

## Relationships between Assessment of Diabetes Therapy, Self-Care Behaviors, and Glycemic Control in Outpatients with Type 2 Diabetes Treated with Glucose-Lowering Agents

### Research Article

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**Received:** Sept 30, 2020; **Accepted:** Oct 17, 2020; **Published:** Oct 20, 2020

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### Abstract

**Objective:** The purpose of this study is to investigate the assessment of therapy of Type 2 diabetes (T2D) patients, as well as their self-care behaviors, and clarify how these are related to glycemic control.

**Materials and Methods:** A questionnaire on the assessment of diabetes treatment and self-care behaviors was completed by 138 outpatients with T2D treated with glucose-lowering agents. Stepwise multiple regression was employed to determine which variables in self-care behaviors affected assessment of diabetes therapy and level of Hemoglobin A1c (HbA1c).

**Results:** The overall assessment of diabetes therapy was positively correlated with HbA1c level ( $p = .353$ ). The assessment of nutrition ( $\beta = .250$ ) and pharmacologic therapies ( $\beta = .513$ ) were significant predictors of overall assessment, though exercise therapy did not. Individual self-care behaviors other than medication adherence affected assessment of nutrition therapy, exercise therapy, and pharmacologic therapy. Furthermore, assessment of nutrition therapy was a significant predictor of HbA1c level. In addition, it was found that T2D patients treated with thiazolidinedione's performed more exercise per day than those without.

**Conclusion:** This study has revealed what care providers should focus on in order to improve glycemic control. The medical interview of assessment and self-care behaviors related to nutrition therapy might be helpful for judging glycemic control. The medical interview of assessment and self-care behaviors related to exercise therapy and the interview of medication adherence might not be helpful for judging glycemic control.

**Keywords:** Assessment of therapy; Glycemic control; Patient-reported outcome; Self-care behaviors; Type 2 diabetes.

### Abbreviations

T2D: Type 2 diabetes

PROs: Patient-Reported Outcomes

HbA1c: Hemoglobin A1c

A1C0: HbA1c level on the day of the questionnaire

DPP-4: Dipeptidyl Peptidase-4

SGLT2: Sodium-Glucose Cotransporter 2

GLP-1: Glucagon-Like Peptide 1

A1C-1: HbA1c level on the day before the questionnaire

## Introduction

Type 2 diabetes (T2D) is a lifestyle disease and its treatment is lifelong, therefore self-management is important for those affected [1]. In addition to the appropriate treatments, such as nutrition, exercise, and pharmacologic therapies, improvement of self-efficacy in patients with T2D is required in order to improve Hemoglobin A1c (HbA1c) and other glycemic control indicators. It is recognized that the self-efficacy of patients with T2D improves self-care behaviors, which in turn improve long-term glycemic control indicators [2]. In addition, improvement of Patient-Reported Outcomes (PROs), which include measures such as treatment satisfaction and quality of life, as well as medical outcomes such as HbA1c is also important in the management of T2D [3]. However, it is speculated that self-efficacy and PROs of T2D patients are related to the assessment of diabetes therapy. If the relationships between the assessment of diabetes therapy, self-care behaviors, and glycemic control in T2D patients are clarified, care providers can provide effective diabetes self-management education and support. To the best of our knowledge, there have been few studies conducted on the assessment of diabetes therapy in T2D patients [4,5]. In this study, we attempt to clarify how assessment of diabetes therapy and self-care behaviors are related to glycemic control in T2D patients by way of a questionnaire given to outpatients with T2D treated with glucose-lowering agents.

## Material and Methods

**Study sample:** This study was approved by the Ethics Committee of Aichi Prefectural University (approval code: 28-6-19) and Ichinomiya Municipal Hospital (approval code: 1143). We originally enrolled 330 T2D patients who visited the outpatient diabetes clinic at Ichinomiya Municipal Hospital in Aichi, Japan, between December 2016 and May 2017. Twenty-one patients who took no glucose-lowering agents, 22 patients who had begun diabetes treatment within the previous 6 months, and 3 patients undergoing dialysis were excluded from the study. In addition, 78 patients who were elderly, had dementia, or were undergoing treatment for other diseases, as well as

36 patients who visited the clinic irregularly or who were scheduled to relocate to another medical institution, were excluded.

**Data collection procedures:** At the time of outpatient visits, the doctor in charge distributed a form that described the purpose of the study and asked whether the outpatients would agree to take the questionnaire. At the time of their next visit, the medical staff gave a questionnaire to the outpatients in exchange for their signed consent form and asked them to answer the questionnaire during the waiting time for their medical examination. The questionnaire consisted of 10 questions, 4 of which concerned the assessment of diabetes therapy (assessment of nutrition therapy, exercise therapy, pharmacologic therapy, and overall assessment), whereas the remaining 6 concerned self-care behaviors related to nutrition, exercise, and pharmacologic therapies. For each question, the patient had to give a score between 3 and 5. Positive assessment proactivity were associated with smaller numbers and negative assessment and inactivity with larger numbers. The outpatients were asked to fill in their patient number instead of their name on the questionnaire, so that, when matching the results of the questionnaire to laboratory data and patient characteristics, neither the researcher nor the doctor in charge would immediately recognize which patient the questionnaire belonged to. After it had been filled, the questionnaire was collected in a collection box installed in the outpatient waiting room, regardless of whether the patient had responded to the questionnaire, so that the medical staff would not immediately know which of the outpatients had responded. Laboratory data and patient characteristics were obtained from electronic medical records.

## Statistical Analysis

Results are presented as the median (range), the mean  $\pm$  the standard deviation, or number with percentages. Statistical analysis was performed using PASW Statistics 25.0 (SPSS Inc., IBM Company, Chicago, IL, USA). The correlation between HbA1c level on the day of the questionnaire (A1C0) and the overall assessment was analyzed using Spearman's rank correlation coefficient. Predictive variables for A1C0, assessment of diabetes therapy, and self-care behaviors related to diabetes therapy were selected using stepwise multiple linear regression. We compared clinical parameters between groups using the Mann-Whitney U test or chi-square test, as appropriate.

The level of statistical significance was defined as  $P < .05$ . Significant correlations were defined as having an absolute value equal to that of the correlation coefficient ( $\rho$ )  $> .2$ . Significant regressions were defined as adjusted  $R^2 > .04$ , and the absolute value of standardized  $\beta > .2$ .

## Results

### Patient characteristics

Although the questionnaire was distributed to all of the 170 qualified patients, 12 patients refused to complete the questionnaire for personal reasons, and 18 did not submit the questionnaire. As a result, we collected 140 questionnaires (82.4% recovery rate). Two of these were excluded from the analysis because the patients had not answered the questions, so the analysis was finally performed using 138 responses (81.2% effective response rate).

**Table 1:** Clinical characteristics of the patients.

Gender, male/female	77 / 61
Age, years	67 (34–84)
Duration of diabetes, years	12.1 (0.5–52.5)
Body mass index, kg/m <sup>2</sup>	24.5 (16.7–37.8)
Systolic blood pressure, mmHg	142 (81–220)
Diastolic blood pressure, mmHg	77 (51–118)
A1C <sup>0a</sup> , %	7.5 (5.4–11.9)
A1C <sup>0a</sup> , mmol/mol	58 (36–107)
A1C-1 <sup>b</sup> , %	7.3 (5.5–11.2)
A1C-1 <sup>b</sup> , mmol/mol	56 (37–99)
HDL cholesterol, mg/dL	49 (26–114)
LDL cholesterol, mg/dL	102 (27–254)
Non-HDL cholesterol, mg/dL	134 (43–278)
Diabetic nephropathy <sup>c</sup> , Stage 1/2/3/4	52 / 48 / 29 / 9
Oral hypoglycemic agents	
Sulfonylureas	25 (18.1)
Glinides	28 (20.3)
α-Glucosidase inhibitors	33 (23.9)
Biguanides	77 (55.8)
Thiazolidinediones	22 (15.9)
DPP-4 inhibitors	101 (73.2)
SGLT2 inhibitors	12 (8.7)
Number of tablets of oral hypoglycemic agents	3.3 (0.0–14.0)
GLP-1 receptor agonists	7 (5.1)
Insulin	44 (31.9)
Number of glucose-lowering agents	2.0 (1.0–7.0)

Patient characteristics are shown in (Table 1). The ratio of male to female patients was 77/61. The median age (range) of patients was 67 (34–84) years. Most (72.5%) patients have normoalbuminuria (diabetic nephropathy stage 1) or microalbuminuria (stage 2). The classification of diabetic nephropathy was based on a report from the Joint Committee on Diabetic Nephropathy in Japan [6]. Most (73.2%) patients take Dipeptidyl Peptidase-4 (DPP-4) inhibitors. The number (percentage) of patients who take sulfonylureas, biguanides, and insulin was 25 (18.1%), 77 (55.8%), and 44 (31.9%), respectively. The median tablets (range) of oral hypoglycemic agents was 3.3 (0.0–14.0) tablets. The median glucose-lowering agents (range) was 2.0 (1.0–7.0). A fixed-dose combination drug was defined as consisting of two isolated drugs and a fixed-dose combination tablet as 0.5 tablets of each single agent. At the time of this study, the once-weekly DPP-4 inhibitors were not available at our hospital.

### Results of the questionnaire

The results of the questionnaire are shown in (Table 2). Although nearly half of patients (49.2%) made overall assessment of diabetes therapy as “very good” or “good”, 21.0%, 18.8%, and 49.1% of patients made assessment of nutrition, exercise, and pharmacologic therapy as such, respectively. While 25.3% of patients had no breakfast and/or lunch, 29.7% of patients had no excess of meals and snacks. Nearly one third of patients (36.2%) exercised more than 3 days per week, and 14.5% of patients exercised more than 7000 steps per day. Nearly two thirds of patients (63.0%) never forgot to take medications, whereas 22.9% of patients would like to reduce or quit medication.

**Table 2:** Results of the questionnaire.

Questions	Score	Respondents, n (%)
1.Overall assessment of diabetes therapy		
Very good	1	34 (24.6)
Good	2	34 (24.6)
Neither poor nor good	3	51 (37.0)
Poor	4	19 (13.8)
Very poor	5	0 (0.0)
2.Assessment of nutrition therapy		
Very good	1	8 (5.8)
Good	2	21 (15.2)
Neither poor nor good	3	56 (40.6)
Poor	4	47 (34.1)

Very poor	5	6 (4.3)
3. Self-care behavior related to nutrition (eating pattern)		
Having meals three times per day	1	103 (74.6)
Not having breakfast or lunch	2	30 (21.7)
Having neither breakfast nor lunch	3	5 (3.6)
4. Self-care behavior related to nutrition (excess meals)		
No excess of meals and snacks	1	41 (29.7)
One excess meal per day	2	73 (52.9)
Two excess meals per day	3	15 (10.7)
More than three excess meals per day	4	10 (7.2)
5. Assessment of exercise therapy		
Very good	1	9 (6.5)
Good	2	17 (12.3)
Neither poor nor good	3	33 (23.9)
Poor	4	37 (26.8)
Very poor	5	42 (30.4)
6. Self-care behavior related to exercise (number of days of exercise)		
7 days (daily) per week	1	10 (7.2)
5–6 days per week	2	19 (13.8)
3–4 days per week	3	21 (15.2)
1–2 days per week	4	46 (33.3)
0 days per week (none)	5	42 (30.4)
7. Self-care behavior related to exercise (steps per day)		
More than 10000 steps	1	9 (6.5)
7000–10000 steps	2	11 (8.0)
5000–7000 steps	3	18 (13.0)
3000–5000 steps	4	27 (19.6)
Less than 3000 steps	5	73 (52.9)
8. Assessment of pharmacologic therapy		
Very good	1	31 (22.5)
Good	2	34 (24.6)
Neither poor nor good	3	69 (50.0)
Poor	4	4 (2.9)
Very poor	5	0 (0.0)
9. Self-care behavior related to pharmacologic therapy (medication adherence)		
Never forgot to take medications	1	87 (63.0)
Forgot to take medications less than once a week	2	33 (23.9)
Forgot to take medications twice or 3 times per week	3	16 (11.6)
Forgot to take medications 4 to 6 times per week	4	1 (0.7)
Forgot to take medications more than 7 times per week	5	1 (0.7)
10. Self-care behavior for pharmacologic therapy (hope for medication)		
Would like to increase medication	1	0 (0.0)
Would like to continue current medication	2	105 (76.1)
Would like to reduce medication	3	22 (15.9)
Would like to quit medication	4	11 (8.0)

## Correlation between A1C0 and overall assessment of diabetes therapy

A1C0 and overall assessment of diabetes therapy showed a significant positive correlation ( $\rho = .353$ ).

## Multiple regression analysis with A1C0 and assessment of diabetes therapy as object variables

(Table 3) shows the results of the multiple regression analysis with A1C0 and assessment of diabetes therapy as object variables. Significant predictive variables for A1C0 were assessment of nutrition therapy ( $\beta = .251$ ), treatment with insulin ( $\beta = .282$ ) and treatment with sulfonylureas ( $\beta = .260$ ).

Significant predictive variables for overall assessment were assessment of pharmacologic therapy ( $\beta = .513$ ) and assessment of nutrition therapy ( $\beta = .250$ ). Significant predictive variables for assessment of nutrition therapy were HbA1c level on the day before the questionnaire (A1C-1;  $\beta = .263$ ), eating pattern ( $\beta = .229$ ), and excess meals ( $\beta = .216$ ). Significant predictive variables for assessment of exercise therapy were the number of days of exercise per week ( $\beta = .453$ ) and steps per day ( $\beta = .283$ ). Significant predictive variables for assessment of pharmacologic therapy were the hope for medication ( $\beta = .296$ ) and A1C-1 ( $\beta = .237$ ).

## Multiple regression analysis with self-care behaviors as object variables

(Table 3) shows the results of the multiple regression analysis with self-care behaviors as object variables. A significant predictive variable for the number of days of exercise per week was diastolic blood pressure ( $\beta = -.207$ ). Significant predictive variables for steps per day were treatment with thiazolidinedione's ( $\beta = -.222$ ) and diastolic blood pressure ( $\beta = -.203$ ). There were no significant predictive variables for the other self-care behaviors.

## Hope for medication

The patients were divided into 2 groups according to the hope for medication: 105 patients who responded, "I would like to increase medication" or "I would like to continue the current medication" (group A) and 33 patients who responded, "I would like to reduce medication" or "I would like to quit medication" (group B). The score of assessment of pharmacologic therapy of group A was significantly lower than that of group B ( $2.3 \pm 0.9$  vs.  $2.7 \pm$

**Table 3:** Multiple regression analysis with A1C0, assessment of diabetes therapy, and self-care behaviors as object variables.

Object variables	Adjusted R <sup>2</sup>	Predictive variables	Standardized β	P
A1C0 <sup>a</sup>	0.205	<b>Assessment of nutrition therapy</b>	0.251	0.002
		<b>Treatment with insulin</b>	0.282	0.001
		<b>Treatment with sulfonylureas</b>	0.26	0.001
		Assessment of pharmacologic therapy	0.187	0.02
Assessment				
Overall	0.501	<b>Assessment of pharmacologic therapy</b>	0.513	<.001
		<b>Assessment of nutrition therapy</b>	0.25	<.001
		A1C-1 <sup>b</sup>	0.171	0.013
		Treatment with GLP-1 receptor agonists	-0.19	0.003
		Number of glucose-lowering agents	0.156	0.016
Nutrition therapy	0.255	<b>A1C-1<sup>b</sup></b>	0.263	0.001
		<b>Eating pattern</b>	0.229	0.003
		<b>Excess meals</b>	0.216	0.005
		Treatment with biguanides	0.191	0.012
Exercise therapy	0.45	<b>Number of days of exercise</b>	0.453	<.001
		<b>Steps per day</b>	0.283	<.001
		Eating pattern	0.162	0.014
pharmacologic therapy	0.2	<b>Hope for medication</b>	0.296	<.001
		<b>A1C-1<sup>b</sup></b>	0.237	0.003
		Number of days of exercise	0.186	0.017
		Non-HDL cholesterol	-0.17	0.029
Self-care behaviors				
Number of days of exercise	0.077	Age of diabetes onset	-0.161	0.061
		<b>Diastolic blood pressure</b>	-0.207	0.016
		Treatment with biguanides	0.188	0.034
Steps per day	0.118	<b>Treatment with thiazolidinediones</b>	-0.222	
		<b>Diastolic blood pressure</b>	-0.203	
		Treatment with sulfonylureas	-0.163	
hope for medication	0.034	Gender	0.203	0.017

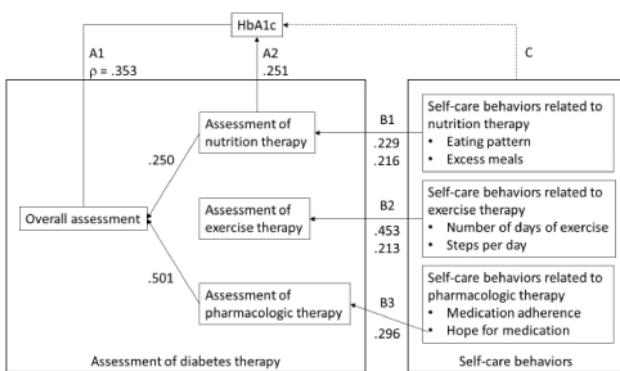
0.8, P = .005). The patients of group B took a significantly higher number of oral hypoglycemic tablets than those of group A [4.0 (0.0-13.0) tablets vs. 3.0 (0.0-14.0) tablets, P = .044]. The other clinical parameters did not differ significantly between the 2 groups (data not shown).

## Discussion

The present study is an attempt to clarify the relationships between assessment of diabetes therapy, self-care behaviors, and glycemic control. It has already been recognized that self-care behaviors improve glycemic control [2, 7-10]. Concerning the assessment of diabetes therapy, Gopalan et al. have demonstrated, using semi-structured interviews, that both glycemic control and self-

care behaviors influence assessment of diabetes therapy [4]. Chen et al. have also demonstrated that assessment of diabetes therapy has a direct effect on self-efficacy [5]. In this study, level of HbA1c, a representative glycemic control index, showed a positive correlation with overall assessment of diabetes therapy (Figure 1-A1), and the assessment of nutrition therapy was seen to affect HbA1c level (Figure 1-A2), suggesting that patients with T2D recognize that the nutrition therapy is fundamental to the treatment of diabetes.

The assessment of pharmacologic therapy and, to a lesser extent, nutrition therapy affected overall assessment of diabetes therapy, though exercise therapy did not. Individual self-care behaviors other than medication



**Figure 1:** Relationships revealed in the present study between the assessment of diabetes therapy, self-care behaviors, and HbA1c. Data are expressed as standardized  $\beta$  unless otherwise indicated. Solid lines or arrows indicate that a causal relationship between two concepts has been demonstrated in the present study (A1; 2; B1-3). Dotted arrows indicate that a causal relationship between two concepts has not been demonstrated in the present study (C).

adherence affected assessment of nutrition therapy, exercise therapy, and pharmacologic therapy (Figure 1-B1-B3). Few patients in this study performed exercise regularly enough to improve glycemic control, which will lead to the low assessment of exercise therapy. Previous studies demonstrated that many individuals with T2D did not meet the recommended physical activity thresholds [11-14]. That is why the assessment of exercise therapy did not affect overall assessment of diabetes therapy. On the other hand, most patients in this study had good medication adherence. Previous studies demonstrated that self-care behavior was high for medication taking in patients with T2D [13,14]. That is why medication adherence did not affect assessment of pharmacologic therapy. In addition, self-care behaviors were not a predictive variable for HbA1c level (Figure 1-C). This contrasts the results of previous studies [2, 7-10], some of which have shown that self-care behaviors associated with nutrition therapy may affect HbA1c level [2, 7-9]. These findings suggest that self-care behaviors of nutrition therapy affect HbA1c level through the assessment of nutrition therapy (Figure 1-B1, A2).

With regard to self-care behaviors related to nutrition therapy, eating patterns that included not having breakfast and/or lunch as well as those that included an excess of meals had a negative effect on assessment of nutrition therapy (Figure 1-B1). A previous study has revealed that not having breakfast can lead to elevations of postprandial glucose after lunch and dinner [15], which is consistent

with the results of the present study. With regard to self-care behaviors related to exercise therapy, a correlation was found between high diastolic blood pressure and a greater number of steps per day and days of exercise per week. A previous study has shown that diastolic blood pressure is positively correlated with the homeostasis model assessment for insulin resistance [16], suggesting that patients with high diastolic blood pressure have high insulin resistance and should be instructed to exercise. With regard to self-care behaviors related to pharmacologic therapy, assessment of pharmacologic therapy was low in patients hoping to reduce or quit glucose-lowering agents. However, these patients took more glucose-lowering tablets than those hoping to continue their dose of current medication. Medications of fixed-dose combination tablets and/or once-weekly tablets could improve the assessment of pharmacologic therapy.

The present study is subject to several limitations. First, the patients for the questionnaire survey were mainly those who are capable of assessing diabetes treatment and who were able to visit our outpatient clinic specializing in diabetes. Thus, our findings may not be applicable to elderly patients. Further, in this study, the causal relationship between medication adherence and pharmacological therapy could not be clarified. This is because the question concerning self-care behaviors for medication adherence was self-reported, and further investigation of the actual medication adherence would be required [17].

## Conclusion

The present study has revealed what care providers should focus on in order to improve glycemic control. The overall assessment of diabetes therapy was positively correlated with HbA1c level, and the assessment of nutrition and pharmacologic therapies affected overall assessment. Individual self-care behaviors other than medication adherence affected assessment of nutrition therapy, exercise therapy, and pharmacologic therapy. The medical interview of overall assessment of diabetes therapy, assessment of nutrition therapy, and self-care behaviors related to nutrition therapy might be helpful for judging glycemic control. On the other hand, the medical interview of assessment of exercise therapy and self-care behaviors related to exercise therapy might not be helpful for judging glycemic control. The medical interview of hope for medication rather than medication adherence might be helpful for judging glycemic control.

## Conflicts of Interest

The authors declare that there is no conflict of interest regarding the publication of this paper.

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