Impact of Self-Monitoring of Blood Glucose on the Lifestyles of Subjects with Fasting Hyperglycemia: A Randomized Controlled Trial

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Abstract: Impact of Self-Monitoring of Blood Glucose on the Lifestyles of Subjects with Fasting Hyperglycemia: A Randomized Controlled Trial: Yasumitsu Takata, et al. Health service station, Home Appliance & Housing Electronics Company of Matsushita Electric Industrial Co., Ltd.—The effect of self-monitoring of blood glucose on its level and the lifestyle of male workers with fasting hyperglycemia was studied. Male workers with fasting plasma glucose levels between 6.1 and 7.7 mmol/l were selected for subjects from those who had been followed up as a high-risk group for diabetes mellitus and volunteered for the trial. A total of 247 subjects were then randomized into control and intervention groups. In the intervention group, the participants were encouraged to monitor fasting blood glucose, check their body weight, and take a daily pedometer reading once a week regularly for 5 months. Fasting plasma glucose and HbA1c were examined at the beginning and the end of the trial. There was no significant change in the fasting plasma glucose level, but there was a statistically significant increase in the HbA1c level (0.1 and 0.2%; p=0.0076) and a decrease in BMI (0.6 and 0.2 kg/m²; p=0.0001) for the intervention and control group, respectively. The effect of intervention on the number of subjects who improved their HbA1c levels (Relative Risk: 6.08 and 95% Confidence Interval: 2.13–17.34) was found to be significant. The subjects in both groups reported a decrease in total energy intake and those in the intervention group achieved an increase in physical activity. Self-monitoring of blood glucose, together with measuring of body weight and walking-steps, helped the subjects make changes in lifestyle toward achieving a reduction in their weight. Accordingly, this method is promising for preventing persons with fasting hyperglycemia from developing diabetes mellitus.

(J Occup Health 2002; 44: 28–33)

Key words: Self-monitoring of blood glucose, Type II diabetes mellitus, Life style intervention, Fasting hyperglycemia

Diabetes mellitus and its complications have become one of the major health problems both in advanced and developing countries. Several studies have shown that lifestyle change toward proper diet and physical exercise is essential to prevent type 2 diabetes mellitus¹ ²). The efficacy of oral medicines for preventing diabetes has also been studied³–⁵). Several well-designed studies on non-pharmacological treatments have already been conducted or started. However they have typically required at least a couple of years and many specialists⁶–¹⁰). Because the target to change is individual lifestyle, self-awareness of inappropriate habits is most important for the subjects. Self-monitoring of blood glucose is now commonly used for diabetes care and it is especially recommended for patients with insulin treatment¹¹). Proponents consider it helpful in achieving and maintaining near-normal blood glucose levels, providing feedback to the health care provider and the patient on therapeutic effectiveness. We believed that this method could urge asymptomatic subjects with a high risk for diabetes mellitus to become aware of and more careful in their habits. We selected subjects with sustained fasting-hyperglycemia and conducted a randomized controlled trial on self-monitoring of blood glucose. We also tried to make a practical program for the prevention of diabetes mellitus as one of the health care activities suitable for workplaces¹²).
which middle-aged male workers with fasting hyperglycemia were subjected and randomized to evaluate the effect of self-monitoring of blood glucose on their glucose and glycosylated hemoglobin A1c (HbA1c) levels along with the educational effect on their lifestyles. The sample size was determined by power analysis to see a decrease of 0.6 mmol/l in the fasting plasma glucose (FPG) level or to see a difference in the number of the population in which blood glucose levels were improved. The minimum size of the population was 121 subjects each for the control and intervention groups.

The study was carried out with the approval of the Matsushita Health Care Organization Ethics Committee. Thirty-eight local health service stations in the workplaces of Matsushita Corporate Group located in various parts of Japan, where one or more full-time occupational physicians and nurses were in attendance, agreed to collaborate in this study. Under a policy set down in 1986, all workers at age of 40 or older in this corporate group received support for an annual health check, including an FPG examination. Workers who had high FPG (>6.1 mmol/l) twice within a year were instructed to undergo a 75 g oral-glucose-tolerance test. Those with diabetic or borderline patterns in the test are defined as a high-risk population according to the '82 Japan Diabetes Society criteria. The subjects had at least 6.1 mmol/l FPG, at least 8.9 mmol/l plasma glucose at 1 h, or at least 6.7 mmol/l plasma glucose at 2 h in the test. Their FPG and HbA1c levels were monitored once every 6 months. They were also educated by occupational nurses and physicians at health service stations in their workplaces for primary or secondary prevention of diabetes mellitus. The study started in September 1999 and ended in May 2000. The self-monitoring period was from November 1999 to April 2000.

**Inclusion and exclusion criteria**

Subjects were selected from among male workers whose recent two FPG levels were between 6.1 and 7.7 mmol/l and who volunteered for the trial. The following persons were excluded as subjects before entry: females, persons medicated for diabetes mellitus or who had been self-monitoring their blood glucose, persons with any chronic heart, cerebral or vascular diseases, persons with gastrectomy, persons unable to exercise, and persons disqualified by the occupational physician in charge. The physician reconfirmed the physical status of the subjects before the trial and received their informed consent. A total of 380 eligible subjects were randomly divided into two groups (190 each for control group and intervention group) at the Matsushita Health Care Center. After entry, those subjects whose FPG levels were between 6.1 and 7.7 mmol/l were further selected for the analysis.

**Intervention program**

Control group. All the following activities were done at the local health service stations. At the beginning and the end of the trial, blood samples were taken from subjects, and nutritionists gave them face to face inquiries to calculate total calorie intake and energy balance by employing a questionnaire on 94 items and food models (Top Business System, Okayama). Furthermore, occupational nurses and physicians advised each subject to adjust total energy intake and nutritional balance based on the calculated data and suggested how to reduce risk factors to prevent diabetes. Dietary advice and information on diabetes mellitus were provided both verbally and in a written brochure. Each subject was then instructed to make one or more plans to change his lifestyle. A questionnaire on individual lifestyle was also collected before and at the end of the study. Three visits to the health service station were made mandatory: one visit for blood sampling and two other 30-min visits either for checking the diet-intake or medical advice, at the beginning and the end of the study for both control and intervention groups.

After the exclusions, the data from 126 men were analyzed for the control group. Among 190 men enrolled in the trial, 53 were not included because they did not meet the protocol criteria on FPG, and eleven more men failed to correctly fill in the study forms required or failed to complete the visits at the end of the study.

Intervention group. Diet advice and information on diabetes were given to the subjects in the same way as for the control group. At the start of the trial, the occupational nurse in charge explained to them how to check blood glucose at home. The subjects were provided with a pedometer, a home blood-glucose-monitor, and test strips (Hoechst Marion Roussel, Tokyo). They were instructed to check their fasting blood glucose level before breakfast, together with body weight, and average pedometer reading once a week for five months. They were also instructed to send the data to the ad hoc computer system at the Matsushita Health Care Center by telephone. These instructions were done on the third visit and an additional 30-min was allocated compared to that for the control subjects. During the study, two physicians in the Center checked the reported data and sent back the data with short comments to the subjects every month.

After the exclusions, 121 men were eligible for the analysis of the intervention group. Among 190 men enrolled in the trial, 187 successfully conducted self-blood glucose measurements throughout the trial period. Fifty-two subjects were not included because the protocol criteria on FPG were not met, and 14 failed to correctly fill in the study forms as required or failed to complete the visits at the end of study.

Examinations. All subjects had an annual health check done, including a 12-lead resting ECG, before the trial.
Blood samples were collected both at the beginning and the end of the trial in the early morning after an overnight fast. The samples were then assayed at the SRL laboratory (Kita-Osaka, Osaka). Plasma glucose and HbA1c were determined by enzyme assay and high-performance liquid chromatography, respectively. Body weight and percent body-fat were measured in light clothing without shoes by a bio-impedance device (National DMW1, Yamatokoriyama, Nara) at the health service station. BMI was expressed as weight in kilograms divided by height in meters squared. All data phoned-in were analyzed at Matsushita Health Care Center.

Statistical analysis

All data are expressed as the mean ± SD. Analysis of baseline characteristics was done with the chi-square test for independence. The paired t-test and Wilcoxon 2-sample test were employed to analyze the difference within each group and between the groups, respectively. The correlation coefficient was determined by Spearman’s correlation coefficient by rank. The effect of the intervention on the change in either the plasma glucose level or HbA1c level were examined by the Mantel-Haenszel method after adjusting baseline age and BMI for the subjects. SAS statistical software (Cary, NC) was employed for the analyses.

Results

This paper shows results for the subjects whose FPG levels at the beginning of the trial were between 6.1 and 7.7 mmol/l. At baseline, statistically insignificant factors in both groups included age, average duration of follow-up as a high risk for diabetes, FPG concentration, HbA1c level, body weight, percent fat value, total energy intake, and other lifestyle variables (Table 1). Obese subjects with BMI higher than 25 accounted for 38% and 47% of subjects in the intervention and control groups, respectively, and there was no significant difference between these percentages (p=0.162). The prevalence of family history in the first and/or second degree of relatives was comparable at 29 and 30% in the intervention and control, respectively. Subjects with a relatively high glucose level (FPG ≥ 7 mmol/l) who might have diabetes was 3.3 and 2.4% in both groups (data not shown). The subjects in the intervention group continued to report their FPG data for three months (n=7), four months (n=10), and five months (n=104). After the trial, the FPG level remained unchanged and the HbA1c level was found to have increased slightly compared with the initial value in both groups. Mean BMI significantly decreased in both groups, whereas percent-fat value decreased only in the intervention group. There was a weak but significant correlation between the changes in BMI and basal FPG levels in the intervention group (Fig 1). In both groups, total energy intake was lower after the trial than at the baseline. This was mostly a reflection of decrease in carbohydrate intake in both groups (data not shown). The subjects in the intervention group were encouraged to do more exercise, and walking longer while commuting than they did before the trial. The decrease in calorie intake from alcohol was 13% in the intervention group and 2% in the control (data not shown).

<table>
<thead>
<tr>
<th>Variable</th>
<th>Intervention Group (n=121)</th>
<th>Control Group (n=126)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline  5 months</td>
<td>Baseline  5 months</td>
</tr>
<tr>
<td>Age (yr)</td>
<td>51 ± 5</td>
<td>52 ± 5</td>
</tr>
<tr>
<td>Duration (yr)</td>
<td>5.9 ± 5.0</td>
<td>5.7 ± 5.2</td>
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<tr>
<td>FPG (mmol/l)</td>
<td>6.8 ± 0.4</td>
<td>6.8 ± 0.4</td>
</tr>
<tr>
<td>HbA1c (%)</td>
<td>5.7 ± 0.5</td>
<td>5.6 ± 0.5</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>68.7 ± 8.0</td>
<td>67.0 ± 7.63</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>24.4 ± 2.6</td>
<td>24.8 ± 2.7</td>
</tr>
<tr>
<td>% FAT</td>
<td>25.4 ± 7.7</td>
<td>24.7 ± 6.8</td>
</tr>
<tr>
<td>Energy intake (kcal/d)</td>
<td>2101 ± 466</td>
<td>1860 ± 343§</td>
</tr>
<tr>
<td>Weight measurement</td>
<td>67%</td>
<td>76%</td>
</tr>
<tr>
<td>Wearing pedometer</td>
<td>22%</td>
<td>22%</td>
</tr>
<tr>
<td>Alcohol-drinking (d/w)</td>
<td>4.7 ± 2.7</td>
<td>4.5 ± 2.7</td>
</tr>
<tr>
<td>Exercise† (d/M)</td>
<td>6.8 ± 9.7</td>
<td>6.1 ± 8.4</td>
</tr>
<tr>
<td>Walking time‡ (min/d)</td>
<td>23 ± 18</td>
<td>26 ± 21</td>
</tr>
</tbody>
</table>

*Number of days doing exercise (including walking) more than 20 min/d. †Total walking time while commuting. Normal HbA1c value is 4.3–5.8%. §p<0.05, ‡p<0.01 vs. baseline value.
The degree of changes in FPG, HbA1c and BMI in both groups was examined (Table 2). There was a significant change in HbA1c and BMI but not in the FPG level between the two groups. The decrease in BMI was 3.6 times greater in the intervention group than in the control. In addition, the number of subjects who had decreased HbA1c levels was significantly larger in the intervention group than in the control although the intervention had no effect on the FPG level (Table 3). The effect of intervention on the decrease in the HbA1c level was six times as great as in the control.

**Discussion**

By monitoring blood glucose levels, subjects with fasting hyperglycemia could obtain immediate feedback of the effect of their eating and exercise patterns on glucose control. Furthermore, the subjects in the intervention group reported the measured FPG, body weight and walking steps by telephone once a week and received written advice once a month to reconfirm their results. These two patterns of feedback were considered to help subjects notice their increased FPG levels and
reinforce efforts to make changes in lifestyle to reduce their body weight or increase their physical activity (Table 1 and Fig. 1). Although self-monitoring of blood glucose level has become common in the management of patients treated with insulin and pregnant diabetes, there has been no report on the application of this technique to subjects with fasting hyperglycemia, i.e., pre-diabetes. This pilot study found evidence that combining self-monitoring of blood glucose with a conventional educational program including diet advice, monitoring body weight and walking steps was highly effective in reducing weight. Thus far, self-management training has been shown to be effective particularly in the short-term as in this study. Further long-term observation would be needed to confirm the effectiveness on sustained glycemic control, other cardiovascular disease risk factors, and ultimately quality of life.

The significant reduction in BMI was unexpected because we did not recommend body weight reduction to all of the subjects, although we showed them the optimum BMI and total calorie intake before the trial and later in the letters sent every month. There is clear evidence that weight loss and dietary modification can normalize carbohydrate metabolism in those diagnosed as having type 2 diabetes. Accordingly, the observed weight reduction was considered useful for preventing those with fasting-hyperglycemia from developing type 2 diabetes mellitus in the future. In the obese subjects, more than 4% weight loss in 12 yr was reported to reduce the risk and the substantial weight gain (>10%) to increase the risk of type 2 diabetes. Moreover, Perry et al. showed that BMI was the dominant risk factor for diabetes by showing a linear relationship between BMI and the incidence of type 2 diabetes. The linear negative relation between changes in body weight and changes in insulin-stimulated glucose disposal, i.e., insulin sensitivity, was also reported in subjects with normal and impaired glucose tolerance, suggesting that significant weight reduction was most important factor for preventing type 2 diabetes. Therefore, the greater the reduction in body weight, the more beneficial would be effect anticipated in the amelioration of insulin resistance and prevention or delaying the onset of type 2 diabetes.

The unchanged FPG level in this study may be attributed to the following reasons. Most of the subjects had already received enough education on preventing diabetes because they had been followed up for 6 yr as a high-risk group. Therefore, the impact of this education program might not be as strong as expected. The second reason was their relatively low levels of fasting glucose, so the change in the monitored value was not large enough to alert the subjects. We monitored the HbA1c level to avoid the risk of overlooking continuously high postprandial glucose, and we observed a gradual increase in this value in both groups. To suppress the blood glucose level, monitoring the postprandial glucose level was considered necessary, as was suggested for patients with diabetes. Obese diabetic individuals were more likely to satisfy the fasting criterion, whereas non-obese diabetic individuals were more likely to satisfy the 2-h criterion for 75 g OGTT. If this was also true for the subjects with a pre-diabetic state, most of these subjects, whose average BMI was less than 25 kg/m² in this study, might develop postprandial hyperglycemia before experiencing an increase in their fasting glucose levels.

In summary, we observed that self-monitoring of blood glucose helped the subjects reduce their body weight and may contribute to ameliorating HbA1c levels in 5 months. Further long-term observation and modification of the methods will be necessary to confirm the beneficial effect of self-monitoring blood glucose on the prevention of diabetes.

Acknowledgments: This study was partly supported by the Ministry of Health and Welfare of Japan and Matsushita Electric Industrial Co., Ltd. We would like to thank Dohi Yuji and Toshikiko Yoshioka of the Health Care Development Office of Matsushita Electric Industrial Co., Ltd., for their technical support and management of the telecommunication and host computer system in the Center. We also thank Mariko Samejima, Harumi Kurita, and Sachiko Arinishi for their devoted assistance. We would like to express our thanks to all of the occupational physicians and nurses who collaborated in recruiting subjects and encouraged them to fully participate in the study.

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