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Clinical Evaluation of OneTouch Diabetes Management Software System in Patients with Type 2 Diabetes Mellitus

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Background: OneTouch Diabetes Management Software (OTDMS) is an efficient way to track and monitor the blood glucose level. It is possible to download data from the OneTouch Ultra via the meter's data port, and to transform the numbers of the blood glucose level into a graph, a chart, or statistics. The objectives of this study were to evaluate whether the use of OTDMS in consultation hours would improve patients' knowledge of diabetes mellitus (DM), compliance, satisfaction with doctor and medical treatment, doctor-patient reliability, and glucose control.
Methods: All patients were randomized into either the OTDMS group using OneTouch Ultra or the control groups not using it. Both groups had conventional DM education and only the OTDMS group used data from OTDMS as explanation materials during consultation hours. At enrollment and after 6 months, we performed a questionnaire survey consisting of the diabetes knowledge test, items for compliance of treatment, patient's satisfaction, doctor-patient reliability, and glycosylated hemoglobin (HbA1c).
Results: We analyzed 6-month follow-up data from 92 patients (OTDMS 42 vs. control 50). Both groups showed significant improvements in HbA1c, diabetes knowledge, compliance, reliability, and satisfaction after 6 months. However, there were no significant differences between OTDMS and control groups overall. Only "weekly frequency of checking blood glucose level" of compliance and "trying to follow doctor's order" of reliability showed better results in the OTDMS group.
Conclusion: Using the OTDMS system for explanation during consultation hours seems to be more helpful to improve patient's compliance and reliability, especially for checking blood glucose level and trying to follow the doctor's order.

Keywords: Diabetes mellitus; Disease management; Education; Self care

INTRODUCTION

To assess the effectiveness of the management plan in glycemic control, patient self-monitoring of blood glucose (SMBG) and glycosylated hemoglobin (HbA1c) have been applied. SMBG reflects the adequacy of treatment, promotes healthy behavior, and improves clinical course. The results of SMBG are valuable and useful for treatment only when it is collected well and analyzed exactly [1,2]. Polonsky et al. [2] reported that appropriate and structured SMBG significantly improved glycemic control and facilitated more timely/aggressive treatment changes in noninsulin-treated type 2 diabetes mellitus (T2DM), without decreasing general well-being. SMBG has become a component of effective therapy.

However, patient-generated SMBG diary records are known to have more recording error compared with meter memory. A systematic review showed three types of recording error in patient diaries, which incorrectly recorded a value that had

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been measured (lack of concordance), failed to record a value that had been measured (under-reporting), and added a value to the diary that had not been measured (over-reporting) [3].

For appropriate SMBG, physicians can correctly identify glycemic abnormalities in SMBG data obtained through structured, episodic SMBG [4]. Collecting blood glucose level and showing it as a time-based graph would help doctors to see blood glucose control intuitionally. Data collection tools such as structured SMBG could help physicians.

OneTouch Diabetes Management Software (OTDMS) is designed to track and monitor the blood glucose level. OneTouch Ultra, via the meter's data port, which connects to a glucometer and computer, makes it possible to download data from a point-of-care testing device and transform the numbers of the blood glucose level into a graph, a chart, or statistics.

It shows all data of blood glucose level with marks of "low," "under control," and "high." It also shows daily variation of blood glucose level with line graph and proportion of "low," "under control," and "high" blood glucose level with a pie chart, as well as the distribution of blood glucose level and the proportion of "low," "under control," and "high" blood glucose level according to time variation.

The purpose of this study was to evaluate whether the use of OTDMS would improve patients' (1) knowledge of diabetes mellitus (DM), (2) compliance, (3) satisfaction with doctor and medical treatment, (4) doctor-patient reliability, and (5) glucose control.

METHODS

Patients

This study was conducted in a single center for diabetes education in Korea from August 2009 to October 2010. Patients who fulfilled the following criteria were included in the study: (1) the diagnosis of T2DM according to World Health Organization classification, (2) current treatment with oral hypoglycemic agent(s) for at least 3 months, and (3) willingness and ability to perform SMBG using OneTouch Ultra. Excluded were patients with a history of drug or alcohol abuse, impaired renal function with serum creatinine ≥1.7 mg/dL, cardiac disease (defined as decompensated heart failure [New York Heart Association classification III and IV], unstable angina pectoris, myocardial infarction within the last 12 months, or severe uncontrolled hypertension [systolic blood pressure when seated >180 mm Hg and/or diastolic blood pressure >110 mm Hg]), proliferative retinopathy and/or advanced neuropathy as judged by the investigator, experience and education using the OTDMS system twice or more, as well as those who were treated with any other drug known to affect blood glucose (i.e., monoamine oxidase inhibitors, β-adrenergic agents, anabolic steroids, and systemic glucocorticoids), were pregnant or breast-feeding, and had the intention to become pregnant. The study was approved by Institutional Review Board of Inje University Sanggye Paik Hospital. All patients provided written informed consent before participating in this study.

Study design

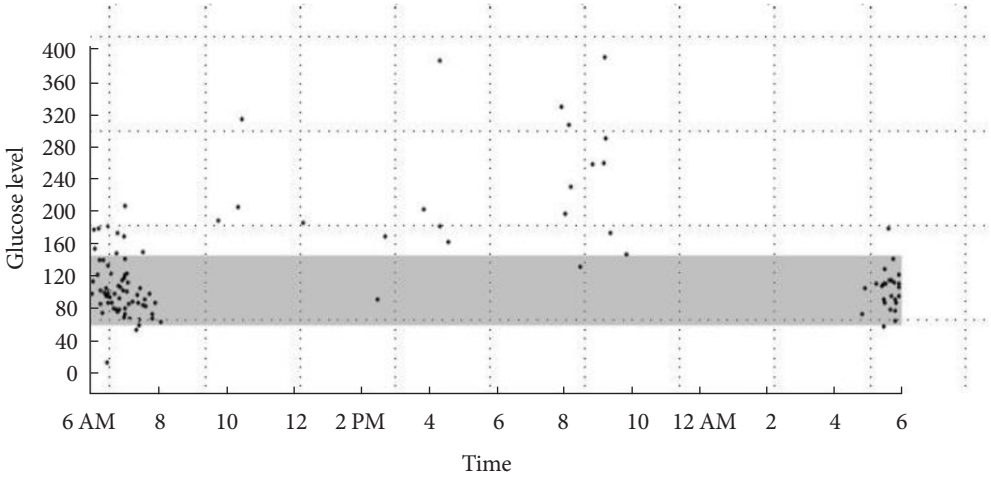
We considered the expansion of diabetes knowledge as the primary outcome. We also compared the changes in compliance for treatment, patient's satisfaction, doctor-patient reliability, HbA1c, and frequency of hypoglycemia as secondary outcomes.

A total of 121 patients with T2DM were randomly assigned into two groups: 63 patients were assigned into the OTDMS group and 58 patients were assigned into the control group. We applied repeated measure analysis of variance (ANOVA) for comparison of changes between the OTDMS and control group. We assumed effect size as 0.2, α error as 0.05, power as 0.8, and dropout as 0.2. We used G power to calculate sample size, and the necessary participants were 45 per each group.

We provided all patients conventional education and a home blood glucose meter that automatically transmits blood glucose data to the hospital. For patients in the OTDMS group, nurses provided an OTDMS's report sheet, which showed blood glucose level not only with numbers but also with bar and graph charts (Fig. 1). Doctors explained and educated using OTDMS's report during consultation hours only for patients in the OTDMS group. Patients in the control group also received conventional medical treatment and education without any supporting materials.

After enrollment, all patients visited the outpatient clinic at 1, 2, 3, and 6 months to evaluate vital signs, adverse events, and compliance. Doctors explained the OTDMS results every visit to patients in the OTDMS group. We tested HbA1c assays at enrollment, after 3 months, and after 6 months. We tested diabetes knowledge, compliance for treatment, doctor-patient reliability, and patient's satisfaction using a questionnaire at enrollment and after 6 months.

The diabetes knowledge test consists of 20 items and six additional items only for insulin users (Tables 1 and 2) [5]. The



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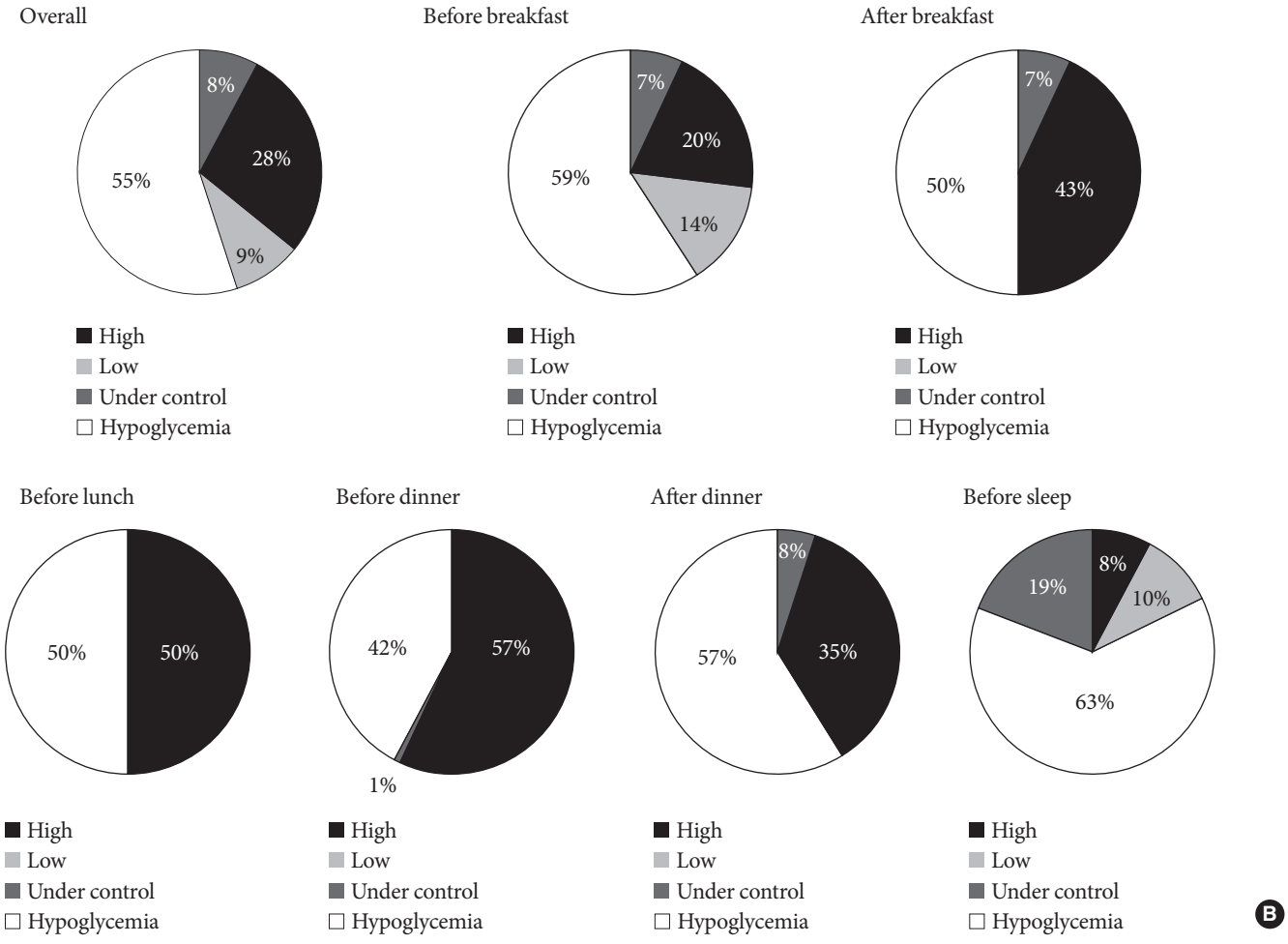

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Fig. 1. For patients in the OneTouch Diabetes Management Software group (OTDMS), nurses provided the report sheet of the OTDMS, which showed blood glucose level not only with numbers but also with bar and graph charts. (A) This graph shows glucose level according to time. (B) Pie chart shows how often a patient achieved the target glucose level.

Table 1. Diabetes knowledge tests given to patients at study enrollment

Test for all patients
1. Which organ makes insulin?
① Kidney ② Pancreas ③ Cardiac ④ Spleen ⑤ Don't know
2. Which is not the purpose of treatment for diabetes?
① Maintain normal blood glucose level ② Maintain current body weight
③ Maintain normal blood pressure ④ Maintain normal blood lipid
3. Which are not foods that diabetic patients can take freely?
① Black tea, green tea ② Cucumber, Chinese cabbage, lettuce
③ Seaweed, brown seaweed, kelp ④ Konjak, agar ⑤ Glucose-free juice
4. What is a symptom of low blood glucose?
① Thirstiness ② Often urination ③ Dried lips and skin
④ Shivering and cold sweating ⑤ Weight loss
5. How many days past does a glycosylated hemoglobin assay reflect?
① One day ② A week ③ 6–10 weeks ④ 6 months ⑤ Don't know
6. What will happen to insulin or diabetic medicine when you exercise regularly?
① Will increase ② Will decrease ③ Will not change ④ Don't know
7. What will happen to blood glucose level when diabetic patients have a virus?
① Will increase ② Will decrease ③ Will not change ④ Don't know
8. Which food contains the most carbohydrates?
① Fried chicken ② Cheese ③ Baked potato ④ Butter
9. What will happen to blood glucose level when you drink glucose-free fruit juice?
① Will increase ② Will decrease ③ Will not change ④ Don't know
10. What is the best treatment for low blood glucose?
① A half can of diet coke ② Cracker with cheese
③ Refined glucose or fruit juice (3/4 cup, 175 mL) ④ Don't know
11. Which activity does not cause low blood glucose?
① Eating between meals ② Having more activities than usual
③ Having no lunch ④ Don't know
12. What happens to the risk of blindness by diabetic eye disease when a diabetic patient manages blood glucose well?
① Increases ② Decreases ③ Does not change ④ Don't know
13. What is the cause of insensibility and numbness?
① Kidney disease ② Nervous system disease ③ Eye disease ④ Liver disease
14. How does the risk of having cardiac disease among diabetic patients compare with that among normal people?
① Increased ② Decreased ③ The same ④ Don't know
15. What do diabetes patients need to do for foot care?
① Sit with crossed legs to circulate blood to feet well
② Remove hardened skin with razor when there is an unpleasant odor
③ Clip toenail in a straight line
④ Use a corn plaster when there is a corn on the foot
16. What happens to the risk of having cardiac disease when blood cholesterol is high?
① Will increase ② Will decrease ③ Will not change ④ Don't know

(Continued to the next page)

Table 1. Continued

Test for all patients
17. What happens to the risk of having cardiac disease if LDL is high?
① Will increase ② Will decrease ③ Will not change ④ Don't know
18. How is the HDL level among diabetic patients generally?
① Increased ② Decreased ③ Unchanged ④ Don't know
19. What is the standard reference 2 hours after a meal to diagnose diabetes?
① 100 mg/dL ② 140 mg/dL ③ 200 mg/dL ④ 250 mg/dL ⑤ Don't know
20. What is the target of regulating glycosylated hemoglobin assays with diabetic patients?
① 7% or less ② 8% or less ③ 9% or less ④ 10% or less ⑤ Don't know
Test only for insulin users
1. How long does Lantus work after injection?
① 2 hours ② 6 hours ③ 12 hours ④ 24 hours ⑤ Don't know
2. What is the best answer about measuring blood glucose level among diabetic patients using insulin?
① Use blood glucose measuring instrument
② It shows blood glucose for latest hours
③ Measure blood glucose at least once a week
④ Don't know
3. Before lunch, you realize that you did not have your insulin injection before breakfast. What do you need to do?
① Skip lunch to decrease blood glucose
② Take the same insulin injection you were supposed to get before breakfast
③ Take twice as much insulin as you normally receive before breakfast
④ Measure blood glucose to determine the quantity of insulin to inject
4. What should you do when you find an unconscious diabetic patient who injected insulin?
① Keep the patient flat and call an ambulance
② Put honey into the patient's mouth and contact the patient's family
③ Let the patient get up and drink juice
④ Don't know
5. When do patients most likely have low blood glucose?
① With too much insulin ② With too little insulin
③ With too much food ④ With too little exercise
6. When do patients most likely have high blood glucose?
① Not enough insulin ② After skipping a meal ③ After having a late snack
④ There is too much ketone in the urine

LDL, low density lipoprotein; HDL, high density lipoprotein.

questionnaire for compliance for treatment and doctor-patient reliability includes three items each (Tables 3 and 4). The 10 cm of visual analog scale was used to determine patients' satisfaction with the doctor and medical treatment. Satisfaction score ranged from none to the most extreme satisfaction, without discrete jumps, such as categorizes of none, little, moderate, some, and very much.

Statistics

We expressed categorical variables with numbers and percentages and presented continuous variables with mean±standard deviation. We performed independent *t*-test and chi-square test to compare age, duration of diabetes, blood glucose profiles, body mass index (BMI), knowledge of diabetes, compliance, and satisfaction between the OTDMS and control

Table 2. Diabetes knowledge tests given after 6 months in the study

Test for all patients
1. What is the normal the blood glucose 2 hours after a meal?
① Less than 140 mg/dL ② Less than 200 mg/dL ③ Less than 250 mg/dL
④ Less than 300 mg/dL ⑤ Don't know
2. What is the normal range of glycosylated hemoglobin assays?
① 6% or less ② 7% ③ 8% ④ 9% ⑤ Don't know
3. What is the target of controlling blood pressure among diabetic patients?
① 130/80 mm Hg or less ② 140/90 mm Hg or less
③ 150/100 mm Hg or less ④ 160/110 mm Hg or less ⑤ Don't know
4. What is the risk of my children having diabetes if I have diabetes?
① Will increase ② Will decrease ③ Will not change ④ Don't know
5. What happens to blood glucose without insulin excretion?
① Increases ② Decreases ③ Does not change ④ Don't know
6. What is the best way to check blood glucose level?
① Urine test ② Blood test ③ Urine test and blood test ④ Don't know
7. What is the diet for diabetic patients?
① Common diets for normal people
② Recommended diets for normal people
③ More carbohydrate than normal diets
④ More protein than normal diets
8. Which of the following foods contain the most fat?
① Low-fat milk ② Orange juice ③ Corn ④ Honey
9. Which of the following foods can diabetic patients take freely?
① Sugar-free food
② Nutrient food
③ Food labeled "sugar-free"
④ Food with 20 Kcal or less per unit
10. What are common symptoms of hypoglycemia?
① Pale, shivering, cold sweat ② Thirst, increased urine
③ Decreased appetite, fever ④ Don't know
11. Which of the following is a symptom of ketoacidosis (acute complications caused by sever hyperglycemia)?
① Shivering ② Sweating ③ Vomiting ④ Low blood glucose ⑤ Don't know
12. If you take fat less, you can lower the risk of ( ).
① Nervous disease ② Kidney disease ③ Cardiac disease ④ Eye disease
13. Which of the following is not associated with diabetes mellitus?
① Eyesight problem ② Kidney problem ③ Nervous problem ④ Lung problem
14. What is the best method of foot management?
① Wash and observe everyday ② Rinse with alcohol everyday
③ Dip into water for 1 hour everyday ④ Put on bigger shoes
15. What happens to the risk of cardiac disease when blood pressure is managed well?
① Will increase ② Will decrease ③ Will not change ④ Don't know

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Table 2. Continued

Test for all patients
16. If HDL is high, what happens to the risk of cardiac disease?
① Will increase ② Will decrease ③ Will not change ④ Don't know
17. What happens to the risk of lowered HDL and increased LDL among diabetic patients?
① Will increase ② Will decrease ③ Will not change ④ Don't know
18. What will happen to the risk of cardiac disease when cholesterol is controlled well among diabetic patients?
① Will increase ② Will decrease ③ Will not change ④ Don't know
19. Which of the following statements is incorrect?
① Insulin is the only treatment for diabetes mellitus
② Sometimes, type 2 diabetes mellitus patients also need insulin treatment
③ Slight weight loss can be helpful for diabetes mellitus patients
④ If fasting blood glucose level is 210 mg/dL, it is abnormally high
20. Which of the following is correct?
① Diabetes mellitus has symptoms all of the time
② Diabetes mellitus can be cured
③ Aging is a risk factor for type 2 diabetes mellitus
④ The best way to examine the blood glucose is the urine test
Test only for insulin users
1. What is the reason for hypoglycemia?
① Less exercise than usual
② Increased meal amount
③ Over amount of insulin injection
④ Less intake of oral hypoglycemic agent than prescribed
⑤ Regular meal time
2. What should type 1 diabetic patients eat?
① Meals and snacks at regular times
② Healthy food that does not contain glucose
③ Anything in case of hunger
④ High-protein, low-fat foods
3. If you are injected with NPH insulin, when does the insulins peek effect show?
① 1–3 hours ② 6–12 hours ③ 12–15 hours ④ Over 15 hours
4. If you are suffering from the flu, what should you do?
① Inject less insulin ② Drink less water
③ Eat more protein ④ Undergo more examination on blood glucose and ketone levels
5. If you were injected with insulin in the morning but you did not have breakfast, What would happen to your blood glucose level?
① Would increase ② Would decrease ③ Would not change ④ Don't know
6. What do you need for management of diabetes mellitus?
① Food, insulin ② Food, exercise, insulin
③ Insulin, exercise ④ Don't know

HDL, high density lipoprotein; LDL, low density lipoprotein; NPH, neutral protamine Hagedorn.

Table 3. Questionnaire on compliance for the treatment

1. Do you visit the hospital on the scheduled day?
① Always ② Usually ③ Sometimes ④ No
2. How many times do you check your blood glucose in a week? _____ times/week
3. Do you take the medicine according to treatment guidance?
① Always ② Usually ③ Sometimes ④ No

Table 4. Questionnaire on doctor-patient reliability

1. Do you understand your doctor's order?
① Always ② Usually ③ Sometimes ④ No
2. Do you try to follow doctor's order?
① Always ② Usually ③ Sometimes ④ No
3. Do you follow doctor's order?
① Always ② Usually ③ Sometimes ④ No

Table 5. The characteristics of all patients in the study

Characteristic	OTDMS (n=42)	Control (n=50)	P value
Age, yr	56.36±8.32	56.94±11.94	0.784
Sex, male/female	20/22	22/28	0.728
Duration of DM, yr	6.75±2.89	5.98±2.87	0.238
Baseline HbA1c, %	8.95±1.69	8.67±1.74	0.430
After 6 months HbA1c, %	8.02±1.43	7.94±1.63	0.797
BMI, kg/m^2	24.90±2.84	24.92±4.11	0.973
Treatment			0.934
OHAs	18 (43)	21 (42)	
OHAs+insulin	24 (57)	29 (58)	

Values are presented as mean±standard deviation or number (%).
OTDMS, OneTouch Diabetes Management Software; DM, diabetes mellitus; HbA1c, glycosylated hemoglobin; BMI, body mass index; OHA, oral hypoglycemic agent.

Table 6. Results of the diabetes knowledge test

Maximum score=1/item	OTDMS		Control		P value
	Before	After	Before	After	
Overall knowledge	0.54±0.23	0.75±0.20	0.57±0.24	0.76±0.19	0.518
Complications of DM	0.73±0.29	0.62±0.19	0.77±0.21	0.60±0.20	0.884
Diet	0.25±0.21	0.49±0.34	0.35±0.24	0.48±0.33	0.341
The goal of DM management	0.30±0.26	0.43±0.30	0.29±0.23	0.43±0.26	0.901
Hypoglycemia	0.64±0.32	0.93±0.26	0.70±0.29	0.92±0.27	0.584
Total score (maximum score=20)	10.86±3.83	12.38±2.96	11.66±3.08	12.20±2.96	0.577

Values are presented as mean±standard deviation.
OTDMS, OneTouch Diabetes Management Software; DM, diabetes mellitus.

groups. We repeated ANOVA to compare difference of changes in knowledge, compliance, and reliability profiles between the OTDMS and control groups. We considered 0.05 as the two-sided statistical significance level. We performed statistical analysis using SPSS version 18.0 (SPSS Inc., Chicago, IL, USA).

For subgroup analysis, we split patients into four groups as follows: (A) patients in the OTDMS group with initial HbA1c <7.5%; (B) patients in OTDMS with initial HbA1c ≥7.5%; (C) patients in the control group with initial HbA1c <7.5%; and (D) patients in the control with initial HbA1c ≥7.5%. We used repeated ANOVA to compare the difference of changes in knowledge, compliance, reliability, satisfaction, and the level of HbA1c. In case of HbA1c, we also checked the groups for significant difference by testing pre- and post-comparison.

RESULTS

Baseline characteristics

In this study, we included 121 patients. Excluded were patients (total 29) who were under 20 years of age (n=3), and who had incomplete data in compliance (n=9), HbA1c (n=13), and BMI (n=4). In total, 92 patients completed this study 42 in OTDMS group and 50 in control group.

We compared baseline characteristics of all patients (Table 5). There was no significant difference in age, sex, duration of

Table 7. Results on compliance, reliability, and satisfaction with doctors

	OTDMS		Control		*P* value
	Before	After	Before	After	
Compliance	7.4±1.0	7.6±0.7	7.7±0.7	7.5±0.9	0.790
Do you visit the hospital on the scheduled day?	3.76±0.48	3.81±0.40	3.82±0.44	3.84±0.37	0.369
How many times do you check your blood glucose in a week? _____ times/week	1.33±2.58	4.02±2.91	1.80±4.11	3.34±2.66	<0.001
Do you take the medicine comply ing with treatment guidance?	3.62±0.62	3.79±0.42	3.84±0.42	3.68±0.57	0.867
Reliability	10.57±1.65	11.10±1.08	10.80±1.58	10.70±1.43	0.257
Do you understand doctor's order?	3.60±0.54	3.83±0.38	3.76±0.48	3.62±0.53	0.615
Do you try to follow doctor's order?	3.52±0.59	3.74±0.50	3.60±0.61	3.66±0.52	0.033
Do you follow doctor's order?	3.45±0.74	3.52±0.51	3.44±0.81	3.42±0.78	0.798
Satisfaction	6.50±2.37	7.64±2.07	6.46±2.87	7.76±2.14	0.928

Values are presented as mean±standard deviation.
OTDMS, OneTouch Diabetes Management Software.

diabetes, the level of HbA1c, BMI, and the type of treatment between the OTDMS and control groups. There was no significant difference in knowledge, compliance, reliability, and satisfaction. We also compared the pattern of medical prescription and the change of medical prescription during intervention. There was no significant difference between the OTDMS and control groups.

Comparison between the OTDMS and control groups

Both groups showed significant improvements in diabetes knowledge, compliance, reliability and satisfaction, and HbA1c during the study period (Tables 6 and 7). However, there were no significant differences between the OTDMS and control groups for the overall score. Only "compliance for the weekly frequency of checking blood glucose level" and "trying to follow doctor's order" showed significant difference. Patients in the OTDMS group showed greater increase in the frequency of checking blood glucose level from 1.33±2.58 to 4.02±2.91/week, whereas in the control group, the frequency changed from 1.80±4.11 to 3.34±2.66/week (P<0.001). "Trying to follow doctor's order" showed significant difference by intervention groups. Patients in the OTDMS groups showed greater increase from 3.52±0.59 to 3.74±0.50, whereas patients in the control group showed a slight increase from 3.60±0.61 to 3.66±0.52 (P= 0.033).

Comparison according to subgroups

We performed repeated ANOVA for the comparison of subgroups by intervention and initial HbA1c level. There was no significant difference of change in diabetes knowledge, compliance, reliability, and satisfaction. There was significant difference in the change of HbA1c as compared with the baseline (P=0.003) among the four subgroups. In detail, subgroups A and C showed slightly increased HbA1c levels, but these changes were not significant (A, from 6.90±0.53 to 7.24±0.86; B, from 9.51±1.44 to 8.23±1.49). Subgroups B and D showed decreased HbA1c levels, and these changes were significant (C, from 6.87±0.47 to 7.03±0.98; D, from 9.44±1.49 to 8.33±1.71). Therefore, we consider that the OTDMS system benefitted only patients with abnormally high glucose level as HbA1c ≥7.5%.

DISCUSSION

This study evaluated whether the use of OTDMS would improve patients' (1) knowledge of DM, (2) compliance, (3) satisfaction with the doctor and medical treatment, (4) doctor-patient reliability, and (5) glucose control. Both groups showed significant improvement in glucose control based on HbA1c at the end of the study. Patients also showed significant increase in diabetes knowledge, compliance, reliability, and satisfaction. However, there was no significant difference between the OTDMS group and the control group for overall

score. Only "compliance with the weekly frequency of checking blood glucose level" and "trying to follow doctor's order" showed significant difference.

The reasons for improvements in all patients regardless of intervention are not clear. We enrolled patients who agreed only. They could have had higher intention to control glucose compared with patients who did not participate. All participating patients received the usual diabetes education and a home blood glucose meter. These overlapping contents between OTDMS and control could weaken the difference. We consider that participation in the study itself would promote patients' knowledge, compliance, reliability, etc. Patients could learn or be stimulated through answering questionnaires. All participating patients also could gain satisfaction through experiencing processes such as the introduction, questionnaire, and feedback.

We conclude that there were no between-group differences for the following reasons: all patients improved; patients who chose to enroll in the study could have already had a higher intention to control blood glucose level, and all patients had the usual diabetes education and received a home blood glucose meter. Fortunately, these factors did not bias the results. Further, we did not hand over the means for patients to control blood glucose level independently. In this study, all patients received the usual medical treatment, and the doctors regulated medicine based on the laboratory results of blood glucose. In addition, the OTDMS system might not be as effective for overall management of blood glucose level in T2DM. In a 6-month randomized controlled trial, the effectiveness of a color-coded HbA1c-graphical record did not improve the HbA1c level among T2DM patients [6]. In other words, it did not improve metabolic control. Moreover, the intervention in this study could be insufficient to promote changes in score. Using a graph, the doctor elaborated on the blood glucose level. However, the consultation time was short, approximately 3 to 5 minutes per visit. This is the usual consultation time in an outpatient clinic in Korea. Consultation time was too short to give appropriate feedback to patients. Meanwhile, some interventions to feedback using computers or mobile devices have reported successes in Korea [7-9]. Appropriate feedback with sufficient time seems necessary for metabolic improvement. The doctor used only the OTDMS's report sheet and did not use other educational materials. The patients wanted to take steps to control their glucose levels so just showing the results may be insufficient.

Even if the OTDMS and control groups did not show significant difference of change in the overall score, we thought that the OTDMS showed some potential possibility to improve self-help in blood glucose control in T2DM. Patients in the OTDMS group showed better improvements in "compliance with the weekly frequency of checking blood glucose level" and "trying to follow doctor's order." First, there could have been better communication or more feedback in the OTDMS group. There is a possibility that the doctors spent more consultation time explaining the OTDMS results with the OTDMS group than they did with the control group. Although we did not measure the time, the difference is possible. The doctors explained the handwritten SMBG logs only when patients showed them to doctors in the control groups. These factors could have affected the results of "trying to follow doctor's order." Second, the OTDMS system could motivate patients to practice more self-management. Patients could understand more easily their own status of blood glucose control by using color marks, graphs, and charts. These could have prompted patients to check and follow the doctor's order.

Some studies about the clinical evaluation of computer-assisted SMBG system showed different results from ours [10,11]. One study found that both the experimental group and the control group had a significant drop in HbA1c during the study period; however, there were no between-group differences, which is similar to our study [10]. However, another study showed that the study group had better improvement of metabolic control compared with the control group [11]. Both studies showed that using the program had a positive effect on self-reported understanding of type 1 DM treatment, perceived importance of testing, the quality of interaction with the physician, patients' diabetes-related behaviors, patient satisfaction, and physician satisfaction [10,11]. These different results might be due to the difference of the study population [10,11]. There were some limitations in the design of our study. First, the sample size was small and follow-up duration was short. Second, the doctors knew which group the patients belonged to, which could have produced bias.

In conclusion, diabetes education was helpful to patients in both the OTDMS group and the control group. It was helpful to improve knowledge, compliance, reliability, and satisfaction. However, patients who used the OTDMS system did not show more improvements for overall score in comparison with the control group who received only conventional medical treatment and diabetes education. Patients received con-

sultation with the OTDMS's report sheet and showed significantly better change in "weekly frequency of checking blood glucose level" and "trying to follow doctor's order." Using the OTDMS system could be more helpful to improve self-help, especially for checking blood glucose level and trying to follow the doctor's order.

CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

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