Impact of intervention for self-management and glycemic control of patients with type 2 diabetes in community pharmacy setting

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Abstract

This study aimed to examine the impact of the Japanese version of the PHOND study technique delivered across five communities by community pharmacists for type 2 diabetes patients who are offered general diabetes treatment. The primary endpoints were changes in diabetes-related laboratory parameters such as haemoglobin A1c (HbA1c) levels and rates of health activity achievement. Sixty-four patients with type 2 diabetes were followed up for six months. HbA1c levels were lower at follow-up than at baseline in the group with baseline HbA1c 7.0% ≤ (7.5%±0.5 vs. 7.3%±0.5). Healthy activity engagement rates were higher at follow-up than at baseline (63.8point ±29.1 vs. 78.3point ±15.9). The PHOND study technique, which involves a collaboration between pharmacists and registered dietitians, may help provide access to care and promote self-management among patients with type 2 diabetes.

Introduction

Type 2 diabetes causes three major complications due to persistent hyperglycaemia: nephropathy, retinopathy, and neuropathy. Diabetic nephropathy accounts for 39.1% of haemodialysis induction cases in Japan [1]. In particular, haemodialysis induction increases the physical and psychological burden of disease and reduces patient quality of life [2]. Monthly medical expenses for dialysis per patient have been estimated at 500,000 yen, which amounts to 1.6 trillion yen per year in Japan overall. Most care expenses are covered by the public health insurance and affect social security costs; therefore, preventing diabetic nephropathy is key to a sustainable healthcare system. M* Adhere Inc. Ltd. has developed a program for pharmacists at insurance-covered pharmacies to support self-management of type 2 diabetes in patients with diabetic nephropathy; the feasibility of this approach was examined in the PHOND Study [3]. The continuity rate of the program was 94.1%, and haemoglobin A1c (HbA1c) levels decreased in participating patients [3]. The PHOND Study involved patients with type 2 diabetes treated at clinics by multidisciplinary teams. However, many patients with type 2 diabetes are treated at clinics that have no resident diabetes specialist; this requires a novel approach to care delivery for this patient group. This study examined whether the PHOND study technique involving pharmacists could promote self-management and improve therapeutic effects for type 2 diabetes patients in a variety of diabetes treatment environments.

Results

Table 1 presents the characteristics of type 2 diabetes patients included in this study. A total of 41 (64.1%) patients were male. Fifty patients (78.1%) were aged ≥ 65 years. Table 2 presents the characteristics of patients with an HbA1c value 7.0%≤, which is associated with a high risk of complications.

Table 1
Baseline clinical characteristics of patients with type 2 diabetes

Characteristics	Overall (n = 64)
Sex, n (%)	
Male	41 (64.1)
Female	23 (35.9)
Age, years	
Mean	66.8 ± 6.5
Group count, n (%)	
< 65	14 (21.9)
≥ 65	50 (78.1)
Body mass index, kg/m^2	
Mean	25.0 ± 4.5
Group count, n (%)	
< 25	41 (64.1)
≥ 25	23 (35.9)
Systolic blood pressure, mmHg	
Mean	128.2 ± 14.4
Diastolic blood pressure, mmHg	
Mean	74.0 ± 10.7
HbA1c levels	
Mean, %	7.0 ± 0.6
Group count, n (%)	
< 7.0	35 (54.7)
≥ 7.0	29 (45.3)
eGFR, mL/min/1.73 m^2	
Mean	69.3 ± 17.3

Values are presented as mean ± standard deviation. HbA1c, haemoglobin A1c; eGFR; estimated glomerular filtration rate; GLP-1, glucagon-like peptide-1; DPP-4, dipeptidyl peptidase-4; SGLT2, sodium-glucose co-transporter 2; α-GI, alpha-glucosidase inhibitor

Characteristics	Overall (n = 64)
Hypoglycaemic drugs	
GLP-1 receptor agonists	3 (4.7)
DPP-4 inhibitors	48 (75.0)
Glinides	6 (9.3)
Insulin	7 (10.9)
Metformin	35 (54.7)
SGLT2 inhibitors	17 (26.6)
Sulfonylureas	15 (23.4)
Thiazolidinediones	8 (12.5)
α-GI	11 (17.2)
Values are presented as mean ± standard deviation. HbA1c, haemoglobin A1c; eGFR; estimated glomerular filtration rate; GLP-1, glucagon-like peptide-1; DPP-4, dipeptidyl peptidase-4; SGLT2, sodium-glucose co-transporter 2; α-GI, alpha-glucosidase inhibitor	

Table 2

Baseline clinical characteristics of type 2 diabetes patients with HbA1c 7.0% ≤

Characteristic	HbA1c 7.0% ≤group (n = 29)
Sex, n (%)	
Male	17 (58.6)
Female	12 (41.4)
Age, years	
Mean	65.7 ± 8.2
Group count, n (%)	
< 65	6 (20.7)
≥ 65	15 (51.7)
Body mass index, kg/m^2	
Mean	24.7 ± 4.6
Group count, n (%)	
< 25	19 (65.5)
≥ 25	10 (34.5)
Systolic blood pressure, mmHg	
Mean	126.8 ± 12.0
Diastolic blood pressure, mmHg	
Mean	74.8 ± 10.5
HbA1c, %	
Mean	7.5 ± 0.5
eGFR, mL/min/1.73m^2	
Mean	74.8 ± 18.4
Hypoglycaemic drug, n (%)	
GLP-1 receptor agonists	0 (0)
DPP-4 inhibitors	26 (89.7)

Values are presented as mean ± standard deviation. HbA1c, haemoglobin A1c; eGFR; estimated glomerular filtration rate; GLP-1, glucagon-like peptide-1; DPP-4, dipeptidyl peptidase-4; SGLT2, sodium-glucose co-transporter 2; α-GI, alpha-glucosidase inhibitor

Characteristic	HbA1c 7.0% ≤group (n = 29)
Glinides	1 (3.4)
Insulin	4 (13.8)
Metformin	19 (65.5)
SGLT2 inhibitors	9 (31.0)
Sulfonylureas	8 (27.6)
Thiazolidinediones	2 (6.9)
α-GI	6 (20.7)

Values are presented as mean ± standard deviation. HbA1c, haemoglobin A1c; eGFR; estimated glomerular filtration rate; GLP-1, glucagon-like peptide-1; DPP-4, dipeptidyl peptidase-4; SGLT2, sodium-glucose co-transporter 2; α-GI, alpha-glucosidase inhibitor

Table 3 presents comparisons of baseline and follow-up estimates of body mass index (BMI), HbA1c levels, estimated glomerular filtration rate (eGFR), health activity achievement rates, medication adherence, and the Diabetes Mellitus Dietary Self-Efficacy Scale (DMDSES) scores. BMI values were lower at follow-up than at baseline (25.0 kg/m^2 ± 4.5 vs. 24.8 kg/m^2 ± 4.4). Systolic blood pressure values were higher at follow-up than at baseline (128.2 mmHg ± 14.4 vs. 132.3 mmHg ± 14.1). The average number of patient-set health activities per patient was 4.3 ± 1.6. The target achievement rate was higher at the end of observation than at the start of the follow-up period (68.5% ±26.9 vs. 78.4% ±15.6). Medication adherence rates (92.6% ±16.0 vs. 96.4% ±10.1) and the DMDSES scores (44.1 points ± 11.4vs. 49.7 points ± 11.7) were higher at follow-up than at baseline.

Table 3
Comparison of patient characteristics at baseline and at six-month follow-up

Characteristic	Baseline	Follow-up	P-value
Body mass index (kg/m^2)	25.0 ± 4.5	24.8 ± 4.4	0.025
Systolic blood pressure (mmHg)	128.2 ± 14.4	132.3 ± 14.1	0.016
Diastolic blood pressure (mmHg)	74.0 ± 10.7	72.5 ± 10.7	0.145
HbA1c (%)	7.0 ± 0.6	7.0 ± 0.6	0.387
eGFR (mL/min/1.73m^2)	69.3 ± 17.3	69.1 ± 16.1	0.405
Target achievement rate (%)	68.5 ± 26.9	78.4 ± 15.6	0.002
DMDSES score (point)	44.1 ± 11.4	49.7 ± 11.7	< 0.001
Medication adherence (%)	92.6 ± 16.0	96.4 ± 10.1	0.009
HbA1c, haemoglobin A1c; eGFR; estimated glomerular filtration rate; DMDSES, Diabetes Mellitus Dietary Self Efficacy Scale			

Changes in BMI values, HbA1c levels, eGFR, blood pressure, target achievement rate, medication adherence rates, and the DMDSES scores were compared in patients with HbA1c 7.0%≤ (Table 4). BMI (24.7 kg/m^2 ± 4.7 vs. 24.4 kg/m^2 ± 4.6) and HbA1c (7.5%±0.5vs. 7.3%±0.5) values were lower at follow-up than at baseline. Systolic blood pressure was slightly higher at follow-up than at baseline (126.8 mmHg ± 12.3 vs. 132.4 mmHg ± 10.1). The target achievement rate at the end of the follow-up period was higher than after a month (74.2%±23.2vs. 778.7%±15.5). Medication adherence rates (88.8% ±21.3vs. 94.0% ±13.6) and the DMDSES scores (43.0 points ± 12.3 vs. 50.8 points ± 10.7) were higher at follow-up than at baseline.

Table 4
Characteristics of type 2 diabetes patients with HbA1c 7.0%≤ at baseline and at the six-month follow-up

Characteristics	Baseline	Follow-up	P-value
Body mass index (kg/m^2)	24.7 ± 4.7	24.4 ± 4.6	0.007
Systolic blood pressure (mmHg)	126.8 ± 12.3	132.4 ± 10.1	0.018
Diastolic blood pressure (mmHg)	74.8 ± 10.7	73.0 ± 12.6	0.189
HbA1c (%)	7.5 ± 0.5	7.3 ± 0.5	0.017
eGFR (mL/min/1.73m^2)	74.8 ± 18.7	72.8 ± 16.2	0.138
Target achievement rate (%)	74.2 ± 23.2	78.7 ± 15.5	0.180
DMDSES score (point)	43.0 ± 12.3	50.8 ± 10.7	0.002
Medication adherence (%)	88.8 ± 21.3	94.0 ± 13.6	0.041

HbA1c, haemoglobin A1c; eGFR; estimated glomerular filtration rate; DMDSES, Diabetes Mellitus Dietary Self Efficacy Scale

Discussion

This program involved patients with type 2 diabetes working with community pharmacists on setting health activity targets. The pharmacists' role was to help patients set a goal that is achievable in 80% of cases without drastic lifestyle changes, while staying consistent with clinical recommendations for disease management. The experience of having successfully achieved a goal allows patients to develop self-efficacy. The average target achievement rate at follow-up was 78.4%±15.6. This high success rate may be partly accounted for by pharmacist support.

Previous reports have suggested that the monitoring of unused medication by a pharmacist increases medication adherence [4], which helps decrease HbA1c levels [5]. In this context, pharmacists may check for leftover medication and provide guidance on disease management, including eliminating barriers to treatment, all of which may also increase patient self-efficacy.

Good self-efficacy may help improve self-management and decrease HbA1c levels [6], reducing the risk of diabetic complications over time. In this study, HbA1c levels at follow-up were significantly reduced in the group with a baseline HbA1c 7.0%≤.

Patients in this study also experienced a significant decrease in BMI. The Japanese Diabetes Mellitus Treatment Guidelines recommend a target BMI of ≤ 25 kg/m^2 in type 2 diabetes patients [7]. In this study, 35.9% of patients had a BMI ≥ 25 kg/m^2. A previous study has shown that pharmacists collaborating remotely with registered dietitians, who provide dietary guidance to patients, may help patients with type 2 diabetes achieve weight reduction [8]. In this program, pharmacists collected dietary and lifestyle

information from patients and shared it with registered dietitians for further assessment, which likely helped optimise body weight. HbA1c levels may decrease with weight loss and improve medication adherence [9, 10]. Patients in this study achieved both weight reduction and improved medication adherence, as well as reduced HbA1c levels, including patients in the high-risk group; setting activity targets to improve medication adherence may have contributed to improved outcomes at follow-up.

In this study, systolic blood pressure values were slightly higher at follow-up than at baseline. In the Japanese population, blood pressure values tend to be higher in winter than in summer, corresponding to temperature changes. The timing of the intervention, which began in the summer and ended in the winter, may account for these findings. In addition, blood pressure fluctuations are larger in men and in older adults than in other groups [11]; this study included a large proportion of older adult males, which may account for these findings.

Patients in this study did not show major fluctuations in eGFR values. In the J-DOIT3 study involving Japanese patients with type 2 diabetes [12], intensive treatments by diabetes specialists significantly suppressed the decrease in kidney function. Consistent with the J-DOIT3 study findings, the our study observed decreases in BMI, blood pressure, and HbA1c values, indicating that renal dysfunction improved in the medium term.

Limitations

There are several limitations in this study. First, this was a cohort study that compared baseline and follow-up values in a group undergoing an intervention; there was no control group. Consequently, the reported findings may be affected by observation bias. Nevertheless, the study outcomes were expressed as laboratory and questionnaire findings, ensuring a level of objectivity. To validate these findings, a study involving a comparison group and medical insurance claims data is required. Second, although this study evaluated treatment adherence, it did not measure this directly. This study counted the remaining rather than the consumed medication, which is likely to be an accurate representation of treatment adherence.

Conclusion

This study demonstrated that the PHOND study technique, which involves interventions by community pharmacists, may help improve outcomes in patients with type 2 diabetes who are treated for diabetes in variety of environments. Clinical parameters, including HbA1c and BMI values, improved even in patients with a high risk of complications, confirming the suitability of this intervention. This type of support is particularly beneficial for patients with an HbA1c 7.0%≤ with a high risk of complications.

Methods

This was a cohort study that compared baseline and follow-up values in type 2 diabetes patients undergoing an intervention; this study lacked a comparison group. This study was conducted in Matsumoto City, Nagano Prefecture, Ibaraki City, Osaka Prefecture, Shimanto City, Kochi Prefecture, Tama City, Tokyo, and Tachikawa City, Tokyo, from April 2017 to March 2020. The follow-up period was six months. The target patients were diagnosed with type 2 diabetes and chronic kidney disease grade ≥ 3 (eGFR of ≤ 30 mL/min/1.73 m^2). Eligible patients were identified by attending physicians based on the relevant criteria and willingness to participate. The exclusion criteria were as follows: (1) severe diabetic complications, and (2) diagnosis of dementia, psychiatric disorder, or cancer. The variables of interest included age, sex, BMI, HbA1c levels, eGFR, blood pressure values, target achievement rate, medication adherence rates, and self-efficacy scores. Blood pressure was expressed as systolic and diastolic blood pressure.

Enhancing self-efficacy helps promote self-care and disease management in patients with type 2 diabetes [13]. Improved self-efficacy is among the goals of patient education provided by community pharmacists. Few tools to measure self-efficacy in patients with type 2 diabetes are available; the DMDSES is useful for the assessment of specific dietary efforts [14] and complements the development of related scales [15, 16]. Therefore, the DMDSES was used as an evaluation index in the M*Adhere Motivational Interactive Program (m-MIP)(R)[3]. The DMDSES has a perfect score of 75 points.

In this study, BMI, HbA1c, eGFR, target achievement rate, medication adherence rate, and the DMDSES value were compared at baseline and at follow-up.

Diabetic microangiopathy, nephropathy, neuropathy, and retinopathy are caused by persistent hyperglycaemia. To control the onset of microangiopathy, blood glucose levels need to be closer to normal, and the short-term goal is HbA1c < 7.0%, which is a value recognized as borderline for the prevention of microangiopathy [4, 17]. Separate analyses were performed because lowering HbA1c in patients with HbA1c 7.0%≤ is particularly important.

Self-management coaching program (m-MIP)

In this program, general practitioners and phaemacists at community pharmacies work together to promote changes in patient behaviour. Patients, enrolled in the programme by their physician, receive a lifestyle improvement plan from a pharmacist at an insurance pharmacy that is to be implemented over a period of six months. This programme aims to improve diet, exercise, and medication adherence. The pharmacist coaches the uptake of the programme by providing education and helping to remove barriers to behaviour change. Specifically, the programme includes the following components: 1) a pharmacist at an i community pharmacy receives training on diabetes research and coaching skills from M*Adhere Inc., 2) the pharmacist provides guidance to patients enrolled in the programme, 3) patients submit food diaries to their pharmacists who forward them to registered dieticians for evaluation that informs further guidance, 4) the pharmacist creates a coaching report with relevant instructions, 5) a pharmacist certified by the Board for Diabetes Educators evaluates the coaching report and provides feedback to the

community pharmacist, and 6) the community pharmacist provides interim patient status updates to the physician who developed lifestyle improvement plan. These are evaluated based on a case review method, accounting for living conditions, medication status, and dietary evaluation, among others. Prescriptions are changed, as required.

Statistical analysis

Normally distributed variables are presented as means ± standard deviations. Categorical variables were analysed using the Fisher exact and chi-square tests and are expressed as counts or percentages. Findings were considered statistically significant at p-values of < 0.05. All statistical analyses were performed using the IBM SPSS Statistics for Windows, version 25.0 (IBM Corp., Armonk, NY).

Ethical considerations

This study was conducted in accordance with the ethical guidelines for medical and health research involving human subjects. The Ethics Board of the Justavia approved the study (Control number: 2020010). Justavia is a medical corporation located in Tokyo, Japan. This study is conducted by obtaining information that anonymized patient information by M* Adhere Inc. Because unlinked, anonymized data were used, The Justavia Ethics Review Board confirmed that this study was not subject to compliance with the Ethical Guidelines for Medical and Health Research Involving Human Subjects. The Justavia Ethics Review Board waived the need of informed consent.

Declarations

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Authors' contributions

TH contributed to the manuscript draft, data curation, study conceptualization, and initial design. TH and SH performed the formal analysis. GI and KA critically reviewed the manuscript. All authors approved the final version of the manuscript and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Conflicts of Interest

TH received lecture fees from Kowa Inc. TH is employed by M* Adhere Inc. The other authors declare no conflict of interest.

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Data Availability:

The datasets used and/or analysed during the study are available from the corresponding author on reasonable request.

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