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# Physician-community pharmacist collaborative care in diabetes management: a pilot study

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### ABSTRACT

**Background:** Attaining therapeutic goals in diabetes mellitus (DM) is often suboptimal due to disease complexity, poor adherence and inadequate patient counseling.

**Aim:** This study evaluated the effectiveness of the collaboration between the physicians and pharmacists in DM management.

**Design and setting:** A pilot study was conducted between January 2015 and December 2015 in diabetic patients from four districts of Lebanon.

**Methods:** A total of 200 patients with type 2 DM were recruited with 12 months of follow-up. A range of clinical measures, including medication adherence and self-care activities, were assessed over a period of 12 months. The protocol consisted of primary care physicians referring patients to community pharmacies. The participants were attended for 30 min in the pharmacy. They were asked to complete a questionnaire and then received counseling on their illness and their medication in an organized manner by the pharmacist once every month for 12 consecutive months. The primary outcome was the change in fasting blood glucose (FBG) after 12 months of follow-up.

**Results:** A total of 200 patients completed the study. The primary endpoint decreased significantly from the baseline after 12 months of follow-up (mean difference: 30 mg/dl; 95% Cl, 28-32; p < .001). The secondary endpoints, such as glycated hemoglobin, also showed an improvement after 12 months of follow-up.

**Conclusion:** Collaborative care between the physician and the pharmacist was successful in reducing FBG and improving patient satisfaction and quality of care over 12 months of follow-up.

#### **ARTICLE HISTORY**

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KEYWORDS Pharmacist role; diabetes mellitus; fasting blood glucose: intervention

#### Introduction

Type 2 diabetes mellitus (T2DM) has become one of the most important public health problems. It is the predominant form of DM worldwide, accounting for 90% of the cases globally [1]. T2DM is a chronic metabolic disease that requires ongoing medical care and patient self-management [2]. Uncontrolled glycemic control is associated with microvascular complications (e.g. neuropathy, nephropathy and retinopathy) as well as macrovascular complications (e.g. coronary heart disease (CHD), congestive heart failure (CHF), cerebrovascular disease (CVD) and peripheral arterial disease (PAD) [3–7].

Globally, the number of people with DM is expected to rise from the current estimate of 285 million in 2010 to 438 million in 2030 [8]. In 2004, annual Lebanese statistics revealed that 13.15% of the adult population had DM [9], with a recent estimation of 14.6% in 2017 [10]. Moreover, a

high complication rate was associated with suboptimal adherence to management and self-care measures [11]. This high prevalence of DM requires prompt enforcement of educational programs and other interventions to prevent and control DM in Lebanon [9].

Controlling DM is an important component in DM management [12]. The pharmacist role among the healthcare team has expanded to involve direct patient care [13]. Several clinical trials have assessed the effect of pharmacist intervention on glycemic control in DM [14–21]. A metaanalysis concluded that pharmacist interventions can improve glycemic control in diabetic patients resulting in a mean difference of 0.68% in glycated hemoglobin (HbA<sub>1c</sub>) [22].

Many obstacles are associated with lack of glycemic goal achievement, with multiple interventions being implemented to overcome these obstacles such as increasing patient involvement and knowledge about the disease [23,24]. Pharmacists can have a considerable impact on DM

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management by providing care programs emphasizing the importance of adherence to medication. Several studies have reported that a significant reduction in blood glucose level was achieved by pharmacist–physician collaboration. Indeed, the Australian Fremantle Diabetes Study showed that pharmacist collaboration in patient counseling significantly decreased the HbA<sub>1c</sub> by a mean of 0.5% over 12 months from a baseline of 7.5% [14]. Another study showed an increase in the percentage of patients (from 14.8% to 43.2%) having HbA<sub>1c</sub> at goal [25].

The aim of this study is to assess the effectiveness of the collaborative practice between community pharmacists and physicians in DM management among the Lebanese population. The primary outcome was to assess the impact of pharmacist counseling on achievement of the target fasting blood glucose (FBG). The secondary outcome was to evaluate the effectiveness of pharmacist counseling on improving patient knowledge about DM and its complications, adherence with medication and balanced diet, regular self-monitoring of blood glucose and social life habits and the effect on HbA<sub>1c</sub> levels after 12 months of pharmacist counseling.

# **Methods**

# Study design

This pilot study was conducted between January 2015 and December 2015 in different pharmacies from 4 districts of Lebanon (North, Bekaa, Beirut and Mount Lebanon). The list of community pharmacies, provided online from the Lebanese Order of Pharmacist, was used to randomly select the study setting. Seventeen community pharmacies were contacted from all Lebanese geographic areas; eight pharmacies refused to participate. Patients who met the eligibility criteria were recruited from an endocrinology outpatient clinic. The recruitment period spanned between October 2014 and December 2014 and a sample size of 200 patients was enrolled in the study. The sample size was based on a convenient sampling from the involved pharmacies.

# Study subjects

Patients were included in the study if they had a confirmed diagnosis of T2DM for  $\geq$ 6 months, were receiving oral hypoglycemic therapy and had an HbA<sub>1c</sub>  $\geq$ 7%. Exclusion criteria were pregnancy, type 1 DM, past or present oncological diseases, serum creatinine >184 mmol/1, macroalbuminuria >300 mg/24 h or the presence of diabetic proliferative retinopathy or neuropathy.

#### Ethical aspect

The research ethics committee at Lebanese International University approved the study protocol and written informed consent was obtained from all the enrolled participants.

# Study questionnaire, baseline measurements and assessments

All community pharmacists and physicians involved in this study underwent training to ensure consistency during the data collection process. Each patient wanting to enroll in this study was interviewed (for approximately 30 min) by a registered pharmacist. The questionnaire was in Arabic, the native language in Lebanon. It consisted of three parts. The first part included patient sociodemographic characteristics, including age, gender, current height and weight, educational level and family history. The second part assessed patient knowledge about the monitoring and prevention of complications. In this section the patients were asked the following guestions: Are you aware about the complications of diabetes? Are you aware of the symptoms of each complication? Are you aware the need for follow-up every year? The final section of the questionnaire assessed fasting blood glucose, HbA1c, frequency of blood glucose monitoring, medication compliance and awareness about the associated side effects.

### Pharmaceutical care interventions

All the patients received counseling on their illness and their medication in an organized manner by a pharmacist. The discussion included information on the complications of DM, the dosage form, the side effects, and the storage of medication, the healthy lifestyle habits and the self-monitoring methods in DM.

A pamphlet was given to the patients to assist with the counselling program. The education program was reinforced every month at each patient visit to the pharmacy to collect their diabetic medication. In addition to disease-based counseling, behavior modification was recommended on the following: self-monitoring of blood glucose at least 3 times/day, physical activity initiation at least 3 times/week, diet modification, medication adherence and smoking cessation.

# **Outcome measures**

All the patients were asked to return after 12 months of follow-up to the endocrinologist to assess their FBG. All the patients were assessed by the pharmacist about medication adherence at baseline and after 12 months. The assessment was based on a questionnaire asked to the patients and scores were given accordingly. Patients who reported taking doses less or more than required per day such as, forgetting doses, intentionally missing or taking extra doses, were classified as non-adherent.

#### Statistical analysis

The questionnaires were coded and the collected data were introduced using Statistical Package for Social Sciences (SPSS) software, version 23.0 (IBM, Armonk, NY) by an independent person who was unaware about the objectives of the study. All continuous variables are presented as mean and standard deviation, and the categorical variables are presented as frequencies. Correlations between disease status and outcomes were determined by the McNemar test, while paired *t*-test was used for comparison of means between the groups before and after counseling. A two-sided p < .05 was considered significant.

# Results

A total of 200 participants with T2DM attending an outpatient physician office were enrolled. The baseline demographics are presented in Table 1. Overall, the mean age was  $59 \pm 11$  years, with 60% males; 28% of the participants were current smokers and 72% had a comorbidity. The mean FBG

 Table 1. Characteristics of the patients who underwent study enrollment and completed the questionnaire.

| Variable  |                   |
|---|-------------------|
| Age, years (mean $\pm$ SD)                          | 59±11.0           |
| Body Mass Index (kg/m <sup>2</sup> )                | $26.2 \pm 4.4$    |
| Gender $-n$ (%)                                     |                   |
| Male  | 120 (60.0)        |
| Female  | 80 (40.0)         |
| Place of residence $-n$ (%)                         |                   |
| Beirut  | 60 (30%)          |
| Mount Lebanon                                       | 46 (23%)          |
| South   | 45 (22%)          |
| North   | 48 (24%)          |
| Bekaa   |                   |
| Patients with other comorbid diseases $-n$ (%)      |                   |
| Hypertension  | 80 (40%)          |
| Dyslipidemia  | 40 (20%)          |
| Coronary artery disease                             | 24 (12%)          |
| Level of education $-n$ (%)                         |                   |
| Illiterate  | 30 (15%)          |
| Primary school                                      | 50 (25%)          |
| Secondary school                                    | 58 (29%)          |
| University  | 62 (31%)          |
| Social habits – n (%)                               |                   |
| Current cigarette smoking                           | 56 (28.0)         |
| Current alcohol                                     | 40 (20.0)         |
| Family history – n (%)                              |                   |
| Diabetes mellitus type 2                            | 50 (25%)          |
| Hypertension (as recorded in patient profile)       | 38 (19%)          |
| Cardiac disease                                     | 30 (15%)          |
| Renal disease                                       | 4 (2%)            |
| Duration of diabetes history, years (mean $\pm$ SD) | $8.2 \pm 6.8$     |
| Personal diabetes history (mean $\pm$ SD)           |                   |
| Fasting blood glucose levels                        | 155 ± 48 mg/dl    |
| Postprandial glucose levels                         | 230 ± 65 mg/dl    |
| HbA <sub>1C</sub>                                   | $7.5\% \pm 1.5\%$ |
| Past medication history                             |                   |
| Monotherapy   | 104 (52%)         |
| Combination   | 80 (40%)          |
| Triple therapy                                      | 16 (8%)           |

and HbA<sub>1c</sub> were  $155 \pm 48 \text{ mg/dl}$  and  $7.5\% \pm 1.5\%$ , respectively; 64% of the participants were adherent to their medication.

After 12 months of follow-up, the mean FBG significantly decreased from 155 mg/dl at baseline to 125 mg/dl (p < .001). The HbA<sub>1c</sub> level at baseline was 7.5% ± 1.4% and after 12 months of follow-up it was 6.8% ± 0.9% (p = .04).

The secondary endpoints were assessed and showed an improvement from baseline after 12 months of follow-up. Compared with baseline values, the intervention showed an increase in patience adherence with medications from 64% to 84% (p = .001). The intervention also showed an increase in the percentage of patient adherence to well-balanced diet (72 to 84%, p = .001) and to regular exercise (60–80%, p = .003) (Tables 2 and 3). Other significant changes include patient awareness about their medications, awareness about disease state and complications.

Most of the patients were satisfied with the scheduled visits (80%), pharmacist assessment (80%), and pharmacist respect, privacy and concern (92%). It is worth noting that all of the enrolled diabetic patients were satisfied with the pharmacist–physician collaborative practice; the impact of the pharmacist on DM management resulted in 100% patient satisfaction. Besides, patient satisfaction with pharmacist counseling, most patients were pleased about DM knowledge and goals (92%), glucose tests interpretation (84%), complication monitoring (84%), and drug use, side effects and dosing (88%).

#### Discussion

Besides being the first study to evaluate the impact of the collaboration between physician and pharmacist involving patients with T2DM in Lebanon, this study shows significant benefits on the FBG and HbA<sub>1c</sub> levels. The current results demonstrate that enhancing disease management and optimizing medication adherence may result in improved DM outcomes [26]. Pharmacist-driven interventions improved FBG, as well as pharmacological and non-pharmacological awareness in Lebanese diabetic patients. Thus, community pharmacists can have significant impact on improving DM clinical outcomes [27].

Pharmacists provide a unique resource for health promoters with their expertise in medication reconciliation, which result in avoiding medication errors (omissions, duplications, dosing errors or drug interactions) [28]. Pharmacists also play a role in providing strategies to improve adherence, side effects and prescription fill management. Results of the

| Table 2. Impact of | pharmacist | counselina o | on patient | knowledge about | disease complications. |
|--------------------|------------|--------------|------------|-----------------|------------------------|
|                    |            |              |            |                 |                        |

| Pharmacist interventions                            | Patients assessment before pharmacist counseling – % ( <i>n</i> ) | Patients assessment after pharmacist counseling – % ( <i>n</i> ) | p    |  |
|---|---|--|------|--|
| Awareness about retinopathy development             | 32 (64)   | 56 (112)   | .072 |  |
| Awareness about nephropathy development             | 36 (72)   | 80 (160)   | .003 |  |
| Awareness about neuropathy development              | 48 (96)   | 88 (176)   | .002 |  |
| Knowledge about symptoms of retinopathy             | 72 (144)  | 84 (164)   | .001 |  |
| Knowledge about symptoms of nephropathy             | 60 (120)  | 80 (160)   | .003 |  |
| Knowledge about symptoms of neuropathy              | 68 (136)  | 72 (144)   | .09  |  |
| Follow-up of retinopathy monitoring on yearly basis | 20 (40)   | 92 (184)   | .01  |  |
| Follow-up of neuropathy monitoring on monthly basis | 17 (80)   | 70 (140)   | .003 |  |
| Follow-up of nephropathy monitoring on yearly basis | 13 (26)   | 60 (120)   | .001 |  |

Table 3. Impact of pharmacist counseling on patient knowledge about drug administration, adherence and side effects.

| Pharmacist interventions                     | Patients assessment before pharmacist counseling – % (n) | Patients assessment after pharmacist<br>counseling – % ( <i>n</i> ) | p    |
|--|--|---|------|
| Adherence with the medication frequency      | 64 (128)   | 84 (168)  | .001 |
| Adherence with the medication timing         | 32 (64)  | 56 (112)  | .072 |
| Adherence with the medication administration | 36 (72)  | 80 (160)  | .003 |
| Knowledge about medication side effects      | 48 (96)  | 88 (176)  | .002 |
| Maintenance of a well-balanced diet          | 72 (144)   | 84 (164)  | .001 |
| Performance of regular exercise              | 60 (120)   | 80 (160)  | .003 |
| Smoking cessation                            | 68 (136)   | 72 (144)  | .09  |

program contributed to the growing evidence supporting the ability of the pharmacists to improve care in diabetic patients [28]. Although definite outcomes such as reduction in microvascular and macrovascular complications were not available, expecting such reductions in DM complications with improved glycemic control and risk factor control is reasonable [29].

The present study indicated significant improvement in FBG values in patients who received pharmaceutical care when compared with baseline. The finding of this study is consistent with those of Jarab et al. conducted in Jordan [30] and Al Mazroui et al. conducted in the United Arab Emirates [20] who reported a significant decrease in FBG at 6-months and 12-months follow-up, respectively. Another study conducted in Brazil over a 36 months period showed a significant decrease in FBG and HbA<sub>1c</sub> in the intervention group after 36 months of participating in the pharmaceutical care program, confirming the importance of pharmacist counselling in the management of T2DM [31].

Moreover, in the current study, the assessment of medication adherence relied upon patient recall, and demonstrated a significant increase in patient adherence after 12 months of follow-up. These results are consistent with the Al Mazroui et al. [20] study, which showed a significantly better selfreported medication adherence compared with the control group patients. Another study conducted by Grand et al. showed a high self-reported medication adherence after pharmacist-patient education about DM [32]. A systemic review showed a significant improvement in medication adherence rate with pharmacist interventions [33]. Our study showed a significant increase in adherence with well-balanced diet and regular exercise engagement but did not show a significant change in patient adherence to non-smoking; this might be due the minimal focus on this area during counseling.

This was the first study conducted in Lebanon regarding pharmacist–physician collaboration in DM management. The results of this study were based on both FBG and HbA<sub>1c</sub> measurements, which minimizes bias. The major limitation of this study was the lack of a control group (i.e. a group with no pharmacist participating in the multidisciplinary team) for direct comparison. Another limitation is that the DM care providers had the final authority on whether to accept the recommendations for changes in patient regimens. However, in a systematic review of the effects of pharmacist interventions in adults with DM, programs that used direct medical management by pharmacists reported greater improvements compared with those that used a design such as the one used in our study [12]. Moreover, this study used a patient-

reported measure of medical adherence, and the results may be affected by recall bias but the improvement is backed by the FBG and HBA1C results. Other limitations include the small sample size, and short study duration since diabetes is a chronic disease and requires prolonged monitoring.

The community pharmacist plays a role in dose optimization and adherence in non-compliant diabetic patients. For this to be effective, a good line of communication between the pharmacists and the medical practices is valuable. This pilot study demonstrates that the physician-pharmacist collaborative care was successful in reducing FBG and HbA<sub>1c</sub> levels and improving patient satisfaction and quality of care. A positive impact of the community pharmacist on achieving the goals is evident by improving outcomes in diabetic patients. Pharmacists tasks are not only limited to medication dispensing but includes a counseling role about improving patient awareness about disease and drugs, and enhancing monitoring of disease progression. Future studies with a larger sample size and conducted over a longer period of follow-up time, are needed to confirm the importance of a pharmacy service. In addition, other DM-related indices such as, lipid profile, change in kidney function indices, vascular events and adverse events like hypoglycemia, require medical care.

#### **Transparency**

# **Declaration of funding**

There is no funding to report for this study.

#### Declaration of financial/other relationships

The authors have no financial or other relationships to disclose. JDA peer reviewers on this manuscript have no relevant financial or other relationships to disclose.

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# Patient consent

Written informed consent was obtained from all the participants enrolled in the study.

#### Ethical approval

The study was approved by the Institutional Review Board (IRB) at Lebanese International University School of Pharmacy.

# Data availability statement

Additional details are available by emailing Dr. Bouchra Bakr Mouhtadi at Bouchra.mouhtadi@liu.edu.lb.

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