<Original Article>

Development and Evaluation of a Program to Promote Self-management of Blood Glucose and Side Effect in Patients with Type 2 Diabetes Undergoing Chemotherapy for Cancer

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ABSTRACT

Objective: To develop a program to promote self-management of blood glucose and side effect in patients with type 2 diabetes undergoing chemotherapy for cancer and evaluate its validity and clinical applicability.
Methods: The program was developed based on the results from a literature review on blood glucose fluctuations and side effect during chemotherapy in patients with diabetes and an empirical study in patients with type 2 diabetes who were diagnosed with cancer and receiving chemotherapy. A total of 10 physicians and nurses who were engaged in treatment of patients with diabetes undergoing chemotherapy participated in the study. A questionnaire survey and an interview survey were conducted to evaluate the program developed.
Results: Regarding the program validity, the participants' responses were generally favorable, while they suggested some points for improvement, including partial revisions and additions to expressions and reconsideration of information providers. As for the clinical applicability of the program, most participants considered that the program can be used clinically for nurses.
Conclusion: The program was generally confirmed to be valid and clinical applicable. Moving forward, the program requires further refinement and verification of its effectiveness in interventional studies.

INTRODUCTION

In patients with diabetes diagnosed with cancer and undergoing chemotherapy for cancer (hereinafter referred to as chemotherapy), blood glucose increases due to steroids used for antiemetic and allergy prophylaxis [1] as well as chemotherapy-induced anorexia and fatigue [2] have been suggested to make self-management of blood glucose difficult. Actual cases of impaired consciousness due to hyperglycemia and fatal accidents due to hypoglycemia in patients with diabetes undergoing chemotherapy have been reported [3]. Moreover, previous studies have shown that side effect to chemotherapy in patients with diabetes are more severe than those in patients without diabetes patients [4, 5] and that diabetes contributes adversely to the quality of life (QoL) of patients undergoing chemotherapy [2]. Therefore, self-management of blood glucose and side effect by patients with diabetes undergoing chemotherapy is important for prevention of life-threatening complications of diabetes, maintenance of QoL, and successful completion of chemotherapy.

However, patients with diabetes are challenged by dif-

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ficulties in self-management of blood glucose and side effect to chemotherapy in parallel. This is because patients with type 2 diabetes, which accounts for approximately 90 % of overall cases of diabetes [6], need to improve and maintain lifestyle through self-management, as certain lifestyle habits, such as overeating and insufficient exercise, are partly responsible for type 2 diabetes [7]. Meanwhile, patients with cancer are required to practice self-management in accordance with side effects of and physical and psychosocial changes from the treatment [8]. Thus, patients with diabetes undergoing chemotherapy face difficulties associated with self-management of two different conditions.

Previous studies have reported that explanations of side effect to chemotherapy provided to patients with diabetes by nurses specializing in cancer treatment tend to include general information only [9] and that approximately 50 % of medical professionals specializing in cancer treatment have never participated in a diabetes-related training course [5]. It has also been reported that care provided to patients with diabetes undergoing chemotherapy varies, because it is not clear as to whether their blood glucose level should be managed by diabetologists or oncologists [10]. Other reports have dealt only with surveys on blood glucose level and side effect during chemotherapy [11–13] as well as implementation of a multidisciplinary care system [14], and support methods for this patient population have not been established.

As described above, patients with diabetes undergoing chemotherapy are in a situation in which appropriate support is not readily accessible, despite the fact that they are required to practice self-management of two different conditions (i.e., blood glucose and side effect). Therefore, there is an urgent need to develop a program that facilitates self-management of blood glucose and side effect during chemotherapy by patients with type 2 diabetes. We believe that the development of this program facilitates self-management of blood glucose and side effects in patients with type 2 diabetes undergoing chemotherapy and contributes to safe use of chemotherapy. Furthermore, whether they are able to successfully manage the first course can also affect patients' motivation for subsequent treatment. Thus, the development of this program is also useful to prevent patients' motivation for treatment from decreasing. Moreover, this program is expected to enable nurses to support patients beyond their area of specialization and contribute to the development of personalized support for patients.

This study aimed to develop a program to promote self-management of blood glucose and side effect in patients with type 2 diabetes undergoing chemotherapy and evaluate its validity and clinical applicability.

SUBJECT and METHODS

Development of the program

This program was positioned as an effort to promote the process of self-management of blood glucose and side effect in patients with type 2 diabetes who underwent chemotherapy [15] for the first time after being diagnosed with cancer. The primary outcome of the promoted process of self-management of patients' blood glucose and side effect by intervention with this program was "completion of chemotherapy according to the treatment schedule" secondary outcomes were expected to (1) no unscheduled visits or emergency hospitalization for acute diabetic complications or serious side effect; (2) no occurrence or aggravation of anxiety or depression; and (3) no deterioration of QoL. The main outcome was that diabetes patients undergoing chemotherapy engaged in self-management of blood glucose and the side effects in order to complete chemotherapy [15] which is also considered by health care providers to be a goal of nursing [16]. Secondary outcomes were set based on the need for both physical and psychological stability in order to complete chemotherapy according to the treatment schedule.

The program content was based on the results of a literature review and patient-based empirical studies [15, 17] conducted by the authors. The goal was set as "patients with type 2 diabetes diagnosed with cancer and undergoing chemotherapy can manage blood glucose and side effects by themselves while maintaining mental stability, and can complete chemotherapy according to the treatment schedule," and eight specific goals were set (**Table1**). The program components were (1) Providing information, (2) Gaining self-monitoring skills, (3) Improving self-efficacy, and (4) Psychological care.

The intervention method was designed for patients with type 2 diabetes who were diagnosed with cancer and were receiving chemotherapy for the first time. It was a face-to-face individualized intervention, emphasizing a dialog between the patient and the nurse. The reason is that self-management of chronic illness is a problem-solving approach and that forming a partnership between the patient and the healthcare provider is of utmost importance [18]. Therefore, we believed patients would follow a problem-solving process for their health issues through dialog with the nurse, enhancing their ability to self-manage their disease.

The intervention period was from before the chemotherapy to after the third course, with four intervention sessions. Each intervention lasted approximately 30 minutes. The intervention provider was a nurse who worked in the outpatient chemotherapy unit. Goals and specifics were set for each intervention (**Table 2**). Five points to remember during the intervention are presented: (1) Information provision should be adjusted in content and quantity according to the

Table 1 Specific goals of the program

Goal 1.	To gain an understanding that blood glucose are susceptible to fluctuations during chemotherapy
Goal 2.	To become capable of self-monitoring of blood glucose and side effect after chemotherapy
Goal 3.	To understand and become capable of implementing methods of dietary therapy adjusted for physical condition
Goal 4.	To understand and become capable of implementing exercise therapy adjusted for physical condition
Goal 5.	To understand the need for and become capable of implementing infection control
Goal 6.	To become capable of implementing preventive measures against progression of peripheral neuropathy
Goal 7.	To become capable of asking questions and communicating concerns related to diseases and treatments to medical professionals
Goal 8.	To become capable of finding a way of mental stabilization appropriate for patient him/herself

patient's knowledge, experience, and level of anxiety. (2) Monitor the patient's expressions and words carefully, and if it is determined that the patient is mentally unstable, stop the intervention temporarily and give priority to psychological care. (3) Involve patients to enhance their sense of self-efficacy. (4) Prior to the intervention, coordinate time with the patient, coordinate tasks with staff, and prepare a quiet environment where the patient can be calmly engaged. (5) Intervention details and evaluation are recorded. In addition, we considered it necessary for the interventionists to understand the contents of the program contents before applying it. Therefore, we prepared a practice guide that describes the background that led to the establishment of the program, the purpose and organization of the program, the specific methods of each intervention, and the content of the information provided.

Evaluation of the program

From among physicians or nurses who were engaged in treatment of patients with diabetes undergoing chemotherapy for cancer, those who consented to participation in the study were eligible. Inclusion criteria were employment at a designated cancer care hospital and at least 5 years of clinical experience. Participants were selected using snowball sampling [19], a method in which participants are introduced to other participants suitable for the study because it was considered impossible to obtain sufficient data through random sampling [20]. A questionnaire and an interview survey were combined to collect data, with interviews conducted to supplement the responses to the questionnaire survey and asking about the reasons for the responses and about areas for improvement and benefits of the program. Each interview lasted approximately 45 minutes and was conducted in a room where privacy could be ensured. The questionnaire survey included 13 items asking about the appropriateness of the target attributes, program goals, intervention techniques, timing and number of interventional sessions, length of an interventional session, contents of respective interventional sessions, and clinical applicability of the program. The answers to the questions were selected from the following four options: agree, somewhat agree, somewhat disagree, and disagree. The data were collected from November 2022 to December 2022.

For analysis of the questionnaire survey responses, the responses to each question were summarized through simple tabulation. Furthermore, for analysis of the interview survey responses, verbatim transcripts of the responses were prepared on paper, and the data were organized according to content similarity to highlight points for program improvement. This study was conducted with approval from the ethical review board of the Osaka Medical and Pharmaceutical University (2022-111). Participants were provided with verbal and written explanations that their participation in the study is voluntary, they are free to withdraw, their privacy is protected, and how the data are managed.

RESULTS

Overview of participant characteristics

From six facilities in Japan, 2 diabetologists, 3 certified nurses in diabetes nursing, 2 clinical oncologists, and 3 certified nurses specializing in cancer or chemotherapy nursing participated in this study. The mean lengths of experience of the physicians and nurses were 19.8 years (SD: 9.1 years) and 22.7 years (SD: 4.3 years), respectively.

Validity of the program

The results of the questionnaire survey on program adequacy are shown in **Table 3**.

To the question asking whether the overall goal of the program was appropriate, 7 out of 10 answered "agree" and 3 out of 10 answered "somewhat agree" respectively. Opinions about goal setting "The goal is high because treatment deferral for reasons beyond the control of individual efforts, such as bone marrow suppression, can be assumed," "The intervention ends after the third course of chemotherapy, so it is impossible to assess whether the treatment was completed."

To the question asking whether the specific goals of the program were appropriate, 5 out of 10 answered "agree"

Table 2 Goals and contents of respective interventional sessions

	First session	Second session	Third session	Fourth session
Timing of intervention	Before first course of treatment	After completion of the first course of treatment	After completion of the second course of treatment	After completion of the third course of treatment
Goal (Number are specific goals of the program)	• To gain an understanding that blood glucose are prone to fluctuations during chemotherapy (1) • To understand methods of dietary therapy adjusted for physical condition (3) • To understand the need for and become capable of implementing infection control (5) • To become capable of conveying questions and concerns related to patient's own diseases and treatments to medical professionals (7)	• To become capable of self-monitoring of blood glucose and side effect after chemotherapy (2) • To understand and become capable of implementing methods of dietary therapy adjusted for physical condition (3) • To understand the need for and become capable of implementing infection control (5) • To become capable of asking questions and communicating concerns related to diseases and treatments to medical professionals (7)	• To become capable of self-monitoring of blood glucose and side effect after chemotherapy (2) • To understand and become capable of implementing exercise therapy adjusted for physical condition (4) • To become capable of implementing preventive measures against progression of peripheral neuropathy (6) • To become capable of asking questions and communicating concerns related to diseases and treatments to medical professionals (7)	• To become capable of self-monitoring of blood glucose and side effect after chemotherapy (2) • To become capable of asking questions and communicating concerns related to diseases and treatments to medical professionals (7) • To become capable of finding a way of mental stabilization appropriate for patient him/herself (8)
Content (Partial excerpt)	**Preparation for intervention** • Information collection from medical records **Intervention** • Hearing of patient's feelings about chemotherapy • *Explanation of why, when, and how much blood glucose increases during chemotherapy, as well as precautions against blood glucose elevation* • *Explanation of possible occurrence of hypoglycemia during chemotherapy and confirmation of how to prevent/handle* • *Explanation of how to deal with sick days* • *Assessment of foot condition*	**Preparation for intervention** • Confirmation of blood glucose and other blood test results before chemotherapy **Intervention** • Confirmation of questions about the first session and hearing of patient's feelings about treatment • *Confirmation of patient's level of understanding about how to deal with sick days and provision of supplementary explanations* • *Explanation of the usefulness of recording blood glucose and side effect after chemotherapy and consultation on how to keep records* • *Explanation of when infection is most likely to occur, common sites of infection, and how to deal with infection* • *Confirmation of how to spend time at home after treatment and emergency contact information*	**Preparation for intervention** • Confirmation of blood glucose and other blood test results before chemotherapy **Intervention** • Hearing of patient's current feelings • *Confirmation of severity of blood glucose fluctuations and side effect as well as measures taken up to the present since the first dose of anticancer agents* • *Consideration on whether to continue or change the measures taken* • *Confirmation of precautions for exercise during chemotherapy and consideration on implementation of exercise therapy* • *Dietary therapy and infection prevention behaviors* • *Introduction to common sites of peripheral neuropathy and ways to slow progression*	**Preparation for intervention** • Confirmation of blood glucose and other blood test results before chemotherapy **Intervention** • Comparison of patterns of blood glucose fluctuations and side effect between the first and second courses and consideration on how to manage blood glucose and side effect during and after the third course • Assessment of patient's psychological state and confirmation of measures to maintain mental stability • To inform the patient that this session concludes the intervention and that the intervention provider is available to help whenever necessary

Note) Interventions in italic are performed mainly on patient's concerns and worries.

Table 3 Appropriateness and clinical applicability of the program

N = 10

	Agree (number of respondents)	Somewhat agree (number of respondents)	Somewhat disagree (number of respondents)	Disagree (number of respondents)
Appropriateness				
Overall goal of the program	7	3	0	0
Specific goals of the program	5	5	0	0
Components of the program	2	8	0	0
Intervention techniques in the program	7	3	0	0
Timing of interventional sessions	5	5	0	0
Number of interventional sessions	4	6	0	0
Length of an interventional session	4	5	1	0
Content of the first interventional session	4	5	1	0
Content of the second interventional session	4	6	0	0
Content of the third interventional session	4	6	0	0
Content of the fourth interventional session	4	6	0	0
Clinical applicability				
The program is clinically applicable.	5	5	0	0
The program is useful for nurses.	7	3	0	0

and 5 out of 10 answered "somewhat agree" respectively. A point for improvement was pointed out: specific details of the goals were difficult to understand. Specific comments included: "it is confusing whether peripheral neuropathy refers to that occurring as a side effect to chemotherapy or that caused by diabetes"; "I do not know what explanations should be provided as diet therapy and exercise therapy for diabetes"; and "I do not know self-monitoring methods for blood glucose of patients receiving oral hypoglycemic drugs."

To the questions about appropriateness of the program structure, intervention techniques in the program, and timing and number of interventional sessions, all 10 respondents answered "agree." No points for improvement were pointed out. As for appropriateness of the length of an interventional session, nine selected positive answers. However, there was an opinion that allocating 30 minutes for each patient is unrealistically difficult.

All participants generally agreed that the content of the first interventional session was appropriate. Opinions about points for improvement included "Provision of explanations about hypoglycemic drugs and information about meals during chemotherapy is difficult because the specific contents vary depending on patient's condition. It is safer if nurses limit their role to checking the patient's level of understanding" and "I would like to see specific details about precautions for hypoglycemic drugs and how to deal with appetite loss specifically in patients with diabetes, because I am confident in providing explanations on those matters."

All participants generally agree that the content of the second interventional session was appropriate. There was a proposal "it would be better to specify the department to contact specifically because patients may be confused about whether they should contact the department of diabetology or oncology in case of emergency."

All participants generally agree that the contents of the third and fourth interventional sessions were appropriate.

Clinical applicability of the program

Regarding the questions about the clinical applicability of the program and its usefulness to nurses, all 10 respondents answered "agree" or "somewhat agree" (**Table 3**). Opinions about points for improvement included "It may be essential to have study sessions for intervention providers before intervention, because the practical guide alone is insufficient to eliminate their uncertainties" and "A template for keeping records of interventional sessions would be helpful to prevent implementation and evaluation from being forgotten and provide continuous support. It will also help reduce the time required to keep records."

Positive opinions about the program included "It is a tool that can be used by nurses to support patients in a systematic manner" and "It is a tool useful to check explicitly whether nurses are involved in diabetes care."

DISCUSSION

Validity of the program

Regarding the appropriateness of the program's overall goal, all participants generally rated positively. Points for improvement included "completion of chemotherapy as scheduled, which is a high goal." It has been reported that patients with diabetes who are undergoing adjuvant chemotherapy for breast cancer are sometimes hospitalized outside of the treatment period. The reasons for this include neutropenia and anemia [21], which suggest that some patients are unable to complete chemotherapy as scheduled due to bone marrow suppression. There is also an opinion that assessing whether the treatment can be completed is difficult because the intervention ends after the third course of chemotherapy. Therefore, it is necessary to re-evaluate the overall goal and how to confirm the completion of chemotherapy by patients as scheduled.

As a point for improvement, use of technical terms, such as "diet therapy," "exercise therapy," and "peripheral neuropathy" was suggested to provoke anxiety and misunderstanding of interpretation in the intervention providers. Nurses specializing in either diabetes or cancer are aware of the difficulties in supporting patients with diabetes undergoing chemotherapy [22]. However, since support methods have not been established, even nurses who are skillful in providing support in their specialized areas are anxious about their knowledge in other areas and are trying to make decisions as effectively as possible based on their limited knowledge and experience. Therefore, expressions used in the program should be revised to avoid technical terms that are frequently used in the area of diabetes or cancer whenever possible.

As for the appropriateness of the length of each interventional session, there was an opinion, from multiple nurses, that our preset limit, a maximum of 30 minutes, was difficult to allocate. According to the 2021 Hospital Nursing and Outpatient Nursing Survey Report [23], approximately 60 % of hospitals have a nursing staff allocation described as "one nursing staff is in charge of multiple examination rooms" in general outpatient settings. On average, 3.1 nursing staff were dedicated to an outpatient chemotherapy department. This result suggests that nurses cannot easily allocate time for patient support. Since this program provides support based on patient–nurse dialog, it is likely to be difficult to substantially shorten the length of an interventional session. Possible measures include operational coordination in advance to secure sufficient time for intervention and cooperation among the departments of diabetology and oncology and the outpatient chemotherapy room to effectively use the waiting time for examinations. Furthermore, more fundamental changes, such allocating a greater number of nursing staff in general outpatient departments, may be worth consideration.

It has been suggested that careful consideration is necessary in determining who should provide information and support to patients with diabetes undergoing chemotherapy. In particular, medical professionals with specialized knowledge of diabetes are preferred as providers of information about diet and exercise during chemotherapy, as such support can be difficult. Some nurses in the cancer area may also lack confidence in their knowledge and ability to provide appropriate information, possibly due to a lack of experience and training in areas outside of their specialization [5]. These findings highlight the need to strengthen collaboration among healthcare providers involved in supporting patients with diabetes during chemotherapy. Additionally, it is believed that changing the nurse in charge of support according to the specific intervention required, rather than having only diabetes or cancer nurses provide support, will enable more effective support that takes advantage of each nurse's expertise.

Clinical applicability

All subjects positively evaluated the clinical applicability of the program. Therefore, we believe this program will enable nurses to support diabetic patients, considering blood glucose and side effects of chemotherapy, and will contribute to building patient care.

For improvement, it is necessary to provide a study session for nurses prior to the program intervention. Yamamoto et al [22]. have reported that self-management support by nurses is difficult because the base of knowledge related to support for patients with diabetes and cancer is not sufficiently developed. Thus, it is necessary to plan and implement training sessions across the diabetes and cancer areas, in which participants can learn from each other.

Limitations of the study and future challenges

A limitation of this study is that the number of study subjects was only 10. Therefore, we believe generalization is limited. Future challenges include refining the program and evaluation indicators and verifying their effectiveness in interventional studies.

CONCLUSIONS

The validity and clinical applicability of a program to promote self-management of blood glucose and side effects in patients with type 2 diabetes undergoing cancer chemotherapy were generally accepted. The improvements included partial revision of overall and specific goal setting, re-examining some informational content, and extra educational support for nurses at the time of intervention that was cross-disciplinary and cross-disciplinary between diabetes and cancer.

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CONFLICT OF INTEREST DECLARATION

The authors declare no conflicts of interest associated with this manuscript.

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