The efficacy of self-monitoring of blood glucose in the management of patients with type 2 diabetes treated with a gliclazide modified release–based regimen. A multicentre, randomized, parallel-group, 6-month evaluation (DINAMIC 1 study)

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Aim: To determine if therapeutic management programmes for type 2 diabetes that include self-monitoring of blood glucose (SMBG) result in greater reductions in glycated haemoglobin (HbA1c) compared with programmes without SMBG in non-insulin requiring patients.

Methods: Multicentre, randomized, parallel-group trial. A total of 610 patients were randomized to SMBG or non-SMBG groups. Patients in both groups received the same oral antidiabetic therapy using a gliclazide modified release (MR)–based regimen for 27 weeks. The primary efficacy end-point was the difference between groups in HbA1c at the end of observation.

Results: A total of 610 patients were randomized: 311 to the SMBG group and 299 to the non-SMBG group. HbA1c decreased from 8.12 to 6.95% in the SMBG group and from 8.12 to 7.20% in the non-SMBG group; between-group difference was 0.25% (95% CI: 0.06, 1.03; \(p = 0.0097\)). Symptoms suggestive of mild to moderate hypoglycaemia was the most commonly reported adverse event, reported by 27 (8.7%) and 21 (7.0%) patients in the SMBG and non-SMBG groups, respectively; the incidence of symptomatic hypoglycaemia was lower in the SMBG group.

Conclusion: In patients with type 2 diabetes, the application of SMBG as an adjunct to oral antidiabetic agent therapy results in further reductions in HbA1c.

Keywords: gliclazide modified release, glycaemic control, self-monitoring of blood glucose (SMBG), type 2 diabetes
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Introduction

Achieving and maintaining optimal glycaemic control is one of the principal aims of disease management in type 2 diabetes. Projections from the United Kingdom Prospective Diabetes Study (UKPDS) suggested that for each 1% reduction in mean glycated haemoglobin (HbA1c), there would be an associated 37% decline in the risk of microvascular complications, 14% lower rate of myocardial infarction and fewer deaths from diabetes or any cause [1]. However, despite current knowledge of the relationship between hyperglycaemia and diabetes-related morbidity and mortality, and a myriad of effective treatment options, the majority of patients are not achieving blood glucose targets [2–4]. Clearly, improvements in methods for achieving glycaemic control are required.

Self-monitoring of blood glucose (SMBG) is a widely accepted tool in patients with type 1 diabetes for the optimization of insulin therapy and hence glycaemic control [5]. The use of SMBG is also recommended in patients with type 2 diabetes treated with insulin [6]. However, although commonly advocated in clinical guidelines [6–9], consensus on whether patients with type 2 diabetes who are not on insulin treatment should monitor their blood glucose levels has not been reached. Reviews that summarized the results of randomized studies in this area up to 1999 concluded that evidence regarding the effectiveness of SMBG in type 2 diabetes was inconclusive [10–13]. More recently, several additional randomized, controlled trials in this area have been performed [14–19]. Reviews that have included these trials concluded that interventions with SMBG were more effective in improving glycaemic control relative to interventions without SMBG [20–22]. However, differences between the studies included in these reviews require the data to be interpreted with caution. Methodological limitations in some of the studies included small sample size, variability in the frequency of glucose monitoring and failure to provide identical instruction on how to adjust lifestyle and medication to modify their glucose levels. In addition, the studies were not homogeneous regarding study populations (e.g. varying baseline HbA1c levels and duration of diabetes) and interventions, and HbA1c was generally the only outcome measure available with no assessment of hypoglycaemic episodes or quality of life.

To provide a more clearly defined answer to the question of whether patients with type 2 diabetes not receiving insulin should monitor their blood glucose levels, there have been a number of calls for an adequately powered, prospective, randomized, controlled trial [10,12,13,23,24]. The Diamicron MR in NIDDM: Assessing Management and Improving Control (DINAMIC 1) study has been designed to address the methodological issues highlighted above inherent in past studies.

The objectives of the study were twofold. First, to evaluate the contribution of SMBG in the management of patients with type 2 diabetes, with an emphasis on glycaemic control. Second, to compare the efficacy, tolerability and acceptability of an identical once-daily gliclazide modified release (MR)–based regimen in patients with type 2 diabetes with and without SMBG. Gliclazide MR is a new formulation of an established treatment for type 2 diabetes that is taken once daily [25]. Gliclazide MR was thought to be an appropriate treatment to fulfil the requirement of identical antidiabetic therapy in the two groups as it combines efficacy in glycaemic control with a low risk for hypoglycaemic episodes [26].

Patients and Methods

Patients

Male and female outpatients aged 40–80 years who had been diagnosed with type 2 diabetes, as defined by the American Diabetes Association [27], were screened at 133 specialist centres in seven countries (Czech Republic, Hungary, Iran, Malaysia, Poland, Slovakia and Turkey). Inclusion criteria were (i) treatment with diet alone for ≥3 months, diet and biguanide or alpha-glucosidase inhibitor or diet plus any insulin secretagogue for <12 months and (ii) HbA1c between 7 and 10%. Exclusion criteria included current management with SMBG; lifestyle or concurrent condition (medical or psychiatric) that could interfere with end-point evaluation (e.g. serious anaemia, haemoglobinopathy and haemolysis) or ability to comply with study procedures including SMBG and diary keeping; abnormalities on laboratory screening including creatinine clearance <20 ml/min and/or serum creatinine >140 μM and alanine aminotransferase (ALT) or aspartate aminotransferase (AST) more than three times the upper limit of the normal range; therapy with systemic glucocorticoids; known contraindication to gliclazide; known drug or alcohol dependence and pregnancy, lactation or planned pregnancy.

Methods

This was a multicentre, randomized, parallel-group, 6-month study conducted between January 2001 and January 2005. The study protocol was approved by the independent local institutional review boards of all
participating centres, and all patients provided written informed consent. The study was conducted in compliance with the ethical principles originating from the Declaration of Helsinki.

Eligible patients were randomized in a sequential manner using a centrally generated random allocation sequence to either the SMBG or the non-SMBG group at week 0. All patients received diet and lifestyle advice, which was reinforced at each clinic visit [28]. Oral antidiabetic agent therapy was standardized for all randomized patients. Those previously on an insulin secretagogue were transferred to gliclazide MR (Diamicron® MR) following the approved dosage recommendations. For other patients, gliclazide MR was added to their treatment at an initial dose of 30 mg once daily. Gliclazide MR doses could be uptitrated at weeks 3, 6, 9 or 18 (to a maximum of 120 mg/day) if fasting plasma glucose (FPG) was >7 mmol/l (7.8 mmol/l in patients over 65 years) on laboratory values or SMBG (where relevant). Back-titration was planned in the case of frequent moderate hypoglycaemia. Biguanide or alpha-glucosidase inhibitor doses were maintained stable at the preinclusion dose. Gliclazide MR was taken once daily before or during a breakfast. The study duration was 27 weeks.

Patients randomized to the SMBG group were instructed in self-monitoring their blood glucose. Approved devices included any of those manufactured by the following companies: Bayer Diagnostics, Roche Diagnostics, Hypoguard, LifeScan and Medisense. Each country involved in the study used one standard blood glucose metre with the following characteristics: glucose measurement in mmol/l, ≥100 measurement memory for time/date/glycaemia, instructions and prompts in the language(s) of the country concerned and user-rechargeable batteries. Instruction included information on how to use the glucose metre, how to check it was working, when to take measurements, how to record them in the patient diary and what to do in the event of asymptomatic hypoglycaemia (measured glucose <3 mmol/l on SMBG without symptoms/signs suggestive of hypoglycaemia) or SMBG-confirmed hypoglycaemia. The appropriate use of the glucose metre was checked at each visit by the study investigator. Subjects assessed their blood glucose on 2 days per week (one working day and one non-working day) at the following times: before each meal (breakfast, lunch and dinner), 2 h after the main meal and before bedtime. Once per month, on a day timed to fall between study visits, subjects were required to increase the frequency of their postprandial measurements to after each of the three main meals.

Both SMBG and non-SMBG patients were required to keep a patient diary to record any symptoms suggestive of hypoglycaemia including information about their last meal, temporal association to antidiabetic agent therapy and actions taken, e.g. resolved after eating and third party assistance required. All patients were provided with information on symptoms, avoidance and management of hypoglycaemia with their patient diary. In the event of suspected hypoglycaemia, subjects in the SMBG group were instructed to take a blood glucose reading and to follow the instructions on management of hypoglycaemia in the patient diary. For patients in the SMBG group, the patient diary also provided a record of the SMBG results.

The primary efficacy end-point was the difference between groups in HbA1c at week 27. HbA1c values were recorded at selection (week –2) and week 27. HbA1c values were measured according to Diabetes Control and Complications Trial (DCCT) standards in a central national laboratory to minimize between-laboratory variability. Secondary efficacy end-points included mean changes from baseline HbA1c and FPG at week 27 and gliclazide MR dose. FPG was measured at weeks –2, 0, 3, 6, 9, 18 and 27 after an overnight fast.

Hypoglycaemic episodes were classified as follows: suspected mild hypoglycaemia (grade 1), suspected moderate hypoglycaemia (grade 2), suspected severe hypoglycaemia with need of third party assistance (grade 3) and suspected severe hypoglycaemia with need of medical assistance (grade 4).

A sample size of 394 patients per randomization group was planned to provide 80% power to detect a 0.3% difference in HbA1c with an overall type 1 error of 0.05. To account for a possible 20% dropout rate, a total of 946 patients (473 per randomization group) were to be recruited for the study.

Randomization group values were compared by means of unpaired t-test. The primary analysis population was the full analysis set, defined a priori in the protocol as all randomized patients who took at least one dose of gliclazide MR during the study, who performed SMBG at least once (for the SMBG group) and with a baseline HbA1c and at least one postbaseline HbA1c value (and after one SMBG measure for the SMBG group). If the week 27 observation was not available, the last observation was carried forward. A 95% confidence interval was assessed for the difference (non-SMBG – SMBG) and a Student’s t-test for independent samples was performed. Ninety-five per cent confidence intervals were also determined for the difference (non-SMBG – SMBG) in the secondary efficacy parameters: mean change from baseline HbA1c and mean change from baseline FPG. All subjects who took at least one dose of gliclazide MR were analysed for adverse events.
Results

Demography and Baseline Characteristics

A total of 610 patients were randomized: 311 to the SMBG group and 299 to the non-SMBG group. The number of patients randomized per country is shown in table 1. In the intent-to-treat population, 271 subjects (87%) in the SMBG group and 248 subjects (83%) in the non-SMBG group completed the study. Overall, 37 patients withdrew from the SMBG group and 47 from the non-SMBG group. A further three withdrawals in the SMBG group and four withdrawals in the non-SMBG group occurred between week 18 and week 27 because of loss to follow-up but were not classified as such because of the protocol definition (loss to follow-up for two or more consecutive visits during the study period). There was no significant difference between groups in the reasons for withdrawal (figure 1).

Patient characteristics at study entry were similar between the randomization groups with the exception of a higher proportion of menopausal women in the SMBG group (88.4 vs. 81.8% in the non-SMBG group) (table 1). Overall, mean known duration of diabetes was 2.79/4.48 and 2.82/3.69 years in the SMBG and non-SMBG groups respectively. Most patients (>70%) had been treated prior to the study with an oral antidiabetic agent including an insulin secretagogue in 78 (45.6%) patients in the SMBG group and 91 (49.5%) patients in the non-SMBG group. Randomization groups were well balanced in terms of medical history and physical examination findings.

There was no significant difference between randomization groups in study duration or duration of treatment intake. The majority of patients received dose increases at each titration visit with no differences between the groups in levels of dose titration. The mean gliclazide MR dose during the study increased from 37 and 38 mg/day for the SMBG and non-SMBG groups, respectively, at inclusion to 62 and 68 mg/day, respectively, at the week 18 visit with no significant difference between randomization groups.

Efficacy

At week 27, there was a significantly greater decrease in mean HbA1c in the SMBG group [from 8.12% (s.d. 0.89%) to 6.95% (s.d. 0.97%)] compared with the non-SMBG group [8.12% (s.d. 0.84%) to 7.20% (s.d. 1.22%)] (figure 2). The treatment group difference in mean HbA1c level (the primary end-point) was 0.25% (s.d. 1.09%); 95% CI: 0.06, 1.03; p = 0.0097. Mean changes from baseline HbA1c were −1.15% (s.d. 1.14%) and −0.91% (s.d. 1.29%) in the SMBG and non-SMBG groups, respectively; treatment group difference was

Table 1 Demographic and baseline characteristics for patients with type 2 diabetes receiving gliclazide MR randomized to SMBG or non-SMBG groups

<table>
<thead>
<tr>
<th>Parameter</th>
<th>SMBG</th>
<th>Non-SMBG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>311</td>
<td>299</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>27</td>
<td>27</td>
</tr>
<tr>
<td>Hungary</td>
<td>43</td>
<td>43</td>
</tr>
<tr>
<td>Iran</td>
<td>16</td>
<td>15</td>
</tr>
<tr>
<td>Malaysia</td>
<td>33</td>
<td>32</td>
</tr>
<tr>
<td>Poland</td>
<td>164</td>
<td>159</td>
</tr>
<tr>
<td>Slovakia</td>
<td>14</td>
<td>15</td>
</tr>
<tr>
<td>Turkey</td>
<td>14</td>
<td>8</td>
</tr>
<tr>
<td>Male, n (%)</td>
<td>150 (48.2)</td>
<td>155 (51.8)</td>
</tr>
<tr>
<td>Female, n (%)</td>
<td>157 (50.5)</td>
<td>143 (47.8)</td>
</tr>
<tr>
<td>Age (years)</td>
<td>55.9 ± 9.3</td>
<td>56.1 ± 9.1</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>84.0 ± 15.6</td>
<td>83.8 ± 16.7</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>30.5 ± 5.3</td>
<td>30.3 ± 5.0</td>
</tr>
<tr>
<td>Systolic blood pressure (mmHg)</td>
<td>140.2 ± 25.3</td>
<td>138.5 ± 17.7</td>
</tr>
<tr>
<td>Diastolic blood pressure (mmHg)</td>
<td>83.6 ± 9.4</td>
<td>84.1 ± 9.2</td>
</tr>
<tr>
<td>Heart rate (bpm)</td>
<td>77.7 ± 7.3</td>
<td>76.6 ± 8.1</td>
</tr>
<tr>
<td>Menopause, n (%)</td>
<td>114 (88.4)</td>
<td>90 (81.8)</td>
</tr>
<tr>
<td>Diabetes duration (years)</td>
<td>2.8 ± 4.5</td>
<td>2.8 ± 3.7</td>
</tr>
<tr>
<td>Glycated haemoglobin (%)</td>
<td>8.12 ± 0.89</td>
<td>8.12 ± 0.84</td>
</tr>
<tr>
<td>Fasting plasma glucose (mmol/l)</td>
<td>8.94 ± 2.29</td>
<td>9.01 ± 2.45</td>
</tr>
<tr>
<td>Diabetes currently treated, n (%)</td>
<td>216 (69.5)</td>
<td>220 (73.6)</td>
</tr>
<tr>
<td>One oral antidiabetic drug</td>
<td>171 (79.2)</td>
<td>184 (83.6)</td>
</tr>
<tr>
<td>Biguanide</td>
<td>73.0 (42.7)</td>
<td>79.0 (42.9)</td>
</tr>
<tr>
<td>α-glucosidase inhibitor</td>
<td>12.0 (7.0)</td>
<td>10.0 (5.4)</td>
</tr>
<tr>
<td>Insulin secretagogue</td>
<td>78.0 (45.6)</td>
<td>91.0 (49.5)</td>
</tr>
</tbody>
</table>

MR, modified release; SMBG, self-monitoring of blood glucose.
All countries showed a trend towards or a significant decrease in mean HbA1c in the SMBG group compared with the non-SMBG group at week 27 with the exception of Poland. The decrease in FPG from baseline to week 27 was similar in both groups, and the difference between treatment groups was small. For the SMBG group, the mean baseline FPG of 8.94 mmol/l (s.d. 2.29 mmol/l) decreased by 1.26 mmol/l (s.d. 2.49 mmol/l). For the non-SMBG group, the mean baseline FPG of 9.01 mmol/l (s.d. 2.45 mmol/l) decreased by 0.97 mmol/l (s.d. 2.54 mmol/l) (figure 4). There was no significant difference between groups in mean change from baseline FPG: mean difference 0.8325 mmol/l (95% CI: –0.477, 2.1422).

Safety

Hypoglycaemia

The most commonly reported adverse event was symptoms suggestive of hypoglycaemia. In the SMBG group, 27 (8.7%) patients had a total of 51 hypoglycaemic events of which 27 were symptomatic, 11 asymptomatic, 11 SMBG-confirmed hypoglycaemia and 2 non-graded. In the non-SMBG group, 21 (7.0%) patients had a total of 66 hypoglycaemic events of which 64 were symptomatic and 2 were non-graded. No patients experienced any severe (grade 3 or 4) symptoms. Symptoms suggestive of nocturnal hypoglycaemia were experienced by three patients in the SMBG group and seven patients in the non-SMBG group. There were only two withdrawals because of hypoglycaemia, both occurring in the non-SMBG group.

Adverse Events

All-causality adverse events were experienced by 41 (13.2%) patients in the SMBG group and 45 (15.1%) patients in the non-SMBG group. The majority of adverse events were of mild or moderate severity.

There were no notable changes in blood pressure or physical examination findings during the study in either group. There was a significant difference in heart rate between the groups with a mean decrease of 1.74 ± 7.95 bpm from baseline for SMBG patients and a mean increase of 0.40 ± 8.80 bpm for non-SMBG patients (p = 0.0034). Both SMBG and non-SMBG groups had similar mean weights at baseline. Both groups were associated with a similar mean weight drop over the course of the study: −0.68 ± 5.70 kg (SMBG) and −0.50 ± 4.01 kg (non-SMBG).

Discussion

The DINAMIC 1 study provides data supporting the value of SMBG as an adjunct to oral antidiabetic therapy in patients with type 2 diabetes. Although the recruitment target was not met, the sample size was large enough to provide 80% power with an overall type 1 error of 0.05. Overall, patients randomized to the SMBG group experienced a significantly greater reduction in HbA1c compared with the non-SMBG group. With SMBG, an additional reduction in HbA1c of 0.25% was observed.
Such a difference could be clinically relevant if sustained in the long term. Results from studies such as the UKPDS suggest that any improvement in glycaemic control across the diabetes range is likely to reduce the risk of diabetes complications [1]. The only country in which there was not a trend towards or a significant decrease in mean HbA1c in the SMBG group compared with the non-SMBG group at week 27 was Poland. The explanation for the lack of difference in the Polish population may be related to a higher percentage of insulin secretagogue use at baseline. The switch to gliclazide MR, as an additional intervention to SMBG, may therefore have had less of an effect on HbA1c. In addition, mean HbA1c in the Polish population was lower compared with other countries. It is known that interventions focused on lowering blood glucose show a greater effect at higher baseline HbA1c levels.

In this study, there was no difference in nutrition or exercise counselling between the two groups, and no specific information was provided to the SMBG group for adjusting behaviour in relation to SMBG results. The glucose control regimen in this trial was identical in both arms and based on a MR sulphonylurea preparation (gliclazide MR 30–120 mg), which provides 24-h glucose control in a single daily dose [29]. The additional improvement in HbA1c levels observed in the SMBG group may therefore be attributable to the practice of regular SMBG. Unlike FPG, meal-based SMBG may enable patients to see the effects of their meal choices and portion sizes. Postprandial SMBG values are often the highest glucose readings of the day and may motivate patients to avoid problem foods, increase physical activity to manage hyperglycaemic excursions or evaluate and adjust doses of antidiabetic agents.

DINAMIC 1 was specifically designed to overcome some of the problems inherent with previous studies that have compared monitoring with non-monitoring groups. Thus, the study was prospectively designed and sufficiently large to show a difference in end-of-study HbA1c levels between the two groups. Other studies that have followed this approach have shown that SMBG was statistically associated with better quality of metabolic control than usual recommendations alone in patients with type 2 diabetes [16,30]. Importantly, in the DINAMIC 1 study, all patients received identical oral antidiabetic therapy with a gliclazide MR–based regimen so that any differences in HbA1c between the groups were a result of SMBG and not because of differences in study medication.

The DINAMIC 1 results contrast with those of the recently published Diabetes Glycaemic Education and Monitoring (DiGEM) study, which found no significant improvement in glycaemic control after 12 months in patients with non-insulin–treated type 2 diabetes using SMBG when compared with those not using SMBG [31]. In DINAMIC 1, patients in the SMBG group were instructed to uptitrate their gliclazide MR dose if FPG levels were >7 mmol/l (7.8 mmol/l in patients over 65 years). In contrast, the DiGEM study was not target driven and it was left to the treating physician to alter oral antidiabetic medication, although it is not known how intensively this was carried out. It is therefore possible that as the readings were not being used by the patients to improve glycaemic control, they ceased to be of relevance. While the apparent benefit associated with SMBG in DINAMIC 1 was modest, it was accompanied by weight loss, albeit minor, and unlike the DiGEM study did not require training of health care professionals. Finally, in the DiGEM study, hypoglycaemia was detected more frequently in the SMBG group than in the unmonitored group. While adjusting medication to avoid hypoglycaemia is not expected to lower HbA1c levels, it is an important safety outcome.

An important consideration is that type 2 diabetes can progress to chronic complications without any symptoms.
and that tools such as SMBG may prove invaluable in the prevention of these conditions. DINAMIC 1 was not designed to determine the effect of SMBG on long-term outcomes, such as cardiovascular end-points. However, a recent retrospective cohort study followed over 3000 subjects from diagnosis of type 2 diabetes for a mean period of 6.5 years [32]. A high proportion of subjects in the study used SMBG while being treated with diet or oral antidiabetic agents (808 of 2515, 32%). The use of SMBG was associated with significant reductions in diabetes-related morbidity and all-cause mortality, which remained in the subgroup of patients who were not receiving insulin, and when statistical adjustments were made for the type of hypoglycaemia treatment received by patients in the two cohorts. The DINAMIC 1 study therefore adds to a growing body of evidence supporting the role of SMBG as a tool to help patients treated with oral agents achieve greater reductions in HbA1c and thus reduce the risk of long-term, diabetes-related complications.

The advent of SMBG has made it possible for patients to obtain immediate, precise feedback on their glucose levels. Thus, they are able to make informed decisions about lifestyle changes and modify their antihyperglycaemic treatments much more precisely. However, the random measurement of blood glucose does not provide adequate information upon which to make decisions. For example, if the prescribed therapy is intended to address high FPG, SMBG should focus primarily on morning glucose levels. Conversely, if postprandial hyperglycaemia is the therapeutic target, 2-h postprandial glucose testing is the more appropriate approach. In this study, subjects assessed their blood glucose 2 days per week with a regimen of pre- and postprandial measurements in addition to before bedtime. It is possible that greater frequency of SMBG might have led to even greater improvements in glycaemic control. Data from a large epidemiological study have shown a link between increased SMBG frequency and improved HbA1c levels [19]. Further studies may therefore be warranted to determine whether more frequent monitoring is cost effective in such a target population and whether there would be any impact on patient compliance.

SMBG is an important tool for minimizing hypoglycaemic events as it allows patients to understand the impact of food choices and physical activity on glucose levels and allows them to gain control of their disease. Understanding blood glucose levels can help patients anticipate situations where high or low blood glucose is likely to be experienced and allows patients to plan ahead to prevent these situations from occurring and to adjust medications, medical nutrition therapy and physical activity. In the current study, it is likely that SMBG enabled patients to pre-empt a symptomatic hypoglycaemic episode as although the total number of hypoglycaemic episodes in the SMBG and non-SMBG groups was similar, the incidence of symptomatic hypoglycaemic episodes was more than twofold greater in the non-SMBG group. Previous studies have shown a low hypoglycaemia risk with gliclazide MR compared with other sulphonylureas [26,33–35]. As there was no comparator arm in this study, it is not known if the frequency of hypoglycaemic events in the SMBG and non-SMBG groups would have differed if patients had been treated with other sulphonylureas.

In this study, at least 70% of patients were being treated with an oral antidiabetic agent at study entry, and gliclazide MR was effective in replacing this monotherapy, achieving reductions in HbA1c levels of approximately 1%. Results for FPG showed a similar trend with mean changes from baseline of −1.26 and −0.97 mmol/l in the SMBG and non-SMBG groups, respectively, reflecting the 24-h glycaemic control that is achieved with a single dose. However, efficacy conclusions in relation to other oral antidiabetic agents cannot be made as all patients necessarily received identical oral antidiabetic therapy with a gliclazide MR–based regimen so that any differences in HbA1c between the groups were a result of SMBG and not because of differences in study medication. In addition, the study environment (regular visits, dietary and lifestyle advice and greater health professional input and interest) is likely to have had some influence on the observed improvement in HbA1c.

As a result of its chronic nature, the severity of its complications and the means required to control them, diabetes is a costly disease not only for the affected individual and their family but also for the health authorities [36,37]. While those challenging the use of SMBG in non-insulin–treated patients frequently cite the added cost of the technique [38], this must be weighed against the potential reduction in long-term complications and associated treatment costs that can be achieved with improved glycaemic control.

In conclusion, the results of this study suggest that when integrated with proper diabetes education, SMBG can improve glycaemic control in patients with type 2 diabetes who are not receiving insulin. In concert with lifestyle interventions and once-daily, effective treatments for glycaemic control, patients can then interpret and act on their blood glucose results to achieve optimal self-management.

Acknowledgement

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References


