an improvement in diabetes management of type 2 diabetics by involving a pharmacist in the multidisciplinary teams in the outpatient clinics. The results suggest the benefits of adding adherence education to the diabetic education programs.

KEYWORDS: Diabetes Mellitus, Adherence, Medication, Self-Care, Clinical Pharmacist, HbA1c, Educational Activities.

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Because of high prevalence of diabetes and its complications, control of diabetes is one of the important components of health care system programs.¹ The prevalence of diabetes was estimated to be 2.8% in 2000 and it is continuously increasing worldwide.² Experts estimate that 7.7% of adults aged 25-64 years, or 2 million adults, suffered from diabetes in Iran in 2008.³

The management of diabetes is complicated and requires life-long therapy. Strict glycemic control has a main role in diabetes manage-

ment.⁴ Although the medication therapy has a successful impact on glycemic control but adhering to the treatment and life style modifications are difficult for patients.⁵ At least 50% of patients are estimated to have inadequate adherence to medication regimens which may lead to suboptimal therapeutic goals and increased hospitalizations.⁶ Non-adherence to treatment among diabetic patients which may be related to passive role of patients in their care has been an ongoing problem for both patients and health care providers.⁷ Among

^a Department of Clinical Pharmacy, Isfahan University of Medical Sciences, Isfahan, Iran.

^b Isfahan Clinical Toxicology Research Center, Isfahan University of Medical Sciences, Isfahan, Iran.

^c Department of Internal Medicine, Isfahan Endocrine and Metabolism Research Center, Isfahan University of Medical Sciences, Isfahan, Iran.

* Corresponding Author

E-mail: farsaei@razi.tums.ac.ir

different strategies for diabetes control, improving adherence plays a key role for optimizing metabolic control.^{6,8}

Patient's education is a keystone of optimal therapy of diabetes and other chronic conditions. When patient's education is conducted effectively, this will lead to more involvement of patient in their care, better self management and improved adherence.^{6,8,9}

Although patient's role has been determined to be a crucial factor in the management of diabetes, a multi-disciplinary approach to education has been suggested to be quite effective as well.¹⁰ As part of a multidisciplinary diabetes care team, pharmacists have a crucial role in providing care and education for patients.¹¹ Patient's education by clinical pharmacists should be aimed for improving adherence, awareness of side effects and knowledge about the medication.¹² Trustworthy relationship between patient and pharmacist can be used to improve diabetes care and outcomes.¹³ Some studies have revealed a range of successful methods by means of pharmacist's interventions in diabetes management.^{6,11,14}

Although several educational programs have been developed for people with type 2 diabetes in Iran, but there is a need to improve the quality of these programs to enhance the knowledge and skills of patients in self management leading to improved adherence. To our knowledge, no study has been conducted to evaluate the effectiveness of a pharmacist-led intervention in the management of diabetes in Iran. This paper presents a new model to incorporate pharmacists in the multidisciplinary teams for management of diabetes in Iran.

Methods

A randomized controlled trial was conducted in Isfahan Endocrine and Metabolism Research Center (IEMRC) to investigate the effect of pharmacist-led education program on glyce-mic control from April 2008 to January 2009.

Inclusion-Exclusion Criteria

Patients with uncontrolled type 2 diabetes (HbA1c > 7%), who were able to read and

write and were in a stable therapeutic condition, were eligible for the study. Patients excluded if they were confused, unwilling to participate or complete the study, unable to communicate verbally or reached HbA1c < 7% during the first month of the study.

Setting

IEMRC outpatient clinic covers more than 90% of diabetic population of Isfahan and follows patients every three months for their disease management. Each patient in this clinic receives an educational program offered by a nurse. The education program covers five areas: 1) definition of diabetes mellitus, urine and blood glucose testing and foot care, 2) diet therapy, 3) controlling measures for diabetes, 4) symptoms and treatment approaches to hypoglycemia and uncontrolled hyperglycemia, and 5) diabetes complications including neuropathy, nephropathy, and retinopathy. All of the present patients either in intervention or control group participated in this program.

Sample Study

One hundred and seventy two patients were randomly selected among eligible patients who met inclusion-exclusion criteria and then allocated into two groups: intervention and control.

Pharmacist-Led Intervention

Patients in intervention group participated in two educational sessions offered by the primary author of this paper after giving informed consent. The first session was about different classifications of anti-hyperglycemic agents, dosages, mechanisms of action, indications, efficacy, adverse effects, medication safety issues, contraindications, warnings/precautions, drug interactions, pregnancy risk factors, lactation and storage. The topic of the second session was adherence and self-management which included definition of adherence, different aspects of adherence, role of adherence in diabetes management, different ways to improve adherence, self care management and different ways to improve it.

At the end of the second session, a diabetes diary log and pill box was given to each diabetic patient recruited in the study. The medication name, blood glucose levels and special events such as sick days and exercise were the type of information recorded in the diary log. The pharmacist also educated patients how to fill the diary log and use that information for self-glycemic control. A questionnaire containing patient demographics and lab results (HbA1c and fasting blood glucose) was filled by the pharmacist for each patient in the intervention group and advice was given according to her/his concerns about diabetes control. Each patient was followed for three months after second educational session by weekly telephone calls and appointments with the pharmacist in IEMRC for the glycemic control. In this educational program, pharmacist attempted to improve adherence by providing medication consultation service, creating an individualized patient schedule on administration times and dosage of each medication, educating the patient on the importance of medication adherence, dietary adherence and exercise on better glycemic control, giving advice on how to reduce adverse effects of medications, and also by teaching how to take medications in the holy month of Ramadan, and how to use pill boxes and diary logs to reduce forgetfulness. The intervention group participated in all education sessions whereas the control group only received the general education offered by the nursing staff.

Data Collection

HbA1c and FBS results of intervention group were collected pre and post intervention and of control group during the three month period of study. Demographic characteristics and laboratory test data of both groups were extracted from the patient charts at the beginning and end of the three month period.

Statistical Analysis

The student t test was used to compare differences in the mean of HbA1c and FBS in each

group at baseline and after three months. In testing the effect of pharmacist-led intervention on glycemic control, an unpaired t test was performed to compare means of HbA1c and FBS of the two groups. Descriptive statistics were used to summarize demographic characteristics. Frequencies were compared using the chi square test or Fisher's exact test. In order to determine the normal distribution of variables the Kolmogorov-Smirnov test was used. The non-parametric Kruskal-Wallis test was used to compare the distribution of ranks between the groups. The statistical analysis was carried out using SPSS for windows (Version 15). Significance was set at a two tailed probability value less than 0.05.

Sample Size

Based on the power of 80% with a 5% margin of error, sample size was calculated to be 172. The Institutional Review Board of Isfahan University of Medical Sciences approved the study protocol.

Results

Data analysis showed there were no significant differences in HbA1c and FBS means between control and intervention groups before intervention ($p > 0.05$), however, significant reductions in HbA1c and FBS ($1.7 \pm 1.4\%$ and 30.8 ± 57.7 mg/dl respectively) were obtained in the intervention group at the end of the study period (Table 1). Also after three months follow up, 44.4% and 3.4% of patients in intervention and control groups, respectively, reached controlled HbA1c (HbA1c $< 7\%$).

A significant relationship emerged between reduction of HbA1c and first measured HbA1c level in the intervention group ($p < 0.001$).

Control and intervention groups were compared for demographic characteristics (age, gender, duration of DM, and level of education), concomitant disease, type and number of medications taken by the study population and the first laboratory data (HbA1c and FBS) before education program and no significant differences were detected (Tables 2-4).

Table 1. Comparison of HbA1c and fasting plasma glucose before and after education in both groups

Variable	Control group	P value	Intervention group	P value
Mean HbA1c (%) (\pm SD)				
Before education	8.9 \pm 1.1 (86)	0.317*	9.3 \pm 1.7 (59)	< 0.001*
After education	9.0 \pm 1.2 (86)		7.5 \pm 1.6 (59)	
Mean fasting plasma glucose (mg/dl) (\pm SD)				
Before education	170.4 \pm 60.6 (86)	0.528*	176.6 \pm 57.5 (86)	< 0.001*
After education	165.9 \pm 54.8 (86)		145.8 \pm 50.0 (86)	
Difference between after and before education**				
HbA1c (%) (\pm SD)	+0.1 \pm 1 (86)	0.317 [†]	-1.7 \pm 1.4 (86)	< 0.001 [†]
FBS (mg/dl) (\pm SD)	-4.5 \pm 65.7 (86)	0.528 [†]	-30.8 \pm 57.7 (86)	< 0.001 [†]

* Independent-sample t test

** (-) indicate decrease in value after education and (+) indicate increase in value after education

[†] Paired samples t test

Discussion

The present study shows that better glycemic control was obtained in the intervention group and that the pharmacist education sessions, pill box, use of diary logs and follow up calls and appointments proved beneficial in reducing mean FBS and HbA1cs significantly.

To our knowledge, this type of intervention is first of its kind to be reported in Iran and shows that pharmacists could have added value in diabetes care management. However, since an aggregate of techniques was utilized in current intervention, it is difficult to show whether each individual component would have differ

ent impact on the final outcomes of the study.

Although there are educational programs in diabetes centers in Iran but the innovation used in this study was educating patients about importance of adherence and different approaches to improve it by utilizing a pharmacist in addition to a pill box, diary log and follow-up calls.

In this educational program, pharmacist tried to increase knowledge and motivation of the patients for better glycemic control. It seems that this educational program may have more effect on motivation and knowledge of patients with higher HbA1c than patients with lower

Table 2. Comparison of demographic characteristics of patients in both groups

Variable	Control group (n = 87)	Intervention group (n = 87)	P value
Sex			
Male	31.8%	36.8%	0.527 [†]
Female	68.2%	63.2%	
Mean age (\pm SD)	52.9 \pm 8.5	53.4 \pm 9.8	0.707*
Mean duration of DM** (\pm SD) (Years)	10.3 \pm 8.2	10.8 \pm 5.3	0.697*
Education			
No education	-	-	
Primary school	67.0%	57.0%	
Secondary school	19.3%	22.1%	
High school diploma	8.0%	5.8%	0.293 ^{††}
Bachelor's degree	3.4%	8.1%	
Above bachelor degree	2.3%	7.0%	

[†] Chi square test

* Independent-sample t test

^{††} Kruskal-Wallis test

** Diabetes mellitus

Table 3. Comparison of concomitant diseases of patients in both groups

Concomitant disease	Control group (n = 87)	Intervention group (n = 87)	P value
Hypertension	77.0%	67.4%	0.177*
Dyslipidemia	82.8%	74.7%	0.199*
Heart disease	-	3.5%	0.121**
Thyroid disease	6.9%	9.3%	1.590*
Renal disease	-	-	-
Average number of concomitant disease	1.67	1.55	-

* Chi square test

** Fisher's exact test

HbA1c. It may be because patients with better glycemic control may be more familiar with the ways to control diabetes than patients with higher HbA1c, before educational program.

Other published studies showed similar results to the present study.^{5,8,10} In the current study patients were given advice for their glycemic control by a pharmacist every week; this continuous follow up may develop a trustable relationship between the pharmacist and patients. This close professional relationship as a part of this educational program might have contributed to a better diabetes control in the study. Suppakitiporn et al revealed that consulting with pharmacist in each visit improve the efficacy of glycemic control program.¹⁴

Provision of a pill box and daily diabetes record for each patient in the intervention group might have contributed to their medication taking behavior. Maier et al showed that using a simple pill box caused a significance decrease in HbA1c.⁵

Companions of patients during three months, close relationship existed between patients and pharmacist, acceptance of pharmacist orders for diabetes control by patients and better glycemic control of patients in the intervention group show the acceptance of pharmacist by patients.

Lindenmeyer et al in the review of five studies revealed a potential benefit of diabetes care interventions by pharmacists to improve medication adherence, especially in providing patient education. These studies focused on taking medications using a system of reminder and packaging and pharmacist-led integrated management to improve adherence and glycosylated hemoglobin.⁶

Other studies have shown that application of self care management principles and adherence program and integration of pharmacist in education program are useful for chronic disease management such as diabetes control.^{1,6,9}

Table 4. Comparison of the type and number of medications taken by patients in both groups

Variable	Control group (n = 87)	Intervention group (n = 87)	P value
Mean no. of medication (\pm SD)	7.5 \pm 2.6	7.7 \pm 3.8	0.701*
No. of DM** medication	4.8 \pm 2.1	4.7 \pm 2.6	0.647*
Type of DM medication			
Oral DM drug	63.2%	51.2%	
Insulin	11.5%	13.1%	0.260 [†]
Oral DM drug + insulin	25.3%	35.7%	
Change of DM medication			
No change	94.2%	98.8%	
Increase or decrease dose	5.8%	1.2%	0.210 ^{††}

* Independent-sample t test

** Diabetes mellitus

[†] Chi square test^{††} Fisher's exact test

Adherence to medication is an important part of glycemic control program.¹⁵ Outpatient health care centers encounter patients with poor adherence to medication which has a great effect on economic, quality of life and physical, mental and social functions of patients.^{16,17} Most type 2 diabetic patients are managed by several anti-hyperglycemic drugs. In the present study type 2 diabetic patients took different medications (7.5-7.7 pills per patient) which revealed the presence of concomitant diseases in the study population (1.55-1.67 concomitant diseases per patient).

Several studies revealed that adherence to medication was significantly associated with better clinical outcomes.¹⁸⁻²⁰ One of the important aspects of this educational program was about adherence, so this educational program may help patients to be more adherent to their medications. According to this concept this educational program will be more efficient for patients with lower adherent or higher HbA1c level.

The association between HbA1c level before education and decrease in HbA1c level after education reveals that this education program was more useful for patients with higher HbA1c level who may have worse adherence.

Because of the major burden of three months follow up on the pharmacist, this study suggests that the clinical pharmacist team is necessary for diabetes management and follow up toward self care in outpatient setting.

This study supports the idea of integration of pharmacist in multidisciplinary health care team and also addition of this intervention in diabetic education curriculum for better glycemic control.

Conflict of Interests

Authors have no conflict of interests.

Authors' Contributions

SF provided assistance in the design and coordination of the study, carried out all the experiments and prepared the first draft of the manuscript. AMS and AHZ provided assistance in the coordination of the study and participated in manuscript preparation. MA coordinated all experiments and

Future studies might be performed to evaluate the effect of community pharmacist on glycemic control by giving a brief advice for adherence, diabetes dairy log, pill box and anti-hyperglycemic medications.

Limitations

Because patients were followed up for their clinical result data, the study was conducted in special population of type 2 diabetic patients who had a documented medical record in IEMRC. This population was familiar with educational programs and every three months visits to their physician, consequently they might be more motivated than other diabetic patients for participating in the pharmacist educational sessions and follow up period so further studies may be required to evaluate the efficacy of this educational program on the other diabetic populations.

Conclusions

This study suggests an improvement in diabetes management by the integration of pharmacist in to multidisciplinary team in the outpatient clinics. The results show the benefit of this type of intervention in diabetes management in Iran.

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