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Original article

Impact of clinical pharmacist-led diabetes management clinic on health outcomes at an academic hospital in Riyadh, Saudi Arabia: A prospective cohort study

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ABSTRACT

Background: Diabetes prevalence is estimated to reach 20.6% by 2030. Studies have illustrated main reasons for uncontrolled patients and concluded: low level of awareness, limited access to healthcare providers, and lack of cooperation between different disciplines. The role of pharmacists has been proven to improve patient-related outcomes, including an improvement in HgA1C readings between 0.54% and 1.6%.

Objectives: This study was conducted to evaluate diabetes-related health outcomes in a pharmacist-led diabetes clinic in terms of HgbA1C level, guideline-recommended routine screenings, medication adherence, and biomarkers of other comorbidities.

Method: A prospective cohort study conducted from August 2017 until July 2018 at an academic hospital. The pharmacist-led diabetes clinic was providing the service for a half-day per week. The study included all adult diabetic patients referred to the pharmacist-led clinic and had -at least- three 3-month apart follow-up visits with no exclusions. The baseline assessments for patients receiving routine diabetic care was performed using HgbA1C level, blood pressure, lipid and thyroid panel, eye and foot examinations, preventive measures, and adherence. The baseline results were compared to the follow-up results thereafter. A descriptive analysis was used to report the differences between intervals. Main outcome measure: (a) Reduction in HgbA1c levels, (b) intervention made by clinical pharmacists in an outpatient setting.

Result: The study included thirty-five patients. The mean ± SD age was 56 ± 10 years old. At baseline, mean HgbA1C was 9.5% ± 1.3%. HgbA1C was ≥10% for 13 patients. Albuminuria was never previously assessed for 14 patients. Twenty percent were receiving incorrect dose compared to the guideline-recommended statin therapy. By the end of study, mean HgbA1C had significantly improved to be 8.3% ± 1.4% (p = 0.0004). Nine patients achieved their HgbA1C goal of <7%. All patients were assessed for albuminuria, and managed accordingly. Thirty-two patients were eligible to receive statin therapy, and prescribed appropriate doses. Additionally, peripheral neuropathy was assessed for all cohort, and seven patients received recommended vaccinations.

Conclusion: Involving clinical pharmacists in diabetes management clinic can provide valuable services, help patients to adhere to the therapeutic plans, and assist physicians to achieve better treatment outcomes.

1. Introduction

Diabetes is the fifth leading cause of death in Saudi Arabia with a prevalence of 17% in 2011. This number is estimated to reach 24.6% by 2030 moving Saudi Arabia up to sixth place (International Diabetes Federation, 2011). There are huge efforts to increase awareness and reduce diabetes and diabetes-related complications rates.

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Several clinical practice guidelines set objectives and cost-effective parameters to assess diabetes and diabetes-related conditions and help to control the disease aiming for lower complications rates and better overall quality of life. In addition, many national and international initiatives were implemented to promote diabetes control, minimize diabetes-related complications, reduce overall economic burden (American Diabetes Association, 2017).

When managing diabetes, glycosylated hemoglobin (HgbA1C) goals must be tailored to match patient's individualized goal and avoid hypoglycemia events. Optimizing other comorbid conditions, e.g. hypertension, dyslipidemia, obesity, is a major goal to reduce complications. Moreover, preventative measures and screenings are important in diabetes management. Cost-effectiveness of many of these interventions have also been studied and proven (American Diabetes Association, 2017).

Several national and international studies have illustrated the reasons for high percentages of uncontrolled diabetic patients and concluded three main reasons: 1) low level of awareness among diabetic patients, relatives and caregivers, and population at high risk to develop diabetes, 2) limited access to healthcare providers due to manpower shortage, and 3) lack of cooperation between different specialties that involve in diabetes management (American Diabetes Association, 2017; Padiyara et al.Please note that the reference style has been changed from a Numbered style to a Name–Date style as per the journal specifications., 2011).

Accordingly, many international studies have evaluated the impact of clinical pharmacists in diabetes management. Padiyara et al (Padiyara et al., 2011) conducted an observational study comparing patients who had at least 2 visits to either a primary care physician as a usual care group or to additional visits in clinical pharmacist clinics as the intervention group. The comparison was in terms of achieving guidelines' recommended targets over more than 300 patients per group. Intervention group achieved recommended targets and objectives by 64.3% compared to only 50% with the usual care group. Moreover, higher percentage received preventative measures, such as recommended vaccinations, in the intervention group (Padiyara et al., 2011).

In another retrospective study included 98 diabetic patients that was conducted to evaluate diabetes-related outcomes in terms of HgbA1C improvement (with a reduction by 1.6%; $p < 0.001$), blood pressure (9-mm Hg and 1.4-mm Hg reduction in systolic and diastolic blood pressure; $p = 0.001$ and $p = 0.038$, respectively), and low-density lipoprotein cholesterol (LDL) (16.3-mg/dL reduction in LDL-C; $p = 0.048$) when managed by a clinical pharmacist in an ambulatory setting in comparison to patients managed by primary care providers. The clinical pharmacist group showed significant positive improvement, in addition to meeting more guidelines' recommended treatment goals (Wallgren et al., 2012).

Furthermore, to evaluate the effect of a pharmacist-physician collaborative care model on diabetes outcomes and determine characteristics that influence this type of care, Aguiar et al. (2016) conducted a randomized controlled trial in a secondary care clinic for 73 type 2 diabetic patients who had uncontrolled HgbA1C at enrollment. Multiple interventional methods were performed, face-to-face consultations and remote telephone support after a routine visit. The greater improvement and attainment of therapeutic goals in the interventional group suggest that the collaborative care model is feasible and more effective for managing diabetic patients (Aguiar et al., 2016).

Since those studies and many others have demonstrated a positive impact of clinical pharmacists in diabetes management clinics on improving both short- and long-term patient-related clinical, including an improvement in HgA1C readings between 0.54% and 1.6%, and financial outcomes (Padiyara et al., 2011; Wallgren et al., 2012; Aguiar et al., 2016; Jarab et al., 2012; Mino-León et al., 2015; Obarcanin et al., 2015; McDonough and Doucette, 2001).

2. Aim of the study

The aim of this study was to evaluate patient-related health outcomes in diabetes management in terms of HgbA1C level, guideline-recommended routine screenings, medication adherence, and biomarkers of other comorbidities for diabetic patients in a pharmacist-led diabetes management clinic. We hypothesize that clinical pharmacist's involvement in diabetes management clinics can lead to favorable health outcomes.

2.1. Ethics approval

The study was approved by the Institutional Review Board (IRB) at King Saud University under approval number E-17-3782.

2.2. Methods

2.2.1. Study design

A prospective cohort study was conducted over 11-month period started from August 2018 until December 2019 at an academic hospital in Riyadh, Saudi Arabia. The clinical pharmacist-led ambulatory care clinic was providing the service for a half-day per week on a weekly basis. Under a collaborative practice agreement, patients were referred to the clinical pharmacist clinic to have close monitoring and follow-up to meet their health-related goals. This collaborative agreement has a detailed scope of practice that allows clinical pharmacists, within this agreement, to provide specific medical services. The agreement is approved and monitored by both parties. The clinical pharmacist providing patient care is a board-certified ambulatory care clinical pharmacist and a certified diabetic educator. The study included all adult type two diabetic patients who were newly referred to the clinical pharmacist clinic for diabetes management and had at least three follow-up visits; each visit is 3-month apart with no exclusions to get reliable HgA1c results. Fifty-two patients were screened and only 34 patients fit the inclusion criteria and enrolled in the study.

2.2.2. Description of interventions

At the time of the study, the baseline assessments of diabetes for patients receiving routine diabetic care were performed and included HgbA1C level, blood pressure, lipid and thyroid panel screening and repeated as indicated. In addition, eye referrals and foot examinations were preformed, and followed-up as necessary to be up-to-date for any therapeutic actions. Therapeutic actions included diabetes medication dose or frequency adjustments, medication addition or alteration. In addition, prescribing appropriate primary prevention of statin and/or aspirin therapy were assessed based on American Diabetes Association (ADA) cardiovascular risk scores and recommendations (American Diabetes Association, 2017). Preventive measures including depression screening, and administration of guidelines-recommended vaccinations were also based on ADA guidelines (American Diabetes Association, 2017). Additionally, the clinical pharmacist was assessing the patients' awareness of importance and impact of lifestyle modifications, i.e. diet and exercise, and adherence to those recommended lifestyle modifications along with adherence to prescribed medications. Moreover, patients' all assessments were documented within patient electronic health record for easier communication with his/her other physicians. The assessments are repeated -as recommended- for follow-up and were compared to the baseline results. Other physicians' assessments and interventions where excluded from our data collection.

2.3. Statistical analysis

Descriptive analysis was used to report the differences between the baseline and follow-up intervals. A paired *t*-test was used for all continuous variables and Chi-squared test for frequencies, after normality was checked, to calculate *p*-values and report the results' significance using SPSS version 20.0 (SPSS Inc., Chicago, US). Statistical significance was established at a p value less than or equal to 0.05.

3. Results

A total of 34 patients had at least three 3-month-apart visits out of 52 enrolled patients. The mean ± SD age was 56 ± 10 years old. Fifty-seven percent of study cohort were female. At baseline, mean HgbA1C was 9.5% ± 1.3%. HgbA1C was ≥ 10% for 37% of patients. Mean systolic blood pressure was 134 ± 25 mmHg, whereas the mean diastolic blood pressure was 79 ± 12 mmHg. The mean body mass index (BMI) among study cohort was 32.3 ± 5.8 kg/m^2. (Table. 1). Albuminuria was never previously assessed in 40% of the patients. Seven patients (20%) were on incorrect doses based on the guideline-recommended statin therapy. Four patients (11.4%) reported medications or diet adherence issues. Only one patient had a depression screening performed and one had received needed vaccines prior visiting the pharmacy-led clinic

By the end of the study period, mean HgbA1C had a statistically significant improvement by 1.2% to be 8.3% ± 1.4% (p = 0.0004). Nine patients achieved their HgbA1C goal of less than 7%. The mean difference in blood pressure was not statistically significant compared to baseline (p = 0.7). Although the difference in mean BMI was not statistically significant, cohort showed continuous reduction in BMI (p = 0.6) (Table.2).

All patients were assessed in terms of albuminuria and managed accordingly. Among the study cohort, 82% were eligible to receive statin therapy, and prescribed appropriate doses while considering their tolerance. All patients reported adherence to medications and diet. Additionally, peripheral neuropathy was assessed using on-site monofilament testing for all cohort and yielded negative results for 94.2% of patients. 82% of the included patients were never done eye examination and received referral to ophthalmology. 80% of the patients were evaluated for any sign of depression, 2 of them were referred to psychologist for further follow up. Seven patients received recommended or seasonal vaccinations (Table.3).

Table 1
Baseline characteristics of enrolled patients at baseline.

Characteristic	Value
Age, mean ± SD	56 ± 10
Gender	N (%)
Male	15 (43)
Female	20 (57)
Diabetes type	
Type I	1 (3)
Type II	34 (97)
Biomarkers	mean ± SD
HgbA1C	9.5% ± 1.3%
Systolic blood pressure	134 ± 25 mmHg
Diastolic blood pressure	79 ± 12 mmHg
Body mass index (BMI)	32.3 ± 5.8 kg/m^2
Comorbidities	N (%)
Hypertension	24 (68)
Dyslipidemia	17 (48)
Thyroid disorders	5 (14)
Obesity, N (%)	9 (25)
Other comorbidities*	10 (28)
Regimen type	N (%)
Insulin-based	16 (45)
Non-insulin-based	19 (55)
Number of medications, mean ± SD	5.7 ± 2

*Other comorbidities included osteoporosis, psychiatric disorders, chronic hepatitis, and chronic heart diseases.

4. Discussion

Involving other health care providers in chronic disease management have been showing positive impact on overall health outcomes (Khdour et al., 2011). Clinical pharmacists are yet considered underutilized healthcare providers in many countries especially in outpatient settings (Carter et al., 2009). The clinic demonstrated a successful collaborative practice in management of diabetic patients in only 6-month period. Results from our study showed positive impact, which allies with previous international studies that assessed the clinical pharmacist impact in similar settings (Alhossan et al., 2016; Stuhec et al., 2019a).

In Saudi Arabia, the number of population affected by diabetes and/or diabetes complications is increasing and prevalence predicted to further increase in future. Several international studies demonstrated an improvement in diabetes and diabetes-related outcomes in settings where clinical pharmacists in an ambulatory care setting are involved in patient management (Alhossan et al., 2016; Stuhec et al., 2019a).

Our clinic was not limited to assessing diabetes outcomes in terms of blood glucose levels alone, additional clinical practices guidelines recommended co-assessment, co-management, preventative measures and/or screenings were performed. The level of care provided by this clinic was based on patient's control status which may need close monitoring on weekly basis or longer periods for those who are controlled or close to targets. The clinical pharmacists provided counseling on diet, exercise, and medication that allow patients to self-manage their own condition. This was reflected in the larger percentage of patients achieving clinical practices guidelines' therapeutic goals when comparing baseline assessments to follow-up visit. The services provided in this pharmacy-led clinic have introduced a bigger image of how diabetic patients should be managed, in terms of reviewing all risks associated with diabetes and applying preventive medicine measures when possible. The improvement in HgbA1C levels over this short period indicates the value of service provided by clinical pharmacists, and open up a channel of collaboration between healthcare providers to provide better care. On the other hand, practicing under collaborative agreements between healthcare providers gives more space to provider better healthcare and links and drives all specialties toward patient care. Collaborative agreements between pharmacists and physicians have proven their positive impact on patient care in different disease states and settings (Stuhec et al., 2019a,b).

One of the reasons that hinders condition control was unintended non-adherence to medication due to insufficient medication supply matched the usual care follow up periods. This necessitates some patients to get their medications via a refill clinic –a service where the provider only refills the previous prescription for 3 months or until next appointment, whichever comes first, without a clinical assessment of the patient's condition. On the other hand, some patients may simply wait with no medications until next follow up to get their medications refilled. Fortunately, this was identified and managed early by providing enough supply, and monitor follow-up period carefully.

It is important to emphasize the positive impact of the clinical pharmacist interventions among study cohort on both hypertension control and weight reduction –although this was not statistically significant, in addition to the implementation of vaccination service and education on its importance as a preventative measure.

Although the study has some limitations including, the inclusion of small number of patients with narrow demographic characteris-

Table 2
Difference between baseline and follow up intervals.

Objective	Therapeutic goal	Baseline visit	Follow-up visit [a]	p-value
HgbA1C, mean ± SD	< 7%	9.5% ± 1.3%	8.3% ± 1.4%	0.0004
BP [b], mean ± SD	140/90 mmHg	SBP: 134 ± 25 mmHg	SBP: 133 ± 12 mmHg	0.8317
		DBP: 79 ± 12 mmHg	DBP: 74 ± 8 mmHg	0.0441
BMI	18.5–24.9 kg/m^2	32.3 ± 5.8 kg/m^2	31.7 ± 5.5 kg/m^2	0.6584

[a] This was the second follow-up visit, 6-month apart from the baseline visit.
[b] Based on ADA guidelines 2017 recommendations.

Table 3
Difference between baseline and follow up intervals for preventive measures.[a]

Objective	No. of patients assessed at baseline visit	No. of patients assessed at follow-up visit [b]	p-value
Aspirin therapy [c]	14 patients	17 patients	0.5033
Statin therapy [c]	23 patients	29 patients	0.1096
Albuminuria	21 patients	35 patients	< 0.0001
Thyroid panel	12 patients	35 patients	< 0.0001
Eye examination	9 patients	29 patients	< 0.0001
Foot examination	3 patients	35 patients	< 0.0001
Depression screening [d]	1 patient	28 patients	< 0.0001
Vaccination [e]	1 patient	8 patients	< 0.0001

[a] Based on ADA guidelines 2017 recommendations.
[b] This was the second follow-up visit, 6-month apart from the baseline visit.
[c] Assessed based on cardiovascular disease (CVD) 10-year risk score.
[d] Using Patient Health Questionnaire-9 (PHQ-9) assessment instrument.
[e] Recommended vaccinations were: influenza, TDaP or TD, and pneumonia vaccines as per each vaccine's recommendation.

tics –mainly, elderly with type two diabetic patients- that might affect the generalizability of the study results. However, this was attributed to having a newly established service where the pharmacist's clinic operates only for 4 h on weekly bases. Despite the small included patients, the study shows significant interventions provided by clinical pharmacists. Also, the risk of selection bias was minimal since all patients visited the clinics were included.

The significant improvement in patients' HgbA1C levels and adaption of guidelines' recommended measures to control diabetes-related outcomes demonstrate promising results of integrating clinical pharmacists into collaborative diabetes management clinics. Many countries don't have interprofessional management teams and rely heavily on physicians and other healthcare providers to manage chronic diseases which may not provide enough care to their patients. Including clinical pharmacists in chronic disease management clinics will help improving health outcomes and reduce costs. The integration between clinical pharmacists in outpatient clinics and other healthcare providers will provide better patient care. The study opens the doors for pharmacists in the country and the region to integrate with other specialties and practice in pharmacy-led clinics to improve patient care, medication utilization, and cost reduction.

Declaration of Competing Interest

All authors declare that they have no conflict of interest either personally or financially.

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