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Community Pharmacist-Based Collaborative Disease Management Program for Patients with Poorly Controlled Diabetes

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Abstract: Objective: Patients with poorly controlled diabetes have more medical complications and are more difficult to manage. The objective of the present study was to evaluate the clinical outcomes of successful implementation of an employer initiated community pharmacist-based disease management program for diabetic patients with poorly controlled diabetes. Methods: Employees with poorly controlled diabetes (glycosylated hemoglobin (A1C) level ≥ 7.5%) were identified from a large diabetes disease management program, in a rural setting in Texas, US. A longitudinal retrospective study was conducted, analyzing clinical indicators in the diabetes patients following the community pharmacist-based disease management program. The program involved a comprehensive drug therapy assessment and individualized disease management education. Primary outcome measured in the present study was A1C levels, assessed at the baseline visit and at the end of the intervention. Results: A total of 64 patients with poorly controlled diabetes were identified. Significant improvement in mean clinical outcome scores was achieved for A1C levels (p = 0.0011). At the end of the 1 year longitudinal intervention, targeted body mass index and A1C goals were attained by 35.9% ($p < 0.001$) and 15.6% patients, respectively. The 10 patients reaching goal levels post intervention were in the group that had baseline A1C of 7.5 to 9%. However, patients with > 9% A1C levels at baseline had a significant reduction (mean 2.1, $p < 0.001$) post intervention. Conclusion: The community pharmacist-based diabetes disease management program improved A1C levels of patients with poorly controlled diabetes.

Key words: Poorly controlled diabetes, community pharmacist, intervention, diabetes disease management program, rural.

1. Introduction

Complications in patients with poorly controlled diabetes, defined by high glycosylated hemoglobin (A1C) levels, are more as compared to patients with moderate glucose levels [1-2]. Every percent increase in the A1C level is associated with increased risk for macro-vascular and micro-vascular complication as well as diabetes and all-cause-related mortality [1]. There is a significant increase in overall cost of medical care with every 1% increase in A1C levels above 7% [2].

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Community pharmacists may be considered appropriate to assume professional responsibility to manage a disease for a target population within the context of a defined protocol of collaborative practice agreement. Inconsistencies in the quality of health care provided, insufficient patient education, and lack of guidance for self-management of diabetes can be addressed by actively involving community pharmacist to optimize delivery of care [3]. Competency of community pharmacists to manage care associated with diabetic patients has been demonstrated in prior disease management studies [4-8]. However, the studies were predominately conducted in managed care organization and community health centers with

relatively fewer studies on employer initiated collaborative programs involving community pharmacists [4, 5]. Further, there is a lack of such collaborative programs in rural settings where there may be a need to address poorly controlled A1C levels in diabetic patients. Compared to urban areas, rural areas experience approximately 17% higher diabetes prevalence rate [9] and face more difficulty in practical implementation of evidence-based management interventions [10, 11]. Moreover, most of the pharmacist based intervention studies are based on entire diabetic populations and hence there is limited scope to interpret the success of pharmacist intervention on patients with high A1C levels. The few studies that have examined the benefit of a pharmacist intervention on patients with poorly controlled diabetes were not conclusive [12-14].

There is a particular need to study the impact of interventions in patients with a high glucose level in a rural setting. It is difficult to obtain near normal concentrations of A1C in patients with poorly controlled type 2 diabetes [15]; hence there is a need to identify interventions that can prove to be successful in this vulnarable group. Successful implementation of an employer initiated DDM (diabetes disease management) program in a poorly controlled diabetes population will highlight the importance of such a program in reducing the burden of the disease and help pool resources between provider groups to assist patients in achieving desired health outcomes.

The objective of the present study was to evaluate the impact of an employer initiated community pharmacist-based DDM program on improving clinical outcomes for patients with poorly controlled diabetes ($\geq$ 7.5% A1C levels) in a rural setting.

2. Patients and Methods

2.1 Design

The present study used a retrospective pretest-posttest design to determine change in clinical outcomes due to pharmacist-based intervention in a community practice setting using a DDM program. Pretest measures were collected at baseline and posttest measures were collected at the end of one-year intervention.

2.2 Patients

The study was approved by the Institutional Review Board of the University. Patients who participated in the study consisted of employees of a large poultry products company who were provided with voluntary option of enrolling in a DDM program. Recruitment started in October 2007 and continued through 2008. Copayments for diabetes prescription medications and medical/testing supplies were waived for enrollees. There were no stringent exclusion criteria, allowing all interested diabetic patients to participate in the DDM program. For the purpose of this study, only patients with A1C levels $\geq$ 7.5% were selected from the enrolled employees, to meet the criteria of poorly controlled diabetes. Patients provided written informed consent prior to data collection.

2.3 Pharmacist Selection

The TPA (Texas Pharmacy Association) collaborated with the poultry company and was responsible for the pharmacist recruitment process. Pharmacists practicing in the area surrounding the organization's location were contacted. Participating pharmacists completed a written exam and skills assessment sessions to prove their knowledge and ability to provide optimal care. They were also required to complete an approved education and training program in DDM based on the ADA (American Diabetes Association) guidelines [16]. Pharmacists were allowed to undertake acceptable variations to the ADA guidelines, per the pharmacists' professional judgments. Ten trained pharmacists participated in this program. In addition to usual dispensing fees for medications, pharmacists were paid on a fee-for-service basis.

2.4 Intervention

A fixed protocol on the intervention process and activities conducted by pharmacy technicians and pharmacists was developed (Appendix A). However, recommendations and actions were customizable by the pharmacist for each patient at any visit. Early activities focused more on developing medication therapies and a care plan, whereas following visits focused on educating and coaching the patient within that care plan.

Patients participating in this DDM program were offered a one-on-one counseling session by the pharmacist. Counseling was provided using educational materials (pamphlets and videos) in English and in Spanish as necessary, on signs and symptoms of diabetes, treatment options, medication and insulin injection technique demonstration, self-monitoring including glucose meter use, importance of diet and lifestyle modification, and expected goals of the treatment. Pharmacists comprehensively assessed patients, recorded side effects and response profiles, and devised a personalized diabetes medication regimen or recommended changes in current treatment regimens. Recommendations were implemented only after approval from the prescribing physician.

Pharmacists maintained proper patient care documentation and provided it to the program administrator. The documentation platform was provided through Outcomes Pharmaceutical Health Care®, an internet based software program that facilitates database management and records outcomes.

2.5 Measures

Clinical outcomes evaluated in present study were categorized as primary and secondary clinical indicators. The primary indicator was A1C (< 7%) levels. Secondary indicators were FSG (fasting serum glucose) (< 130 mg/dL), BMI (body mass index) (< 30 kg/m^2), and complete lipid profiles including HDL (high density lipoprotein) (> 40 mg/dL for males and > 50 mg/dL for females), LDL (low density lipoprotein) (< 100 mg/dL), DBP (diastolic blood pressure) (< 80 mm Hg), SBP (systolic blood pressure) (< 130 mm Hg), TG (triglycerides) (< 150 mg/dL), and TC (total cholesterol) (< 180 mg/dL). These clinical indicators were measured at baseline and follow up visits. Criteria for target values of clinical outcomes were based on ADA guidelines of 2005 [16]. Measurement of clinical indicators depended upon the stability of the clinical parameter, previous abnormalities, history of cardiovascular events, and as described in the protocol.

2.6 Data Analysis

De-identified data was obtained for analyses. A repeated measures pre-post study was conducted. Subjects acted as their own control and improvement was measured by comparing the patients' baseline clinical indicators to measurements at the last follow up visit. The data on clinical indicators collected was analyzed using SAS version 9.2. Paired t-test was used to evaluate the change in mean levels of the clinical indicators pre and post intervention. The chi-squared test was used to assess the proportion of patients reaching goal post intervention. Discrete analysis of patients in the two A1C categories, 7.5%-9% and > 9%, were also conducted to account for any differences in improvement of patients A1C levels as a function of baseline A1C level.

3. Results

Of the 137 patients enrolled in the DDM, 64 patients with poorly controlled diabetes were identified and included in the study. The mean (SD) age of patients was 52.4 (12.2) years and 52.5% were females. Patient visits ranged between 1and 6, with an average (SD) of 3.5 (1.8) visits during the intervention period.

Significant improvement in clinical outcomes were noticed with respect to percentage change in A1Clevel ($p = 0.011$) (Table 1). Mean scores for most of the clinical indicators also improved but did not differ significantly from the baseline.

Although all patients included in the study had high

A1C levels, the majority were also not at goal at baseline with respect to the other clinical indicators (Table 2). Number of patients reaching targeted BMI levels (< 30 kg/m^2) (38.9%) increased significantly (p < 0.01) post intervention.

Of the 64 patients with A1C ≥ 7.5%, 45.3% had A1C between 7.5-9% and 54.7% had A1C > 9% (Table 3). All patients that belonged to the 7.5-9% A1C group reached goal levels (A1C < 7%) post intervention. The majority of the patients with A1C levels between 7.5-9% at baseline reduced their A1C level by 1-2% (p = NS) while the majority of patients in the > 9% baseline A1C group reduced their A1C level by 3-4% post intervention (p < 0.001).

4. Discussion

The authors' study indicates that community pharmacist-based DDM programs can be beneficial for management of poorly controlled diabetes in the rural population. Within one year, there was significant reduction in A1C levels, in addition to enhancement of other clinical indicators.

While all diabetic patients are at risk for medical complications, the prevalence of complications increase with A1C levels [1]. Healthcare providers have difficulty managing patients with poor glycemic control [17]. The authors' study affirms the positive impact of pharmacist intervention on the diabetic

Table 1 Change in clinical outcomes due to the pharmacist-based diabetes disease management program.

Clinical indicators	Mean (SD) values			*P* value
	Baseline	Post-intervention	Difference from baseline	
FSG, mg/dL	205.1 (82.6)	171 (68.1)	-34.1 (109.5)	0.059
A1C, %	9.6 (2.1)	8.4 (1.5)	-1.2 (2.4)	0.0011[a]
BMI, kg/m^2	33.4 (7.6)	33.4 (7.2)	-0.1 (2.7)	0.83
HDL, mg/dL	44.5 (13.3)	44 (15.1)	-0.2 (8.1)	0.624
LDL, mg/dL	105.5(42.1)	97.4 (39.7)	-8.3 (29.2)	0.122
DBP, mm Hg	87.8 (9.4)	85.7 (8.9)	-2.2 (11)	0.705
SBP, mm Hg	139.2 (19.9)	135.2 (19)	-4 (18.8)	0.079
TG, mg/dL	182 (146.4)	209.2 (162.6)	27.2 (90.9)	0.082
TC, mg/dL	194.5 (64.4)	190.6 (64.8)	-3.9 (30.8)	0.427

FSG, fasting serum glucose; A1C, glycosylated hemoglobin; BMI, body mass index; HDL, high density lipoprotein; LDL, low density lipoprotein; DBP, diastolic blood pressure; SBP, systolic blood pressure; TG, triglycerides; TC, total cholesterol; SD, standard deviation

[a] Statistically significant at p < 0.01.

Table 2 Increase in number of patients attaining therapeutic goals post intervention for other clinical indicators.

Clinical indicators	n(%) of patients at goal			*P* value[a]
	Sample (N)	Baseline	Post-intervention	
FSG, mg/dL	40	8 (20)	11 (27.5)	0.86
BMI, kg/m^2	49	15 (30.6)	19 (38.9)	0.008[c]
HDL, mg/dL	35	13 (37.1)	13 (37.1)	0.186
LDL, mg/dL	33	16 (48.5)	24 (72.7)	0.286
DBP, mm Hg	6	1 (16.7)	3 (50)	0.273
SBP, mm Hg	62	17 (27.4)	22 (35.5)	0.985
TG[b], mg/dL	37	20 (54.1)	17 (46)	0.9
TC, mg/dL	39	21 (53.9)	25 (64.1)	0.099

FSG, fasting serum glucose; A1C, glycosylated hemoglobin; BMI, body mass index; HDL, high density lipoprotein; LDL, low density lipoprotein; DBP, diastolic blood pressure; SBP, systolic blood pressure; TG, triglycerides; TC, total cholesterol.

[a] Calculated for change in number of patients at goal pre and post intervention, using chi square test.

[b] The number of patients reaching TG goal decreased post intervention.

[c] Statistically significant at p < 0.01.

Table 3 Descriptive statistics of glycemic control by A1C% categories.

Variables	A1C% category		
	Total sample (A1C% ≥ 7.5)	A1C% (≥ 7.5-9)	A1C% (> 9)
Frequency of patients, n (%)	64	29 (45.3)	35 (54.7)
Patients at goal post intervention, n (%)	10 (15.6)	10 (100)	0
A1C% at baseline, mean (SD)	9.6 (2.1)	8.2 (0.5)	11 (2.1)
A1C% post intervention, mean (SD)	8.1 (1.5)	8 (1.1)	8.9 (1.8)
Reduction in A1C% post intervention, mean (SD)	1.2 (2.4)[a]	0.2 (1)	2.1 (3)[b]
Reduction in A1C% after intervention, n (%)			
Patient with no reduction or increase	22 (44)	13 (52)	9 (36)
Patients with <= 1% reduction	9 (18)	7 (28)	2 (8)
Patient with 1.1%-2% reduction	6 (12)	4 (16)	2 (8)
Patients with 2.1%-3% reduction	7 (14)	1 (4)	6 (24)
Patients with > 3% reduction	6 (12)	0 (0)	6 (24)

A1C, glycosylated hemoglobin; SD, standard deviation.

[a] Statistically significant at $p < 0.01$.

[b] Statistically significant at $p < 0.001$.

subpopulation with high A1C levels. These positive findings are in accordance with other pharmacist-based disease management studies of patients with poorly controlled diabetes [12-14]. Comparisons between these studies should be made accounting for discrepancy in the definition of poorly controlled diabetes. The definition has been found to range from ≥ 7.5% to ≥ 9% in the literature [12-14, 18, 19]. In the authors' study, they included patients with A1C levels ≥ 7.5%. This was in consideration of the baseline A1C stratification defined by the American Association of Clinical Endocrinologists/American College of Endocrinology algorithm [19]. They did not include the 6.5-7.5% category since it did not meet the poorly controlled diabetes condition.

While there was improvement with respect to A1C levels post intervention in both the groups, 7.5%-9% A1C and > 9% A1C, the improvement was not consistent. As a percent reduction, the impact of DDM was higher for those with higher baseline A1C levels. However, all patients who reached goal levels post intervention belonged to the group with baseline A1C levels 7.5%-9%. The inability of patients with > 9% A1C levels to reach the < 7% A1C goal based on ADA guidelines, can be explained by previous literature which states that higher A1C levels increases the difficulty of reaching the therapeutic threshold [15]. Patients at baseline A1C levels of 7.5%-9% were more likely to reach therapeutic A1C goals. The significant reduction in A1C levels for the > 9% A1C group was expected since higher baseline A1C levels have been associated with greater reduction in mean A1C level post pharmacist intervention [13]. Considering the increased odds of allied co-morbidities associated with percent increase in A1C level in diabetic patients, successful implementation of pharmacist based DDM in this study seems promising in reducing not only the diabetes burden but also the burden of associated co-morbidities [20].

The mean reduction in A1C level in the present study was greater in comparison to the Diabetes Ten City Challenge outcomes, as may be expected for a patient population with higher baseline A1C level. A meta-analysis study supports the significant impact of disease-management programs on A1C levels [21]. However, the above-mentioned study also indicated that only programs with high frequency of pharmacist-patient interactions led to significantly greater reduction compared to programs with low frequency of interaction. According to the definition used in that study, the authors' study reported low frequency patient-pharmacist contact (once per 2

months). It is commendable that in spite of the low frequency of patient-pharmacist contact in this study, there was significant reduction in mean A1C level. More patient-pharmacist contact could have resulted in significant improvement in other clinical outcomes in the study. In addition to A1C level, the number of patients reaching clinical goals in our study was also higher for DBP (50%). The higher percent of patients reaching the DBP goal should be inferred with caution since the sample size for the DBP calculation was not sufficient due to missing values. Some irregularities were observed with respect to TG levels post intervention, and the finding is consistent with previous studies [22, 23]. It is reported that these lipid-related characteristics improve eventually with glucose control [24].

While the study further establishes improvement of clinical outcomes through the DDM program, the results from the study should be interpreted in view of a few limitations. The study results are conservative given the small sample size and may be less generalized to a larger population. Moreover, due to the small sample size, effect of individual elements of the intervention in delivering the improved outcomes could not be assessed. The patients served as their own control and there was not a separate control group. Due to the nature of the study design, the patients' compliance with pharmacist recommendations, which could have influenced the attainment of therapeutic goals, was not assessed. Further, the pharmacists' interactions with physicians and physicians' response to pharmacists' recommendations were not formally tracked and were considered part of the intervention. Physicians however, were reported to be thankful to pharmacists for their value added services based on anecdotal data of the pharmacists' experiences.

In conclusion, the community pharmacist-based DDM program improved A1C levels of patients with poorly controlled diabetes. While significant reduction of other clinical parameters could not be assessed due to small sample size, reduction in mean A1C level and increase in number of patients reaching target A1C level was high enough to assert clinical significance. The study also reemphasizes how a collaborative approach between employers, pharmacists, pharmacist technician and physicians can effectively promote disease management in patients with poorly controlled diabetes. Further studies, with larger sample size and with longer follow-up period in rural settings may be required to measure how a successful disease management program influences employee productivity as well as the economic benefits to employers.

Key Points

Employer initiated collaborative diabetes disease management programs are beneficial for management clinical outcomes in poorly controlled diabetic patients.

Community pharmacists can have a significant impact on improving clinical outcomes of poorly controlled diabetic patients in the rural population.

CONFLICT OF INTERESTS

The authors have no conflicts of interest relevant to this article.

DISCLOSURE

J. David Hayes is a speaker for Novo-Nordisk Pharmaceuticals and Pfizer Pharmaceuticals.

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Appendix A: Pharmacist-Based Diabetes Diseases Management Program

Initial Visit	
Technician Responsibility	**Pharmacist Responsibility**
Schedule initial appointment and mail patient history and medical information forms to patients Have patients fill out Diabetes Knowledge Assessment and Treatment Motivation Questionnaire forms Record patient weight, height, waist circumference, BMI, SBP, DBP Record results by point-of-care testing (A1C, HDL, LDL, TG, FSG) Prepare master medication list; include current prescription and over-the-counter medications Verify forms (fill in the blanks), discuss confidentiality and get releases signed	Review patient history, master medication list, laboratory test results Review Diabetes Knowledge Assessment and Treatment Motivation Questionnaire forms Interpret results Assess patient status and needs, family support Develop goals based on patient needs and diabetes knowledge assessment and treatment motivation (3 maximum) Discuss using the patient's 'value' words ("I will…" statements) Examples: Medication compliance, initiate or improve exercise, healthier food choices, lose mutually agreed-on amount of weight by next appointment Discuss how to track future missed work/school days due to diabetes (initial assessment is 0 –assume no past history) Discuss next appointment, including getting a fasting glucose the morning of the appointment Schedule follow-up appointment Thank patient, conclude appointment Complete worksheet Notify physician if irregularities are noted Notations of next steps beyond protocol (special patient needs, other services necessary)
Follow up visits[a] (1-5)	
Technician Responsibility	**Pharmacist Responsibility**
Update patient history Update master medication list Record missed days, hospitalizations Record weight, height, waist circumference, BMI, SBP, DBP, FSG Record A1C levels Record HDL, LDL, TG Carry out foot screening[2-3] Notify pharmacist	Review patient history, master medication list, lab results Provide disease state education: Discuss meal planning and education; educate about medication, glucose monitoring, diabetes self-care and hypoglycemia[b] Reinforce previous session education; discuss diabetes with patients; educate about acute changes—hypoglycemia, hyperglycemia, sick day management, travel consideration[c] Review previous education session; educate about long term complication, self-care and behavioral change[d-f] Review previous education; preview progress—activity levels and nutrition changes; review glucose reading—identify problem areas and address[e] Confirm pertinent areas covered and reinforce appropriate information and interpret results; determine and discuss nutrition and activity levels; discuss any education topic as needed Determine and discuss family support, nutrition and activity level Foot care education—if concerns contact physician Assess patient status and goals—redefine goals if necessary Assess patient status and goals—focusing mainly on problems identified with glucose reading[f] Discuss missed work days and hospitalizations—determine causes and number Discuss next appointment, including getting a fasting glucose the morning of the appointment Schedule follow-up appointment Thank patient, conclude appointment Complete worksheet Notify physician if irregularities are noted Notations of next steps beyond protocol (special patient needs, other services necessary)

[a] All the mentioned procedures in the protocol were conducted by the technician and pharmacist, unless otherwise mentioned.

[b] Conducted only during the first follow up visit.

[c] Conducted only during the second follow up visit.

[d] Conducted only during the third follow up visit.

[e] Conducted only during the fourth follow up visit. The fourth follow up visit was scheduled only if the pharmacist believed that the patient required additional monitoring.

[f] Conducted only during the fifth follow up visit.