ORIGINAL ARTICLE

INTERNATIONAL JOURNAL OF RESEARCH IN PHARMACEUTICAL SCIENCES

Published by JK Welfare & Pharmascope Foundation Journal Home Page: www.ijrps.com

Impact of Clinical Pharmacist Interventions in Management of Diabetes in Primary Care in Saudi Arabia

Maha Aldraimly*[1], Syed Azhar Bin Syed Sulaiman[2], Ahmed Ibrahim Nouri[2], Salma Fahad Alanazi[3], Reem Fahad Alanazi[3], Saeed Ur Rahman[1], Nawaf Fahad Alanazi[3]

[1]King AbdulAziz Medical City, Riyadh, Saudi Arabia
[2]Universiti Sains Malaysia, Penang, Malaysia
[3]Vision Colleges, Riyadh, Saudi Arabia

Article History:

Received on: 05 Sep 2021
Revised on: 06 Oct 2021
Accepted on: 08 Oct 2021

Keywords:

Clinical Pharmacist,
Diabetes,
Primary Care,
Intervention,
Quality of Life,
Pharmaceutical Care

ABSTRACT

The study aimed to identify the impact and effectiveness of clinical pharmacist intervention on the management and overall quality of life of diabetic patients. Two cross-sectional studies using SF36 Health Survey, involving physicians and pharmacists at the Ambulatory Care Department in Riyadh, Saudi Arabia. Diabetic patients showed significant improvements in their QoL in terms of general health, energy and fatigue, pain scores, and social, emotional, and physical functions. Moreover, PC was found to have a significant impact on diabetes related QoL along with various outcome indicators, such as HbA1c, random blood sugar, and lipid profile in such patients. Additionally, satisfactory knowledge, good practice in identifying prescription errors were found among pharmacists. This study reveals that clinical pharmacists are valuable members of interdisciplinary primary care teams in ambulatory care. This can positively impact glycemic control in patients with type 2 diabetes and improve their quality of life. Also, the current study presented that a satisfactory extent of pharmaceutical care by an ambulatory clinical pharmacist was effective in improving HbA1c in patients with diabetes. A clinical pharmacist in ambulatory care was found to be eminent and of an added value to the patients, physicians, and healthcare team.

*Corresponding Author

Name: Maha Aldraimly
Phone: +966 56 577 2757
Email: marsn-2008@hotmail.com

ISSN: 0975-7538

DOI: https://doi.org/10.26452/ijrps.v12i4.4909

Production and Hosted by

IJRPS | www.ijrps.com

INTRODUCTION

To evaluate the impact of the clinical pharmacist in an ambulatory care setting. Clinical pharmacists performed interventions on patients with chronic diseases: mainly diabetes, hypertension, and dyslipidemia. The current chapter presents the methodology of the interventions undertaken, results obtained, and discussion. Conclusions about the impact of clinical pharmacists in the management of diabetes and its complications are presented in the following chapters. The study aimed to evaluate if pharmaceutical care can improve disease knowledge, adherence to medications and rehabilitation, and quality of life (HRQOL) in patients with type 2 diabetes.

Ethics Approval

The study was approved by Institution Review Board (IRB) at National Guard Health Affairs, King Abdul Aziz Medical City, Riyadh, Saudi Arabia.

METHODS

A trial was designed to evaluate the objective and was conducted in three outpatient centers of National Guard hospitals in Riyadh, Saudi Arabia. A longitudinal study follows individuals to see how things change over time. Hence, the study was a longitudinal prospective interventional study to evaluate the direct impacts of treatment or preventive measures on disease. A prevalence-based sample size determination was made. Previous literature has reported a varying prevalence. The prevalence of diabetes in Saudi Arabia is 25% (Aldossari *et al.*, 2018). A target significance level of 5%, a confidence level of 95%, and a power of $\geq$ 80% were set. The Cochran equation allows calculating an ideal sample size provided a required level of precision, pet confidence level, and the expected proportion of the disease in the population. Hence, by applying Cochran's equation, the minimum required sample size for the study. The sample size obtained was 287 and a 10% drop-out rate was added in the final count to yield 315 patients. This figure was considered as required sample size, who were recruited for intervention and control arms.

The study included atients attending KAAMC primary clinics, patients between the ages of 30 and 75 years, patients having uncontrolled hypertension, LDL equal to or more than 2.6 mmol/dL for diabetic patients, patients with HbA1c of 7.5% or above, patients taking oral antidiabetic drugs plus insulin. On the other hand, exclusion criteria were patients with a non-essential or secondary cause of hypertension, pregnancy, HIV, cancer patients, patients on insulin therapy (Type 1 diabetes), newly diagnosed diabetics, patients with controlled diabetes (HbA1c $\leq$7%).

The study was conducted in the Khasm Al-Aan primary care center, (Health Comprehensive Specialized Clinic, HCSC), and Umm Al-Hamam clinic (National Guard Comprehensive Specialized Clinic, NGCSC) where clinical pharmacists are present and practicing routine care along with family medicine physicians on daily basis. Patients from these two clinics were the target group for inclusion in the present study. For purpose of comparison, an equivalent number of patients in other NGHA family medicine centers were enrolled as control groups.

The study was carried out at three centers; two of them have clinical pharmacy services and one does not. The samples were divided into the Intervention arm: patients that would receive clinical pharmacist care and the Control arm: patients at an outpatient clinic that does not have a clinical pharmacy service, in which the patients would not receive care by a clinical pharmacist.

The training of the pharmacists was conducted for four weeks with a total of 8 lectures of 1-hour duration starting at 9 am on weekdays, i.e., Sunday to Thursday. The training also encompassed briefing about the study protocol, questionnaires, and forms to be used as well as patient diaries. The training module and disease education literature were also provided to them for self-study at home. A lecture on pharmaceutical care and counseling skills for pharmacists was given. The training was based on the topics: diabetes disease information, pathophysiology, disease epidemiology, symptoms, risk factors, diagnosis and treatment, self-care and quality of life in DM, the importance of adherence to treatment goals, brief introduction about the role of pharmacists in self-care.

Physicians at the clinics received a referral form including the inclusion/exclusion criteria developed by the clinical pharmacist. The referral form requested them to refer these patients to the clinical pharmacist to follow up on their treatment. The clinical pharmacist would review medications, patient history, laboratory tests, and overall assessment and would then develop a medication therapy management plan and contact the physician to discuss. A joint plan would then be agreed upon between the clinical pharmacist and the physician. The clinical pharmacists would keep following up on the patients' adherence, provide patient education, and report on drug therapy problems. Each session to follow up with the patients would take around 45–50 minutes. The clinical pharmacists would document their interventions and recommendations in a 'clinical pharmacist intervention form'. The clinical pharmacist collected a basal metabolic profile of each patient upon their first visit. Also, a QoL questionnaire (SF36) was collected from each patient upon the first visit to compare it later with a similar questionnaire at the final visit. There was a period of one year between the first and final visits. During this duration, the patient was followed up every three months, i.e., four visits within the year. Baseline data was collected when the patient visited the physician for the first time. Baseline laboratory tests were also scheduled before the next visit; however, the management of BP began at the first visit. In the combined physician–pharmacist care group, the patient was referred to the clinical pharmacist who reviewed the patient's chart in detail and made an assessment, and discussed medication adherence and therapy options with both the physician and the patient. Hypertension, dyslipidemia, and diabetes parameters of the control group were monitored (Table 2 and Table 3).

Table 1: Patients' data at baseline

Patient information	Entire sample (N = 301) Frequency (%)	Intervention group (N = 150) Frequency (%)	Control group (N = 151) Frequency (%)	P value
Gender				0.45*
Male	106 (38.2)	38 (25.2)	68 (45.3)	
Female	195 (64.7)	112 (74.8)	83 (54.7)	
Marital status				0.636*
Single	43	34	9	
Married	206	83	123	
Other	52 (17.3)	33	19	
Education				0.486*
Educated	246 (81.7)	137 (92.4)	109 (72.18)	
No formal education	55 (18.3)	13 (8.6)	42 (27.8)	
Occupation				0.381*
Employed	133 (44.2)	51	82	
Retired	54 (17.9)	34	20	
Un-employed	114 (37.9)	49	65	
Monthly Income				0.821*
2500 < 5000	120 (39.9)	62 (44.6)	58 (38.4)	
5000 < 10,000	181 (60.1)	77 (55.4)	93 (61.5)	

Table 2: Parameters of patients in control group during the study[£] (n = 151)

Variables	Visit 1 Mean + SD	Visit 2 Mean + SD	Visit 3 Mean + SD	Visit 4 Mean + SD	P-value
Age (years)		60.5 ± 7.8			
Weight (kg)	81.5 ± 14.4	81.9 ± 15.2	83.4 ± 14.2	82.1 ± 15.6	0.084
SBP (mm Hg)	150.6 ± 15.6	149.1 ± 21.2	147.8 ± 18.7	147.8 ± 19.5	0.002*
DBP (mm Hg)	87.1 ± 13.8	82.1 ± 14.1	82.8 ± 11.4	81.3 ± 12.2	<0.0001*
Pulse (per minute)	87.0 ± 12.6	83.0 ± 13.2	83.1 ± 14.5	80.9 ± 12.6	<0.0001*
Random BS (mmol/L)	12.0 ± 3.7	12.1 ± 3.7	11.7 ± 2.9	11.0 ± 2.9	0.009
HbA1c (%)	9.4 ± 1.2	9.4 ± 1.1	9.5 ± 1.2	9.4 ± 1.1	0.015*
T Cholesterol (mmol/L)	4.6 ± 0.8	4.3 ± 0.9	4.3 ± 0.8	4.2 ± 0.7	<0.0001*
Triglycerides (mmol/L)	1.5 ± 0.6	1.6 ± 0.6	1.6 ± 0.6	1.6 ± 0.5	0.087
HDL (mmol/L)	1.0 ± 0.2	0.9 ± 0.2	0.9 ± 0.2	0.9 ± 0.2	0.116
LDL (mmol/L)	3.0 ± 0.6	2.7 ± 0.8	2.6 ± 0.7	2.7 ± 0.6	<0.0001*
BUN[@] (mmol/L)	6.1 ± 1.9	6.2 ± 1.8	6.7 ± 5.5	6.7 ± 4.7	0.225
Creatinine (μmol/L)	85.6 ± 24.6	92.8 ± 85.5	86.7 ± 24.4	86.9 ± 24.6	<0.0001*
Albumin (g/L)	47.4 ± 7.9	47.7 ± 6.9	47.9 ± 6.9	48.1 ± 6.9	0.103

* Significance level P < 0.05 (Repeated measures ANOVA-Wilks' Lambda test was used)
[£] follow-up for one year, three months between each visit
[@] BUN Blood Urea Nitrogen

Table 3: Laboratory parameters of intervention group on follow-up£ (n = 150)

Variables	Visit 1 Mean + SD	Visit 2 Mean + SD	Visit 3 Mean + SD	Visit 4 Mean + SD	P-value
Age (years)		54.1 ± 9.1			
Weight (kg)	81.8 ± 13.5	82.5 ± 12.0	81.6 ± 14.2	81.5 ± 12.0	0.001*
Systolic BP (mmHg)	127.8 ± 16.0	125.2 ± 13.3	126.7 ± 10.9	126.1 ± 8.8	0.825
Diastolic BP (mmHg)	71.2 ± 10.0	69.2 ± 7.3	71.5 ± 7.9	72.2 ± 7.7	0.516
Pulse (per minute)	84.0 ± 9.6	82.4 ± 11.0	83.5 ± 9.3	81.4 ± 7.0	0.022*
Random BS (mmol/L)	13.2 ± 4.7	10.4 ± 3.9	9.7 ± 3.4	8.6 ± 2.4	<0.0001*
HbA1c (%)	9.9 ± 1.9	9.4 ± 1.7	9.0 ± 1.5	8.5 ± 1.6	<0.0001*
Cholesterol (mmol/L)	4.6 ± 0.9	4.3 ± 0.8	4.3 ± 0.8	4.2 ± 0.6	<0.0001*
Triglycerides (mmol/L)	1.7 ± 0.6	1.5 ± 0.5	1.5 ± 0.5	1.5 ± 0.5	<0.0001*
HDL (mmol/L)	1.0 ± 0.2	1.0 ± 0.2	1.0 ± 0.2	1.1 ± 0.3	0.116
LDL (mmol/L)	3.0 ± 0.8	2.5 ± 0.7	2.4 ± 0.6	2.3 ± 0.5	<0.0001*
BUN (mmol/L)	7.1 ± 7.9	7.0 ± 7.8	6.8 ± 7.7	7.0 ± 8.5	<0.0001*
Creatinine (μmol/L)	87.2 ± 20.6	86.1 ± 20.5	85.1 ± 20.7	84.4 ± 20.5	<0.0001*
Albumin (g/L)	47.4 ± 6.9	46.3 ± 6.9	45.5 ± 6.8	44.8 ± 6.7	<0.0001*

*Significance level P < 0.05 (Repeated measures ANOVA-Wilks' Lambda test was used)
£follow-up for one year, three months between each visit

There were two treatment groups, i.e., the control group (CG) and the intervention group (IG). Patients in the intervention group received usual care and consultation with pharmaceutical care provided by pharmacists while those in the control group received usual care and consultation without pharmaceutical care.

The outcome variables were systolic blood pressure (SBP) and diastolic blood pressure (DBP), which were measured at each visit, and the laboratory data (HbA1c, post-prandial blood sugar level, lipid profiles, and kidney and liver function tests) were collected every three months for one year (a total of four times). SF-36 scores, indicating the bio-psychosocial parameters of included patients, were used to measure their QoL. Data were entered and analyzed using Statistical Package of Social Sciences (SPSS) software. A codebook with variables and their labels was created. Categorical variables were expressed as frequencies and percentages and summarized in tables. Associations between continuous variables were presented in graphs and expressed with the help of means and standard deviations. Significant differences between the control and intervention groups were determined based on the outcomes measured (continuous or categorical) using the t-test and/or Chi-square correlation test. A P-value of ≤ 0.05 was considered to be significant between the intervention and the control groups.

RESULTS

Impact of clinical pharmacist interventions on clinical outcomes

For the sake of this research, patients in the intervention group will be referred to as cases. Table 1 shows the baseline characteristics of the study population.

All the cases were asked to complete a questionnaire to assess their existing QoL, using form SF36. Table 4 and Table 5 show the responses given by the cases for each item. When asked about their overall general health, many of them, i.e., 45.7% said that it was not bad, while one-third of them, i.e., 33.1% declared it as bad and only 21.2% were having a good QoL. When the health status of these cases was compared at the one-year follow-up, the vast majority said that their health status had become worse or much worse, 23.2% found it the same, and only 4% said that their health was better than in the previous year.

Study participants were also asked about their QoL after the intervention had been provided to them. The changes in their life and their capabilities of performing their routine daily work after they had received PC in addition to the conventional care was also noted, and form SF36 was completed by the same cases who had been recruited pre-intervention. Table 4, Table 5 and Table 6 below demonstrates the responses given by the partici-

Table 4: Mean difference between first and final visit in the laboratory parameters of both groups

Variable	Cases		Control		P-value
	M	SD	M	SD	
Weight (kg)	0.40	7.29	1.06	7.23	0.549
Systolic BP (mm Hg)	–1.97	16.08	–2.87	20.94	0.676
Diastolic BP (mm Hg)	0.89	12.04	–5.43	14.87	<0.0001*
Pulse (per minute)	–2.85	10.71	–6.27	13.68	0.017*
Random BS (mmol/L)	–4.66	4.27	–1.04	4.25	<0.0001*
HbA1C (%)	–1.63	1.63	0.00	1.50	<0.0001*
Cholesterol (mmol/L)	–0.38	0.89	–0.35	1.08	0.787
Triglycerides (mmol/L)	–0.17	0.60	0.08	0.51	<0.0001*
HDL (mmol/L)	0.08	0.23	0.01	0.20	0.010*
LDL (mmol/L)	–0.63	0.75	–0.31	0.75	<0.0001*
BUN (mmol/L)	–0.11	11.41	0.62	5.01	0.475
Creatinine (μmol/L)	–2.74	26.26	1.24	3.30	0.067
Albumin (g/L)	–2.62	9.05	0.70	10.65	0.004*

*Significance level P < 0.05 (Non-parametric test used when needed)

pants post-intervention.

The Table 7 show the pre and post-intervention comparison in cases using SF36 questionnaires. Significant differences were found between pain scores, social function, general health, emotional wellness, energy and fatigue, physical function, and limitation in physical and emotional roles of the study participants after provision of the intervention.

DISCUSSION

The role of the clinical pharmacist is still being investigated in many countries. In Saudi Arabia, the role of the clinical pharmacist in an inpatient setting is becoming increasingly important. However, it is very uncommon for clinical pharmacists to work in an outpatient setting. The current study aimed at shedding light on the impact of clinical pharmacists in outpatient clinics by investigating their role in improving diabetes management, its complications, and the QoL of diabetic patients. By reviewing the patients' profiles, treatment plan, discussions with the physician, patient education, improved drug adherence, and vigorous follow-up, the current study was able to report positive impacts of the clinical pharmacists. Compared to inpatients, Davis *et al.* (2005) reported PC to be a useful adjunct to conventional management of diabetes in primary care, because monitoring of drug therapy can prevent problems associated with adverse drug reactions and polypharmacy. It can also minimize prescription errors and can ensure compliance (Al-Quteimat and Amer, 2016). After participating in the educational sessions, pharmacists reported that good communication skills, collaboration with other healthcare providers, and an empathic attitude towards patients can sustain such goals. In line with the study findings, (Merks *et al.*, 2016) also suggested that the practice of PC by pharmacists can be effective in improving not only clinical outcomes but also the QoL of diabetes patients. Specifically, the implementation of PC results in enhanced glycaemic control and a lower risk score in Type II DM patients (Al-Mazroui *et al.*, 2009). Vlcek *et al.* (2009) also found acceptable knowledge in their study of pharmacists. The study by Alhabib *et al.* (2016) showed a promising attitude, an interest in improving their knowledge, and a recognition of the importance of PC in the practice of their profession. The authors also concluded that those individuals who received the PC had a statistically significant drop in blood pressure, HbA1c, lipid profile, and ultimately CHD and an improvement in their QoL, all of which are consistent with the findings of the study. The clinical pharmacists started to follow up with diabetes patients where they showed high HbA1c levels. As the study progressed and upon following visits, HbA1c levels decreased, whereas the patients in the control group did not experience any improvement in HbA1c. As HbA1c is considered as one of the most important markers for diabetes control, this study reflects that the input of clinical pharmacists was valuable in diabetes control. In conjunction with the current study, the Fremantle study (Clifford *et al.*, 2005) demonstrated a decrease in the glycaemic levels and systolic as well as diastolic BPs of the participants receiving PC, and HbA1c reduced

Table 5: Responses to questionnaire by intervention patients before intervention; n = 151

Questions	Responses (%)					
	Very bad	Bad	Not bad	Good	Very good	Excellent
General health	0	50 (33.1)	69 (45.7)	32 (21.2)	0	0
	Much worse	Worse	Same	Better		
Health compared to last year	27 (17.9)	83 (55)	35 (23.2)	6 (4)		
Does your health limit your:	Never	Less	More			
Vigorous activities	10 (6.6)	56 (37.1)	85 (56.3)			
Moderate activities	19 (12.6)	86 (57)	46 (30.5)			
Lifting/carrying groceries	35 (23.2)	82 (54.3)	34 (22.5)			
Climbing several flights of stairs	13 (8.6)	45 (29.8)	93 (61.6)			
Climbing one flight of stairs	34 (22.5)	80 (53)	37 (24.5)			
Bending, kneeling, stooping	108 (71.5)	21 (13.9)	22 (14.6)			
Walking >1 mile	32 (21.2)	80 (53)	39 (25.8)			
Walking several blocks	68 (45)	70 (46.4)	13 (8.6)			
Walking one block	85 (56.3)	60 (39.7)	6 (4)			
Bathing or dressing yourself	137 (90.7)	8 (5.3)	6 (4)			
In last 4 weeks: (physical health)	No	Yes				
Cut down amount of time	10 (6.6)	141 (93.4)				
Accomplished less	16 (10.6)	135 (89.4)				
Limited kind of work	21 (13.9)	130 (86.1)				
Difficulty in performing work	18 (11.9)	133 (88.1)				
In last 4 weeks: (emotional problems)	No	Yes				
Cut down amount of time	10 (6.6)	141 (93.4)				
Accomplished less	18 (11.9)	133 (88.1)				
Did not work carefully as usual	12 (7.9)	139 (92.1)				
	Never	Low	Moderate	High	Severe	
Problems interfered with work (past 4 weeks)	1 (.7)	10 (6.6)	69 (45.7)	64 (42.4)	7 (4.6)	
	No pain	Very low	Low pain	Moderate	Too much	Severe pain
Bodily pain (past 4 weeks)		2 (1.3)	16 (10.6)	51 (33.8)	73 (48.3)	9 (6)
	Never	Low	Moderate	High	Severe	

Continued on next page

Table 5 continued

Questions	Responses (%)					
	Very bad	Bad	Not bad	Good	Very good	Excellent
Pain interfered with work (past 4 weeks)		12 (7.9)	76 (50.3)	58 (38.4)	5 (3.3)	
In past 4 weeks:	Never	Rarely	Sometimes	Mostly	Always	All time
Did you feel full of pep?	18 (11.9)	79 (52.3)	49 (32.5)	4 (2.6)	1 (.7)	
Have you been a nervous person?		9 (6)	37 (24.5)	31 (20.5)	59 (39.1)	15 (9.9)
Felt so down that nothing could cheer you	5 (3.3)	34 (22.5)	63 (41.7)	25 (16.6)	23 (15.2)	1 (.7)
Felt calm and peaceful	3 (2)	46 (30.5)	67 (44.4)	27 (17.9)	8 (5.3)	0
Have a lot of energy	26 (17.2)	84 (55.6)	31 (20.5)	6 (4)	4 (2.6)	0
Felt downhearted and blue	108 (71.5)	25 (16.6)	14 (9.3)	2 (1.3)	2 (1.3)	0
Felt worn out	3 (2)	6 (4)	25(16.6)	32 (21.2)	56 (37.1)	29 (19.2)
Have you been a happy person?	0	43 (28.5)	78 (51.7)	19 (12.6)	11 (7.3)	0
Feel tired?	0	10 (6.6)	23 (15.2)	18 (11.9)	41 (27.2)	59 (39.1)
Interference in social activity	Never 1 (.7)	Infrequently 46 (30.7)	Sometimes 83 (55.3)	Mostly 19 (12.7)	All time 1 (.7)	
	Mostly wrong	Wrong	Don't know	True	Mostly true	
Get sick a little earlier than others	57 (37.7)	2 (1.3)	16 (10.6)	3 (2)	73 (48.3)	
As healthy as anybody else	63 (41.7)	0	50 (33.1)	0	38 (25.2)	
Expect health to get worse	10 (6.6)	0	126 (83.4)	0	15 (9.9)	
Health is excellent	46 (30.5)	0	81 (53.6)	0	24 (15.9)	

Table 6: Responses to questionnaire by patients after intervention (N = 151)

Questions	Responses					
	Very bad	Bad	Not bad	Good	Very good	Excellent
General health	0	0	0	3 (2)	96 (63.6)	52 (34.4)
	Much worse	Worse	Same	Better	Much better	
Health compared to last year	0	0	2 (1.3)	63 (41.7)	86 (57)	
Does your health limit your:	Never	Less	More			
Vigorous activities	42 (27.8)	101 (66.9)	8 (5.3)			
Moderate activities	75 (49.7)	73 (48.3)	3 (2)			
Lifting/carrying groceries	116 (76.8)	32 (21.2)	3 (2)			
Climbing several flights of stairs	57 (37.7)	93 (61.6)	1 (.3)			
Climbing one flight of stairs	147 (97.4)	4 (2.6)	0			
Bending, kneeling, stooping	149 (98.7)	2 (1.3)	0			
Walking >1 mile	130 (86.1)	21 (13.9)	0			
Walking several blocks	149 (98.7)	2 (1.3)	0			
Walking one block	151 (100)	0	0			
Bathing or dressing yourself	151 (100)	0	0			
In last 4 weeks: (physical health)			No	Yes		
Cut down amount of time			138 (91.4)	13 (8.6)		
Accomplished less			129 (85.4)	22 (14.6)		
Limited kind of work			96 (63.6)	55 (36.4)		
Difficulty in performing work			141 (93.4)	10 (6.6)		
In last 4 weeks: (emotional problems)			No	Yes		
Cut down amount of time			137 (90.7)	14 (9.3)		
Accomplished less			137 (90.7)	14 (9.3)		
Did not work as carefully as usual			125 (82.8)	26 (17.2)		
		Never	Low	Moderate	High	Severe
Problems interfered with work (past 4 weeks)		48 (31.8)	95 (62.9)	6 (4)	1 (.7)	1 (.7)
	No pain	Very low	Low pain	Moderate	Too much	Severe pain
Bodily pain (past 4 weeks)	57 (37.7)	85 (56.3)	5 (3.3)	2 (1.3)	0	2 (1.3)
		Never	Low	Moderate	High	Severe

Continued on next page

Table 6 continued

Questions	Responses					
	Very bad	Bad	Not bad	Good	Very good	Excellent
Pain interfered with work (past 4 weeks)		98 (64.9)	49 (32.5)	2 (1.3)	0	2 (1.3)
In past 4 weeks:	Never	Rarely	Some-times	Mostly	Always	All the time
Did you feel full of pep?	0	0	5 (3.3)	36 (23.8)	103 (68.2)	7 (4.6)
Have you been a nervous person?	7 (4.6)	132 (87.4)	11 (7.3)	0	1 (.7)	0
Felt so down that nothing could cheer you	115 (76.2)	31 (20.5)	5 (3.3)	0	0	0
Felt calm and peaceful	4 (2.6)	2 (1.3)	1 (.7)	40 (26.5)	92 (60.9)	12 (7.9)
Have a lot of energy	1 (.7)	2 (1.3)	13 (8.6)	54 (35.8)	77 (51)	4 (2.6)
Felt downhearted and blue	142 (94)	7 (4.6)	1 (.7)	0	1 (.7)	0
Felt worn out	7 (4.6)	120 (79.5)	21 (13.9)	0	3 (2)	0
Have you been a happy person?	0		4 (2.6)	19 (12.6)	123 (81.5)	5 (3.3)
Feel tired?	5 (3.3)	138 (91.4)	7 (4.6)	0	1 (.7)	0
	Never	Infrequently	Some-times	Mostly	Always	All time
Interference in social activity	85 (57.8)	55 (37.4)	3 (2)	2 (1.4)	0	2 (1.4)
	Mostly wrong	Wrong	Don't know	True	Mostly true	
Get sick a little earlier than others	129 (86.6)	16 (10.7)	2 (1.3)	0	2 (1.3)	
As healthy as anybody else	2 (1.3)	0	3 (2)	16 (10.7)	128 (85.9)	
Expect health to get worse	94 (63.5)	10 (6.8)	43 (29.1)	0	1 (.7)	
Health is excellent	4 (2.6)	0	4 (2.6)	12 (8.1)	129 (86.6)	

by an average of 0.5% over the 12-month follow-up period from a baseline of 7.5%, even though there was no change in the control group. Moreover, the decreasing trend in HbA1c was also found in RBS in both genders of diabetic patients who received PC as compared to controls, who showed an initial decrease with a dip and then a gradual increase, in contrast to a consistent downward trend observed in the cases. Likewise, Farsaei et al. from Iran revealed a significant decrease in HbA1c (Farsaei *et al.*, 2011), and Suppapitiporn et al. also reported improved efficacy of glycaemic control in each consultation visit with a pharmacist (Suppapitiporn *et al.*, 2005). Taken together, such inferences suggest the success of PC towards reducing mean glycaemic values. An RCT found a significant reduction in SBP, in addition to blood glucose and HbA1c levels in the intervention group in comparison to the control group after a period of 12 months. Other community-based studies (Barber *et al.*, 1999) have demonstrated a greater reduction, i.e., 2% over a shorter period (3–4 months) but from a higher baseline mean HbA1c (11%) in an outpatient clinic setting. Another study reported a mean reduction of 0.4%, i.e., from 7.5% to 7.1% in HbA1c over four years. Yet, six-monthly follow-ups did not show any advantage of PC over routine care in terms of improvement in HbA1c (Clifford *et al.*, 2011). Likewise, a prospective study that was conducted to investigate the impact of PC on QoL in T2DM patients in a private tertiary hospital in South India found it effective in modifying outcome indicators in an eight-month follow-up period. Mean values of HbA1c decreased from 8.44% to 6.73% ($P < 0.01$) and fasting blood glucose from 195.57 to 107.25 mg/dl between the baseline and end-line interviews in the PC group. Treatment satisfaction score also improved in a similar pattern. Improvement in the intervention group was particularly noted in reductions concerning worries, the future and the living condition domains of the patients. The age range of the participants in both the groups was between 32 and 85 years old with an approximately equal male-to-female ratio, which was also similar to the current study (Sriram *et al.*, 2011). Also, a few other studies with a similar one-year follow-up period to the present research have pointed out that overall changes for the better in the lifestyle of diabetic patients were observed. Correr *et al.* (2011) reported that the intervention group in their study presented a noteworthy improvement, i.e., 8.6% in health-related QoL compared to the control group (1.6%) in terms of impact and satisfaction domains after 12 months of follow-up. Korcegez *et al.* (2017) at the end of their 12-month study period in Northern Cyprus also observed a significant reduction in HbA1c, from 8.29% to 7.55%, and in fasting blood glucose in its intervention arm that was given PC. No significant differences were found between the groups in HDL, LDL, triglycerides, and total cholesterol levels ($P = 0.063$, 0.331, 0.896 and 0.04, respectively). This was in contrast to the findings of the present study, as a consistent fall was noticed in LDL, total cholesterol and triglycerides, whereas an increase in HDL was observed when compared to baseline across both the genders. Although DBP, BMI and triglycerides were lower in the intervention group, it was not significant. Total cholesterol, LDL and HDL were significantly higher in the intervention group than in the control group, which is in contrast to current study, where LDL, cholesterol and triglycerides were lower and HDL was higher in cases compared to controls in the post-intervention period (Ali *et al.*, 2012). In the Asheville Project, Cranor and Christensen also reported significant improvements in glycaemic control, LDL and blood pressure (Cranor and Christensen, 2003). Similar to the present study findings, other studies have also revealed the beneficial effect of pharmacist intervention on lipid profiles. For instance, Bellary et al. showed a significant decline in total cholesterol (Bellary *et al.*, 2008). The conclusions obtained from the findings of the present study indicate that PC has a noticeable impact on certain laboratory parameters including glycaemic levels (HbA1c and RBS) and lipid profile (cholesterol, LDL, HDL and triglycerides) in diabetic patients, along with improvements in the general health of the cases. A positive association was also seen between high education and the presence of higher levels of HDL, and lower levels of LDL, RBS and HbA1c. PC was hence found to be valuable and helpful in supporting diabetic patients in dealing with their disease with regard to improvements in their clinical and biochemical profile, to prevent complications and to promote good health and wellbeing. Clinically significant differences were obtained in terms of post-prandial blood glucose (PPBG) levels (7.4 ± 1.7 vs. 10.4 ± 2.0 mmol/L) between intervention and control groups, respectively. The increase in the percentage of the intervention group that reached target PPBG was from 12.0 to 54.0% ($P = 0.001$), while those that reached the target HbA1c increased from 52.0% from 10.5% initially. HbA1c values were improved for the intervention group compared to the control group ($7.8 \pm 1.9\%$ vs. $9.5 \pm 2\%$; $P = 0.001$), respectively. Input from pharmacists resulted in a greater proportion of the intervention group participants attaining comprehensive clinical outcomes for diabetes in com-

Table 7: Pre-Post comparison of changes in SF36 of patients (N = 151)

Theme	Mean Pre	Mean Post	Mean Diff.	SD	t-test	P-value
Pain Q21–22	87.6	35.7	51.9	17.2	37.2	<0.001
Social function Q 20, 32	42.2	48.1	5.9	17.8	4.1	<0.001
General health Q 1, 33–36	23.9	57.9	34	14.1	29.7	<0.001
Emotional wellness Q 24–26, 28, 30	15.6	47.8	32.2	14.4	27.4	<0.001
Energy fatigue Q 23, 27, 29, 31	25.1	73.7	48.7	19.3	31	<0.001
Physical function Q 3–12	11.8	44.7	32.8	19.2	21	<0.001
Physical role limitation Q 13–16	16.5	89.2	72.7	28.9	30.9	<0.001
Emotional role limitation Q 17–19	11.9	91.2	79.2	31	31.4	<0.001

*Q2 was not included in any thematic analysis as per reference

parison to the control group (Ahmad *et al.*, 2015).

As the patients were still in primary care, they did not develop severe complications and the cases did not deteriorate. This was obvious from the results reported, especially from the renal function tests, so the renal marker did not show any differences. If any of these complications do arise, the patient goes to inpatient or specialized care, and is no longer under primary or FP care. Hence, the involvement of the clinical pharmacist in early intervention decreases the burden of the disease in terms of minimizing hospital admissions and complications and, in turn, the costs of disease management.

The current study implemented Short Form 36 (SF-36) questionnaire. SF-36 is the most widely used general health status tool. The questionnaire consists of eight items that cover the aspects of: [1] physical functioning; [2] role-physical; [3] pain; [4] general health; [5] vitality; [6] social functioning; [7] role-emotional; and [8] mental health (Ware and Sherbourne, 1992). Changes in fewer than four SF-36 scores are considered as small, four to 10 as moderate, and more than 10 as large (Contopoulos-Ioannidis *et al.*, 2009). In the current study, around seven parameters were seen to have improved in the post-intervention phase of the study. The results provided some preliminary evidence that PC can have a positive impact on HRQoL in diabetics, with the evidence pointing towards a larger effect on mental health than on physical health; however, the findings are inconclusive, as different scales were used to assess the QoL and so it is difficult to compare the studies (Krass and Dhippayom, 2013).

A study using the SF36 questionnaire focused on the change in the QoL of participants after PC was given to them. QoL is well accepted and is one of the most important outcomes and goals in the treatment of diabetes. Improvements were seen in the domains of general health, physical aspects, functional capacity, pain, vitality, and mental health. Such improvements in the QoL of patients may be partly attributed to their increased contact with the clinical pharmacist because of their uncontrolled diabetes, but it is also possibly associated with appropriate adherence to lifestyle changes following counseling.

In practical terms, among additional benefits was the contribution by the qualified pharmacist having prior exposure to diabetes-specific medication issues with formal education, who could implement the present PC model after the patients were selected as cases. Hence, the pharmaceutical care process was meant to complement formal diabetes education. It was found that pharmacists developed good relationships with individual patients and other allied health personnel during the study; another factor that might have contributed to improved outcomes. Our PC model was flexible and can be adapted to a variety of settings. The pharmacist in this study was working relatively independently, but the program could be easily and conveniently implemented by diabetes educators, physicians, pharmacists, and other health professionals in an outpatient or inpatient setting. In this regard, the data from this study, as well as from others, argue that the pharmacist can be beneficial in addition to the integrated care for patients with T2D (Irons *et al.*, 2002; Krass *et al.*, 2011; Wagner *et al.*, 2001).

The study established the favorable impact of clinical pharmacists in accomplishing a primary therapeutic goal for overall diabetes control in patients with diabetes mellitus, in addition to the routine care provided by the physician in ambulatory care set up in Saudi Arabia. The improved QoL indicates the advantages of pharmacist-driven education and the significance of consultations with a pharmacist in an ambulatory setting, as physicians are usually not able to deliver prolonged counseling and hours of consultation; their follow-ups are not fre-

quent, and hence many of the patients' questions remain unanswered. On the other hand, pharmacists' follow-ups led the patients to air their queries and to clarify their perceptions, as they understood well the importance of maintaining a healthy lifestyle by managing their diabetes.

CONCLUSION

Pharmaceutical Care was found to have a positive impact on diabetes-related QoL, along with various other outcome indicators, such as HbA1c, RBS, and lipid profile, for T2DM patients. Inferences achieved also recognized the favorable influence of the clinical pharmacist in practicing PC to attain therapeutic goals, in addition to the overall control of their patients' diabetes, along with the routine care offered by the physician. Such improvements noticeably indicate the need to incorporate the input from clinical pharmacists with routine care in the hospital as well as in outpatient settings to maximize the benefits for diabetic patients. Moreover, these strategies can also be applied to various chronic illnesses so that the maximum number of patients can experience beneficial effects in controlling and managing their respective illnesses. The study established the favorable impact of clinical pharmacists in accomplishing a primary therapeutic goal in patients having diabetes mellitus for overall diabetes control; in addition to the routine care provided by the physician. The improved QoL indicated the advantages of pharmacist-driven education and the significance of consultations with a pharmacist in a hospital setting as physicians are usually not able to deliver prolong counseling and hours of consultation, their follow-ups are not frequent and hence many of the patients' questions remain unanswered. On the other hand, pharmacists' follow-up led the patients to take out their queries and clarify their perceptions as well as they understood the importance of maintaining a healthy lifestyle by managing their diabetes. Hence, the study can reimburse that an ambulatory care clinical pharmacist is effective in identifying drug therapy problems. Though in terms of monetary value, the study did not tap into these factors and whether the involvement of clinical pharmacists resulting in significant cost savings to the institution or not.

ACKNOWLEDGEMENT

The authors acknowledge the healthcare staff in King Abdulaziz Medical City for their help to accomplish the current study, in terms of documents provision, clean environment, and any direct or indirect help from their side.

Funding Support

The study was not sponsored by any funding.

Conflicts of Interest

The authors do not have conflicts of interest to declare.

REFERENCES

Ahmad, A. D., Elnour, A. A., Yousif, M. A., Farah, F. H., Akasha, H. A., Abasaeed, A., Shehab, A., Kalbani, N. A., Nuaimim, S. A., Bhagavathula, A. S., Shehab, O. A., Amoodi, A. A. A. 2015. Pharmacist's interventions to improve clinical outcomes in patients with type 2 diabetes mellitus: Nyala City, South Darfur State, Sudan. *International Journal of Diabetes in Developing Countries*, 35(4):578–587.

Al-Mazroui, N. R., Kamal, M. M., Ghabash, N. M., Yacout, T. A., Kole, P. L., McElnay, J. C. 2009. Influence of pharmaceutical care on health outcomes in patients with Type 2 diabetes mellitus. *British Journal of Clinical Pharmacology*, 67(5):547–557.

Al-Quteimat, O. M., Amer, A. M. 2016. Evidence-based pharmaceutical care: The next chapter in pharmacy practice. *Saudi Pharmaceutical Journal*, 24(4):447–451.

Aldossari, K. K., Aldiab, A., Al-Zahrani, J. M., Al-Ghamdi, S. H., Abdelrazik, M., Batais, M. A., Javad, S., Nooruddin, S., Razzak, H. A., El-Metwally, A. 2018. Prevalence of Prediabetes, Diabetes, and Its Associated Risk Factors among Males in Saudi Arabia: A Population-Based Survey. *Journal of Diabetes Research*, 2194604.

Alhabib, S., Aldraimly, M., Alfarhan, A. 2016. An evolving role of clinical pharmacists in managing diabetes: Evidence from the literature. *Saudi Pharmaceutical Journal*, 24(4):441–446.

Ali, M., Schifano, F., Robinson, P., Phillips, G., Doherty, L., Melnick, P., Laming, L., Sinclair, A., Dhillon, S. 2012. Impact of community pharmacy diabetes monitoring and education programme on diabetes management: a randomized controlled study. *Diabetic Medicine*, 29(9):e326–e333.

Barber, N., Wilson, A., Willson, A. 1999. Churchill's clinical pharmacy survival guide. Churchill Livingstone. ISBN: 978-0443055362.

Bellary, S., O'Hare, J. P., Raymond, N. T., Gumber, A., Mughal, S., Szczepura, A., Kumar, S., Barnett, A. H. 2008. Enhanced diabetes care to patients of south Asian ethnic origin (the United Kingdom Asian Diabetes Study): a cluster randomised controlled trial. *The Lancet*, 371(9626):1769–1776.

Clifford, R. M., Batty, K. T., Davis, T. M. E., Davis, W., Stein, G., Stewart, G., Plumridge, R. J. 2011. A

randomised controlled trial of a pharmaceutical care programme in high-risk diabetic patients in an outpatient clinic. *International Journal of Pharmacy Practice*, 10(2):85–89.

Clifford, R. M., Davis, W. A., Batty, K. T., Davis, T. M. 2005. Effect of a Pharmaceutical Care Program on Vascular Risk Factors in Type 2 Diabetes. *Diabetes Care*, 28(4):771–776.

Contopoulos-Ioannidis, D. G., Karvouni, A., Kouri, I., Ioannidis, J. P. A. 2009. Reporting and interpretation of SF-36 outcomes in randomised trials: systematic review. *BMJ*, 338:a3006.

Correr, C. J., Melchiors, A. C., Fernandez-Llimos, F., Pontarolo, R. 2011. Effects of a pharmacotherapy follow-up in community pharmacies on type 2 diabetes patients in Brazil. *International Journal of Clinical Pharmacy*, 33(2):273–280.

Cranor, C. W., Christensen, D. B. 2003. The Asheville Project: Factors Associated with Outcomes of a Community Pharmacy Diabetes Care Program. *Journal of the American Pharmaceutical Association (1996)*, 43(2):160–172.

Davis, T. M., Clifford, R. M., Davis, W. A., Batty, K. T. 2005. The role of pharmaceutical care in diabetes management. *The British Journal of Diabetes and Vascular Disease*, 5(6):352–356.

Farsaei, S., Sabzghabaee, A. M., Zargarzadeh, A. H., Amini, M. 2011. Effect of pharmacist-led patient education on glycemic control of type 2 diabetics: a randomized controlled trial. *Journal of Research in Medical Sciences*, 16(1):43–49.

Irons, B. K., Lenz, R. J., Anderson, S. L., Wharton, B. L., Habeger, B., Anderson, H. G. 2002. A Retrospective Cohort Analysis of the Clinical Effectiveness of a Physician-Pharmacist Collaborative Drug Therapy Management Diabetes Clinic. *Pharmacotherapy*, 22(10):1294–1300.

Korcegez, E. I., Sancar, M., Demirkan, K. 2017. Effect of a Pharmacist-Led Program on Improving Outcomes in Patients with Type 2 Diabetes Mellitus from Northern Cyprus: A Randomized Controlled Trial. *Journal of Managed Care and Specialty Pharmacy*, 23(5):573–582.

Krass, I., Dhippayom, T. 2013. Pharmaceutical care–impact on quality of life in patients with type 2 diabetes: a review. *Clinical Audit*, 17.

Krass, I., Mitchell, B., Song, Y. J. C., Stewart, K., Peterson, G., Hughes, J., Smith, L., White, L., Armour, C. 2011. Diabetes Medication Assistance Service Stage 1: Impact and sustainability of glycaemic and lipids control in patients with Type 2 diabetes. *Diabetic Medicine*, 28(8):987–993.

Merks, P., Swieczkowski, D., Jaguszewski, M. 2016. Patients' perception of pharmaceutical services available in a community pharmacy among patients living in a rural area of the United Kingdom. *Pharmacy Practice*, 14(3):774.

Sriram, S., Chack, L. E., Ramasamy, R., Ghasemi, A., Ravi, T. K., Sabzghabaee, A. M. 2011. Impact of pharmaceutical care on quality of life in patients with type 2 diabetes mellitus. *Journal of Research in Medical Sciences*, 16(Suppl 1):S412–S418.

Suppapitiporn, S., Chindavijak, B., Onsanit, S. 2005. Effect of diabetes drug counseling by pharmacist, diabetic disease booklet and special medication containers on glycemic control of type 2 diabetes mellitus: a randomized controlled trial. *Journal of the Medical Association of Thailand* , 88(Suppl 4):S134–S141.

Vlcek, J., Malý, J., Dosedel, M. 2009. Pharmaceutical care of patients with diabetes mellitus and its relationship to clinical pharmacy. *Vnitrni Lekarstvi*, 55(4):384–388.

Wagner, E. H., Grothaus, L. C., Sandhu, N., Galvin, M. S., McGregor, M., Artz, K., Coleman, E. A. 2001. Chronic Care Clinics for Diabetes in Primary Care: A system-wide randomized trial. *Diabetes Care*, 24(4):695–700.

Ware, J. E., Sherbourne, C. D. 1992. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. *Medical Care*, 30(6):473–483.