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Original Article

Intensified glucose self-monitoring with education in Saudi DM patients

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Abstract: The purpose of this study is to assess the impact of intensified SMBG with patient education on DM patients at the Eastern province of Saudi Arabia. 60 poorly controlled adult type 1 and 2 DM patients (30 intervention; 30 control) were included in this 4-month case-control study. All patients were subjected to the same educational program at baseline. Controls were followed up after 3 months. The intervention group was followed monthly. Fasting blood glucose, HbA1c and lipid profile levels were the main outcome measures. The intervention arm showed significant reduction in the post-fasting glucose (P<0.001) and HbA1c (P<0.001) levels as well as a significant increase in glucose testing (P<0.001) than pre-levels. Both post-fasting glucose and HbA1c levels were significantly lower in the intervention arm than the control arm (P<0.001 and P=0.001, respectively). The intervention group also showed higher improvement in knowledge, attitude and behavior than the controls (P<0.001). Short duration of structured periodic SMBG with patient education significantly improved glycemic control in all DM patients, regardless of the type or mode of treatment. It facilitated timely and aggressive treatment modification and encouraged patient self-care behavior.

Keywords: Diabetes, self-monitoring of blood glucose, glycemic control, diabetes self-management education

Introduction

Diabetes mellitus (DM) is an enormous growing public health problem in Saudi Arabia [1]. It is linked to increased risk of severe cardiovascular complications, morbidity and mortality which can be reduced by optimal glycemic control [2]. Although hemoglobin A1c (HbA1c) is a good indicator for long-term glycemic control, it does not provide information about intraday glycemic variability. On the other hand, self-monitoring of blood glucose (SMBG) can detect acute glycemic excursions, distinguish between fasting, pre- and post-prandial hyperglycemia as well as hypoglycemia [3]. Hence, it is considered an important adjunct to HbA1c which together, provides the best assessment of glycemic control [3, 4].

Currently, SMBG is a core component for routine DM management as it can provide immediate feedback on the acute effects of lifestyle choices and medications on glycemic control. However, its value and utility lies in using the collected data for a subsequent action including modifying patients lifestyle and adjusting medication. To be a more effective tool, SMBG should be linked with a structured educational program that is taught to DM patients including data collection and interpretation to promote positive self-care behavior [4, 5]. The present study aimed to explore the impact of intensified periodic SMBG with comprehensive patient education on the glycemic control of DM patients in the Eastern province of Saudi Arabia.

Materials and methods

Study design

This is an interventional study using the quasi single blind experimental design with pre- and post-comparison conducted from December the 1st 2011 to March the 30th 2012 at the Diabetes Center in Dammam Medical Complex, the biggest diabetes center in the Eastern

Province which serves about 10,000 DM patients. The study proposal was reviewed and approved by the Alexandria Faculty of Medicine Research and Ethics Committee and the health authority in Saudi Arabia. Patients were given the information about the study purpose and procedures before provision of an informed written consent. Patients in the control arm received the usual care approved by the Ministry of Health, Saudi Arabia. Patients had the right to refuse participation or withdraw from the study without compromising best available care. Confidentiality of the collected data was maintained in all phases of the study.

Target population and sampling

The target population was all DM patients attending the center. Eligible participants were adult patients (≥18 years) with an established diagnosis of type 1 or 2 DM of any duration, treated with any hypoglycemic agent and experienced uncontrolled glycemic state (HbA1c>8.0%). Pregnant women, children and patients who were unable to establish communication or answer questionnaire independently due to illiteracy, cognitive deficit, hearing or visual impairment were excluded. Those previously exposed to intensified diabetes education sessions were also excluded. Patients attending the center during December 2011 for follow up and meeting the inclusion criteria were oriented and asked for participation. Consenting patients were assigned a number. A total of 60 patients were recruited: 30 patients with odd numbers were assigned to the intervention arm and 30 patients with even number were assigned to the control arm. The study has been limited to 30 patients in both intervention and control arms due to limited resources and time constraints.

Goal and objectives of the education program

Patients in the intervention arm were subjected to an education program which aims at achieving optimum glycemic control (HbA1c<6.0). The program was implemented for 4 months (baseline and 3 monthly follow-up visits). The goal was to improve patients' lifestyle in terms of physical activity, dietary regimens and medications according to blood sugar level readings. The objectives of the intervention were to enhance patients' knowledge about the disease, increase adherence by developing favorable attitudes towards management plan and acquire skills on monitoring and interpreting blood glucose levels. Learning objectives related to cognitive domain include: definition and types of DM, symptoms of hyperglycemia and hypoglycemia, associated risk factors and complications, management plan and measures for preventing further complications. In the affective domain, the objective is to believe that adherence to treatment, adopting a healthy eating pattern, and exercising regularly will result in good metabolic control. Lastly, the learning objective in the psychomotor domain is to select foods with low carbohydrates, take prescribed medications on time, daily exercise for 30 minutes, frequent monitoring of blood glucose level using a glucometer and proper insulin injection.

The intervention

All patients in the intervention group had a one-on-one initial education session followed by three more sessions every month during follow up. A one hour initial education session was conducted by the researchers and a health educator in which patients were educated about the disease, types, risk factors, symptoms, seriousness, management, self-care, food items of low carbohydrate and high fiber content, exercise, and SMBG. Patients received posters, leaflets and video films as audiovisual aids as well as pamphlets to remind them of the education session with focus on insulin injection, SMBG, nutrition and exercises. All patients received free Accu-Check device (Roche Diagnostics Turkey A.S.) with strips and were shown how to self-monitor blood glucose levels daily and track readings during the whole study period. In addition, patients were instructed to conduct intensified 7-points glucose measurements (pre-prandial and 2-hour postprandial at each of the 3 meals and at bedtime) monthly in the day prior to the follow up visit. They were provided with a printed schedule to record 7 readings. Patients on insulin were taught how to self-inject. In each follow up visit, patients spent 30 minutes face-to-face consultation with the researchers during which problem-solving skills related to hyperglycemia and hypoglycemia were explored. The endocrinologist continued or modified pharmacologic treatment guided by the intensified 7 points glucose readings. Patients in the control group were exposed to the same education intervention but were not supplied with Accu-Check device nor advised to self-monitor. They continued

Table 1. Baseline characteristics of patients in the intervention and control arm

Parameter	Intervention group	Control group	*P*-value
N	30	30	
Age (years)	50.80 ± 15.52	48.97 ± 14.21	0.635
Weight (kg)	78.66 ± 9.09	81.45 ± 12.55	0.329
Systolic blood Pressure (mmHg)	132.80 ± 21.83	137.47 ± 16.57	0.355
Diastolic blood Pressure (mmHg)	82.53 ± 8.78	86.10 ±11.01	0.171
Glucose test (per week)	2.23 ± 5.64	1.70 ± 2.20	0.631
Fasting blood sugar mmol/l	9.68 ± 3.21	9.50 ± 1.63	0.791
HbA1c (%)	10.10 ± 1.65	9.98 ± 1.58	0.763
Total Cholesterol mmol/l	4.87 ±0.76	5.20 ± 0.87	0.115
HDL-Cholesterol mmol/l	1.38 ± 0.96	1.27 ± 0.38	0.351
LDL-Cholesterol mmol/l	2.98 ± 0.61	3.20 ± 0.72	0.223
Triglycerides mmol/l	1.73 ± 0.92	1.66 ± 0.62	0.734
Knowledge score (%)	55.33 ± 5.68	55.67 ± 5.12	0.812
Attitude score (%)	43.33 ± 9.13	43.17 ± 9.69	0.946
Practice score (%)	35.67 ± 8.07	34.50 ± 9.32	0.606
Total Score (%)	47.42 ± 5.47	47.25 ± 4.75	0.904

Note: Data presented as mean ± standard deviation; *P*-value significant at <0.05.

with their routine follow-up at 3-month intervals.

Monitoring and evaluation of the intervention

The intervention was monitored and evaluated using a combination of questionnaire interview, observation of performance, and laboratory investigations. Records of patients' demographic information (age, sex, contact information) and detailed medical history were collected. To monitor compliance to the recommended behavior, patients were asked at baseline and follow up visits to recall the previous 24-hour dietary intake to assess the total caloric, carbohydrate, protein, fat and sugar intake. For physical activity, patients were asked the number of days they exercised in the past week. The times patients missed medications in the preceding week were used to assess medication adherence. The number of glucose testing in the preceding week was the indicator of SMBG practice. According to patients' response, the educational intervention was tailored to encourage improvement in diet, exercise behaviors and enhancing patient's positive attitudes. Participants were also motivated to adhere to medications and continue tracking of glucose readings as instructed. A pre- and post-KAP (Knowledge, Attitude and Practice) questionnaire was developed by the researchers for the evaluation of the impact of the intervention. A score of one was given for every right answer. A summary score was developed for each domain and for the whole test. Medical assessment at the initial and last visits was considered for evaluation of the outcome of the intervention and included measurement of blood pressure, weight and height. Blood sample was obtained to test for fasting blood glucose, HbA1c and lipid profile. Also the type, number and doses of glucose lowering treatment and any carried modification to treatment during the monthly follow up visits of the study period were recorded.

Statistical analysis

SPSS version 16 (SPSS Inc. Chicago, IL, USA) was used for data entry and analysis. Data was presented as mean and standard deviation. Paired and independent t-tests were used to compare mean values of HbA1c, fasting blood sugar, total cholesterol, triglyceride, lipoproteins (HDL and LDL), weight and KAP score pre- and post-intervention as well the inter- and intra-differences between groups. Significance was set at $P<0.05$.

Results

Baseline data

The present study included 60 patients equally allocated to intervention (n=30) and control arm (n=30). The age of the participants ranged from 18-82 (49.9 ± 14.8) years and was mostly women (78.3%). Majority of the patients had type 2 DM (93.3%) and 6.7% had type 1 DM. Patients were treated with insulin (30.0%), oral hypoglycemic agents (78.3%) or their combination (13.3%). No significant differences between groups were detected with respect to age, base

Table 2. Comparison of pre- and post-intervention parameters among groups

Parameter	Intervention group (n=30)			Control group (n=30)		
	Pre-	Post	*P*-value	Pre-	Post	*P*-value
Weight (kg)	78.66 ± 9.09	77.98 ± 8.23	0.160	81.45 ± 12.55	81.20 ± 11.65	0.552
Systolic blood Pressure (mmHg)	132.80 ± 21.83	131.10 ± 17.61	0.225	137.47 ± 16.57	136.90 ± 15.05	0.340
Diastolic blood Pressure (mmHg)	82.53 ± 8.78	81.83 ± 7.17	0.171	86.10 ±11.01	85.33 ± 7.87	0.326
Glucose test (per week)	2.23 ± 5.64	11.67 ± 7.06	<0.001	1.70 ± 2.20	1.93 ± 1.741	0.199
Fasting blood sugar (mmol/l)	9.68 ± 3.21	8.91 ± 3.01	<0.001	9.50 ± 1.63	9.31 ± 1.72	0.225
HbA1c (%)	10.10 ± 1.65	8.53 ± 1.39	<0.001	9.98 ± 1.58	9.87 ± 1.56	0.097
Total Cholesterol mmol/l	4.87 ± 0.76	4.78 ± 0.75	0.089	5.20 ± 0.87	5.17 ± 0.85	0.160
HDL-Cholesterol mmol/l	1.21±0.38	1.37 ± 0.26	0.007	1.27 ± 0.38	1.29 ± 0.34	0.211
LDL-Cholesterol mmol/l	2.98 ± 0.61	2.89 ± 0.60	0.103	3.20 ± 0.72	3.16 ± 0.65	0.173
Triglycerides mmol/l	1.73 ± 0.92	1.63 ± 0.82	0.108	1.66 ± 0.62	1.61 ± 0.59	0.084
Knowledge score (%)	55.33 ± 5.68	84.75 ± 3.73	<0.001	55.67 ± 5.12	75.25 ± 4.32	<0.001
Attitude score (%)	43.33 ± 9.13	63.00 ± 8.96	<0.001	43.17 ± 9.69	52.17 ± 10.06	<0.001
Practice score (%)	35.67 ± 8.07	50.50 ± 9.13	<0.001	34.50 ± 9.32	39.83 ± 10.46	<0.001
Total Score (%)	47.42 ± 5.47	70.75 ± 4.48	<0.001	47.25 ± 4.75	60.62 ± 4.75	<0.001

Table 3. Percentage change in Pre- post-intervention parameters among groups

Parameter	Intervention group	Control group	*P*-value
N	30	30	
Weight (kg)	-0.72 ± 3.19	-0.15 ± 2.78	0.463
Systolic blood Pressure (mmHg)	-0.61 ± 6.79	-0.27 ± 2.34	0.799
Diastolic blood Pressure (mmHg)	-0.59 ± 3.84	-0.29 ± 5.75	0.812
Glucose test (per week)*	9.43 ± 4.50	0.23 ± 0.97	<0.001
Fasting blood sugar mmol/l	-8.04 ± 9.99	-1.90 ± 9.26	0.017
HbA1c (%)	-15.20 ± 7.77	-0.99 ± 3.70	<0.001
Total Cholesterol mmol/l	-0.89 ± 14.97	-0.64 ± 2.87	0.929
HDL-Cholesterol mmol/l	17.01 ± 18.18	2.28 ± 5.21	<0.001
LDL-Cholesterol mmol/l	-2.73 ± 11.33	-0.59 ± 4.99	0.350
Triglycerides mmol/l	-3.18 ± 13.65	-1.89 ± 13.73	0.716
Knowledge score	54.30 ± 12.67	38.69 ± 12.24	<0.001
Attitude score	49.33 ± 28.82	30.88 ± 16.29	0.003
Practice score	44.94 ± 21.57	16.78 ± 14.86	<0.001
Total KAP Score	50.39 ± 12.23	28.92 ± 8.37	<0.001

Note: Data presented as mean ± standard deviation; *P*-value significant at <0.05.

line clinical, laboratory findings and KAP (**Table 1**).

Intervention outcomes

All intervention patients (n=30) performed some sort of lifestyle changes in their food intake, exercise, and monitoring. They were all subjected to adjusting and intensifying therapy including initiating insulin therapy in type 2 DM when indicated. The proportion of those receiving insulin alone or in combination (43.3%) almost doubled (80.0%) at the end of the study.

Table 2 shows that the intervention arm had a significant increase between pre- and post-intervention in the mean frequency of glucose testing from 2.23 ± 5.64 to 11.67 ± 7.06 times per week (P< 0.001). The rate of increase in the test performance was slightly higher among insulin users (9.75 ± 5.96 times per week) than among non-users (9.22 ± 3.39 times per week) with no significant difference. Fasting blood sugar was also significantly reduced by 0.77 mmol/l. Reduction in fasting glucose level was higher among insulin users (0.94 ± 0.50 mmol/l) than non-users (0.51 ± 1.12 mmol/l) though not significant. Post-HbA1c (8.53 ± 1.39%) was significantly lower than the pre-HbA1c levels (10.10 ± 1.65%) (P<0.001). The mean reduction of HbA1c was modestly higher among insulin users (1.9 ± 1.17%) than non-users (1.35 ± 0.59%). **Table 2** shows that the mean of post-HDL (1.37 ± 0.26 mmol/l) was significantly higher than pre-HDL (1.21 ± 0.38 mmol/l) (P=0.007). The mean increase was slightly higher among insulin users (0.20 ± 0.15 mmol/l) than non-users (0.18 ± 0.35 mmol/l). Meanwhile, the mean weight, systolic and diastolic blood pressure, total cholesterol, LDL and triglycerides showed no change. Patients in both

the intervention and control arm showed a significant improvement in their knowledge, attitude and behavior (P<0.001). No significant differences were observed in other outcome parameters, **Table 2**.

Group comparisons

The post-outcome measures were compared between both intervention and control groups using independent T-test (**Table 3**). It reveals a significantly higher increase in the number of glucose testing (P<0.001) and the percentage increase in HDL (P<0.001) in the intervention compared to the control group. A significantly higher percentage decrease in fasting blood sugar (P=0.017) and HbA1c (P<0.001) was observed. The percentage differences in weight, blood pressure and lipids were not significantly different between groups. The percentage increase in all KAP scores were significantly higher in the intervention compared to the control group (P<0.001 for knowledge, practice and total score and P=0.003 for attitude).

Discussion

Poorly controlled DM leads to serious complications and early death imposing a large economic burden on the individual, healthcare systems and countries. Hence, care of DM patients is of growing importance to public health. For proper control of DM, it is essential for patients to actively participate in their own management such as appropriate diet, physical activity, blood glucose monitoring and adherence to medication [1, 5].

The role of DSME is to improve patients' understanding of their condition and the importance of disease control. It also enhances self- management practices, problem solving and active collaboration with care givers to improve clinical outcomes, overall health status and quality of life [5, 6].

The objective of SMBG is to collect detailed information about blood glucose profile at several time-points to provide feedback on the effect of self-care practice and pharmacotherapy. Hence, it can facilitate lifestyle and therapeutic modifications and increase patient empowerment and adherence to treatment [4, 5].

Previous studies demonstrated a positive impact for DSME on metabolic control indicators [7, 8]. The present study found that educational intervention significantly increased KAP scores in both groups, although the control group signified that conjugating educational intervention with existing routine care was not enough to improve metabolic indicators. This negative effect could be related to the low frequency of educational activity and short duration of the intervention. The improvement in KAP scores and number of glucose testing was significantly higher in the intervention arm than controls, indicating that repetition of educational message is more effective in promoting self-management behavior in both types of DM. Other educational study recorded significant improvement of fasting blood sugar, HbA1c and HDL levels among type 1 DM patients who were followed up daily for 3 months [7]. Research on type 2 DM patients reported significant improvement in fasting blood sugar level, HbA1c value and knowledge score after one year. It was adopting weekly educational sessions for three months then biweekly support group sessions [8].

For optimum benefit and better glycemic control, the international guidelines recommended linking DSME with SMBG in the daily management of DM patients on insulin or/and oral hypoglycemic agents and those not achieving glycemic control targets. SMBG includes patients' continuous monitoring via periodic pre- and postprandial measurements. Both patients and healthcare providers are trained to modify lifestyle and medications in response to SMBG values [4, 5]. Although different studies confirmed the impact of SMBG on achieving better glycemic control [9, 10], it proved to increase distress, worry and depressive symptoms [11, 12]. Patients must employ several mental and physical tasks to balance their food intake, physical activity and medicine to maintain target glucose levels [13]. For many patients, the burden of self-management may cause distress. Fears about complications and guilt when they get "off track" with their self-care may also contribute to their distress in both insulin and non-insulin-treated patients. With over use, SMBG can become overwhelming and adversely affects patients' quality of life [13, 14]. These concerns can discourage patients and influence adherence to self-care prac-

tices with lack of control leading to more discourage [13].

Intensified structured SMBG is another regimen where patient is instructed to generate glucose profiles at 4-7 points on certain days per week or month. The data available guide the care provider for more frequent real-time adjustment of diabetes medications. Studies proved that it significantly improves glycemic control [10, 15, 16], as well general well-being (GWB), depression and distress scores [16].

The present study adopted this strategy. Obtained results helped all patients to make appropriate and timely modifications in their food intake, exercise, and monitoring. The day prior to visit the patient conducted 7-point glucose readings. Because the HbA1c value is relatively useless as a marker for short term changes [10], the investigators depended on the monthly intensified 7-point SMBG information to make timely and aggressive treatment changes. The study confirmed the hypothesis that more frequent testing and therapy adjustments could result in faster improvement in glycemic control in both insulin and non-insulin treated subjects. A similar study achieved better glycemic control within a shorter duration of 6 weeks, but with higher frequency of 7-point SMBG (3 days/week with weekly clinic visits) [9, 10]. Scavini and colleagues conducted a study with 4-point glucose profile for 3-day per week and a clinic visit every 3 month which resulted in better control after one year [15]. High frequency and/or long duration may add a burden on the patient causing distress affecting quality of life. However, this was not assessed in the present or those studies. After 12 months, Polonsky reported better control with 7-point glucose profile for 3-day every 3 month without decreasing GWB [16].

Benefits from SMBG in insulin-treated patients are more consistent than studies in non-insulin-treated patients [9, 17]. Some investigators documented significant glycemic control with SMBG [9, 10, 16], while others reported negative findings [18, 19] even with increased depression scores [12]. In the present study, both insulin and non-insulin-treated patients benefitted from conjugating DSME and SMBG as denoted by the significant improvement in glycemic control. Facilitating early initiation of insulin therapy when indicated might play a role in the improvement among type 2 DM patients. Karter et al recorded a similar conclusion [9]. Inconsistency of results may be due to differences in study designs, inclusion criteria, culture and characteristics of patients, structure, duration and frequency of the intervention, adherence to the protocol, mode of care delivery, collaboration between patients and their care-giver, and study imitations [5, 16].

In summary, this study observed that even with short duration, intensified monthly SMBG combined with education was effective in improving glycemic control, HDL levels as well KAP scores in both insulin- and non-insulin treated patients. It facilitated timely and aggressive treatment modification including early initiation of insulin therapy in type 2 DM when indicated and encouraged patient self-care behavior. It is feasible and has the advantage of rapid correction of glycemic variability at lesser effort and manpower. Further studies are recommended to better assess the benefits, optimal use, impact on quality of life and cost-effectiveness of intensified SMBG. Furthermore, SMBG is recommended as an essential part of daily DM management regardless of type and mode of treatment. The strategy of adjusting medications at monthly intervals based on intensified SMBG data can be adopted in conjunction with the HbA1c results to achieve better glycemic control.

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Disclosure of conflict of interest

None.

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