Meal-Related Structured Self-Monitoring of Blood Glucose

Effect on diabetes control in non–insulin-treated type 2 diabetic patients

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OBJECTIVE — To investigate the effect of meal-related self-monitoring of blood glucose on glycemic control and well-being in non–insulin-treated type 2 diabetic patients.

RESEARCH DESIGN AND METHODS — This 6-month study, which included 6 months of follow-up, adopted a prospective, multicenter, randomized controlled design. Subjects were randomized to two groups: one group used a blood glucose–monitoring device, kept a blood glucose/eating diary, and received standardized counseling; the control group received nonstandardized counseling on diet and lifestyle. The primary efficacy parameter was the change in HbA_{1c}. Secondary efficacy variables included changes in body weight, lipids, and microalbumin and changes in treatment satisfaction and well-being.

RESULTS — In the per-protocol analysis, the use of a self-monitoring blood glucose device significantly reduced HbA_{1c} levels by 1.0 ± 1.08% compared with 0.54 ± 1.41% for the control group ($P = 0.0086$); subgroup analysis showed three types of responders. Body weight, total cholesterol, and microalbumin improved when using a glucometer, but there was no statistically significant difference between the two groups. Treatment satisfaction increased in both groups to a similar extent ($P = 0.9$). Self-monitoring resulted in a marked improvement of general well-being with significant improvements in the subitems depression ($P = 0.032$) and lack of well-being ($P = 0.02$).

CONCLUSIONS — Meal-related self-monitoring of blood glucose within a structured counseling program improved glycemic control in the majority of non–insulin-treated type 2 diabetic patients in this study. The finding of three types of responders will be important for future planning of counseling and educational interventions.

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The U.K. Prospective Diabetes Study showed that the quality of blood glucose control plays a central role in the development of micro- and macroangiopathy in type 2 diabetes and that improved glycemic control clearly reduces the occurrence of secondary diabetes complications (1). Thus, monitoring blood glucose status is an important tool in diabetes treatment procedures. In a recent position statement on tests used for monitoring the glycemic status, the American Diabetes Association recommended self-monitoring of blood glucose (SMBG) to be included in diabetes management (2). The efficacy of SMBG in type 2 diabetic patients is, however, still questionable (3) and lacking high-quality randomized controlled trials (3,4). Various smaller studies have demonstrated that SMBG leads to an improvement of glycemic control in mostly overweight type 2 diabetic patients if the procedure is meal-related with a fixed regimen (5–10). A positive correlation between SMBG and the reduction of HbA_{1c} levels has also been described in a recent large observational study about the relationship between self-monitoring frequency and glycemic control (11). Frequent monitoring (at least daily) significantly improved HbA_{1c} levels in type 2 diabetic patients, treated with insulin, oral antidiabetics, or diet only. Less frequent monitoring was also effective. A recent response letter to *Diabetes Care* also reported a positive association between regular SMBG and consistent discussions about the monitoring with a health care provider and glycemic control: HbA_{1c} levels significantly improved with regular monitoring (12). Theoretically, meal-related SMBG could lead to better compliance with diet or other treatment interventions, eventually resulting in better glycemic regulation.

The present study was designed to investigate the effect of meal-related SMBG on diabetes control in non–insulin-treated type 2 diabetic patients on a biometrical basis. Additionally, the effects on the burden of diabetes were assessed by measuring well-being and treatment satisfaction.

RESEARCH DESIGN AND METHODS

— The study was designed as a prospective, randomized, controlled, multicenter parallel group comparison between non–insulin-treated type 2 diabetic patients using an SMBG device and a control group; the study duration was 6 months plus 6 months of follow-up. Subjects were recruited by 21 centers in Germany and Austria; the study was conducted in an outpatient setting by family practitioners and hospitals. Type 2 diabetic patients with a BMI >25 kg/m^2, with HbA_{1c} values between 7.5 and 10%, and treated either with diet alone or diet in combination with sulfonylureas or metformin were included into the study. Further inclusion criteria were age between 45 and 70 years, diabetes known for at least 3 months, and participation in a diabetes educational program within the previous 2 years. Patients were ex-

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Abbreviations: PP, per-protocol; SMBG, self-monitoring of blood glucose.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

Table 1— *Counseling algorithm (ref. 13; physician-patient session at weeks 0, 4, 12, and 20; standardized questions)*

1. Increase of **self-perception** by keeping an eating/well-being diary and monitoring blood glucose
2. Promotion of **self-reflection**
   Experience with SMBG: What worked well? What did not work well?
   Greatest problem when using SMBG?
   Most important factor to facilitate SMBG?
   Information required on this factor?
3. Enhancement of **self-regulation**
   Ideas how to use SMBG results and diary entries to improve metabolic control
   Patient's assessment of probability of achieving set goals (%)

cluded if they were incapable of maintaining an eating diary and of documenting their state of well-being (relative or complete illiteracy), if they showed sensomotor disturbances that might impair unassisted SMBG (ametropia, motor function impairments, etc.), if they had used regular (trained, systematically used, etc.) SMBG during the 6 months before the start of study, or if they had participated in another clinical trial within 30 days before the start of study. Pregnant or lactating females as well as females without a safe contraception method were not allowed to enter the study. Further exclusion criteria were concurrent treatment with other antidiabetic agents such as insulin or treatment with nonselective β-blockers, glucocorticoids, amphetamines, or anabolic agents; diet reduction during the course of the study (<1,000 kcal/day); serum creatinine >3 mg/dl; or serum transaminases >50 units/l. Patients with serious underlying medical or psychiatric conditions or drug or alcohol abuse were also excluded. Since some of the participants were to be treated with acarbose (equally randomized to both groups), acarbose-related exclusion criteria also applied. The study was conducted in accordance with Good Clinical Practice and the Declaration of Helsinki. The protocol was approved by the corresponding ethics committee of each participating center. Written informed consent was obtained from all participating patients.

A total of 250 patients were enrolled and randomized within blocks of eight to receive one of the two treatments (week –2). During a 2-week run-in period, patients in the SMBG group were instructed in the use of a blood glucose device with sensor disc (Glucometer Dex) and requested to measure blood glucose six times (before and 1 h after main meals) on 2 days per week (one weekday and on Sunday) and to record the values obtained in a combined diary for blood glucose data and documentation of eating habits and their state of well-being (all entries were counted and checked for plausibility). It was explained to the patients that SMBG plus their diary would provide them with information about their day-to-day glycemic control, allowing them to make appropriate adjustments to their diet and lifestyle (if applicable), eventually resulting in improved diabetes control. The patients were seen every 4 weeks. During the 24 weeks of intervention, SMBG patients received a defined counseling algorithm (13) of six questions focusing on self-perception, self-reflection, and self-regulation (Table 1) at weeks 0, 4, 12, and 20. At these visits, nurses also assessed the correct use of the monitoring device by the patients and accuracy of self-monitoring was checked using wet chemical analysis (HemoCue). Patients continued using the glucometer during the follow-up period. The control group received nonstandardized counseling with a focus on their diet and lifestyle during these visits. Before the study, staff of all centers was simultaneously trained in counseling and diary discussions. Assistants and nursing staff received structured instructions on the correct use of the monitoring device, DCA 2000, and HemoCue and learned how to supervise and document the correct use and documentation by the patients. During the study, protocol adherence was controlled by regular monitor visits and audits.

Per-protocol (PP) analysis was performed as the main efficacy analysis. Patients were included in the analysis if they met protocol criteria, completed the entire study, showed valid efficacy parameter measurements, and were ≥70% compliant. The primary efficacy parameter was the change in HbA_{1c} after 24 weeks of SMBG (end point); HbA_{1c} was determined using the DCA 2000 analyzer (quality assurance by national central laboratory, standard calibration). Secondary efficacy parameters were changes in body weight, lipids, and microalbumin and changes in well-being and treatment satisfaction (measured by the *Patient Well-being Questionnaire* and the *Diabetes Treatment Satisfaction Questionnaire* [14,15]). Efficacy laboratory parameters and body weight were assessed at randomization and at 8, 16, and 24 weeks, and questionnaires were completed independently at randomization, 24 weeks, and follow-up and sealed in an envelope by the patient. HbA_{1c}, body weight, SMBG acceptance, treatment satisfaction, and well-being were also assessed during two visits in the 6-month follow-up period.

Data analysis was carried out using the SAS program (version 6.12). Sample size was estimated assuming a mean difference of 0.7% in HbA_{1c} between SMBG and control group at the end of study with a SD of 1.4% ($\alpha = 0.05$, $\beta = 0.2$). Allowing for the multicenter design and possible dropouts, at least 72 patients were required for each treatment arm. Evaluation of the primary efficacy parameter consisted of an ANCOVA for the end point with baseline as covariate and SMBG as the main effect. Secondary efficacy parameters were analyzed in an exploratory manner, and all psychosocial study aspects were evaluated by Psychonomics (Cologne, Germany).

RESULTS — Of the 250 randomized patients, 223 were included in the PP analysis (SMGB group, $n = 113$; control group, $n = 110$). Table 2 summarizes the baseline demographic characteristics, which compared well between the two groups. The mean BMI exceeded 30 kg/m^2 in both groups and "obesity and other hyperalimentation" were recorded as medical history findings for almost half of the patients.

There were no statistically significant differences between the groups regarding baseline efficacy parameters (Table 2). Values for total cholesterol, triglycerides, and microalbumin were slightly but not significantly lower ($P > 0.1$) in the SMBG

Table 2—*Baseline demographic characteristics and efficacy variables of the PP population*

Characteristic	No self-monitoring	Self-monitoring	*P*
Age (years)	60.5 ± 6.6	58.7 ± 7.6	0.3846
Gender			
Female (%)	48.2	47.8	0.8546
Male (%)	51.8	52.2	
Duration of diabetes (months)	62.6 ± 47.3	65.5 ± 57.2	0.5335
Body weight (kg)	89.6 ± 16.5	88.2 ± 15.4	0.3810
BMI (kg/m^2)	31.9 ± 5.5	31.0 ± 4.6	0.5224
HbA_{1c} (%)	8.35 ± 0.75	8.47 ± 0.86	0.8535
Total cholesterol (mg/dl)	227.5 ± 52.5	221.1 ± 41.2	0.3277
Triglycerides (mg/dl)	237.4 ± 192.8	204.2 ± 133.3	0.2966
Microalbumin (mg/l)	44.5 ± 63.4	42.7 ± 68.3	0.5305
Treatment satisfaction score	27.0 ± 6.6	27.6 ± 7.1	0.5006
General well-being total score	26.5 ± 5.9	26.4 ± 5.4	0.8576

Data are means ± SD.

group. The primary efficacy variable, HbA_{1c}, improved in both groups during the 24-week study period with a statistically significant difference at end point between the groups (95% CI 0.11–0.77; $P = 0.0086$, Fig. 1*A*). HbA_{1c} was reduced by 0.54 ± 1.41% in the control group (end point 7.81 ± 1.52%) and 1.0 ± 1.08% in the SMBG group (end point 7.47 ± 1.27%). A cluster analysis using complete linkage identified three response types among the patients using a self-monitoring device. Figure 1*B* shows the impact of SMBG on HbA_{1c} in relation to these response types. Fifty-eight percent of patients showed continuous improvement (mean difference at end point −1.6%) with a sharp decline in the first 8 weeks. Patients with delayed success (18%) experienced an increase in HbA_{1c} for the first 8 weeks followed by a reduction to 7.9 ± 1.0% at end point (mean difference −0.6%). The third subgroup (failure, 24%) showed an initial HbA_{1c} reduction, which increased to 8.5 ± 1.0% at end point (mean difference 0.1%). Further analysis of the response types showed that patients with delayed success had longer diabetes duration with more impaired blood glucose control. Analysis of the failure subgroup revealed that these patients did not differ in number and accuracy of monitoring from the other two groups but showed a high degree of theoretical reflections in combination with lacking self-regulation. During follow-up, 87% of the patients continued self-monitoring; metabolic status remained stable.

Body weight reduction at end point was greater in the SMBG group (mean difference −1.96 ± 2.99 kg) than in the control group (−1.62 ± 3.54 kg). This difference, however, was not statistically significant ($P = 0.332$). An assessment of the SMBG group according to response type showed a mean difference in body weight at end point of −2.7 kg for patients with continuous success, −1.5 kg for patients with delayed success, and −1.2 kg for failures. Examination of the lipid profile changes revealed improvement of total cholesterol levels for the SMBG group (mean difference at end point −3.46 ± 27.84 mg/dl) while levels in control patients increased by 0.2 ± 29.37 mg/dl. Triglyceride levels improved more strongly in the control group (mean difference at end point

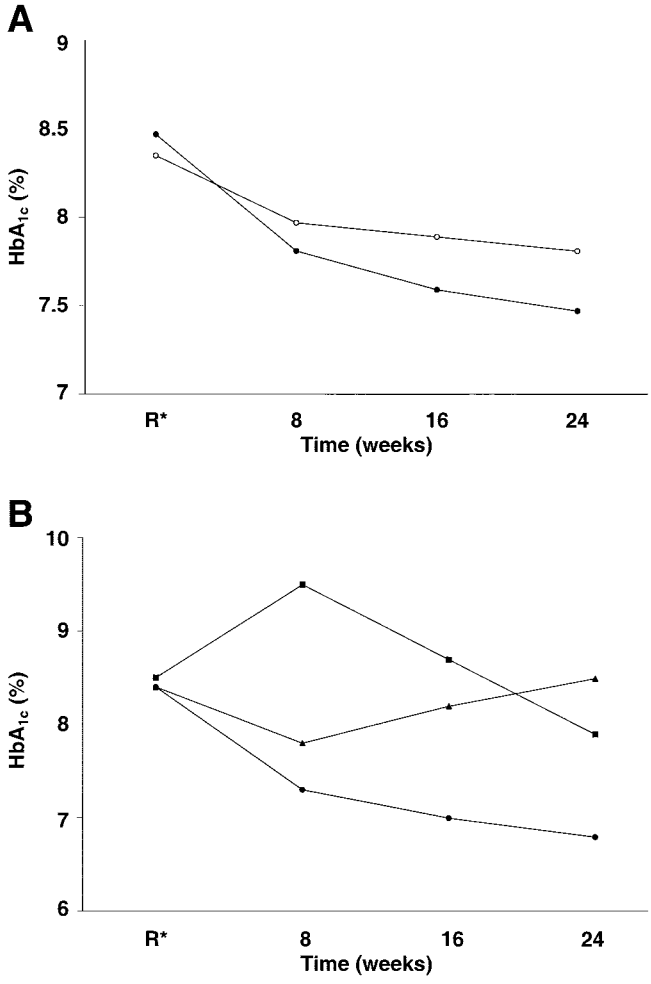

Figure 1—*Change in HbA_{1c} in the PP population during a 24-week study period.* A: *Comparison between SMBG (●) and control group (○).* B: *Comparison between various response types in the SMBG group (●, continuously successful; ■, with delayed success; ▲, failure). *Time of randomization.*

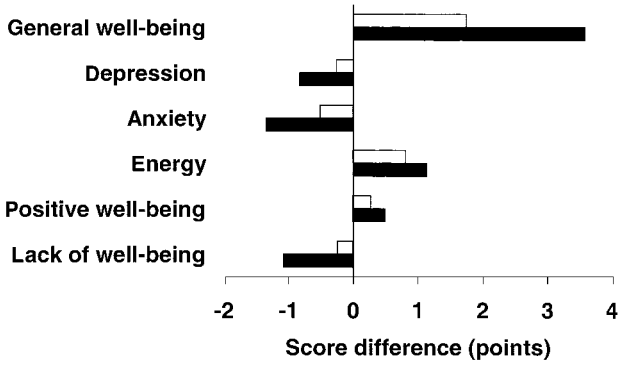

Figure 2—*The well-being of the patient measured by the* Patient Well-being Questionnaire*; score differences from baseline after a 24-week study period (■, self-monitoring; □, no self-monitoring).*

−19.87 ± 107.01 mg/dl) than in SMBG patients (−7.1 ± 139.97 mg/dl). Microalbumin increased in control patients (2.76 ± 46.32 mg/l) compared with a reduction in SMBG patients (−4.55 ± 41.67 mg/l). There was no statistically significant difference in these parameters between the groups (total cholesterol $P = 0.146$, triglycerides $P = 0.965$, and microalbumin $P = 0.123$).

Treatment satisfaction increased in both groups to a similar extent (mean difference at end point 3.6 ± 7.63 points for control, 3.52 ± 7.19 points for SMBG; $P = 0.9$). Well-being markedly improved when using a blood glucose–monitoring device ($P = 0.053$). Figure 2 shows the differences from baseline to end of study in the scores for the five subitems of the *Patient Well-being Questionnaire*. All items improved in the SMBG group with statistically significant changes for depression ($P = 0.032$) and lack of well-being ($P = 0.02$).

Nurses' assessment of the self-monitoring procedure showed that the blood glucose device was used correctly by all patients and that evenly all blood sampling and measurements were carried out correctly. Accuracy of the sensor device checked with wet chemical analysis showed ≥15% deviation in only 3.6% of the tested samples. The average number of weekly measurements was 24.8 ± 3.9 per patient, which is twice as many as requested. The main reason for this result was that the patients were experimenting with their favorite meals. The blood glucose/eating diary was regularly used by 97.9% of the patients and 98.5% recorded the data correctly. Almost all patients assessed the diary very positively.

CONCLUSIONS — In the present study a significant improvement was demonstrated in glycemic control among non–insulin-treated type 2 diabetic patients who used meal-related SMBG in combination with the educational tools of an eating diary, documentation of their feelings of well-being, and a standardized counseling program.

Self-monitoring proved to be feasible for the majority of patients in this study. The low rate of premature termination, high number of accurately performed tests, and accurate diary entries, as well as good adherence to the monitoring schedule, showed that patients coped well with this intervention strategy. The fact that 87% of the SMBG group still monitored their blood glucose levels at the end of the follow-up period underlines the acceptance of using the device, as does the increase in treatment satisfaction score. A subgroup analysis of the SMBG group identified a nonresponse type in 24% of the patients. These patients performed tests frequently and accurately but showed a high degree of theoretical reflections in combination with lacking self-regulation. They reflected a lot about their experience with the monitoring device but did not manage to act on their findings. Self-monitoring might be an incorrect management strategy for this particular group. This problem is addressed in a follow-up paper with psychological emphasis.

As in the study of Muchmore et al. (5), body weight was reduced in both intervention groups with no statistically significant differences between the groups. There was, however, a correlation between weight loss and HbA_{1c} reduction relating to patients' response type in this study: "continuously successful" patients showed twice the reduction in HbA_{1c} and nearly twice the reduction in body weight compared with patients with delayed success during the study period. Microalbumin and total cholesterol tended to improve using a glucose-monitoring device, but these changes did not reach statistical significance.

A recent study in Italian type 2 diabetic patients investigated the impact of SMBG on quality of life (16). The analysis showed that an SMBG frequency of at least one measurement per day was significantly related to higher levels of distress, worries, and depressive symptoms among non–insulin-treated patients. Frequency of at least one measurement a week was still significantly related to higher scores for diabetes health distress and diabetes-related worries. Another recent secondary analysis of a mailed survey also found that diabetes-specific health behaviors such as dietary adherence might negatively affect quality of life by increasing the level of perceived diabetes-related burden (17). These findings were in contrast to the results of the present study. Treatment satisfaction did not deteriorate when using a self-monitoring device regularly under a fixed regimen. It improved to a similar extent in both the SMBG and control groups and can probably be related to the similar amount of counseling attention patients in both groups received. Well-being markedly improved when using a glucometer, particularly in the scores for depression and lack of well-being. Regular measurements were mentioned as the most substantial problem in this intervention strategy but did not seem to have much effect on the general well-being of the patients.

Keeping a diary and recording eating habits and SMBG measurements causes patients to reflect more on their disease and the measures to improve their present status, thus enabling them to adopt a more autonomous disease management. This may be initially confusing or distressing, in particular for those patients with a more severe course and longer duration of diabetes. However, acceptance of the disease and willingness to change behavior related to diabetes may result in an improvement of quality of life. The benefit of self-monitoring probably lies in its effect as an educational modality and the increased staff attention patients received.

In summary, a positive effect was shown in this study by using meal-related SMBG in combination with an eating diary and a structured counseling program for feedback and reinforcement in the improvement of the glycemic status in non–insulin-treated type 2 diabetic patients.

APPENDIX

Members of the SMBG Study Group

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