ORIGINAL RESEARCH ARTICLE

The Effect of a Pharmacist-Intervention Program on Clinical Outcomes in Diabetes Mellitus Patients

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ABSTRACT

Background: Clinical pharmacists are skilled in identifying patient medication-related problems such as adverse drug responses and non-adherence. Pharmacists participate in diabetes management teams and offer direct patient treatment using several practice models in different ambulatory practice settings. The objective is to evaluate the effect of a pharmacist-intervention program on clinical outcomes in diabetes mellitus patients.

Materials and methods: The cohort consisted of diabetes patients attending multi-speciality care hospitals. Eligible patients were randomly assigned in a 1:1 ratio to the intervention and control groups. Each patient in the intervention group was counselled by the research pharmacist. The measure of diabetes self-management was assessed using the Summary of Diabetes Self –Care activities (SDSCA) questionnaire.

Results: 150 patients out of this population met the inclusion criteria. The study succeeded in proving the effect of pharmacist-led patient education in the improvement of the quality of life and clinical parameters of diabetes. The pronounced differences in the SDSCA scores of the test group and control group signify the impact of interventions and the consistency of the scale as well.

Conclusion: The effect of pharmacist-led interventions on diabetic treatment outcomes was evaluated. The results recommend the need for extensive pharmacist-led intervention programs in metabolic disorder management.

Keywords: Diabetes Mellitus; Role of Pharmacist, Diabetes Self-Care, interventions, pharmaceutical care, glycemic control, patient counselling

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INTRODUCTION

Diabetes is one of the leading causes of death in Indian patients. With a rise in living standards, diabetes and related problems have been rising in India in recent years.[1,2] Compared with high-income areas, developing countries are deficient in the effective management of diabetes screening in the general population. Developing countries usually present with rapid population growth, an ageing population, an unhealthy local diet, urbanisation, obesity, an unhealthy lifestyle, and a lack of access to quality health care. The need for effective strategies that facilitate early diagnosis, advanced management, and primary prevention is driven by the economic cost of diabetes.[3]

Pharmacotherapy with oral hypoglycemic agents and insulin are the therapeutic options for achieving ideal glycemic control however, diabetes patients' poor medication adherence frequently limits the efficacy of this approach. Self-management techniques are essential for diabetes management. Meal planning, exercise, and medication adherence are the mainstays of a healthy lifestyle. Patient education programmes have been put in place to inform patients about their active responsibilities in the care of their diseases.[4,5]

Intervention techniques effectively supplement medications in the treatment of diabetes. Patient-mediated interventions, which involve interacting with patients or using information given to patients, attempt to improve illness control.[6] Also, it has been demonstrated that patient-centred services led by a variety of medical specialists, including pharmacists, improves outcome.[7]

Pharmacists with clinical expertise are skilled in identifying patient medication-related problems such as adverse drug responses and non-adherence. Pharmacists participate in diabetes management teams and offer direct patient treatment using several practice models in different ambulatory practice settings through collaborative drug therapy management agreements. Pharmacists often have prescription authority and offer patient education and therapeutic suggestions. A discussion of medications intended to promote patients' awareness of the condition and adherence to treatment illustrates a pharmacist-led diabetes care service.[8]

The position of the chemist has undergone tremendous transformation over the years. There is a remarkable transition from purely dispensing to offering clinical services that involve patient education, hands-on patient care, and team-based chronic illness management. The expansion of the role of the chemist has been made possible by specialised training for pharmacists, including residency programmes and certificate programmes. For instance, by distributing prescriptions, offering education, and, with additional certification, prescribing and administering vaccinations and medications, community pharmacists as well are ideally positioned to increase access to care for individuals in their community.[9] Clinical pharmacists who have completed a residency programme have received more specialised training in patient care and are typically assigned to work with a team of medical professionals in a clinic environment.[10,11] As healthcare moves from fee-for-service models to value-based care, which is delivered with the quadruple goals of increasing population health, reducing the cost of care, enhancing the patient experience, and improving provider satisfaction, there are unique opportunities for pharmacists. There are numerous manifestations of pharmacist-managed diabetes treatment[12.] The current study thus evaluates the effect of pharmacist interventions in diabetes management.

METHODOLOGY

Study design, settings, and subject: The current observational study adopted a prospective cohort design. The cohort analysis was conducted with 137 patients for 15 months at the outpatient diabetic clinic of a private hospital in Palakkad, Kerala. The research was conducted between January 2021 and July 2022, with a 15-month follow-up period following the initial consultation. A research clinical pharmacist worked two hours per day at the outpatient diabetes clinic during the week. The Institutional Ethics Committee of the Ahalia International Foundation in Kerala approved this investigation. Date of approval on October 14, 2020.

Patient recruitment and Randomization: Eligible patients were randomly assigned in a 1:1 ratio to the intervention and control groups using an unrestricted randomization technique. Throughout the study, audits of the randomization procedure were performed at regular intervals. Patients who regularly attend the hospital outpatient diabetic clinic and had a diabetes mellitus diagnosis for at least 6 months with HBA1c levels greater than 7% met the inclusion criteria. Patients with comorbidities including chronic kidney disease stage 4 or 5, or undergoing haemodialysis, active cancer diagnosis, undergone organ transplant, human immunodeficiency virus or acquired immune deficiency syndrome, pregnancy, polycystic ovary syndrome, drug or alcohol abuse, and Alzheimer's disease patients were excluded. Written informed consent was obtained from the study participants. Finally, A total of 150 diabetes patients (75 test group and 75 control group) attending an outpatient diabetic clinic were recruited into the study. During the study period, 7 patients from the test arm and 6 patients from the control arm dropped out from the study. Therefore, a total of 137 patients (68 test arm; 60 control arm) completed the study period.

Sample size: Based on published data[13] on the variability (standard deviation [SD]=2.1%) of A1c in patients with type 2 diabetes, a sample size calculation indicated an absolute difference of more than 1% in

A1c, with = 0.05 and a power of 90%, requiring a sample size of 69 patients in both the test and control groups. Due to the possibility of patients missing follow-up (10%) appointments, it was estimated that 75 patients would be required for each cohort.

Intervention: In addition to the physician visit following randomization, each participant in the intervention group also had an appointment with the research clinical pharmacist. Using questionnaires, medical reports, and hospital records, the clinical researcher collected baseline data for each patient in both categories. Demographic and disease characteristics, medication regimen, fasting glucose, and A1c levels were included in the data. The test group reviewed their medication and treatment plans over five meetings with a pharmacist that are spaced three months apart. Each patient was counselled by the research pharmacist about the value of self-monitoring blood glucose (SMBG), a healthy diet, exercise, and foot care. A Diabetes information brochure was provided as well at each appointment. Information on type 2 diabetes, complications, drugs, treatment objectives, and self-care was provided in the brochures.[14,15] SDSCA questionnaire has been asked to fill at the beginning of the study and at the end of the study in both the groups.

The control group met with the clinical research pharmacist at the beginning and end of the 15-month period to obtain laboratory and questionnaire data. The patients in the control group received conventional diabetes outpatient care.

SDSCA Questionnaire[16]

The measure of diabetes self-management was assessed using the Summary of Diabetes Self –Care activities (SDSCA) questionnaire. It is multidimensional, and each section is scored independently**.** The SDSCA measure is a brief self-report questionnaire of diabetes self-management that includes items assessing general diet, specific diet, exercise, blood-glucose testing, and foot care. Scores are calculated for each of the five regimen areas assessed by the SDSCA. The number of days per week on a scale of 0–7, mean number of days for various items in the questionnaire and specific score for additional items were assessed for parameters general diet, specific diet, exercise, blood-glucose testing, and foot care. The questionnaire being in English, was translated to the regional language Malayalam for the ease of understanding of the study subjects. Linguistic validation was carried out prior to application.

Data analysis: Data analysis of the diabetes patients were determining in accordance with the scoring pattern of the SDSCA questionnaire and CONSORT reporting guidelines used to validate the research data[17]. The method of pharmacist intervention is depicted in Figure 1.

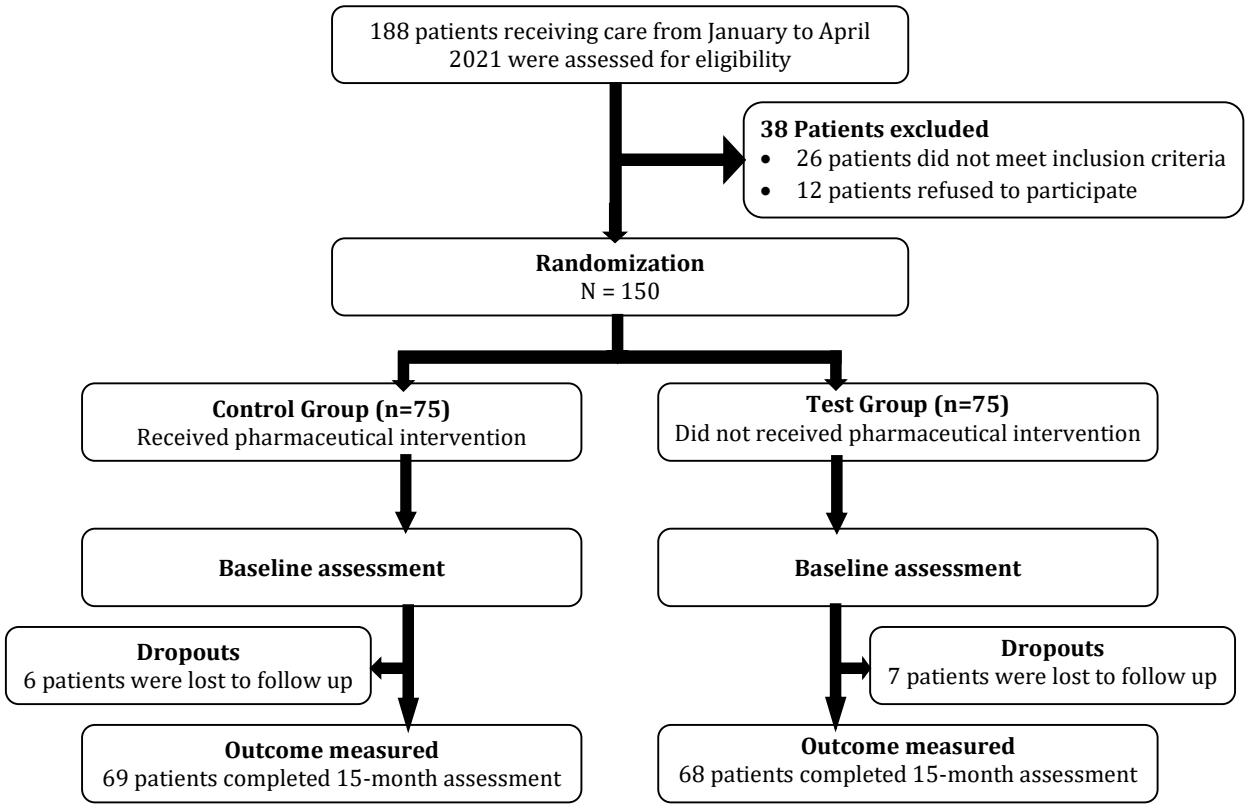

Figure 1: Details of diabetic patient's systematic review study diagram

Statistical analysis: Collected data were cleaned using the Prism statistical analysis software. Clear-cut variables are presented as counts and percentages, whereas continuous variables were given as means, standard deviations, and interquartile ranges. The weighted data were shown as a mean and percentage with a 95% confidence interval in descriptive statistics. We used odds ratios to perform a logistic regression analysis to determine risk factors. All models included a baseline value adjustment. Since the missing data were not restored or imputed, we believed that they were randomly absent. Without accounting for multiple testing, the threshold for statistical significance was set at 0.05%, although all P values were interpreted by the overall data pattern.

RESULTS

The target population obtained during the study period in this study was 500 patients. Only 137 patients out of this population met the inclusion criteria. The test arm comprised of 68 subjects while the control arm had 69 subjects. The SDSCA questionnaire was used to report scores on general diet, specific diet, exercise, blood sugar testing, and foot care.

Socio-demographic and Clinical characteristics of the study participants: This study indicated that among the study participants 36 (52.94%) of the test group and 38 (55.07%) of the control group were male, 61 (89.79%) in the test group and 59 (85.5%) in the control were married. The mean ±SD age of participants was (52.24 ±11.55) years in test group and (51.95 ± 10.12) years in control group. The patient's characteristics are shown in the table 1.

Self- care Activities: Patients in the test group achieved significant improvement than control group in their total diet score (+ 2.43 day/week vs. +1.56 day/week, P <0.0001), total specific diet score (+2.42 day /week vs. +1.09 day /week, P <0.0001), total exercise score (+2.53 day/week vs. + 1.66 day/week, P <0.0001), total blood glucose measurement (+2.65 day/week vs.+ 1.28 day/week P <0.0001) and total foot care (+2.01 day/week vs.+ 1.37 day/week P <0.0001). Patients in the control group also achieve significant improvements in all the domains. However, in all domains the reductions in the test group were significantly larger than that in the control group (net difference: P <0.0001). The significant improvement in self-care activities among the test group may be attributable to the pharmacist's intensive education on non-pharmacological treatment.

Table 1: Patients demographic and clinical characteristics

Demographic and clinical characteristics	Test Group, n=68	Control Group, n=69	p-value
Age in years, mean ± SD (median)	52.24 ± 11.5 (54)	51.95 ± 10.12 (51)	0.632
Gender, n (%)			
Male	36 (52.94)	38 (55.07)	0.789
Female	32 (47.05)	31 (44.92)	
Marital status, n (%)			
Married	61(89.79)	59 (85.5)	0.486
Single divorced, or separated	7 (10.39)	10 (14.5)	
Residence, n (%)			
Urban	50 (73.52)	47 (68.11)	0.432
Rural	18 (26.47)	22 (31.88)	
Socio economic status, n (%)			
Poor	5 (7.35)	3 (4.34)	0.287
Medium	47 (69.11)	52 (75.36)	
Rich	16 (23.52)	14 (20.28)	
Social support, n (%)			
Strong	26 (38.23)	21 (30.4)	0.214
Moderate	30 (44.11)	29 (42.02)	
poor	12 (17.64)	19 (27.53)	
Smokers, n (%)	12 (17.65)	14 (28.99)	0.073
Drinkers, n (%)	23 (33.82)	24 (34.78)	0.865
Duration of diabetes in years, mean ± SD (median)	10.12 ± 4.90 (10)	7.88 ± 3.84 (7)	<0.001
Comorbid condition, n (%)			
hypertension	30 (44.11)	45 (56.21)	0.128
dyslipidaemia	32 (47.05)	31 (44.9)	0.731
Thyroid disease	5 (7.35)	8 (11.59)	0.308
Rheumatoid arthritis	1 (1.47)	4 (5.7)	0.244
CAD	6 (8.82)	6 (8.69)	0.953
obesity	7 (10.29)	2 (2.89)	0.090
Depression	3 (4.41)	7 (10.14)	0.251
Number of prescribed medications, n (%)			
0- 5 types, n (%)	28 (41.17)	31 (44.92)	0.625
≥6 types, n (%)	40 (58.82)	38 (55.07)	
Anti-diabetic medications, n (%)			
Insulin	4 (5.88)	2 (2.89)	0.378
OHA	14 (20.58)	16 (23.1)	0.648
Insulin + OHA	50 (73.52)	51 (73.91)	0.910

Table 2: Changes in Self-Care Activity Score among test and control groups

Self-care Activities		Test Group (n=68)				Control Group (n=69)				P value*
		Baseline	End of study	Mean difference	P value	Baseline	End of study	Mean difference	P value	
Total diet score	m±sd	3.91 ± 1.13	6.34 ± 0.88	2.43	<0.001	2.7 ± 1.04	4.26 ±1.21	1.56	<0.001	<0.001
	med	3.75	6.5			3.0	4.0			
Total specific diet score	m±sd	2.72 ± 0.80	5.14 ± 1.03	2.42	<0.001	2.58 ± 0.62	3.67 ± 0.76	1.09	<0.001	<0.001
	med	2.6	2.6			2.6	3.6			
Total exercise score	m±sd	3.52 ± 1.68	6.05 ± 1.2	2.53	<0.001	2.13 ±1.14	3.79 ± 1,39	1.66	<0.001	<0.001
	med	3	6.25			2.0	4.0			
Total blood glucose measurement	m±sd	3.27 ± 1.89	5.92 ± 1.45	2.65	<0.001	1.77 ±1.5	3.05 ± 1.66	1.28	<0.001	<0.001
	med	3.0	7.0			2.0	3.0			
Total foot care	m±sd	2.23 ± 1.14	4.24 ± 1.19	2.01	<0.001	1.96 ± 0.6	3.33 ± 0.8	1.37	<0.001	<0.001
	med	1.8	3.8			1.8	3.0			

m±SD – mean ± standard deviation; med – Median; *Statistical significance between mean difference of two groups

Table 3: Changes in clinical outcome measures between groups

Outcome Measures		Test Group (n=68)				Control Group (n=69)			
		Baseline	End of study	Mean difference	P value	Baseline	End of study	Mean difference	P value
A1c (%)	m±sd	10.45±1.79	6.8 ±0.82	-3.65	<0.001	9.97±2.03	7.88±1.36	- 2.09	<0.001
	med	10.3	6.8			9.5)	8		
FBG (mg/dL)	m±sd	202.75±5.41	101.95±13.49	-100.98	<0.001	205.33±63.89	135.72±63.49	-69.61	<0.001
	med	192	99.5			196	113		
BMI (kg/m^2)	m±sd	27.32±5.41	26.39±4.2	-0.93	<0.001	25.31±3.47	25.39±3.45	0.08	0.58
	med	26.9	24.95			25.2	25.2		

FBG -Fasting blood Glucose; m±SD – mean ± standard deviation; med – Median; A1c - hemoglobinA1c, BMI - body mass index

Outcome measures: The main outcome measure was change in A1c, secondary outcome measures were changes in fasting blood glucose and BMI, which were measured at baseline and up to 15 months. The effects of the pharmacist-led care program on clinical outcomes and self-care activities were determined by comparing the test and control groups' baseline values with their results. At baseline assessment, A1c, and fasting blood glucose were similar between the groups (Table 2). At the conclusion of the 15-month study period, the intervention patients attained a greater reduction in A1c values than the control patients (-3.65 % vs. -2.09 %; P < 0.00001). Both groups demonstrated significant reductions in fasting blood glucose between baseline and the end of the study period (Table 3; Test group: -100.98 mg/dL, versus control group: -69.61 mg/dL). At the end of the study period, the test group demonstrated there is significant reductions in BMI (-0.93 kg/m^2 vs. +0.08 kg/m^2) compared to the control group.

DISCUSSION

The body needs blood glucose to maintain normal metabolic functions. Any deviation from the blood glucose range might have negative effects and raise the risk of morbidity and mortality. The results of the current study presented an increase in blood sugar levels in patients without pharmacist care, which may be attributed to a lack of knowledge of the disease conditions, medication and self-care. The t-test statistics for means of blood sugar testing yielded t (67) = 9.1318 and p <0.00001. Since p <0.05, a significant difference was observed between the mean values of pre-intervention and post-intervention groups in the test groups.

Diabetic patients in the test group showed better glycaemic control post-intervention and presented with lower blood sugar levels. The results varied from the systematic review findings of Toobert et al, where they studied the summary of diabetes self-care activities measure with results from 7 studies and a revised scale.[16] A positive impact of pharmacist education was observed among diabetic patients in disease management, medication adherence and self-care knowledge. The SDSCA scale monitored the significance of blood sugar testing effectively. Hence, blood glucose is one of the crucial factors in determining disease progression, necessitating documentation as a crucial component of clinical surveillance.

It was confirmed from the study that diabetic patients after pharmacist counselling exercised regularly and attained control of their diabetic conditions. Kirwan J P et al also studied the impact of exercise on diabetic management and recommends exercise as central to effective lifestyle prevention and management of type 2 diabetes.[18] As recommended by Umpierre D, Ribeiro PAB, Schaan BD and Ribeiro JP blood sugar levels should be monitored before, during, and after exercise.[19]

Comparative analysis of foot ulcers in patients provided with and without patient education showed that pharmacist intervention had a significant impact in reducing foot ulcers. Diabetic foot ulcers are common complications in patients admitted to the hospital for severe diabetes. A diabetic foot ulcer is a typi-

cal long-term consequence of diabetes treatment, and its influence causes significant morbidity and mortality.[20] Pharmacists play an important functional role in patient education about maintaining regular foot hygiene, and nail care, and foot care is critical for lowering the chance of an accident that can lead to ulcer formation. Foot ulcers tend to worsen in patients without pharmacist-associated patient education. Control had a lower incidence of diabetic foot ulcers thus proving the pharmacist-educated diabetic patients had better awareness about disease, medication and self-care. The data were agreeable with the findings of Subbulakshmi et al. In Diabetes mellitus patients with peripheral artery disease of the lower limb, ulceration promotes infection in deep tissues and neurological abnormalities. In this disorder, bacterial contamination infects the skin's protective layer, causing the epidermal layer to deteriorate. Amputation is also required in diabetic patients with diabetic foot ulcers to minimise infection in the lower extremities.[21]

The diet also plays an important part in diabetes treatment. Pharmacists should emphasise the importance of nutrition during one-on-one sessions with patients.[22] White ND studied the diet and nutrition requirements in diabetes patients. Their study explains that when a patient consumes an excessive amount of carbohydrates, insulin levels rise, perhaps leading to an increase in blood glucose levels.[23] Patients without education on diet care reported an increase in blood glucose levels due to a lack of knowledge of food metabolism. The test group presented lesser complications than the former.

Self-care is a key factor for diabetes patients to maintain quality of life and to prevent serious disease complications. At the same time, effective pharmacist interventions help the patient improvise their awareness in self-care. Self-care standardized assessment tools are thus important to evaluate and to promote self-care in diabetes patients.[24,25] The use of a validated SDSCA scale for scoring is the mainstay of the study. Nutritional management, exercise and physical activity, blood glucose monitoring as well as medication utilization are some major aspects regarding self-management in diabetes.[26]

Education is essential for the self-care of individuals with diabetes mellitus. In the present study, it is intriguing that individual diabetes education had a substantial impact on the total SDSCA score. In the test group, average A1c levels decreased significantly from 10.3 % to 6.75 % (P<0.00001). In other studies, conducted in a variety of contexts, reductions in A1c values have been attributed to pharmaceutical care program.

The sluggish development of pharmaceutical care in Kerala can be attributed to several obstacles, such as physicians' negative attitudes toward expanding the pharmacist's role in the patient care process and the absence of effective pharmaceutical care training. Our study demonstrated the significance of the clinical pharmacist's role in enhancing clinical outcomes for diabetic patients in Kerala, despite all existing barriers. Jarab's investigation revealed the same problems.[27] Choe et al. reported a reduction in mean A1c values from 10.1% to 8.0% in 41 intervention patients with type 2 diabetes who received a clinical pharmacy intervention similar to that used in the present study, compared with 39 control group patients whose A1c values decreased from 10.2% to 9.3% (P value for between-group difference in change amount = 0.03).[28]

The improvements in A1c observed in the present study may be attributable to the integrated clinical pharmacist intervention with respect to providing individualized education on various self-care activities, enhancing adherence to prescribed medication, and regular telephone contact. Self-care practices are an excellent starting point for controlling blood glucose, and their primary result is achieving metabolic control. During the 15-month study period, patients who received pharmaceutical care demonstrated a significant improvement in their FBG levels compared to those who received standard care. Al Mazroui et al[29] reported a significant decrease in FBG in patients who received pharmaceutical care intervention at the conclusion of a 12-month follow-up period. Existing literature provides evidence of the advantageous effects of exercise on blood glucose control in diabetic patients.[30,31]

Self-care activities such as diet, SMBG, and foot care demonstrated significant improvements. In a six-month community pharmacy setting, Mehuys et al. reported significant improvements in the domains of specific diet and foot care.[32] Nonetheless, Clifford et al. found no change in either exercise participation or the intensity of regular activity over the course of the study.[33] Significant improvements in self-care activities in our study may be attributable to the pharmacist's intensive education regarding non pharmacological treatment and the availability of a different pamphlet (e.g., containing suggestions about a healthy diet, SMBG, and foot care) at each visit.

In a randomized controlled trial, found that pharmacists were effective at increasing the number of days per week that patients engaged in healthful diet and diabetes self-care activities[34]. Patients who received clinical pharmacy services in the present study reported significantly higher levels of physical activity than patients in the control group. The reported significant improvement in SMBG among intervention patients was not unexpected and could be attributed to the clinical pharmacist's provision of high-quality information regarding blood glucose values indicative of hyperglycemia and hypoglycemia and how to respond appropriately to these results. At the conclusion of the study, foot care was substantially improved among the intervention patients. Similar results were found by Mehuys et al[32].

The significant differences between the means of the population subsets in the test and control group, con-

firm the validity and reliability of the SDSCA scale. The retrospective research design adopted and the comparison with a control group remains the major strength of the study. The comparison ensures the validity of the results obtained. The study also paves the foundation for extensive research in pharmacist interventions and patient care in diabetes management. The restriction of the sampling frame to 150 and unrestricted randomization were the major limitations of the study.

Conclusion

The study succeeded in proving the effect of pharmacist-led patient education in the improvement of the quality of life and clinical parameters of diabetes. The pronounced differences in the SDSCA scores of the test group and control group signify the impact of interventions and the consistency of the scale as well. The study demonstrates that pharmaceutical care for diabetic patients shows equivalent efficiency to pharmacotherapy with OHA or insulin. Clinical pharmacist-led interventions are a significant part of disease management, particularly in metabolic disorders like diabetes, where lifestyle and medication adherence are important factors.

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Abbreviations

SMBG: Self-monitored blood glucose
HBA1C: Glycosylated haemoglobin
OHA: Oral hypoglycemic agents

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