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Impact of Clinical Pharmacist Diabetes Clinic on the Improvement of Health Outcomes in Type 2 Diabetes Subjects

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Abstract

AIM: This study aimed to evaluate the improvement of HbA1c, lipid profile, blood pressure readings, and weight in type 2 diabetes at the clinical pharmacist diabetes clinic (CPDC) in ambulatory care clinic.

METHODS: A retrospective study was conducted at a CPDC; the clinical pharmacist role was to follow-up the referred uncontrolled type 2 diabetes patients and providing comprehensive management.

RESULTS: A total of 419 patients were included the study. The mean ± standard error of the mean (SEM) age was 58.9 ± 0.59 years old. Sixty-two percent of the patients were female. At baseline, mean HbA1C ± SEM was 10.69% ± 0.06%, mean low-density lipoprotein (LDL) ± SEM was 2.66 ± 0.04 mmol/l. After 3 months of follow-up, HgbA1C had a statistically significant improvement by a reduction of 1.69% to be 9% ± 0.09% (95% confidence interval [CI] [1.50–1.87], $p < 0.001$). Moreover, mean HbA1C had a statistically significant improvement after 6 months of follow-up compared to baseline by 1.78% to be 8.9% ± 0.21% (95% CI [1.33–2.22], $p < 0.001$). LDL had a statistically significant improvement after 3 months by 0.24 mmol/l to be 2.42 ± 0.04 mmol/l (95% CI [0.15–0.35], $p < 0.001$) and after 6 months of follow-up by 0.28 mmol/l to be 2.38 ± 0.04 mmol/l (95% CI [0.20–0.36], $p < 0.001$).

CONCLUSION: The results stated that the clinical pharmacist anticipated care is achievable and had significant effect in the reduction of HbA1C and LDL levels in patients with uncontrolled type 2 diabetes.

Introduction

Diabetes is a progressive disease that is associated with serious complications and increase morbidity and mortality rates. Globally, it was estimated that approximately 463 million adults (20–79 years) were living with diabetes in 2019 and by 2045, this will rise to 700 million [1], [2]. In 2013, it was estimated that diabetes directly caused 1.5 million deaths globally and additional 2.2 million deaths were attributable to high blood glucose complications [1], [3]. Diabetes and its complications could be treated, avoided, or delayed with diet, physical exercises, medications, regular screening, and treatment for complications [4], [5]. Diabetes is considered the leading cause of blindness, kidney failure, and limb amputations [4], [6]. In addition, diabetic patients have a two-to-four-fold risk of stroke and death by heart diseases [4], [7].

Management of patients with polypharmacy especially those with type 2 diabetes and its complications required special care. The clinical pharmacists had a crucial role in choosing the proper doses, guiding patients to proper use of medication and offering enough education [8], [9]. The collaboration between physician and clinical pharmacist leads to improvement in the clinical outcome of diabetic patients who had polypharmacy [8]. Diabetes clinical pharmacist conducted around the world, and it showed great efficacy in reducing cardiovascular risk, stroke, and other diabetes complications. Furthermore, this will minimize the cost of recurrent hyperglycemia and hospital admission. Therefore, the researchers planned to design this research to be conducted in this specific clinic and for those specific populations. Pharmacist-administered diabetes education and management services have been reported in many studies to improve glycemic control over standard treatment, as well as to improve control of blood pressure and dyslipidemia [10]. The integration of clinical pharmacists in chronic disease management especially diabetes within a collaborative practice agreement will enhance drug utilization, improve disease-related outcomes, reduce cost, and promote the overall patient experience [9], [11].

In Brazil, a randomized controlled trial conducted in a secondary diabetic care clinic for 80 patients with type 2 diabetes, HbA1C level at baseline was ≥7.0%, and aged 40–79 years demonstrated that the pharmacist–physician collaborative care model had a greater reduction in HbA1c compared to the usual care (–0.79 vs. –0.16; p = 0.010), respectively [12]. Moreover, a retrospective study conducted at an ambulatory diabetes clinic in Qatar showed that the collaborative pharmaceutical care service significantly reduced HbA1c level by 1.4%, fasting plasma glucose (FPG) by 41.3 mg/dL, body mass index (BMI) by 1 kg/m^2, systolic blood pressure (SBP) by 14.9 mmHg, and diastolic blood pressure (DBP) by 8.7 mmHg from baseline to 12 months (p = 0.001), while there was no significant reduction in the lipid profile [13].

In Saudi Arabia, a prospective cohort study was conducted for poorly controlled type 2 diabetes at a tertiary hospital to study the impact of the pharmacist-led diabetes clinic on glycemic control. A total of 34 patients were included in the study. The study reported that the pharmacist-led diabetes clinic significantly reduced the mean HbA1c level by 1.2% (from 9.5% to 8.3% after 3 months follow-up). However, the study found that the mean BMI level non-significantly reduced by 0.6 kg/m^2 (from 32.3 kg/m^2 to 31.7 kg/m^2 after 3 months follow-up) [14].

Aim of the study

The aim of this study was to evaluate the improvement of HbA1c, lipid profile, blood pressure readings, and weight in type 2 diabetes at the clinical pharmacist diabetes clinic (CPDC) in the ambulatory care clinic. The research hypothesis was that the clinical pharmacist role in such a clinic can lead to a significant improvement in patients' outcomes.

Ethical approval

The Institutional Review Board (IRB) at Prince Sultan Medical Military City approved the study (approval number 1532).

Methods

Setting

The study was conducted at Alwazarat primary care center of Prince Sultan Medical Military City in Riyadh, Saudi Arabia. Alwazarat primary care center runs many clinics such chronic illness clinic that provides services to military personnel, civil employed personnel in the military organizations, and their dependents.

Study design

A retrospective study was conducted at Alwazarat primary care center in Riyadh, Saudi Arabia. In the CPDC, the clinical pharmacist is part of the multidisciplinary team and has a role in monitoring the patients' improvement after the referral to the clinic. Physicians refer patients to the clinical pharmacist for additional care in response to several triggers, such as poor glycemic control, lack of understanding of their disease and medications, poor adherence, or difficulty in self-monitoring of glucose or insulin administration. At the first visit, the clinical pharmacist accesses the information from the patient's electronic medical record, such as medical and social history, current medications, and laboratory data (HbA1C, FPG, renal function, liver function, electrolytes, albumin/creatinine ratio, lipid profile levels, and vitals sign). Moreover, the clinical pharmacist should collect further information from the patients regarding diet, exercise, and immunizations. The clinical pharmacist must do medication review, educate patients, set the goals (with clear outcomes and timeline), orders laboratory tests as needed, and provide a glucometer if the patients do not have one. When necessary, clinical pharmacists adjust drug regimens in accordance with the protocol and decide a pharmacotherapy plan, add, or remove medication after taking the in-charge physician agreement. The visits either routine visits within 1–3 months or urgent visits within 1 – 2 weeks with an average visit duration of around 30 min. The researchers going to check all laboratory data after 3 months of follow-up to see the improvement and then another laboratory check after another 3 months to finalize the results. Data were collected for visits between December 2020 and July 2021.

Inclusion criteria

- All type 2 diabetes patients aged more than 18 years, referred to CPDC with or without uncontrolled blood pressure or dyslipidemia were included in the study.

Exclusion criteria

The following criteria were excluded in the study:

1. Patients with baseline HbA1c <9%
2. Patients had no follow-ups history after 3 months and 6 months.

Outcomes

The primary outcomes were the changes in HbA1c and low-density lipoprotein (LDL) levels after 3 and 6 months of CPDC.

The secondary outcomes were the changes in weight, BMI, triglyceride (TG), SBP, and DBP after 3 and 6 months of CPDC.

Statistical analysis

The researchers analyzed data using Excel 365 and IBM SPSS statistic 2021 (version 28). Values expressed as mean with standard error of mean (SEM). Moreover, descriptive data were generated for all variables. Data pre- and post-referral to clinic compared using a paired-samples *t*-test and the level of statistical significance were act at (95% confidence interval, P value).

Results

Four hundred and eighty patients were enrolled from medical records using the CPDC census. Thirty-two patients were excluded, because they had no follow-ups history after 3 months and 6 months. Twenty-nine patients were excluded because they had baseline HbA1c <9%. Finally, 61 patients were excluded based on the exclusion criteria (Figure 1).

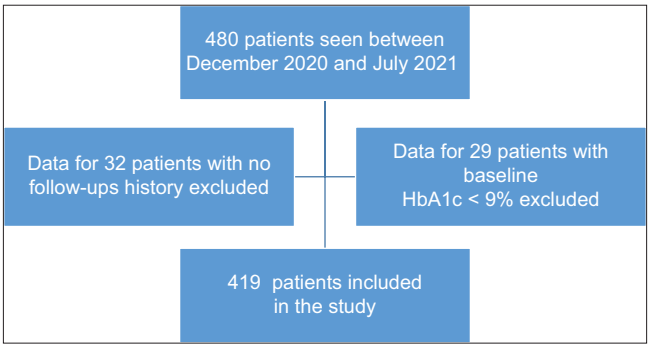

Figure 1: Inclusion and exclusion criteria (impact of clinical pharmacist diabetes clinic on the improvement of health outcomes in type 2 diabetes subjects)

A total of 419 patients were included in the study. The mean ± SEM age was 58.9 ± 0.59 years old. Sixty-two percent of the patients were female. At baseline, mean HbA1C ± SEM was 10.69% ± 0.06%, mean weight ± SEM was 81.5 ± 0.8 kg, mean BMI ± SEM was 32 ± 0.51, mean TG ± SEM was 2.04 ± 0.18 mmol/l, mean LDL ± SEM was 2.66 ± 0.04 mmol/l, and mean SBP ± SEM was 131.5 ± 0.83 mmHg, whereas the mean DBP ± SEM was 72 ± 0.6 mmHg. Table 1 summarizes the characteristics of the patients at baseline and follow-ups (3 months and 6 months after the baseline visit).

After 3 months of follow-up, mean HbA1C had a statistically significant improvement by a reduction of 1.69% to be 9% ± 0.09% (95% confidence interval [CI] [1.50–1.87], p < 0.001). Moreover, mean HbA1C had a statistically significant improvement after 6 months of follow-up compared to baseline by 1.78% to be 8.9% ± 0.21% (95% CI [1.33-2.22], p < 0.001) (Figure 2 and Table 1).

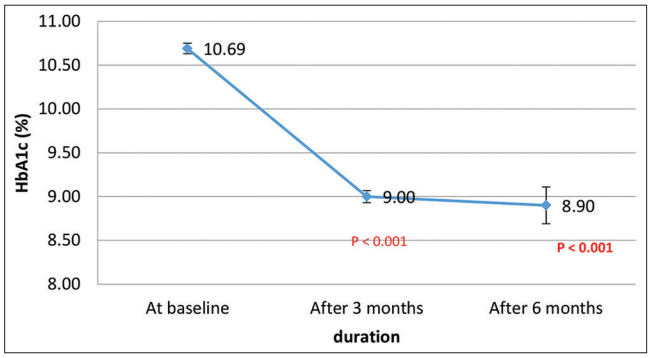

Figure 2: HbA1c changes

After 3 months of follow-up, mean LDL had a statistically significant improvement by 0.24 mmol/l to be 2.42 ± 0.04 mmol/l (95% CI [0.15–0.35], p < 0.001). Moreover, mean LDL had a statistically significant improvement after 6 months of follow-up by 0.28 mmol/l to be 2.38 ± 0.04 mmol/l (95% CI [0.20–0.36], p < 0.001) (Figure 3 and Table 1).

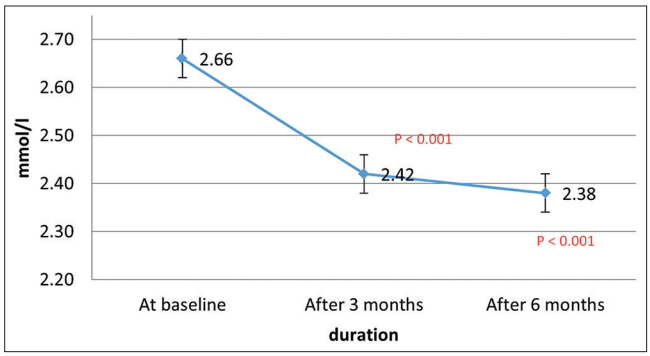

Figure 3: Low-density lipoprotein changes

Moreover, TGs mean difference after 3 months was statistically significant compared to baseline

Table 1: Characteristics of the patients at baseline and follow-up

Parameter	Follow-up				
	Baseline	3 months	95% CI (p)*	6 months	95% CI (p)**
n	419	-		-	
Male (%)	160 (38)				
Female (%)	259 (62)				
Age	58.9 ± 0.59	-		-	
Primary outcomes					
HbA1c (%)	10.69 ± 0.06	9.0 ± 0.07	1.50–1.87 (<0.001)	8.9 ± 0.21	1.33–2.22 (<0.001)
LDL (mmol/L)	2.66 ± 0.04	2.42 ± 0.04	0.15–0.35 (<0.001)	2.38 ± 0.04	0.20–0.36 (<0.001)
Secondary outcomes					
Weight (kg)	81.5 ± 0.8	80.6 ± 0.8	0.32–1.40 (<0.001)	80.7 ± 0.8	0.06–1.54 (<0.05)
BMI (kg/m^2)	32 ± 0.51	30.35 ± 0.57	0.69–2.6 (<0.001)	31.3± 0.34	0.158–1.16 (<0.05)
TG (mmol/L)	2.04 ± 0.18	1.88 ± 0.06	0.04–0.28 (<0.05)	1.85 ± 0.23	−0.478–0.87 (0.29)
SBP (mmHg)	131.5 ± 0.83	130.6 ± 0.85	−0.73–2.6 (0.134)	128.3 ± 0.73	1.6–4.7 (< 0.001)
DBP (mmHg)	72 ± 0.60	71.2 ± 0.65	−0.42–2.0 (0.1)	71 ± 0.65	−0.33–2.28 (0.072)

*The difference between baseline data and 3 months data,**The difference between baseline data and 6 months data. Data presented as mean ± SEM in baseline and follow-ups unless otherwise indicated. 95% CI and p value calculated using paired sample *t*-test. CI: Confidence interval, SEM: Standard error of mean, HbA1c: Glycated hemoglobin, LDL: Low-density lipoprotein, BMI: Body mass index, TG: Triglycerides, SBP: Systolic blood pressure, DBP: Diastolic blood pressure.

($p < 0.05$). SBP mean difference after 6 months was statistically significant compared to baseline ($p < 0.001$). Similarly, the weight and BMI show statistically improvement in the follow-up of 3 months and 6 months versus the baseline. Weight mean differences after 3 months and 6 months were statistically significant compared to baseline ($p < 0.001$ and $p < 0.05$, respectively). BMI mean difference after 3 months and 6 months were statistically significant compared to baseline ($p < 0.001$ and $p < 0.05$, respectively). Finally, DBP mean difference after 3 months and 6 months was not statistically significant compared to baseline ($p = 0.1$ and $p = 0.07$, respectively).

Discussion

The present study found that the mean HbA1c level decreased after 3 months of CPDC follow-up and after 6 months decreased even more (1.69% reduction to reach 9% and 1.78% reduction to reach 8.9%, respectively). Interestingly, this reduction was clinically significant after 3- and 6-month follow-up as well, although the mean HbA1c level did not reach the optimal HbA1c level for diabetic patients (i.e., HbA1c <7% [4]). According to The United Kingdom Prospective Diabetes Study, the clinical consequences for every 1.0% decrease in HbA1c levels are fabulous; because each 1.0% reduction in the HbA1c is accompanied by a relative risk reduction of 21% for any diabetes-related endpoint, 14% for myocardial infarction, 37% for microvascular complications, and 21% for diabetes-related deaths [15]. As mentioned in the literature review, these results are consistent with those of the previous several studies that stated that clinical pharmacist has a crucial role in improving HbA1c among these subjects [11], [12], [13], [14].

The therapeutic goal for LDL level in diabetic patients is <2.59 mmol/l [16]. Intriguingly in our study, the mean LDL level reduced from abnormal mean LDL level (2.66 mmol/l) to reach the therapeutic goal mean LDL level after 3- and 6-month follow-ups (2.42 mmol/l and 2.38 mmol/l, respectively). Therefore, the results were statistically and clinically significant. HbA1c and LDL results in this study are corroborated by similar findings in the previous studies that illustrated significant reduction as well [17], [18], [19].

Another important finding was the reduction in patients' mean weight and mean BMI after 3 months and then slightly elevated after 6 months follow-up. Surprisingly, the improvement was considered significant in both periods. This was also found in the literature, where mean BMI decreased after 12-month follow-up [13], and against the prospective cohort study conducted in Saudi Arabia [14]. However, this study brought a new finding regarding the rapid reduction in both outcomes at the beginning, and then a correction of this rapid reduction. Despite increasing insulin doses and sedentary lifestyle during the COVID-19 pandemic, the improvement in the mean weight was remarkably and that could be due to using of Semaglutide injection (Ozempic) in some subjects [20], [21], or due to dietary and exercise instructions given to the patients [22].

In a systematic review, 14 studies have been measured the beneficial effect of the pharmacist interventions on BMI [23]. The results showed two studies stated reduction compared with the control groups. However, the statistically significant reduction was only in one study [24].

Moreover, TGs reduced significantly after 3 months. However, the reduction continued after 6 months of follow-up but was statistically not significant; these results must be studied furthermore in the upcoming research. In the systematic review, data for TGs were reported in 12 studies [23]. Nine out of 12 studies reported a greater improvement in TGs outcome compared with the control groups. But only two studies observed a statistical significance improvement between the intervention and the control groups [17], [25].

Finally, the mean SBP reduction was both clinically and statistically significant after 6 months of follow-ups as the mean SBP reduced from 131 mmHg to 128.3 mmHg (target SBP <130 mmHg [4]), while the reduction in mean DBP was insignificant at all durations. The rationale behind the insignificant improvement in the DBP might be that the mean DBP at baseline was not considered high (within the target DBP <80 mmHg [4]) which showed insignificant reduction during the intervention periods.

Clinical implication

- We highlighted the need to better standardization of CPDC interventions across the country. This would require a collaboration between the health-care providers in the institutions, and more national collaboration among hospital pharmacy departments across the country
- Journal editors should ensure the rigorousness of the description of the interventions performed and the outcomes measured in article accepted for publication.

Limitations

The patients could be comanaged by the multidisciplinary team in the chronic illness clinic in parallel to the services provided by the clinical pharmacist, which may affect the patients' outcomes.

Conclusion

In the present study, it has been concluded that the CPDC interventions had a significant effect on the HbA1c, weight, BMI, LDL, and SBP which could help in preventing or delaying diabetes complications. Interestingly, this significant improvement was attained without using complex regimens of anti-diabetic medication.

Strength and weakness

The large sample size has been given strength to the current study. Nevertheless, the weakness was not including a control group in the study.

Future research is essential to assess TG changes, the long-term benefits, and the reliability of clinical pharmacist follow-up on health care outcomes such as hospitalization and emergency visits. Also, future researches are required to monitor other chronic diseases and compliance to medications.

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