Self-monitoring of blood glucose—Psychological aspects relevant to changes in HbA$_{1c}$ in type 2 diabetic patients treated with diet or diet plus oral antidiabetic medication

Marcus Siebolds, Oliver Gaedeke, Ulrich Schwedes

on behalf of the SMBG Study Group

Abstract

Objective: To investigate the influence of psychological aspects on glycemic control in type 2 diabetic patients treated with diet alone or diet plus oral antidiabetic medication using meal-related self-monitoring of blood glucose (SMBG). These psychological aspects refer to the process of self-management including the tendency to structure situations and activate resources (self-perception), to accept options for action (self-reflection) and to believe in self-efficacy (self-regulation).

Methods: In a randomized controlled 6-month group comparison study, one group (n = 113; mean age 58.7 years) used a blood glucose monitoring device, kept a blood glucose/eating diary and received standardized counseling focusing on self-perception, self-reflection and self-regulation. A control group (n = 110; mean age 60.5 years) received non-standardized counseling on diet and lifestyle.

Results: Statistically significant endpoint differences between the SMBG and the control group were seen in glycemic control (p = 0.0086) and the well-being item ‘depression’ (p = 0.032). All aspects of counseling were influenced by SMBG with the extent of self-perception and self-reflection gradually increasing over time. Three HbA$_{1c}$ response types were identified among SMBG patients: continuous-achievers, late-achievers and non-achievers.

Conclusion: This study identified processes (structuring the situation and activating resources, accepting options for action and believing in self-efficacy) which lead to a change in the metabolic profile. SMBG coupled with structured counseling provided patients with a tool for taking on more self-control and resulted in an improved outlook on life.

Practice implications: This short-term intervention involved a structured counseling algorithm which requires 5–10 min of physician–patient contact and a structured documentation of metabolic control by the patient and can be taught by a diabetes training team within 4 h. The identification of the different response types might be of importance in clinical practice as it enables the physician to determine the right counseling option.

© 2005 Published by Elsevier Ireland Ltd.

Keywords: Counseling and psychological aspects; Non-insulin-treated type 2 diabetes; Psychological process of change; Quality of life; Self-monitoring of blood glucose

1. Introduction

Diabetes mellitus is a progressive metabolic disorder which affects an increasing number of people—the worldwide rise in number of adults with diabetes has been estimated at 122%, from 135 million in 1995 to 300 million in 2025 [1].
The UKPDS has demonstrated that intensive blood glucose control is essential for reducing the risk of diabetic complications in type 2 diabetic patients [2]. Essentially, no glycemia thresholds have been observed for any type of diabetes complication: the lower the glycemia, the lower the risk of complications [3]. Self-monitoring of blood glucose (SMBG) has been recommended by the American Diabetes Association as a test for monitoring the glycemic status [4], but it is still controversially discussed as a tool for non-insulin-treated type 2 diabetic patients [5] because methodologically meaningful studies into this question are lacking. We recently reported the efficacy of structured, meal-related SMBG accompanied by brief counseling undertaken by the attending physician in a prospective, randomized group comparison [6]. Patients using a blood glucose device showed significant improvements of glycemic control with marked improvements in quality of life. Recent findings reported in a response letter also led to a positive association between regular SMBG and improvements of glycemic control with marked improvements in quality of life [7].

Self-management is considered an important part of diabetes care [8] but the demands of day-to-day diabetes management often cause considerable psychological stress [9]. Substantial research in the field of psychological theory and interventions in patients with type 2 diabetes has been undertaken in the last decades. In a systematic review by Peters, four theoretical key concepts were identified: perceptual congruence, mutual goal setting, readiness to change and tailored intervention [10]. Metabolic control was shown to be influenced by the quality of patient-provider communication [11]. The theory of systemic family therapy developed by the group of De Shazer is well established in Germany. The important aspect of this theory is the development of a realistic contact between patient and provider for treatment [12]. The practical impact of these theories underline the development of an instrument for easy-to-teach patient-provider communication, and a very simple brief consultation model for general practice [13]. For the development of this instrument, Antonovsky’s theory was also taken into account [14]. According to Antonovsky, the process of self-management includes the tendency to structure situations and activate resources (self-perception), to accept options for action (self-reflection) and to believe in self-efficacy (self-regulation); an improvement in any of these three aspects appears to influence the self-control behavior. Knowledge of these defining patterns is of paramount significance for the planning of counseling and educational intervention: an awareness of the efficacy of these aspects facilitates the further specific development of counseling and educational models. In the development of structured counseling and educational programs, it is of major interest which psychological aspects during the counseling and education of diabetic patients are of importance for the metabolic outcome. In particular, time course studies of such psychological aspects are of great interest. The present study evaluated the results of the previously mentioned study by Schwedes et al. [6] with respect to these counseling and educational aspects.

2. Patients and methods

2.1. Participants and study design

The present study was part of a prospective, randomized, controlled, multicenter parallel group comparison in Germany and Austria between type 2 diabetic patients treated with diet alone or diet plus oral antidiabetic medication using an SMBG device and a control group over a period of 6 months with 6 months follow-up; it was conducted in an outpatient setting by family practitioners and hospitals. The study design has been previously detailed [6]. A total of 223 patients (SMBG \( n = 113 \), control \( n = 110 \)) were included in the primary efficacy analysis (per-protocol). Table 1 summarizes the baseline demographic characteristics for this population which compared well for both groups.

During a 2-week run-in period, patients in the SMBG group received intensive training in the use of a blood glucose device with sensor disc and the correct documentation of the measurements. They were requested to measure blood glucose six times (before and 1 h after main meals) on 2 days per week (one weekday/one Sunday) and to record the values obtained in a combined diary for blood glucose data, documentation of eating habits and their state of well-being. During the 24 weeks of intervention, a counseling algorithm [13] adapted to the needs of SMBG users was used in the counseling sessions for SMBG patients in Weeks 0, 4, 12 and 20. The counseling format was built on a structured brief interview of six central questions which the physician had to cover in exactly the same manner throughout the entire study (Table 2). Answers were documented in counseling protocols. This dialogue aimed to promote and support change processes in the way patients deal with their diabetes by improving SMBG management. Better glycemic control and improved treatment satisfaction were hoped to be achieved by promoting three key aspects of self-management therapy for this patient group: (i) increase of self-perception by keeping a daily diary and thus becoming more familiar with the diabetes in terms of eating habits, well-being and the significance of SMBG; (ii) promotion of

<table>
<thead>
<tr>
<th>Table 1 Baseline demographic characteristics of patients performing SMBG (( n = 113 )) and patients not using SMBG (( n = 110 ))</th>
<th>Self-monitoring</th>
<th>No self-monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>58.7 ± 7.6</td>
<td>60.5 ± 6.6</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female (%)</td>
<td>47.8</td>
<td>48.2</td>
</tr>
<tr>
<td>Male (%)</td>
<td>52.2</td>
<td>51.8</td>
</tr>
<tr>
<td>Duration of diabetes (months)</td>
<td>65.5 ± 57.2</td>
<td>62.6 ± 47.3</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>31.0 ± 4.6</td>
<td>31.9 ± 5.5</td>
</tr>
</tbody>
</table>

Data are expressed as mean ± S.D.
self-reflection by answering five interview questions which encourage thinking in structured terms about SMBG in a solution-oriented counseling program; and (iii) enhancement of self-regulation by considering the collected and documented information and drawing conclusions from it for better glycemic control. These three key aspects cover the psychological model formulated by Antonovsky [14]: to structure situations and activate resources, to accept options for action and to believe in self-efficacy. At the end of each session, patients were asked to assess the prospective success of their plans. The processes of self-perception and self-reflection were intended to come from the patients themselves, with the physician assuming the role of the supportive and motivating companion (patient-centered approach). Self-regulation was intended as a joint process by patient and physician. Physicians could be familiarized with this interview technique within 4 h; during clinical practice each counseling session required only 5–10 min as nurses assessed the correct use of the monitoring device by the patients and checked the accuracy of self-monitoring using wet chemical analysis. The control group received non-standardized counseling with a focus on their diet and lifestyle during these visits.

The metabolic outcome was assessed by the change in HbA1c after 24 weeks of SMBG (endpoint); body weight was measured as a secondary variable. HbA1c was determined using the DCA 2000 analyzer (quality assurance by national central laboratory, standard calibration) at visit 1 (week 2); further samples were taken at 0, 8, 16 and 24 weeks when body weight was also recorded. The effects of SMBG on quality of life and treatment satisfaction were measured by the ‘patient well-being questionnaire’ (WBQ 22) and by the ‘diabetes treatment satisfaction questionnaire’ (DTSQ) [15,16]. Questionnaires were completed at 0 and 24 weeks during the corresponding visits.

2.2. Data analysis

Data analysis was carried out using the SAS® program (version 6.12). Evaluation of HbA1c consisted of an analysis of covariance (ANCOVA) for the endpoint with baseline as covariate and SMBG as the main effect. Questionnaires were analyzed using psychometric assessment procedures (ANOVA, a between-within-design). Entries into the counseling protocol were assessed qualitatively: they were categorized according to content (e.g. category ‘eatings habits’ or category ‘use of SMBG device’) by two independent assessors using the methods described by Mayring [17]; agreement between the assessors was satisfactory (kappa = 0.75). All entries differing in allocation to categories were discussed in a formal approval procedure; an agreed assignment was then made to one of these categories. Frequency of categorized patient reports was then used as an evaluation criterion. The complete linkage method (determined by the similarity measure Pearson’s correlation coefficient) was used as a cluster analysis to detect typical HbA1c profiles among SMBG patients. This analysis categorized them according to the similarity of their HbA1c profiles over the study period irrespective of their actual HbA1c values.

3. Results

3.1. Influence of SMBG on metabolic control and quality of life

A significant improvement of glycemic control, as measured by the change in HbA1c, and an increase in treatment satisfaction and quality of life for patients using a self-monitoring device, have been previously described [6]. Table 3 provides an overview of these data.

3.2. Psychological aspects

The brief counseling sessions between physician and SMBG patient focused on the three aspects: self-perception, self-reflection and self-regulation (Table 2). Table 4 shows the frequency of reports for each of these three categories. The main entries for the category self-perception were ‘feeling of threat’ (such as diabetes complications and high blood glucose levels) and ‘dissatisfaction with blood glucose values’. Compared to the entries on self-reflection and self-regulation however, self-perception was less often mentioned during counseling.

The categories self-reflection and self-regulation show the patients’ ideas on improving glycemic control. Patients were more aware of nutrition, stress and exercise in relation to their blood glucose data as expressed in the continuous frequencies of entry during the study period. The issue ‘acceptance of diabetes’ was only mentioned at the first two counseling sessions (weeks 0 and 4). Aspects of self-regulation (nutrition, stress, exercise, diary use) were most frequently discussed in relation to the possible reduction of blood glucose levels. The counseling interview was dominated by the issue ‘nutrition’. Frequency of reports of all aspects decreased during the course of the study.
Table 3
Baseline values and changes from baseline in metabolic control and quality of life parameters after 6 months in patients performing SMBG and patients not performing SMBG

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Baseline SMBG</th>
<th>Baseline No SMBG</th>
<th>Endpoint SMBG</th>
<th>Endpoint No SMBG</th>
<th>Difference SMBG</th>
<th>Difference No SMBG</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1c (%)</td>
<td>8.47 ± 0.86</td>
<td>8.35 ± 0.75</td>
<td>7.47 ± 1.27</td>
<td>7.81 ± 1.52</td>
<td>−1.0 ± 1.08</td>
<td>−0.54 ± 1.41</td>
</tr>
<tr>
<td>Body weight (kg)</td>
<td>88.2 ± 15.4</td>
<td>89.6 ± 16.5</td>
<td>85.9 ± 15.4</td>
<td>87.8 ± 15.4</td>
<td>−2.3 ± 3.3</td>
<td>−1.6 ± 3.5</td>
</tr>
<tr>
<td>Treatment satisfaction score</td>
<td>27.58 ± 7.13</td>
<td>26.95 ± 6.61</td>
<td>31.1 ± 4.78</td>
<td>30.57 ± 5.54</td>
<td>3.52 ± 7.19</td>
<td>3.6 ± 7.63</td>
</tr>
<tr>
<td>General well-being total score</td>
<td>50.52 ± 8.47</td>
<td>50.66 ± 9.46</td>
<td>54.03 ± 8.24</td>
<td>52.55 ± 10.47</td>
<td>3.58 ± 7.01</td>
<td>1.75 ± 7.33</td>
</tr>
</tbody>
</table>

Subscale scores
- Depression: 3.18 ± 2.69
- Anxiety: 5.24 ± 3.24
- Energy: 7.91 ± 2.5
- Positive well-being: 14.81 ± 2.83

Data are expressed as means ± S.D. Statistically significant endpoint differences between the groups are: *p = 0.0086, **p = 0.032.

3.3. HbA1c response types

As reported by Schwedes et al. [6], the cluster analysis of the HbA1c profiles revealed three response types among SMBG patients: 58% showed continuous improvement, 18% experienced delayed success and 24% were unsuccessful in improving glycemic control. Fig. 1 shows the HbA1c profiles of the different response types. The continuous-achievers showed gradually declining HbA1c values over time with a sharper decline over the first 10 weeks (mean difference between baseline and endpoint −1.6%). In contrast, the group of late-achievers experienced an HbA1c increase in the first 10 weeks followed by a gradual decline (mean difference −0.6%). The non-achievers did not succeed in reducing HbA1c levels during the study period; an initial reduction was followed by a slight increase towards endpoint (mean difference 0.1%).

Examination of quality of life issues regarding the three response types showed no differences on the basis of the WBQ but revealed a significant effect on treatment satisfaction in the DTSQ. Treatment satisfaction scores significantly increased for continuous- and late-achievers compared to non-achievers (4.5 points at endpoint for continuous-achievers, 4.7 points for late-achievers and 3.6 points for non-achievers; p = 0.004).

When examining patients’ entries about their probability assessment for achieving their set goals (counseling algorithm, Table 2), no significant differences between the response types were found. It was, however, observed that late-achievers generally suggested the lowest and non-achievers the highest probabilities for achieving their behavior targets. Only the continuous-achievers assessed their target achievement with increasing accuracy over the course of the study.

3.4. Analysis of psychological aspects according to response type

In order to analyze the inner processes (revealed in the counseling sessions of the SMBG patients) according to HbA1c response type, the three psychological aspects self-perception, self-reflection and self-regulation were plotted versus the corresponding HbA1c values (Fig. 1). Continuous-achievers with their continuously decreasing HbA1c levels mainly discussed self-regulation during counseling sessions—with declining frequency over time (from 37% at week 0 to 26% at week 20). Issues of self-reflection increased during the study period and self-perception, whilst remaining at an overall low level, also showed a slight increase towards the end of the study (to 12% at week 20). Late-achievers experienced an increase in HbA1c values during the first 10 weeks of the study during which the counseling subjects of self-reflection and self-perception were increasingly mentioned (up to 20% for both at week 12). Aspects of self-regulation were more frequently discussed in the beginning but became less important with decreasing HbA1c values (from 45% at week 0 to 20% at week 20). Similar to the other two response types, self-regulation issues were most frequently discussed at the start of the study by the group of non-achievers. Frequency of reports continuously declined during the first 12 weeks followed by an increase—coinciding with an increase in

Table 4
Influence of psychological aspects on treatment success assessed by the brief counseling algorithm

<table>
<thead>
<tr>
<th></th>
<th>Week 0</th>
<th>Week 4</th>
<th>Week 12</th>
<th>Week 20</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-perception</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Feeling of threat</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Dissatisfaction</td>
<td>5</td>
<td>3</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>(with blood glucose)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Self-reflection</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Awareness (e.g. nutrition, stress)</td>
<td>19</td>
<td>24</td>
<td>22</td>
<td>22</td>
</tr>
<tr>
<td>Acceptance of diabetes</td>
<td>5</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Self-regulation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nutrition</td>
<td>35</td>
<td>34</td>
<td>30</td>
<td>21</td>
</tr>
<tr>
<td>Weight loss</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Diary use</td>
<td>6</td>
<td>6</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Exercise</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>2</td>
</tr>
</tbody>
</table>

Frequency (%) of SMBG patient reports on self-perception, self-reflection and self-regulation.
HbA1c levels. In contrast to the other response types non-achievers discussed aspects of self-reflection (30% at week 0) and self-perception (22% at week 0) more often at the beginning of the study. After 20 weeks, these issues had become less important (15% for self-reflection and 11% for self-perception).

4. Discussion and conclusion

4.1. Discussion

A recent systematic review of randomized controlled trials has shown the effectiveness of self-management training in type 2 diabetes, particularly in the short term [18]. One observation was that educational interventions involving patient participation and collaboration seemed to be more effective than didactic interventions in improving glycemic control. For future planning of counseling and educational concepts relating to a patient-orientated and quality-assured care, precise knowledge of psychological and counseling influencing aspects are of interest. In this study, we investigated these aspects and their relation to glycemic control in connection with the self-management tool SMBG.

The process of self-management includes the tendency to structure situations and activate resources (self-perception), to accept options for action (self-reflection) and to believe in self-efficacy (self-regulation). All these aspects were influenced by the intervention. Patients’ perception of their metabolic situation improved leading to a greater reflection about how to improve metabolic control but at the same time leading to increasing dissatisfaction with their blood glucose levels. They felt that they ‘should be able to do better’. Interestingly, this dissatisfaction did not result in negative changes in treatment satisfaction or quality of life scores (even non-achievers reported increased treatment satisfaction). Self-monitoring coupled with a structured instrument of brief counseling obviously provided patients with a tool for taking on more self-control. The ‘feeling of helplessness’ markedly decreased and diabetes acceptance was no longer a topic after the first two counseling sessions. The improvement in ‘depression’ and the overall improved total well-being score showed that SMBG did not put additional strain on the patient. On the contrary, the burden was reduced by using the SMBG device.

Our findings are in contrast to two recent studies [19,20]. Franciosi et al. [19] reported higher HbA1c levels and a higher psychological burden associated with SMBG in non-insulin treated type 2 diabetes patients, however, they did not investigate if these patients received instructions on using their blood glucose data to change their diabetes-related behavior. The second paper suggested a negative association between diabetes-specific self-management behavior such as diet adherence and quality of life by increasing the level of perceived burden [20].

The positive change in the sub-item ‘depression’ is interesting as clinical and subclinical expressions of depression are associated with hyperglycemia in both type
higher HbA1c levels were significantly associated with a deterioration in general well-being [23]. The improvement in WBQ scores in the present study supports these results. The question remains, however, whether reduced depression and improved general well-being were achieved by improved HbA1c levels or by the feeling of ‘being more in control’ which patients perceived when using a self-monitoring device and changing their diabetes-related habits accordingly. When WBQ scores of different HbA1c response types among the SMBG population were compared, no differences between the three groups could be detected. Failure to improve glycemic control (non-achievers) did not result in worse quality of life scores than for the successful continuous achievers. The feeling of ‘being in control’ might therefore be the contributing factor to an improved outlook on life.

The most important aspect of physician–patient discussions in the counseling sessions was the subject of self-regulation because it provided patients with concrete support for individual behavior control. Social aspects were not considered to be significant by the patients, based on the low frequency of mentioning the social support of their spouses. Only a few patients suggested that spouses should be included in educational classes and given information about the disease. Body-related aspects of diabetes management clearly dominated the discussions; diet was seen as the most important tool in improving blood glucose values.

Patients’ evaluation of the probability to reach set goals revealed different assessments according to response type. Continuous-achievers showed increasing accuracy in estimating achievement of their behavior targets while non-achievers tended to overestimate their ability to achieve self-defined goals. This was coupled with a failure to progress beyond a reflective level in counseling to a self-regulatory level in terms of trial and change. For patients with this behavior pattern, structured, meal-related SMBG in connection with a counseling program does not seem to be the right treatment choice.

Counseling is often still a neglected aspect of patient education for people with a chronic disease in Western Europe [24] and although diabetes is the area with the best established structures for patient education in Germany, too many patients still do not receive a sufficiently comprehensive standardized education program for managing their diabetes. Alternatively, they receive the information so late that they already suffer from diabetes complications which could have been prevented [25]. There are structured programs in place, which mostly combine information, strategies for behavioral changes, and self-management strategies; however, improvements in these programs are still needed.

5. Conclusion

This study identified aspects of the process of self-management (structuring the situation and activating resources [self-perception], accepting options for action [self-reflection] and believing in self-efficacy [self-regulation]) which lead to a change in the metabolic profile of patients using blood glucose self-monitoring. SMBG coupled with structured brief counseling provided patients with a tool for taking on more self-control and resulted in an improved outlook on life.

5.1. Practice implications

With rising numbers of patients with type 2 diabetes and increasingly less time for counseling in the medical care of these patients, an understanding of the effects and problems of brief counseling is of great importance. The present study can contribute in three ways:

i. Self-monitoring of blood glucose coupled with structured counseling provides patients with a tool for taking on more self-control and results in an improved outlook on life. The identification of the different response types continuous-achiever, late-achiever and non-achiever might be of importance in clinical practice as it enables the physician to determine the right counseling option. Identifying a patient as a non-achiever who will not respond to the treatment option of SMBG and structured brief counseling can save time, costs and energy in a busy practice setting.

ii. The brief counseling format presented here, which requires 5–10 min of patient–physician contact- was efficacious in the improvement of metabolic control.

iii. This short-term intervention involves only a structured interview and a structured documentation of metabolic control by the patient and can be taught by a diabetes training team within 4 h.

The satisfactory experiences gained with this form of short-term counseling call for further research into the development of such programs.

Acknowledgement

The study was funded by an unrestricted grant from Bayer AG.

Appendix A

Members of the SMBG Study Group

B. Braune, Lilienthal; C. Bruns, Wertach; F. Burgmayer, Langquaid; R. Daffner, Rottenburg; R. Engler, Gars am Inn; P. Genthner, Welzheim; V. Gohlke, Rain; T. Haak, Diabetes
Clinic Bad Mergentheim; D. Heim, Nürnberg; H. Lembcke, Braunschweig; G. Mahla, Feldafing; C. Petersen, Schleswig; H. Pohlmeier, Clemenshospital Münster; H. Samer, Haag; C. Schmidt, Weinstadt; U. Schwedes, General Hospital Barmbek; M. Siebolds, Catholic University of Applied Science, Cologne; G. Vielsmaier, Altdorf; T. Wascher, Medical Clinic, Karl-Franzens-University, Graz; W. Werry, Wilhelmshaven.

References


