

A Telephone-Delivered Intervention to Improve Glycemic Control in Type 2 Diabetic Patients

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This study was performed to investigate the effect of a telephone-delivered intervention on glycemic control and body mass index in Korean type 2 diabetic patients. 38 patients were randomly selected, with 20 assigned to a telephone group and 18 to a control group. The goal of the intervention was to keep blood glucose concentrations close to the normal range. The intervention was applied to the telephone group for 12 weeks. It consisted of continuous education and reinforcement of diet, exercise and medication adjustment, as well as frequent self-monitoring of blood glucose levels. Telephone intervention was performed twice per week for the first month, and then weekly for the second and third months. Subjects were requested to write self-management logs, including blood glucose, diet and an exercise diary. The diet diaries were analyzed by a dietitian, and subjects instructed about the results by telephone counseling or mail. All medication adjustments were communicated to the subjects' diabetes specialist. Glycosylated hemoglobin (HbA_{1c}), fasting blood glucose (FBG) and 2-hour postprandial glucose were measured before, and after, the intervention.

Patients in the telephone group had a mean decrease of 1.2%, with those in the control group having a mean increase of 0.6%, in HbA_{1c}. There were no significant differences in the body mass index (BMI) between the two groups.

These findings indicated that a telephone-delivered intervention would improve HbA_{1c}, but would not affect BMI.

Key Words: Telephone, glycemic control, type 2 diabetic patients

INTRODUCTION

Approximately 7.0% of the Korean population are likely to have diabetes,¹ and it is predicted that more than 10% of the Korean population will be afflicted with diabetes in the 21st century.² The United Kingdom Prospective Diabetes Study (UKPDS) data showed 9% of patients with type 2 diabetes develop microvascular disease, with 20% having a macrovascular complication within 9 years of diagnosis.³

The Diabetes Control and Complications Trial (DCCT)⁴ and the Kumamoto Study⁵ showed that a near-normal glycemic control reduces the development and progression of microvascular and neuropathic complication by approximately 50% in type 2 diabetes mellitus. Additional analyses⁶ have indicated that the therapy required to achieve near normalization of blood glucose levels is cost-effective in comparison with other treatments. The American Diabetes Association (ADA) has recommended that all persons with diabetes should attempt to achieve near normalization of blood glucose levels.⁷ Epidemiological analysis of the UKPDS data showed a continuous relationship between the risk of microvascular complications and hyperglycemia, such that, for every percentage point decrease in glycosylated hemoglobin (HbA_{1c}), there was a 35% reduction in the risk of a microvascular complication.³ The DCCT have shown for every 1% reduction in the HbA_{1c} value, there was a 40 to 50% reduction in the risk of microvascular and neuropathic complications.

Weight gain was disadvantaged with intensive blood glucose control. The risk of weight gain, particularly in patients treated with insulin, is

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perceived by patients as a difficulty that limits their ability to achieve improved glucose control.³ The DCCT also reported on the consequences of weight gain associated with intensive management.⁴

However, many Korean diabetic patients do not adhere to health regimens well, with the exception of three or four visits to a physician per year.⁸ Algorithms exist for diabetes care, but are complex and difficult for physicians to follow, given patient load, diversity of patients seen, lack of information systems and time constraints. Therefore, low-cost methods are required.⁹ Several research studies have shown that the use of various telemedicine approaches have had a positive impact on patient blood glucose control, and that over the long term these approaches will result in the reduction or elimination of diabetes mellitus related complications.¹⁰ Telephone care programs especially are a viable strategy for bringing diabetes management services into patients' homes and improving their glycemic control.⁹

The present study evaluated that a telephone-delivered intervention would improve glycemic control and body mass index (BMI) with type 2 diabetes mellitus in a randomized controlled trial.

MATERIALS AND METHODS

A randomized comparison experimental design of pre and post-test groups was used to assess the effectiveness of a telephone-delivered intervention on the HbA_{1c} and BMI in type 2 diabetic patients.

Subjects

Participants were recruited from the endocrinology outpatient department of a tertiary care hospital located in an urban city of South Korea. The hospital in question is a university-affiliated medical center with 800 beds. The data was collected between October 2000 and March 2001. Diabetes was diagnosed according to the ADA criteria.¹¹ The selection criteria dictated that subjects should be able to perform blood glucose self-testing and self-injection of medication, and understand the goals, methods and procedures.

Patients were excluded if they had < 7% HbA_{1c}, were mentally ill, and had severe cardiovascular diseases or uncontrolled hypertension. A total of 50 patients met these criteria and agreed to participate. They were randomized by a toss of a coin, and assigned to one of two groups, either telephone (n=25) or control (n=25). Only 38 subjects completed the entire study, 20 telephone and 18 control. Of the 12 subjects not completing the study, 2 moved to another city and 10 dropped out before completing the post-test.

The demographic and clinical characteristics are presented in Table 1. The age range was between 45 to 73 years, and there was no significant difference between the control and telephone groups for any of the demographic or clinical characteristics.

Description of intervention

For the control group, routine care (visiting a physician every 3 months) was given. The goal of the telephone-delivered intervention was to improve the blood glucose level. The target blood glucose values for the telephone-delivered intervention group (telephone group) were as follows: (1) HbA_{1c} < 7%, (2) fasting blood glucose (FBG) < 120 mg/dl and (3) 2-hour postprandial glucose < 160 mg/dl. Before the intervention, the diabetic care booklet and a daily log, developed by the researchers, were offered to each patient who were given 30 minutes instruction on their use by a researcher. The booklet was 49 pages in length and was offered free of charge to the telephone group. It contained the nature of the disease, risk factors, diet therapy, exercise, drug therapy, hypoglycemia management, sick day management, and how to record a daily log.

Telephone intervention was provided to the telephone group by one of the researchers for a period of 12 weeks. This consisted of continuous education and reinforcement of diet, exercise and medication adjustment, as well as frequent self-monitoring of blood glucose levels. The telephone group was required to log blood glucose levels more than twice a day, and to keep daily diet and exercise logs. A researcher contacted the telephone group at least twice a week for the first month, and then weekly for the second and third

Table 1. Socio-demographic and Clinical Characteristics of Study Participants at Enrollment

Characteristics	Telephone(N=25)	Control(N=25)	t or χ^2	p
Age (years)	59.2 \pm 7.2	62.0 \pm 5.7	1.53	0.133
Gender			0.00	1.000
Male	9 (36.0)	9 (36.0)		
Female	16 (64.0)	16 (64.0)		
Education level				0.395
Less than middle school	10 (40.0)	13 (52.0)	0.73	
More than high school	15 (60.0)	12 (48.0)		
Job			0.14	0.709
Yes	10 (40.0)	8 (34.8)		
No	15 (60.0)	15 (65.2)		
Smoking				0.710*
Yes	5 (20.0)	3 (14.3)		
No	20 (80.0)	18 (85.7)		
Drinking			3.72	0.054
Yes	10 (40.0)	3 (14.3)		
No	15 (60.0)	18 (85.7)		
Duration of diabetes (month)	158.1 \pm 99.3	162.4 \pm 83.5	0.16	0.871
Diabetes family				
Yes	12 (48.0)	13 (61.9)	0.89	0.346
No	13 (52.0)	8 (38.1)		
Drug				1.000*
None	1 (4.0)	0 (0.0)		
OHA	15 (60.0)	14 (56.0)		
Insulin	7 (28.0)	8 (32.0)		
OHA+Insulin	2 (8.0)	3 (12.0)		
HbA _{1c} (%)	8.8 \pm 1.1	8.3 \pm 0.9	1.87	0.068
FBG (mg/dl)	178.0 \pm 54.2	171.8 \pm 54.9	0.40	0.689
PP2h (mg/dl)	309.6 \pm 95.9	278.3 \pm 63.1	1.32	0.192
BMI (kg/m ²)	24.6 \pm 2.6	24.4 \pm 2.6	0.21	0.838

Data are Mean \pm SD or N (%).

OHA, Oral hypoglycemic agent; PP2h, 2-hour postprandial blood glucose.

*Fisher's exact test.

months. The total frequency of telephone counseling averaged sixteen times per subject. The duration of each counseling session lasted, on average, twenty-five minutes. A registered dietitian analyzed subjects' daily calorific intake, and made appropriate recommendations for diabetic

dietary control, based on the subjects' diet and exercise patterns. Following this, the analyzed results and dietary recommendations were mailed to the subjects. The researcher would adjust medications after reviewing the blood glucose log and discussing the glucose values with the patients.

All medication adjustments were communicated to the subjects' diabetes specialist.

Procedures and measures

The study was approved by the Medical Research Ethics Committee of the university hospital. Verbal consents were obtained from those who agreed to participate in this study. Before the telephone-delivered intervention, demographic features, body weight and height for BMI, HbA_{1c}, FBG and 2-hour postprandial glucose were measured as pre-test data. The telephone intervention was provided to the telephone group by one of the researchers for a period of 12 weeks, with the counseling appointments being scheduled based for the subjects convenience. HbA_{1c}, FBG, 2-hour postprandial glucose and BMI were measured 12 weeks following the acquisition of the baseline post-test data.

HbA_{1c} was determined by a high-performance liquid chromatography technique employing a Variant II (Bio-Rad, Hercules, California, USA). FBG and 2-hour postprandial glucose were analyzed by the glucose oxidase method using an HITACHI 7600 (Hitachi, Hitachi, Japan). BMI was calculated as weight (kilograms) per height (meters squared).

Statistical analysis

The data was analyzed by the SAS program.

The χ^2 -, t- and Fisher's exact tests were used to test for the homogeneity of the demographic and clinical characteristics between the two groups. The paired t-test was used for comparison of differences between the pre- and post-test values in each group. The independent two-sample test was used for comparing the differences between the two groups before and after the intervention.

RESULTS

Glycemic control

From the pre-tests, no significant differences were found in the HbA_{1c}, FBG, and 2-hour postprandial glucose in the two groups. The telephone group had greater decreases in HbA_{1c} values than in the controls ($t=4.87$, $p=0.000$). The average change in the HbA_{1c} values were -1.2% (7.7% at post-test minus 8.9% at pre-test) ($t=3.72$, $p=0.002$) and 0.6% (9.0% at post-test minus 8.4% at pre-test) ($t=3.25$, $p=0.005$) in the telephone and the control groups, respectively (Fig. 1). Patients in the telephone group had a mean decrease of 15.7 mg/dl in their FBG level compared with a decrease of 6.9 mg/dl in the controls, but there were no statistical differences (Fig. 2). Patients in the telephone group had a mean decrease of 42.6 mg/dl in 2-hour postprandial glucose compared with an increase of 19.6 mg/dl in the controls, and again there were no statistical differences (Fig. 3) (Table 2).

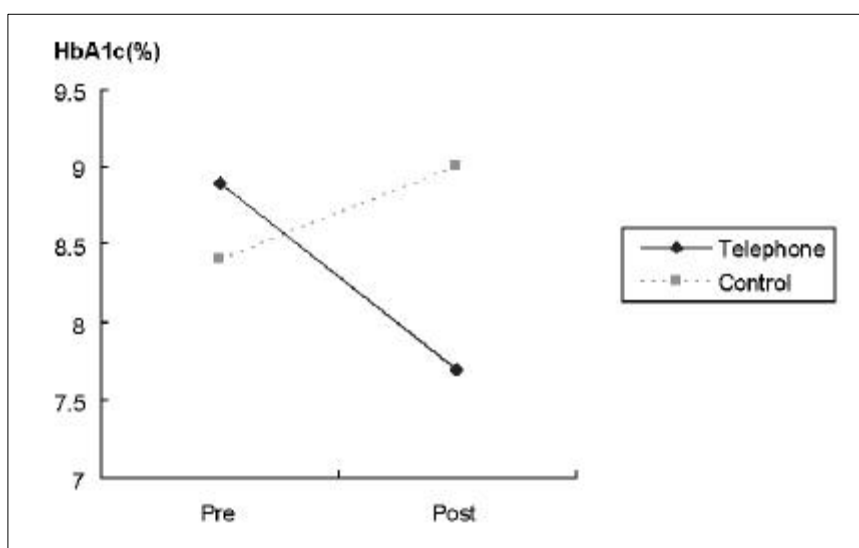


Fig. 1. Mean change in level of HbA_{1c}.

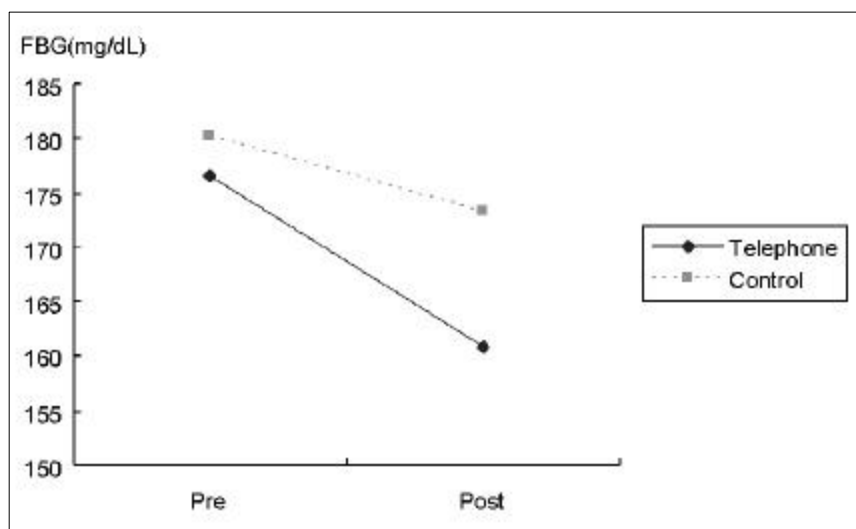


Fig. 2. Mean change in level of FBG.

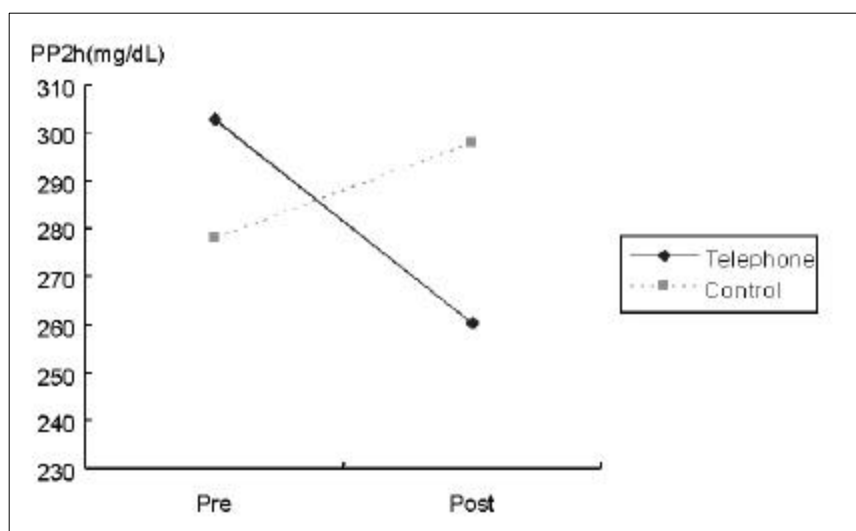


Fig. 3. Mean change in level of PP2h.

BMI

No significant differences were found in the BMI between the two groups in the pre-tests. Patients in the telephone group had an increase of 0.3 kg/m^2 in their BMI compared with an increase of 0.2 kg/m^2 in the controls, but there were no statistical differences between the two groups (Fig. 4) (Table 2).

DISCUSSION

The relationship between HbA_{1c} and the risk of developing microvascular complications has been convincingly demonstrated in the DCCT,⁴ and

confirmed in type 2 diabetes by the UKPDS.³ As a result, they showed that a near-normal glycemic control reduces the development and progression of microvascular and neuropathic complications.

This study was performed to see if a telephone-delivered intervention would improve the HbA_{1c} and BMI in patients with type 2 diabetes mellitus in a randomized controlled trial. In this randomized controlled trial, the HbA_{1c} decreased 1.2 percentage points in the telephone group after a period of 12 weeks. Recently, Piette et al.¹² demonstrated that patients in an automated telephone disease management system, with a telephone nurse group, resulted in the decrease of HbA_{1c} values over the 1-year study period. The type 2

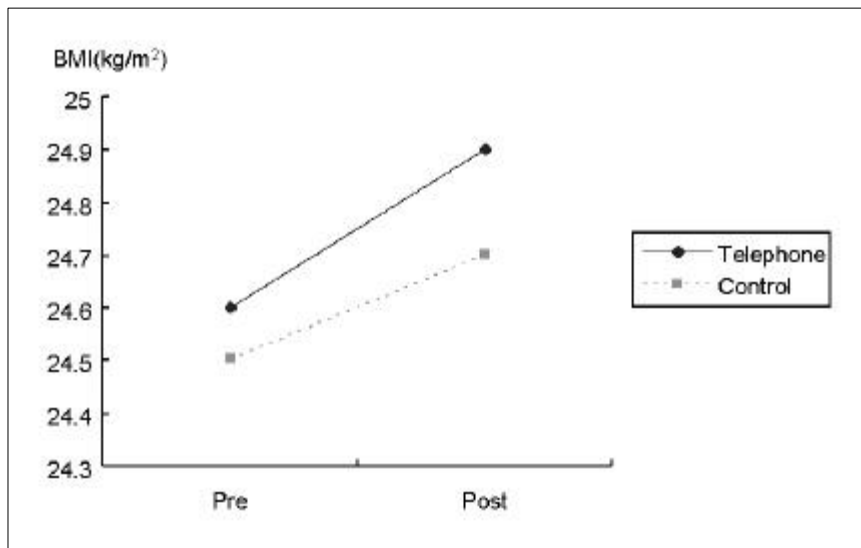


Fig. 4. Mean change in level of BMI.

Table 2. Effect of the Intervention on Glycemic Control and BMI

	Pre-test	Post-test	t ^a	p	Difference (Post-test)-(Pre-test)	t ^b	p
HbA _{1c} (%)							
Telephone	8.9 ± 1.2	7.7 ± 1.0	3.72	0.002	-1.2 ± 1.5	4.87	0.000
Control	8.4 ± 1.0	9.0 ± 1.2	3.25	0.005	0.6 ± 0.9		
FBG (mg/dl)							
Telephone	176.6 ± 56.0	160.9 ± 56.8	1.35	0.193	-15.7 ± 52.0	0.45	0.245
Control	180.2 ± 62.4	173.3 ± 53.4	0.43	0.675	-6.9 ± 68.5		
PP2h (mg/dl)							
Telephone	302.8 ± 94.0	260.2 ± 76.6	1.66	0.114	-42.6 ± 114.8	1.86	0.071
Control	278.0 ± 71.7	297.6 ± 89.1	1.04	0.315	19.6 ± 75.3		
BMI (kg/m ²)							
Telephone	24.6 ± 2.8	24.9 ± 2.8	1.94	0.068	0.3 ± 0.6	0.52	0.607
Control	24.5 ± 2.6	24.7 ± 2.6	1.13	0.278	0.2 ± 0.6		

Data are Mean ± SD. Telephone group (N=20), Control group (N=18).

PP2h, 2-hour postprandial blood glucose.

^apaired t-test.

^bindependent two-sample test.

diabetic patients in the nurse case management group had a mean decrease of 1.7 percentage points in the HbA_{1c} during the 12 month study period.⁹ An electronic case manager for diabetes control decreased the HbA_{1c} by 0.8 and 0.9 percentage points at 6 and 12 months, respectively.¹³

These results confirm that the use of various telemedicine approaches have a positive impact on patient HbA_{1c} control. It is believed that a telephone-delivered intervention, over a 12 week period, would improve the HbA_{1c}.

In this study, patients in the telephone group

had a mean decrease of 15.7 mg/dl in FBG levels compared with a decrease of 6.9 mg/dl in the controls, but there were no statistical differences. Most of the patients could not reach below 120 mg/dl of the target FBG. Continuous follow-up care is required for patients who could not get a target FBG value, which was suggested by the report of Pettitt et al.¹⁴ who found that the risk of microvascular complications were increased in patients with FBG concentration above 140 mg/dl. Balkau et al.¹⁵ has also shown an increased risk of cardiovascular disease with concentrations of FBG just above the normal range.

Patients in the telephone group had a decrease of 42.6 mg/dl in 2-hour postprandial glucose compared with an increase of 19.6 mg/dl in the controls, but there were no statistical differences in this study. Postprandial hyperglycemia has been associated with increased risk of microvascular and macrovascular complication. Hanefeld et al.¹⁶ found that postprandial glucose was an independent risk factor for mortality in patients with newly diagnosed type 2 diabetes. Although the 2-hour postprandial glucose level of the telephone group tended to decrease after intensive therapy, it was still above the target 2-hour postprandial glucose level. The causes of 2-hour postprandial hyperglycemia in this study are as follows: firstly, most patients did not know the importance of keeping a normal postprandial blood glucose. Secondly, in self-monitoring of blood glucose, patients usually tested fasting blood glucose, especially pre-breakfast blood glucose. Patients reported that they frequently failed to check 2-hour postprandial blood glucose, especially within a work environment or if going out. The postprandial glucose of the control group showed an increasing nature, therefore, the exposure of the control group to postprandial hyperglycemia was a severe problem. It must be emphasized that health care-givers educate the patients on the importance of maintaining target postprandial glucose.

The DCCT⁴ reported the adverse consequences associated with intensive management, such as weight gain. Our results reported that patients in the telephone group had a mean increase of 0.3 kg/m² in their BMI compared with 0.2 kg/m² in the controls, but there were no statistical dif-

ferences. These results were similar to those of Aubert et al.⁹ and Ohkubo et al.,⁵ who found no statistical significant differences in weight gain between intensively and conventionally insulin treated lean patients with type 2 diabetes.

Of the 12 subjects not completing the study, 2 moved to other cities and 10 dropped out prior to completing the post-tests. The dropped subjects were all employed men. The telephone-delivered intervention was found to improve glycemic control. However, telephone-delivered intervention is limited, especially by time convenience and location of the recipient. Therefore, internet-based systems are often more acceptable and accessible for these patients.

In conclusion, a near-normal glycemic control, delivered by telephone would improve HbA_{1c}, but would not significantly affect BMI.

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