Use of a Blood Glucose Monitoring Manual to Enhance Monitoring Adherence in Adults With Diabetes

A Randomized Controlled Trial

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Background: Frequent blood glucose (BG) monitoring is a critical component of diabetes management, yet many barriers exist to consistent monitoring.

Methods: In this randomized controlled trial, we sought to determine if an educational manual, the Blood Sugar Monitoring Owner’s Manual (BGMOM), could increase adherence to BG monitoring by helping patients form realistic expectations and responses to BG monitoring results. The 199 participants were recruited from a multidisciplinary diabetes clinic and had high-risk diabetes (hemoglobin A1C ≥8.0%); 35% had type 1 diabetes mellitus. Participants were randomized to 1 of 3 groups: BGMOM intervention (BGM+), attention control (BG meter only [MT]), or standard care (SC). The BGM+ and MT groups received BG meters and meter education; the BGM+ group also received BGMOM booklets. The SC group received usual care. Data gathered during 6 months of follow-up included BG monitoring frequency and hemoglobin A1C measurement.

Results: Monitoring frequency increased significantly in the BGM+ group (1.9±1.3 to 2.8±1.5 times daily, P<.001) but only slightly in the MT group (1.7±1.3 to 2.0±1.3 times daily). The BGM+ group experienced the greatest improvement in hemoglobin A1C level (BGM+: −0.13±1.28; MT: −0.04±1.31; SC: 0.04±1.10). Further, a higher percentage of those in the BGM+ group (61%) improved their glycemic control compared with the other groups (44%; P=.05). Finally, the BGM+ group displayed the most knowledge about the definition of hemoglobin A1C (P=.04) and reported the least amount of negative affect about out-of-range BG monitoring results (P=.03).

Conclusion: As an adjunct to standard diabetes education and support, a manual such as the BGMOM can help optimize BG monitoring and glycemic control.

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Successful Management of Diabetes

Successful management of diabetes, as with any chronic illness, requires self-care. Many psychosocial determinants affect self-management of diabetes, including diabetes-specific knowledge, social isolation and support, health beliefs and attitudes, illness severity, and treatment modality. Conflicting expectations and perceptions between health care professionals and patients can significantly hinder establishment of proper self-care. Indeed, diabetes education alone has not consistently produced behavior modifications that promote improvement in glycemic control. Thus, educational support must convey realistic expectations regarding diabetes management and address issues related to diabetes-specific emotions or affect to encourage successful behavior change.

Blood glucose (BG) monitoring is the foundation of diabetes management, because BG monitoring results provide guidelines for meal planning, exercise, and medication use. More frequent BG monitoring has been associated with better glycemic control in patients with type 1 and type 2 diabetes mellitus. Nonetheless, numerous barriers to BG monitoring exist, including discomfort, inconvenience, cost, difficulty performing the task, lack of knowledge regarding how to interpret BG monitoring results, and fear of “bad” BG monitoring results. Annual sales of BG strips suggest that patients with type 1 diabetes monitor BG levels 1 to 2 times daily and patients with type 2 diabetes monitor BG levels 1 to 2 times weekly. Recognizing the link between BG monitoring and improved glycemic control, 3 of us designed an educational booklet, the Blood Sugar Monitoring Owner’s Manual (BGMOM), with the goal of improving the physical and emotional well-being of patients with diabetes by increasing adherence to BG monitoring.
To evaluate the effectiveness of the BGMOM in increasing BG monitoring frequency, we conducted a 6-month, prospective randomized controlled trial with adults characterized as being at high risk (ie, hemoglobin A1C level ≥8.0%). By selecting this group, we had an opportunity to assess improvement during a short-term intervention. We hypothesized that exposure to diabetes education alone would be insufficient to alter monitoring behavior but that greater adherence would result from the attention to expectations and affective responses to BG results provided by the BGMOM.

METHODS

PARTICIPANTS

The 199 participants were patients at the Joslin Diabetes Center in Boston, Mass, with type 1 (35%) or type 2 (65%) diabetes. Exclusion criteria included a medical history of established renal disease (serum creatinine level ≥2.0 mg/dL [≥176.8 μmol/L]), major visual impairment, myocardial infarction within the last 6 months, or major psychiatric disorder. Female patients were excluded if they were pregnant. At enrollment, participants’ most recent hemoglobin A1C values were 8.0% or greater. The Joslin Committee on Human Studies approved the study protocol.

PROCEDURES AND MEASURES

Eligible patients were contacted by mail and telephone before a regularly scheduled visit. Informed written consent was obtained at the visit, followed by randomization to 1 of 3 study groups: BGMOM intervention (BGM+), attention control (BG meter only [MT]), or standard care (SC) (Figure 1). Sequential recruitment continued until enrollment was complete. Ten percent of those contacted declined participation. The final sample was composed of 50 patients in each of the BGM+ and MT groups and 99 patients in the SC group.

Each participant in the BGM+ and MT groups received a BG meter, a 30-minute diabetes education session focused on BG monitoring, and support from a certified diabetes educator (M.T.L. and K.A.C.). Patients received new meters (Accu-Chek Advantage; Roche Diagnostics, Indianapolis, Ind) but were not given glucose test strips; instead, they received prescriptions for monitoring supplies covered by health insurance as mandated by Massachusetts state law.18 Participants in the BGM+ group also received the BGMOM, and the certified diabetes educator reviewed the manual during the same 30-minute session. Patients in the SC group received their usual care. Usual care encompassed individual or group standard diabetes education as accredited by the American Diabetes Association (ADA).

The BGMOM is an 18-page color manual that was developed to diminish barriers to BG monitoring without significant cost or time. It targets patients with type 1 or type 2 diabetes who are receiving various therapies and provides practical information on the mechanics of BG monitoring, as well as approaches to help patients process their emotions concerning diabetes and BG monitoring (Table 1 and Figure 2). We created the manual to accommodate a middle school reading level to allow for a broad range of abilities. The manual advocates that feedback provided by monitoring be positive, regardless of the BG monitoring result. It emphasizes that monitoring is not a test but a check and that BG monitoring results are not good or bad but in range or out of range. It also provides a definition of hemoglobin A1C and how it can be used to guide diabetes management.

Study participants were followed up for 6 months. Data, collected by medical record review and surveys, included frequency of BG monitoring, hemoglobin A1C level measurement results, knowledge of BG monitoring and hemoglobin A1C, affect regarding BG monitoring results, and satisfaction with diabetes management and care. Baseline BG monitoring frequency was not available in the SC group. Hemoglobin A1C values (reference range, 4%-6%) were obtained at baseline and during follow-up. Patients in the BGM+ and MT groups completed the
Blood Glucose Monitoring/Health Information Survey at baseline. Participants in all 3 groups completed the Blood Glucose Monitoring/Health Information Survey and the Satisfaction with Diabetes Health Care Survey at study’s end. The Blood Glucose Monitoring/Health Information Survey includes questions about the patient’s social situation, educational level, family and medical history, and BG monitoring frequency, as well as a short section addressing the patient’s diabetes-specific knowledge and affect regarding BG monitoring. The Satisfaction with Diabetes Health Care Survey contains questions regarding the self-assessed quality of diabetes care and relationships with health care professionals.

STATISTICAL ANALYSIS

Statistical analyses were performed with SAS statistical software, version 8.2 for Windows (SAS Institute Inc, Cary, NC). Means ± SDs are presented unless otherwise indicated. Both univariate and multivariate analyses were performed. The primary outcome measure was frequency of BG monitoring. Secondary outcome measures included glycemic control, knowledge of hemoglobin A1c, and affect regarding BG monitoring results. Analysis of variance, unpaired t tests, Fisher exact test, and χ² analyses were used to compare outcome measures among and between groups. Paired t tests were used to determine significant change within groups.

RESULTS

BASELINE CHARACTERISTICS

At entry, the study population had a mean age of 49.2 ± 13.0 years (range, 18-66 years), a duration of diabetes of 10.7 ± 6.2 years (range, 1-33 years), a body mass index (calculated as weight in kilograms divided by the square of height in meters) of 30.1 ± 6.3, and a hemoglobin A1c level of 9.1% ± 1.1%. For insulin-treated patients, the mean duration of insulin therapy was 7.7 ± 3.8 years. Independent of group assignment, patients with type 1 diabetes were checking BG levels 2.4 ± 1.3 times daily, whereas patients with type 2 diabetes were checking levels 1.6 ± 1.2 times daily (P = .003). Glycemic control did not differ between patients with type 1 (9.0% ± 1.1%) and type 2 diabetes (9.1% ± 1.1%).

The 3 groups were similar with respect to age, sex, ethnicity, educational level, body mass index, type of diabetes, therapy, and duration of diabetes (Table 2). The BGM + and MT groups had a similar frequency of daily BG monitoring at baseline (BGM+: 1.9 ± 1.3; MT: 1.7 ± 1.3). The hemoglobin A1c level was also similar between the groups, although it was slightly higher in the BGM + group compared with the SC group (9.3% ± 1.2% vs 8.9% ± 0.9%; P = .06).

FREQUENCY OF BG MONITORING

At study’s end, patients in the BGM + group were checking BG levels significantly more often (2.8 ± 1.5 times daily) than patients in both the MT (2.0 ± 1.3 times daily; P = .01) and SC (2.1 ± 1.7 times daily; P = .04) groups. The increase in monitoring frequency during the study was significant for the BGM + group (P < .001) but not for the MT group. In the BGM + group, 98% of patients increased or maintained their frequency of BG monitoring compared with baseline. This was significantly higher
than the percentage of patients in the MT group (79%) who increased or maintained their monitoring frequency during the study (P = .02; Figure 3). Patients in the BGM group were more than 10 times as likely as patients in the MT group to increase or maintain their BG monitoring frequency (odds ratio, 10.3; 95% confidence interval, 1.2-85.7). Although BG monitoring frequency was similar between the BGM and MT groups at baseline, a significantly higher percentage of participants in the BGM group (35%) were checking their blood glucose levels 4 times daily or more at study’s end than patients in the MT group (12%; P = .01; Figure 3).

In the BGM group, daily frequency of BG monitoring increased significantly for patients with type 1 and type 2 diabetes. Participants with type 1 diabetes were checking BG levels 2.6±1.1 times daily at baseline and 3.5±1.3 times daily at study completion (P = .004; Figure 3). Participants with type 2 diabetes were checking BG levels 1.5±1.3 times daily at baseline and 2.3±1.4 times daily at study completion (P = .007). In the MT group, no significant change occurred in daily monitoring frequency for patients with type 1 (baseline: 2.1±1.6; completion: 2.5±1.7) or type 2 (baseline: 1.6±1.2; completion: 1.8±1.1) diabetes.

**SURVEY RESPONSES**

At study’s end, a significant difference was observed among groups in participants’ ability to define hemoglobin A1C correctly (Figure 4). A higher percentage of those in the
BGM+ group (88%) was able to correctly define hemoglobin A1C compared with those in both the MT (63%) and SC (75%) groups (P = .04). A significantly smaller percentage of the BGM+ group participants (38%) reported negative affect regarding BG monitoring results than those in either the MT (69%) or SC (57%) groups (P = .03; Figure 4). However, no difference in reported satisfaction with medical care was noted among the 3 groups.

**GLYCEMIC CONTROL**

At study’s completion, no significant differences had occurred in glycemic control among the 3 groups (BGM+: 9.3%±1.7%; MT: 9.1%±1.3%; SC: 9.0%±1.5%), but the BGM+ group demonstrated the greatest improvement in hemoglobin A1C levels (BGM+: −0.13%±1.28%; MT: −0.04%±1.31%; SC: 0.04%±1.10%). Although no group had significantly lower hemoglobin A1C values at study’s end, a comparison of baseline and follow-up hemoglobin A1C levels revealed that most participants in the BGM+ group improved their glycemic control. To examine change in glycemic control, participants were classified according to whether their control did or did not improve during the study. The MT and SC groups were combined because the percentage of those with improved control in each group was identical (44%). A higher percentage of those in the BGM+ group (61%) improved their hemoglobin A1C level compared with the other groups combined (P = .05; Figure 5). The BGM+ group also had the highest percentage of participants (26%) with a hemoglobin A1C level of 8.0% or lower at study’s end (MT: 20%; SC: 19%). There were no significant changes in glycemic control for patients with type 1 or type 2 diabetes in any of the groups.

**MULTIVARIATE ANALYSES**

In a multivariate model (R²=0.26, P<.001) controlling for age, sex, duration of diabetes, educational level, and socioeconomic status, group assignment (P = .02) was a significant predictor of BG monitoring frequency at study completion, confirming the univariate findings (Figure 6). As expected, type of diabetes was also a significant predictor in the model, with patients who had type 1 diabetes monitoring more frequently (3.0 times daily) than patients with type 2 diabetes (1.8 times daily). Finally, in a multivariate model (R²=0.13) controlling for age, sex, duration of diabetes, type of diabetes, educational level, socioeconomic status, and baseline hemoglobin A1C level, assignment to the BGM+ group (P = .03) was a significant predictor of improvement in glycemic control at study’s end.

The ADA has estimated total health care expenditures attributable to diabetes at approximately $132 billion, with the average expenditure per patient more than twice that of the patient without diabetes.21 A simple, inexpensive intervention such as the BGMOM, aimed at increasing frequency of BG monitoring and improving glycemic control, has the potential to benefit a greater number of patients, at a lower cost, than enrolling small numbers of patients in intensive management regimens.

Participants in our study appeared to benefit from the BGMOM. Almost all who received the BGMOM either maintained or increased their BG monitoring frequency. Patients who received the BGMOM reported significantly less negative affect about elevated BG monitoring results and displayed a greater understanding of hemoglobin A1C than patients in the other groups. Finally, patients in the BGMOM group were more likely to improve their glycemic control at study completion than the other groups. Thus, the BGMOM, a relatively simple and inexpensive tool, was associated with increased BG monitoring frequency and patient knowledge, less negative affect concerning out-of-range BG levels, and improved glycemic control.

The Diabetes Control and Complications Trial and the UK Prospective Diabetes Study support improvement of diabetes control to reduce the risk of late complica-
were checking BG levels less frequently at baseline than recommended by the ADA. At study’s end, however, patients with type 1 diabetes who had received the BGMOM were checking BG levels an average of 3.5 times daily, exceeding the ADA’s recommendation. Participants with type 1 diabetes in the MT group were still checking less frequently (2.5 times daily) than recommended. Among patients with type 2 diabetes, participants who received the BGMOM significantly increased their frequency of daily monitoring to 2.3 times daily, whereas those in the MT group did not (1.8 times daily).

Success in managing diabetes requires maintenance of the patient’s self-care routine. Assisting patients in taking an informed and extensive role in the management of their diabetes is crucial to long-term success. The BGMOM helps patients by providing practical information and tools for overcoming common barriers to optimal monitoring frequency. In standard diabetes education, patients are instructed in the mechanics of BG monitoring and are often given guidelines regarding food intake, activity, and medication use for out-of-range BG monitoring results. Although cognitive and behavioral responses are taught in the clinical setting, patients’ emotional responses and adaptation to this uncomfortable task often go unaddressed. Negative emotions experienced by patients in response to out-of-range BG monitoring results may deter them from consistent monitoring behavior and contribute to suboptimal glycemic control.27 Thus, although it can be difficult and time consuming for health care professionals to address barriers to BG monitoring, it is an essential component of diabetes care because studies continue to support the tight association between BG monitoring frequency and hemoglobin A1C value outcomes.

Since the Diabetes Control and Complications Trial and the UK Prospective Diabetes Study, researchers and health care professionals continue to evaluate management strategies aimed at improving glycemic control in type 1 and type 2 diabetes. No single approach has consistently yielded improved glycemic outcomes. Thus, multiple interventions are likely necessary to enhance treatment adherence and improve glycemic control. A major focus of the BGMOM addresses the inherent fluctuations of BG levels in diabetes and the attendant need to prevent self-blame and frustration from interfering with frequent BG monitoring. The BGMOM can serve as a psychoeducational tool that addresses some of the behavioral barriers to adherence while presenting BG monitoring in a straightforward and positive manner.

A simple-to-use, easily distributable tool like the BGMOM can positively affect patients’ diabetes self-management without straining personnel or financial resources. The incorporation of a manual, such as the BGMOM, as an adjunct to regular health care visits may enhance diabetes self-care and improve health outcomes while imposing minimal requirements of time, expense, and diabetes-specific expertise on health care professionals.

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Additional Information: The BGMOM was written by Ms Lawlor and Drs Anderson and Laffel. Copies of the manual are available from the corresponding author.

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