INTRODUCTION

Diabetes mellitus causes various complications, such as retinopathy, neuropathy, and nephropathy and treatment, including lifestyle modification, is required from an early stage. In Japan, medical costs related to the treatment of diabetes mellitus, including lifestyle modification, is required from an early stage.

Background: In Japan, there is a pressing need to improve community health care to cope with the rapid aging of the population. In this context, there have been private-sector-led approaches to enhance community dietary support by employing dietitians in pharmacies. Objectives: To evaluate the effects of collaboration between dietitians and pharmacists working in pharmacies to support patients with type 2 diabetes. Methods: A single group pre- and post-comparative study was conducted on patients with type 2 diabetes mellitus. The intervention period was 6 months. During the intervention period, the dietitians provided dietary support to the patients after first providing them with medication guidance. The contents of these instructions were shared with the pharmacists. The contents of the instructions were recorded, and confirmed in monthly meetings with the principal investigator. The primary endpoint was the Hemoglobin A1c (HbA1c) level, and the secondary endpoints were high-density lipoprotein-cholesterol (HDL-c), low-density lipoprotein-cholesterol (LDL-c), Triglyceride (TG), degree of dietary self-management, degree of unbalanced diet and satisfaction with pharmacy services. Results: Eight patients completed the intervention period. The first patient’s intervention started in March 2021, and all patients’ interventions were completed by December 2021. The primary endpoint, the mean (SD) HbA1c, was 7.26 (0.96) at baseline and decreased to 6.63 (0.79) after 6 months (p=0.028, r=0.72). Also, the HDL-c increased from 55.00 (14.81) to 63.14 (10.11) (p=0.110, r=0.51) and the Diabetes Mellitus Self Efficacy Scale score increased from 51.67 (8.31) to 60.17 (8.45) (p=0.025, r=0.79) and the patient satisfaction score increased 24.0 (4.0) to 26.1 (3.3) (p=0.161, r=0.51). Moderate decreases were also observed in LDL-c (p=0.235, r=0.47) and TG (p=0.368, r=0.37). Conclusions: Collaboration between dietitians and pharmacists working in pharmacies may improve the dietary habits and glycemic control of patients with type 2 diabetes. To verify this hypothesis more reliably, randomized controlled trials need to be conducted.

Keywords: Community pharmacy; Dietitians; Collaboration; Type 2 diabetes

A pilot study of Pharmacist-Dietician Collaborative support and Advice (PDCA) for patients with type 2 diabetes in community pharmacy: A single-arm, pre-post study

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Abstract

Background: In Japan, there is a pressing need to improve community health care to cope with the rapid aging of the population. In this context, there have been private-sector-led approaches to enhance community dietary support by employing dietitians in pharmacies. Objectives: To evaluate the effects of collaboration between dietitians and pharmacists working in pharmacies to support patients with type 2 diabetes. Methods: A single group pre- and post-comparative study was conducted on patients with type 2 diabetes mellitus. The intervention period was 6 months. During the intervention period, the dietitians provided dietary support to the patients after first providing them with medication guidance. The contents of these instructions were shared with the pharmacists. The contents of the instructions were recorded, and confirmed in monthly meetings with the principal investigator. The primary endpoint was the Hemoglobin A1c (HbA1c) level, and the secondary endpoints were high-density lipoprotein-cholesterol (HDL-c), low-density lipoprotein-cholesterol (LDL-c), Triglyceride (TG), degree of dietary self-management, degree of unbalanced diet and satisfaction with pharmacy services. Results: Eight patients completed the intervention period. The first patient’s intervention started in March 2021, and all patients’ interventions were completed by December 2021. The primary endpoint, the mean (SD) HbA1c, was 7.26 (0.96) at baseline and decreased to 6.63 (0.79) after 6 months (p=0.028, r=0.72). Also, the HDL-c increased from 55.00 (14.81) to 63.14 (10.11) (p=0.110, r=0.51) and the Diabetes Mellitus Self Efficacy Scale score increased from 51.67 (8.31) to 60.17 (8.45) (p=0.025, r=0.79) and the patient satisfaction score increased 24.0 (4.0) to 26.1 (3.3) (p=0.161, r=0.51). Moderate decreases were also observed in LDL-c (p=0.235, r=0.47) and TG (p=0.368, r=0.37). Conclusions: Collaboration between dietitians and pharmacists working in pharmacies may improve the dietary habits and glycemic control of patients with type 2 diabetes. To verify this hypothesis more reliably, randomized controlled trials need to be conducted.

Keywords: Community pharmacy; Dietitians; Collaboration; Type 2 diabetes

INTRODUCTION

Diabetes mellitus causes various complications, such as retinopathy, neuropathy, and nephropathy and treatment, including lifestyle modification, is required from an early stage. In Japan, medical costs related to the treatment of diabetes exceed 1.2 trillion yen per year, and the Ministry of Health, Labour and Welfare (MHLW) has designated diabetes as one of the most critical diseases to monitor. In order to improve the lives of patients, it is necessary to have a good knowledge of their background and lifestyle and for this reason, the role of community medicine is significant. The role of pharmacies in providing health support to the community has also been actively discussed, as shown by The Asheville Project and the published results from various randomized control trials RCTs. In Japan, there have been efforts to implement a Japanese version of the Asheville Project and RCTs showing the effectiveness of lifestyle modification support by pharmacy pharmacists for diabetic patients have been conducted.

Yaghoubi M et al. conducted a meta-analysis of these studies and showed that the interventions of pharmacy pharmacists can be expected to lower blood glucose levels in patients with type 2 diabetes. However, despite the popularity of these studies, pharmacists lack confidence in their ability to provide lifestyle support to patients. Against this background, the private sector in Japan has begun to take the initiative in placing dietitians in pharmacies. In these pharmacies, dietitians are employed concurrently as dispensing clerks, and are expected to provide dietary support to patients in between their work as dispensing clerks. This approach has clinically rich potential, as it can simplify access to dietary therapy for patients and can have a positive impact on avoiding hypoglycemia. However, it has been pointed out that pharmacies often lack the infrastructure to educate dietitians and that dietitians feel that they are not able to use their expertise due to their already busy workload as dispensing clerks. We conducted an interventional study to examine the effects of continuous patient support by dietitians working in such pharmacies. We hereby report the results of this pilot study.
OBJECTIVE

The aim of this study was to examine the effects of dietary support for patients with type 2 diabetes through collaboration between dietitians and pharmacists working in pharmacies.

METHODS

Study design

This study was a single-arm, pre-post comparative study. The intervention period was 6 months. During the intervention period, dietary counseling was provided to patients by a dietitian working at a pharmacy and medication guidance was then provided by a pharmacist.

Inclusion and exclusion criteria of the study

The patients enrolled in this study were type 2 diabetic patients on medication, aged 20-80 years. The exclusion criteria were as follows: serious complications (retina, gangrene of lower limbs, dialysis), abnormalities in chewing and swallowing functions, receipt of other private dietary support services, a history of psychiatric or neurological disorders and a history of malignancy.

Training

Prior to the intervention period, a three-hour online study explanation and training session was provided to the dietitians involved in the intervention. The training was conducted under the supervision of a diabetologist and included role-playing on how to listen to dietary habits and provide dietary support to diabetic patients. In addition, video materials were posted on YouTube (limited access) so that they could be viewed as needed. In addition, four types of booklets were prepared and the dieticians were told to distribute them as needed. During the intervention period, an online meeting was held once a month for about 30 minutes between the primary investigator (PI) and the dietitian at each store. When necessary, the PI referred the participants to the co-investigator, a diabetologist.

Outcomes

The primary outcome was the change in Hemoglobin A1c (HbA1c). The secondary outcomes were low-density lipoprotein-cholesterol (LDL-c), Triglyceride (TG), high-density lipoprotein-cholesterol (HDL-c), degree of unbalanced diet, degree of dietary self-management and satisfaction with pharmacy services. Blood test data were obtained by asking the patients to bring the results received during their clinic visits to the pharmacy. The degree of unbalanced diet, degree of dietary self-management and satisfaction with pharmacy services were obtained by distributing the questionnaires to the patients at the pharmacy and having them fill them out on the spot. In order to reduce the potential for bias caused by patients hesitating to answer the questionnaires, the completed questionnaires were submitted in envelopes that were not accessible to the pharmacy staff. To assess the degree of unbalanced diet, we used a Henshoku scale developed by Imada et al. The Henshoku scale consists of 15 questions to be answered using a 4-point scale. The highest score is 60 and the lowest score is 15. Lower scores indicate more balanced diets. To assess the degree of dietary self-management, we used the Diabetes Mellitus Dietary Self Efficacy Scale (DMDSES) developed by Yasukata et al. The DMDSES is a 15-item questionnaire with a six-point scale. A higher score indicates higher self-efficacy for dietary therapy for diabetes.

The risk rate of the paired t test was set at 5%. All analyses were performed using IBM SPSS Statistics 27 (IBM Japan, Tokyo).

RESULTS

Nine patients were recruited for the study at three pharmacies. One person dropped out during the intervention period. An analysis was conducted on the 8 patients who completed the intervention period. The information of the patients included in the analysis is shown in Table 1. The mean age was 70.1 years and 62.5% of the patients were male. Half of the patients had complications of hypertension or dyslipidemia. The physical activity level was 1 in 75.0% and 3 in 25.0%. None of the patients smoked and 37.5% drank alcohol.

The changes in the primary and secondary endpoints from baseline to 6 months are shown in Table 2. The mean (SD) of HbA1c, the primary endpoint, was 7.3 (1.0) at baseline and 7.1 (1.0) at the end of the intervention period. The changes in the primary and secondary endpoints from baseline to 6 months are shown in Table 2. The mean (SD) of HbA1c, the primary endpoint, was 7.3 (1.0) at baseline and 7.1 (1.0) at the end of the intervention period.

Table 1. Patients attributes (n=8)

| Patients attributes | n=8 |
|---------------------|-----|
| Age (Mean (SD))     | 70.1 (7.0) |
| Sex (male (%))      | 62.5 |
| Complications (%)*  |     |
| HT                  | 50.0 |
| DL                  | 50.0 |
| HU                  | 12.5 |
| Others              | 25.0 |
| No complications    | 25.0 |
| Physical activity level (%) |     |
| 1                   | 75.0 |
| 3                   | 25.0 |
| Family composition (%) |     |
| Single              | 25.0 |
| With spouse         | 75.0 |
| Smoking habits (%)  | 0.0  |
| Alcohol habits (%)  | 37.5 |

SD: standard deviation
*HT: hypertension, DL: dyslipidemia, HU: hyperuricemia
Others: duodenum ulcer (n=1), Osteoporosis (n=1)

Table 2. Changes in the primary and secondary endpoints from baseline to 6 months

| Endpoint               | Baseline Mean (SD) | End of Intervention Mean (SD) | Change |
|------------------------|--------------------|--------------------------------|--------|
| HbA1c (mmol/L)         | 7.3 (1.0)          | 7.1 (1.0)                      | -0.2   |
| LDL-c (mmol/L)         | 2.7 (0.9)          | 2.5 (0.8)                      | -0.2   |
| HDL-c (mmol/L)         | 1.4 (0.4)          | 1.5 (0.5)                      | 0.1    |
| Triglycerides (mmol/L)| 1.8 (1.0)          | 2.0 (1.2)                      | 0.2    |
| Blood pressure         | 130/80 mmHg        | 128/80 mmHg                    | -2/0   |
| BMI                    | 25.0 (4.0)         | 24.8 (3.9)                     | -0.2   |

SD: standard deviation
Diabetes Mellitus Dietary Self Efficacy Scale

TG: Triglyceride, HDL-c: high-density lipoprotein-cholesterol, DMDSES: The HbA1c: Hemoglobin A1c level, LDL-c: low-density lipoprotein-cholesterol, interventions can improve glycemic control, but as far as the satisfaction score. Many studies have shown that collaborative and an increase in the degree of dietary self-management and in a significant decrease in HbA1c, a significant increase in HDL-c, patients with type 2 diabetes. A 6-month intervention resulted in lifestyle: it has been reported that physical activity, smoking cessation, weight loss, alcohol consumption, Mediterranean diet, etc. can result in an increase in HDL-c. In this study, as well, changes in patients’ lifestyles can be inferred from these results. Although the changes in the LDL-c and TG values were not statistically significant, we believe that more definite effects can be expected to appear with continued intervention. The improvement in the degree of dietary self-management assessed by the DMDSES had the largest effect size of all the outcomes. This may be due to the fact that the dietitian provided continuous dietary advice over a period of 6 months, which encouraged the patients to develop healthy eating habits and helped them follow the dietary regimen. On the other hand, the score of the Henshoku scale tended to worsen over the intervention period, although this was not statistically significant. We believe that one of the reasons for this may be that the patients at the beginning of the intervention were not able to correctly evaluate the degree of their own unbalanced diet and became able to evaluate it correctly as a result of the continuous dietary support from the dietitian.

There was only one dropout in this study, which suggests that the design of the study was not overwhelming for any of the dietitians, pharmacists, or patients. We also believe that the monthly follow-up by the principal investigator was one of the factors that reduced the number of dropouts. Furthermore, we believe that this follow-up contributed to maintaining the motivation of the interventionists and the quality of the interventions.

The limitations of this study are as follows. First, this was a pilot study with a small number of subjects. Second, it was a single-group study, so we cannot be sure of causality. Thirdly, it was not possible to objectively assess the changes in the patients’ eating habits. Although the brief-type self-administered diet history questionnaire (BDHQ) is a standard questionnaire for dietary habits, it has 80 questions and requires a lot of time to answer, so we decided that it was not suitable for answering in a pharmacy waiting room. Furthermore, even this questionnaire cannot be said to be objective, as it is left to the subjectivity of the respondents.

Despite the above limitations, we believe that this study is significant as it proposes a new and effective form of diabetes care in community medicine.

CONCLUSION

Dietary collaborative support by pharmacy dietitians and pharmacists may improve the dietary habits of patients with type 2 diabetes and improve their glycemic control status.

DECLARATIONS

Author’s contributions
MS designed and conducted the study, analyzed the data, and wrote the manuscript. NS provided general research advising. NI and KS assisted in conducting the study. MO provided general research advising. All authors read and approved the final manuscript.

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Availability of data and materials
Supporting data for the findings of this study are available from the corresponding author on request. The data are not publicly available for privacy and ethical reasons.

Table 2. Comparison of outcome measures at baseline and after 6 months (n=8)

|               | Baseline Mean (SD) | After 6 months Mean (SD) | P value | Effect size (r) |
|---------------|--------------------|--------------------------|---------|-----------------|
| HbA1c (%)     | 7.3 (1.0)          | 6.6 (0.8)                | 0.028   | 0.72            |
| LDL-c         | 98.0 (28.6)        | 89.0 (17.0)              | 0.235   | 0.47            |
| TG            | 144.0 (30.4)       | 125.4 (33.0)             | 0.368   | 0.37            |
| HDL-c         | 55.0 (14.8)        | 63.1 (10.1)              | 0.110   | 0.51            |
| Henshoku-scale| 21.1 (5.6)         | 23.1 (4.6)               | 0.074   | 0.66            |
| DMDSES        | 51.7 (8.3)         | 60.2 (8.4)               | 0.025   | 0.79            |
| Satisfaction  | 24.0 (4.0)         | 26.1 (3.3)               | 0.161   | 0.51            |

HbA1c: Hemoglobin A1c level, LDL-c: low-density lipoprotein-cholesterol, TG: Triglyceride, HDL-c: high-density lipoprotein-cholesterol, DMDSES: The Diabetes Mellitus Dietary Self Efficacy Scale
Ethics approval and consent to participate

This study was conducted in compliance with the ethical guidelines for “Medical Research Involving Human Subjects.” This study was conducted with the approval of the Research Ethics Review Committee of the Osaka University of Pharmaceutical sciences (currently Osaka Medical and Pharmaceutical University) (Approval No: 0072). Informed consent was obtained from all study participants prior to their participation. This study is registered with University Hospital Medical Information Network (UMIN000040102).

Conflicts of interest

There are no conflicts of interest to declare.

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References

1. The Japan Diabetes Society, Treatment Guide for Diabetes 2020-2021. Bunkodo, Tokyo, pp31-47.
2. Laiteerapong N, Ham SA, Gao Y, et al. The Legacy Effect in Type 2 Diabetes: Impact of Early Glycemic Control on Future Complications (The Diabetes & Aging Study). Diabetes Care. 2019;42(3):416-26. http://doi.org/10.2337/dc17-1144
3. Ministry of Health, Labour and Welfare, Overview of National Health Care Expenditures
4. https://www.mhlw.go.jp/toukei/saikin/hw/k-iryohi/17/dl/kekka.pdf
5. Cranor CW, Christensen DB. The Asheville Project: Short-term outcomes of a community pharmacy diabetes care program. J Am Pharm Assoc. 2012;52(6):838-50.
6. Cranor CW, Bunting BA, Christensen DB. The Asheville Project: long-term clinical and economic outcomes of a community pharmacy diabetes care program. J Am Pharm Assoc (Wash). 2003;43(2):173-84. http://doi.org/10.1331/108658003321480713
7. Krass I, Armour CL, Mitchell B, et al. The Pharmacy Diabetes Care Program: assessment of a community pharmacy diabetes service model in Australia. Diabet Med. 2007;24(6):677-83. http://doi.org/10.1111/j.1464-591.2007.02143.x
8. Ali M, Schifano F, Robinson P, et al. Impact of community pharmacy diabetes monitoring and education programme on diabetes management: a randomized controlled study. Diabet Med. 2012;29(9):e326-33. http://doi.org/10.1111/j.1464-5941.2012.03725.x
9. Furukawa A, Asada Y, Mori T, et al. [Japanese Model of Asheville Project. Its Overview and Initiative]. Yakugaku Zasshi. 2016;136(2):251-8. http://doi.org/10.1248/yakushi.15-00268-2
10. Okada H, Onda M, Shoji M, et al. Effects of Lifestyle Intervention Performed by Community Pharmacists on Glycemic Control in Patients with Type 2 Diabetes: The Community Pharmacists Assist (Compass) Project, a Pragmatic Cluster Randomized Trial. Pharmacology & Pharmacy. 2016;7:124-132. http://doi.org/10.4236/pp.2016.73016
11. Fuji H, Mori T, Furukawa A, et al. [Pilot Study of “Japanese Model of Asheville Project” How Did It Work?]. Yakugaku Zasshi. 2016;136(2):259-63. http://doi.org/10.1248/yakushi.15-00268-3
12. Yaghoubi M, Mansell K, Vatanparast H, et al. Effects of Pharmacy-Based Interventions on the Control and Management of Diabetes in Adults: A Systematic Review and Meta-Analysis. Can J Diabetes. 2017;41(6):628-641. http://doi.org/10.1016/j.cjdi.2017.09.014
13. Eades CE, Ferguson JS, O’Carroll RE. Public health in community pharmacy: a systematic review of pharmacist and consumer views. BMC Public Health. 2011;21;11:582. http://doi.org/10.1186/1471-2458-11-582.
14. Kizaki H, Ota T, Mashima S, et al. Questionnaire survey investigation of the present status of dietetic consultation at community pharmacies from the perspectives of registered dietitians and pharmacists. BMC Health Services Research. 2021;21:935. http://doi.org/10.1186/s12913-021-00695-9.
15. Hori Y, Uchida H, Shimizu J, et al. A study of the actual conditions of registered dietitians and dietitians working in insurance pharmacies and drugstores. Jpn J Nutr Diet. 2021;79(4):242-52.
16. Shoji M, Sakane N, Ito N, et al. A cross-sectional study of demonstrating expertise and job satisfaction in pharmacists and dietitians working in community pharmacies in Japan. Pharmacy Practice. 2022;20(1):2605. http://doi.org/10.18549/PharmPract.2022.1.2605
17. Imada S, Hasegawa T, Sakai N, et al. Clinical developmental studies in eating problem (2) —A development of Henshoku scale—. Studies in the humanities and sciences, 2006;47:123-148.
18. Yasukata F. A study regarding the development of a tool for developing self-efficacy in regard to dietary self-management for diabetes patients. Doctoral dissertation. Graduate School of Medicine, University of Tokyo. 1997.
19. Armando PD, Martinez Pérez SR, Martí Pallarés M, et al. Development and validation of a Spanish language patient satisfaction questionnaire with drug dispensing. Pharm World Sci. 2008;30(2):169-74. http://doi.org/10.1007/s11199-008-9158-3
20. Hedges LV. What are effect sizes and why do we need them? Child development perspectives. 2008;2:167-171.
21. Norton MC, Hafman ME, Buzzard LN. Impact of Physician-Pharmacist Collaboration on Diabetes Outcomes and Health Care Use. J Am Board Fam Med. 2020;33(5):745-753. http://doi.org/10.3122/jabfm.2020.05.200044
22. Matzke GR, Moczygemba LR, Williams KJ, et al. Impact of a pharmacist-physician collaborative care model on patient outcomes and health services utilization. Am J Health Syst Pharm. 2018;75(14):1039-1047. http://doi.org/10.2146/ajhp170789
Shoji M, Sakane N, Ito N, Sunayama K, Onda M. A pilot study of Pharmacist-Dietician Collaborative support and Advice (PDCA) for patients with type 2 diabetes in community pharmacy: A single-arm, pre-post study. Pharmacy Practice 2022 Apr-Jun;20(2):2657. https://doi.org/10.18549/PharmPract.2022.2.2657

23. Aguiar PM, da Silva CHP, Chiann C, et al. Pharmacist-physician collaborative care model for patients with uncontrolled type 2 diabetes in Brazil: results from a randomized controlled trial. J Eval Clin Pract. 2018;24(1):22-30. http://doi.org/10.1111/jep.12606

24. Singh IM, Shishehbor MH, Ansell BJ. High-density lipoprotein as a therapeutic target: a systematic review. JAMA. 2007;298:786-798.