ORIGINAL ARTICLE

Evaluative Research on Pharmacist-managed Diabetes Care: Focus on Self-Monitoring of Blood Glucose

PI Sealy[1], DN Ignacio[1], G Legall[2]

ABSTRACT

Objective: *Pharmacists have not demonstrated the ability to manage chronic diseases such as Type 2* Diabetes Mellitus*, which is an ongoing problem in Trinidad and Tobago. The primary objective was to demonstrate that pharmacists can assist patients to achieve at least a 1% decrease in glycosylated haemoglobin (HbA_{1c}).*

Methods: *A randomized, controlled Pharmacist Evaluative Research Study compared the efficacy of pharmacist-managed care (the intervention), and routine standard management (control) of poorly controlled (abnormal HbA_{1c} , blood pressure, blood glucose and lipid panel) adult diabetic patients. Participants in the intervention group met with the pharmacist at their respective primary care sites on a regular basis for an assessment of adherence to medications, barriers to adherence and education. Control group participants consisted of patients receiving routine care by their primary physician but with no direct intervention by the pharmacist except for the filling of prescriptions.*

Results: *Seventy-five patients were initially recruited. Of these, 48 (20 intervention and 28 control) met the inclusion criteria. It was only possible to analyse the result from 20 patients: 14 (70%) intervention and 6 (21.4%) control because of incomplete collected data. A minimum decrease of at least 1% HbA_{1c} was obtained by 8 (57%) intervention participants compared to 2 (33%) in the control group; while HbA_{1c} remained unchanged for two participants, each in the intervention and control groups (14% and 33%, respectively).*

Conclusion: *We could not conclude any statistical or clinical significance in the paper as the data could only be analysed using descriptive methods. Building a culture of research among pharmacists may promote the use of pharmacists as adjunctive healthcare practitioners to achieve better patient outcomes.*

Keywords: Chronic diseases, *diabetes mellitus*, glycosylated haemoglobin, managed care, pharmaceutical care, pharmacists

Investigación Evaluativa sobre Atención a la Diabetes Gestionada por los Farmacéuticos: Enfoque del Automonitoreo de la Glucosa en Sangre

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RESUMEN

Objetivo: *Los farmacéuticos no han demostrado ser capaces de manejar el tratamiento de enfermedades crónicas como el tipo 2* Diabetes mellitus*, que es un problema actual en Trinidad y Tobago. El objetivo principal fue demostrar que los farmacéuticos pueden ayudar a los pacientes a lograr al menos una disminución del 1% en hemoglobina* (Hba_{1C}).

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Métodos: *Un Estudio de Investigación Evaluativa Farmacéutico controlado aleatorio, comparó la eficacia de la atención gestionada por los farmacéuticos (intervención) y el manejo estándar de rutina (control) de pacientes diabéticos adultos con pobre control (niveles anormales de hemoglobina glicosilada, presión arterial, glucosa en sangre, y perfil lipídico). Los participantes en el grupo de intervención se reunieron de manera regular con el farmacéutico en sus respectivos centros de atención primaria para evaluar el cumplimiento con los medicamentos, así como los obstáculos a la observancia y la educación. Los participantes del grupo de control eran pacientes que recibían atención de rutina de parte de su médico primario, pero sin intervención directa del farmacéutico, excepto para el llenado de prescripciones.*

Resultados: *Setenta-cinco pacientes fueron reclutados inicialmente. De estos, 48 (20 de intervención y 28 de control) cumplían los criterios de inclusión. Debido a que los datos recopilados estaban incompletos, sólo fue posible analizar el resultado de 20 pacientes: 14 (70%) de intervención y 6 (21.4%) de control. Una disminución mínima de al menos 1% de HbA_{1C} fue obtenida por 8 (57%) participantes de intervención en comparación con 2 (33%) en el grupo de control, mientras que el HbA_{1C} permaneció inalterado para 2 participantes, cada uno en los grupos de intervención y control (14% y 33%, respectivamente).*

Conclusión: *Los datos apoyan la hipótesis de que la gestión de los farmacéuticos como profesionales complementarios de la salud, posibilita lograr mejores resultados en los pacientes, a diferencia de lo que ocurre en ausencia de tal gestión.*

Palabras clave: Enfermedades crónicas, *diabetes mellitus*, hemoglobina glicosilada, atención gestionada, atención farmacéutica, farmacéuticos

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INTRODUCTION

Diabetes, especially Type 2 Diabetes (90%), is an ongoing problem for many nations. The world-wide prevalence of diabetes estimated by World Health Organization (WHO) was approximately 175 million in 2000 and is predicted to be at least 366 million by 2030, among adults ≥ 20 years of age (1, 2). Approximately two-thirds of persons with diabetes live in developing countries (3). The WHO estimate for Trinidad and Tobago in 2000 was 60 000 and is projected to increase to 125 000 if current trends prevail (4). Recent data (unpublished) from the Trinidad and Tobago (TT), Ministry of Health (MoH) indicate that the Chronic Disease Assistance Programme (CDAP), since its inception in 2003 to 2009, has provided medicines for approximately 226 435 diabetic patients. The National Insurance Property Development Company [NIPDEC] procures and manages the distribution of medicines for CDAP on behalf of the MoH (5). This figure represents approximately 38% of the total patient population receiving treatment through CDAP; the total cost of diabetes treatment amounted to 285 million USD (6).

A report by the Pan American Health Organization (PAHO) indicates that diabetes mellitus is one of the leading health problems in the Caribbean, contributing significantly to morbidity and mortality, and adversely affecting both the quality and quantity of life (7). Deaths from diabetes ranked # 2 (#1 is ischaemic heart disease) for all age groups for both genders for the period 1998 to 2000 (8). In TT, ethnicity is an important risk factor since persons of South Asian origin have a higher prevalence of diabetes than other ethnic groups (8). Poor glycaemic control has been shown to manifest in costly lifelong morbidities, including blindness, kidney failure, amputations and cardiovascular disease (9, 10). The economic burden of treating long-term diabetes complications is well-documented (9, 10). Improving glycaemic control in patients with Type 2 diabetes mellitus can prevent or delay the onset or slow the progression of microvascular and macrovascular complications (11–15).

The MoH through CDAP provides medications for many special conditions, including diabetes. Chronic Disease Assistance Programme was instituted as a patient-centred intervention programme to better manage diabetes and to prevent or significantly slow-down the progression of diabetes-related complications. The diabetic patients who have accessed the programme to date have retrieved medications from 253 public and private pharmacies from the prescriptions of approximately, 1000 physicians in TT (5). Diabetes was recorded as the

second (the first is heart disease) leading cause of death for all age groups in TT for the years 1998 to 2000 (16). Research data in the United States of America support the effective use of clinical pharmacists to successfully manage diabetes in patients who were poorly controlled (14, 17–20). Clinically trained pharmacists can assist primary care providers (physicians) to achieve desired outcomes.

Current statistics infer that much attention should be given to diabetes care. The global prevalence of diabetes was estimated to be 9% among adults in 2014 (21); diabetes caused an estimated 1.5 million deaths in 2012, while greater than 80% of those deaths occurred in low- and middle-income countries (4, 22); approximately half of the deaths, due to diabetes have occurred in persons under the age of 70 years; 55% of diabetes deaths are in women; and WHO projects that deaths due to diabetes will increase by ≥ 50% in the next 10 years if urgent action is not implemented (23). Diabetes and its complications impose significant economic consequences on individuals, families, health systems and countries. Therefore, imposing a healthy diet, regular physical activity, maintaining a normal bodyweight and avoiding tobacco use can prevent or delay the onset of Type 2 diabetes (24). Research supports the perception that poorly managed diabetes results in medical consequences (diabetic retinopathy, and neuropathy, amputation, kidney failure, cardiovascular disease and death), which imposes a significant economic burden on healthcare resources (3, 15).

This is a pioneer study to evaluate the impact of pharmacist intervention on glycaemic control and other health-related, clinical outcomes in diabetic patients. The objective was to determine if there was a decrease of at least 1% in glycosylated haemoglobin (HbA_{1c}) and improved medical outcomes (blood pressure (BP), blood glucose (BG), and lipid panel (triglyceride [TG], low density lipid-cholesterol [LDL-C], and high-density lipid-cholesterol [HDL-C]) after pharmacist interventions.

METHODS

Randomization

Phase I consisted of training pharmacists in diabetes management by a Certified Diabetes Educator over a three-day workshop, after which a certificate was awarded to 56 pharmacists; many of these pharmacists indicated a willingness to participate in the study.

This pharmacist evaluative research study (PHARMERS) was a randomized, control, longitudinal study, involving two cohorts (intervention *versus* routine care) of poorly controlled (abnormal parameters: HbA_{1c}, BG, BP, TG, LDL-C and HDL-C tests) adult diabetic patients across TT. Enrolment and patient participation in the study were voluntary and subject to the completion of the consent form. This study was approved by the Ethics Committee of The University of the West Indies and all Regional Health Authorities (RHAs) of the MoH. Pharmacists recruited the patients based on specified criteria. The criteria for participation included ambulatory adult (> 18 years), Type 1 and 2 diabetic patients selected from private and public institutions, who were in receipt of and used medications from CDAP.

Participants were excluded for any of the following categories:

i. Pregnancy
ii. Age < 18 years
iii. Diminished mental capacity
iv. Prisoner
v. End-stage renal disease
vi. Diminishing visual acuity
vii. Inability to perform home blood glucose monitoring
viii. $HbA_{1c} < 7$

In addition, patients who failed to adhere to instructions given by the pharmacist for the duration of the study were excluded.

The study attempted to recruit 92 patients. Each pharmacist was required to select four patients, 50% of whom were assigned randomly to the intervention group and the others to the control group. The pharmacist was responsible for preparing an individualized care plan for each patient with the assistance of two clinical coordinators. Participants in the intervention group met with the pharmacist at their respective primary care sites on a regular basis (monthly or quarterly) for an assessment of adherence, HbA_{1c}, BG and BP testing, barriers to optimizing BG and BP, current medication regimen, diet, exercise and individualized education. The control group consisted of routine care by their primary physician but with no direct intervention by the pharmacist, except for the filling of a prescription. Each patient was monitored for 12 months from the date of enrolment. Baseline tests were performed on all participants and included: HbA_{1c}, BP, lipid panel (HDL-C, LDL-C, TG), and demographics (age, gender, height and weight); these variables were measured at each monthly follow-up visit. The primary outcome measure was a decrease of at least 1% in HbA_{1c} level.

Statistical Analysis

Descriptive (frequency tables and summary statistics) and inferential statistics (linear regression and tests of equality of means) were employed to analyse the efficacy of the intervention using IBM SPSS Statistics, version 21 (IBM Corp., Armonk, NY).

RESULTS

Demographic

Eleven pharmacists participated in the study and assessed 75 Type 2 diabetic patients (Figure) at the end of the data collection period; however, only 20 completed the study.

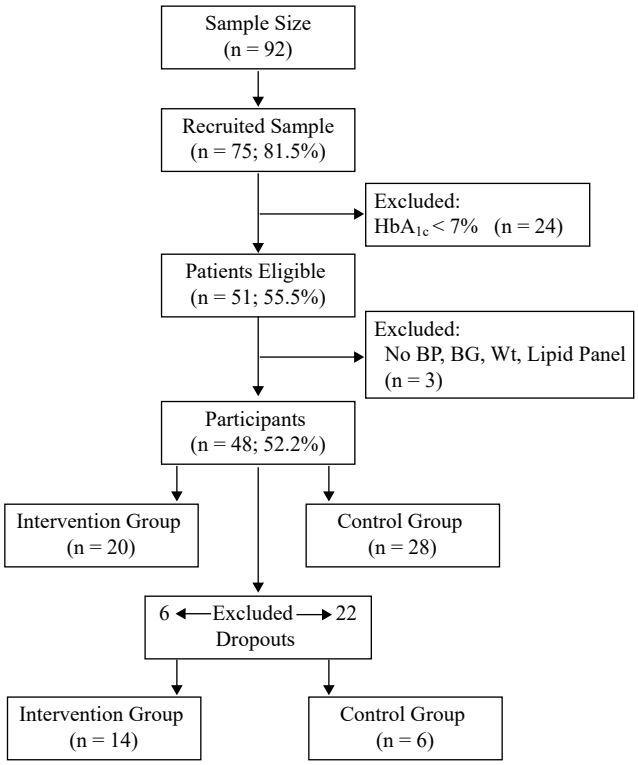

Figure: Trial flow diagram.

Therefore, only descriptive analysis was performed. The attrition rate among the intervention group was 30% and 78.6% for the control. The overall attrition rate was 58.3%.

Selected summary statistics of age and weight of patients who completed the study can be seen in Table 1.

Table 1: Summary statistics

Variable	Group Mean (SD)	
	Intervention n = 14	Control n = 6
Age	59.4 (13.2)	54.4 (22.81)
Weight	72.7 (7.07)	80.0 (29.29)

The frequency distribution of selected demographic variables is shown in Table 2. The patients were predominantly female (n = 14; 70%), had no higher than a secondary school education (n = 15; 75%) and had been diagnosed for over ten years (n = 10; 50%).

Table 2: Frequency distribution of selected demographic variables

Variables	n	%
Gender		
Male	6	30.0
Female	14	70.0
Ethnicity		
Indo-Trinidadian	1	5.0
Afro-Trinidadian	4	20.0
Mixed	2	10.0
Unknown	13	65.0
Highest level of education		
Primary	8	40.0
Secondary	7	35.0
Other (Unspecified)	1	5.0
Unknown	4	20.0
Years since diagnosed		
1–5	4	20
6–10	1	5
11–20	5	25
> 20	5	25
Unknown	5	25

Outcomes

Eight patients in the intervention group (57.1%) experienced a ≥ 1% decrease in HbA_{1c} compared to two patients (33.3%) in the control group Table 3.

Table 3: Alterations in HbA_{1c}, levels by treatment group

	Treatment n = 14 (%)	Control n = 6 (%)
Decrease	8 (57.1)	2 (33.3)
Increase	4 (28.6)	2 (33.3)
No change	2 (14.3)	2 (33.3)

The change in BP and weight from baseline can be observed in Table 4.

Among the intervention group, seven and five patients, respectively, had decreases in weight and blood pressure. Among the intervention group, improvements were observed in LDL-C only for three patients while HDL-C, LDL-C and TG were maintained by 11, 7 and nine patients, respectively Table 5.

Medications

The participants, collectively, were prescribed medications for 1) diabetes: metformin, insulin, gliclazide and

Table 4: Decrease in HbA_{1c}, blood pressure and weight from baseline

Measures (%)	Intervention n = 14			Control n = 6		
	Decreased	Increased	Unchanged	Decreased	Increased	Unchanged
BP	35.7%	14.3%	50.0%	16.7%	50.0%	33.3%
Weight	50.0%	35.7%	14.3%	50.0%	0.0%	50.0%

Key: BP – Blood pressure, HbA_{1c} – Glycosylated haemoglobin

Table 5: Change in lipid panel variables from baseline

Measures (%)	Intervention n = 14			Control n = 6		
	HDL-C	LDL-C	TG	HDL-C	LDL-C	TG
Maintained						
HDL > 40 mg/dL						
LDL < 100 mg/dL	78.6%	50.0%	64.2%	66.6%	0.0%	50.0%
TG < 150 mg/dL						
Improved						
HDL < 40 to > 40 mg/dL						
LDL > 100 to < 100 mg/dL	0.0%	21.4%	0.0%	0.0%	16.7%	0.0%
TG > 150 to < 150 mg/dL						
Uncontrolled/unchanged						
HDL < 40 mg/dL						
LDL >100 mg/dL	21.4%	28.6%	35.8%	33.3%	83.3%	50.0%
TG > 150 mg/dL						

Key: HDL – high density lipoprotein, LDL – low density lipoprotein, TG – Triglycerides

diamicron; 2) hypertension: nifedipine, enalapril, atenolol, bendrofluazide and lisinopril; 3) hypercholesterolaemia: simvastatin and rosuvastatin; and 4) cardiovascular disorders: isosorbide dinitrate, aspirin and and glyceryl trinitrate. Medications were not stated for six patients. Several patients had co-morbidities; six with hypertension, four with hypercholesterolaemia and five with cardiovascular disorders. Some patients were on other medications, such as omeprazole.

DISCUSSION

There was no difference between the patients with respect to initial or baseline age and weight. The success of the intervention was a decrease of ≥ 1% in HbA_{1c} among 57% of intervention patients, compared to 33% of control patients. This suggests that pharmacists who participated in the training programme acquired the competencies necessary to achieve similar successes among diabetic patients as demonstrated by Wishah *et al* (25). Our findings showed a reduction in HbA_{1c} ranging from 1.1 to 2.5 in the intervention compared to a mean of 1.92 in the control group. Choe *et al* reported a statistically significant (p = 0.03) reduction in HbA_{1c} values (1% to 8%) in the intervention group of patients with Type 2 diabetes who received pharmaceutical care from a clinical pharmacist compared to the control group (17). In our study, the decrease in HbA_{1c} by the intervention was progressive, meaning that the decrease was consistent for each consecutive period under observation.

The results also showed that weight reduction, ranging from 1.1 to 6.7 lb, was achieved by four (57.1%) of the intervention patients compared to two (33.3%) in the control group who had reductions of 3.3 and 4.4 lb, respectively. Our findings were similar to other preliminary data by Cutler *et al* (18); these researchers revealed that patients who received targetted educational and lifestyle interventions (including weight reduction) by healthcare professionals, among them pharmacists, achieved desired parametric endpoints with improved cost-benefits and cost-effectiveness (15, 26).

Our findings seem to support the results of the literature, which is replete with pharmacist intervention studies. These have shown that patient adherence and improved clinical indicators (HbA_{1c}, lipid panel, *etc*) redounded to reduced complication risk, which ultimately prolonged life (27–31). Additional benefits of the intervention group included lipid panel: HDL-C and TG parameters were maintained, while LDL-C was

maintained or improved Table 5, accompanied by a reduction in weight and BP Table 4.

Limitation

Many pharmacists initially agreed to participate but failed to commit for unknown reasons. The patient cohort was too small, therefore, better methods for recruitment needed to be explored. The failure of patients to document key measurements (SMGB, BP), as requested by the pharmacist, was responsible for the exclusion of these patients in the statistical analysis. All of these factors reinforced the importance of preventing patients from absconding in order to reduce the high attrition rate.

CONCLUSION

The authors do acknowledge that since only descriptive methods were possible, the findings regarding the success of the intervention and its benefits to the patient are inconclusive. An important merit of the findings is the problem of patient attrition and its impact on epidemiological studies in developing countries. Failure to form evidence-based judgment regarding the success and benefits of this study provides strong evidence in favour of efforts to reduce patient attrition in public healthcare. The stakeholders (RHAs and Health Planners) can offer incentives to pharmacists for greater participation in the management of patients with diabetes in various healthcare settings across TT. Additionally, pharmacists need to be equipped and trained for participation in disease management research studies. An integral aspect of future research involves taking steps to develop a culture of research among pharmacists.

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