Accuracy and Reliability of Reporting Self-monitoring of Blood Glucose Results in Adults With Type 1 and Type 2 Diabetes

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ABSTRACT

OBJECTIVE

To determine the accuracy and reliability of reporting of self-monitoring of blood glucose results by adults with types 1 and 2 diabetes during 2 different periods.

METHODS

Sixty adults (15 with type 1 diabetes on intensive management and 45 with type 2 diabetes on conventional management) who were part of separate clinical trials participated. Logbooks were compared with meter-downloaded results from the first 2 months (period 1) and last 2 months (period 2) of each trial. Reported values were categorized as clinically accurate (≤15% difference between logbook and meter), modified (>15% difference), phantom (absent in meter) or omission (absent in logbook).

RESULTS

Only 53% of type 1 and 59% of type 2 patients were very reliable (>90% of values clinically accurate) in their reporting by period 2. Inaccuracies consisted of phantom and omitted values but did not represent an attempt to improve the

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RÉSUMÉ

OBJECTIF

Déterminer la précision et la fiabilité des résultats de l'autosurveillance de la glycémie transmis par des adultes atteints de diabète de type 1 ou 2 au cours de deux périodes.

MÉTHODES

Soixante adultes (15 atteints de diabète de type 1 recevant un traitement intensif et 45 atteints de diabète de type 2 recevant un traitement classique) participant à des essais cliniques distincts ont pris part à l'étude. Les journaux des patients ont été comparés aux résultats téléchargés à partir d'un indicateur de glycémie pendant les deux premiers mois (période 1) et les deux derniers mois (période 2) de chaque essai. Les résultats transmis ont été classés comme étant cliniquement exacts (différence ≤ 15 % entre le journal et l'indicateur), modifiés (différence > 15 %), fictifs (non existants dans l'indicateur) ou omis (absents dans le journal).

RÉSULTATS

Seulement 53 % des patients atteints de diabète 1 et 59 % des patients atteints de diabète de type 2 étaient très fiables (> 90 % des résultats étaient exacts) pour transmettre les résultats au moment de la période 2. Les erreurs étaient des résultats fictifs ou omis, mais n'étaient pas commises en vue d'améliorer le profil clinique. Les patients qui étaient très fiables avaient un contrôle de la glycémie optimal, étaient plus satisfaits et moins inquiets (qualité de vie) et étaient plus confiants (auto-efficacité) en ce qui a trait à la prise en charge du diabète.

CONCLUSIONS

À eux seuls, les journaux sur la prise en charge du diabète par le patient peuvent induire en erreur. Par conséquent, nous recommandons aux cliniciens de se servir aussi des données téléchargées à partir de l'indicateur de glycémie pour prendre des décisions éclairées quant aux soins cliniques des patients atteints de diabète.

clinical profile. Individuals who were very reliable had optimal glycemic control; were more satisfied and less worried (quality of life); and were more confident (self-efficacy) in their diabetes self-management.

CONCLUSIONS

Relying solely on logbooks for self-management data can be misleading. Therefore, we recommend that clinicians also use meter-downloaded data to inform decision-making in the clinical care of patients with diabetes.

INTRODUCTION

Diabetes management includes self-monitoring of blood glucose (SMBG) as a critical component of clinical decision-making. According to the American Diabetes Association's 1996 consensus statement on SMBG, healthcare professionals should use SMBG data to make clinical decisions concerning the nutritional and pharmacological management of diabetes and to teach patients how to make self-care management decisions (1). However, for SMBG to be useful to both the patient and healthcare team, data must be accurate and reliable. The development of memory-equipped blood glucose (BG) meters allows clinicians to validate the accuracy of patients' SMBG logbooks.

In 1984, Mazze and colleagues were the first to publish results assessing the accuracy of SMBG reporting by comparing it to meter-downloaded results (2). Over a 2 week period, they evaluated the SMBG logbooks of 19 subjects with type 1 diabetes who were unaware of the memory capacity of the BG meters. Findings revealed that 26% of self-reported logbook values differed from the meter memory, and 75% of subjects reported mean BG values that were significantly lower than the actual values stored in the meter memory. Since then, other studies (3-5) have confirmed these results, including one in subjects using continuous insulin infusion or insulin pumps (3) and one in subjects with gestational diabetes (4). Interestingly, when subjects were aware that BG values reported in logbooks were being compared to those in meter memory, the accuracy of reporting increased (6).

Aside from the accuracy of reporting, other information critical to diabetes management can be gathered from memory-equipped BG meters, such as adherence to recommended SMBG frequencies (5). Since SMBG continues to play a critical role in the management of diabetes (7) and because it has been over a decade since the issue of reporting accuracy has been addressed, the goal of our study was to determine whether there was still a significant problem with respect to the accuracy of SMBG reporting in adults with type 1 and type 2 diabetes and whether there were any predictors of accuracy. Specific objectives of our study were as follows: to determine the accuracy and reliability of self-reported BG values in the logbooks of patients with type 1 and type 2 diabetes over a 2 month period and whether there were changes 6 or 10 months later; to evaluate adherence to recommended SMBG frequencies; and to identify potential predictors of accuracy in both populations.

DESIGN AND METHODS

Participants

Adults between the ages of 18 and 65 years attending the Metabolic Day Centre of the Royal Victoria Hospital, Montreal, Quebec, Canada, were recruited to participate in 2 independent studies. Adults with type 1 diabetes participated in a 12 month trial to compare 3 treatment strategies used in intensive management (8). Adults with type 2 diabetes participated in an 8 month nutrition-education trial to assess the impact of teaching them how to incorporate added sugar choices or sweets into their daily meal plan (9). SMBG reporting in logbooks was a critical feature of both studies. The Royal Victoria Hospital's Ethics Committee approved both studies, and all study participants signed a consent form.

Methods

Participants in both trials were provided with a Precision QID BG meter (MediSense Inc., Abbott Laboratories Inc., Montreal, Quebec, Canada) and sufficient test strips for the entire duration of the principal studies. The research coordinators for each study demonstrated proper use of the meter. Participants with type 1 diabetes were asked to perform SMBG at least 4 times per day. Participants with type 2 diabetes were asked to perform SMBG at least 4 times in the same day once a week (before meals and at bedtime) and 7 times in the same day once per month (before meals, 1 hour after meals and at bedtime).

During every follow-up visit (monthly for type 1, every 2 months for type 2) all results recorded in the meter memory, including any extra or other meters used, were downloaded and analyzed using a data management program provided by MediSense Inc. This program produces instant screen results and printouts that include all BG results by date and time. These results were cross-validated with the self-reported logbook entries covering the same period of time (from the date/time of the oldest downloaded value to the downloading date) by the respective research coordinators. Measures of the accuracy and reliability of participants' reporting were calculated by comparing the logbook recordings with the memory-downloaded results, which were used as the standard. The analyses reported in this paper were conducted during the initial and final 2 months of each study protocol.

Although participants were aware that BG results would be downloaded from the meters, discrepancies between self-reported logbook and meter-downloaded results were not discussed between patients and healthcare professionals.

SMBG results were categorized as clinically accurate (a ≤15% difference between logbook and meter); modified (a >15% difference between logbook and meter); phantom (a value reported in the logbook but absent in the meter); or omission (a value found in the meter but not reported in the logbook). Omissions were assessed only for individuals with type 1 diabetes, since those with type 2 diabetes had not been instructed to record extra SMBG results.

Reliability of reporting by patients was determined based on the percentage of values that were accurately reported: that is, clinically accurate plus no phantom or omitted values. Participants were categorized as being very reliable (>90% of values accurately reported); fairly reliable (50 to 90% of values accurately reported); or unreliable (<50% of values accurately reported).

Glycemic control was assessed using glycosylated hemoglobin (A1C) every 2 to 3 months as determined by the local hospital laboratory. Glycemic control was categorized according to the 1998 clinical practice guidelines for the management of diabetes in Canada as *optimal* (<115% of upper limit of normal [ULN]); *suboptimal* (115 to 140% of ULN); or *inadequate* (>140% of ULN) (10). Measures of accuracy were compared with glycemic control for both groups at the end of the assessment periods.

To evaluate perceived quality of life, both study populations completed the Diabetes Quality of Life questionnaire (11,12) that was used in the Diabetes Control and Complications Trial (13). Subjects with type 1 diabetes also completed a diabetes-related self-efficacy questionnaire (14).

Table 1. Baseline characteristics of participants

	Type 1 diabetes (n=15)	***Type 2 diabetes (n=45)***
Age, years	38±2.4	57±1.2
Sex, male:female	6:9	30:15
Duration of diabetes, years	18±2	9±1
Diabetes management, % subjects		
Insulin	100	36
Oral antihyperglycemic agents and insulin	N/A	11
Oral antihyperglycemic agent only	N/A	42
Diet only	N/A	11
Glycemic control, % ULN	129±7.4	136±5.0
Category of glycemic control, n (% subjects)*		
Optimal	5 (33)	14 (31)
Suboptimal	5 (33)	19 (42)
Inadequate	5 (33)	12 (27)
BMI, kg/m^2	24.7±0.8	30.2±0.8

Unless otherwise indicated, data are mean±SE
*Categories of glycemic control were determined according to percent of ULN: optimal, ≤115%; suboptimal, 115 to 140%; inadequate, >140% (10)

BMI = body mass index
N/A = not applicable
ULN = upper limit of normal

Statistical analyses

Statistical analyses were performed using the Statistical Package for Social Sciences, version 9 (SPSS Inc., Chicago, Illinois, USA). Data are presented as means±SE. Frequencies were used to calculate the percentage of clinically accurate, modified, phantom and omitted values. Assessment of relationships among variables was done using Pearson Product Moment Correlation analyses, Chi-square analyses and one-way analysis of variance (ANOVA). A level of $p<0.05$ was considered statistically significant.

RESULTS

SMBG data were collected from 15 patients with type 1 diabetes and 45 patients with type 2 diabetes. Table 1 outlines the baseline demographic profiles of these 2 groups. Individuals with type 1 diabetes had a mean age of 38 years, had been diagnosed 18 years previously and had a mean A1C of 129% of the ULN. They were treated intensively with multiple injections of insulin (3 injections of human regular insulin before meals and NPH insulin at bedtime) and instructed to use SMBG results, diet and exercise to adjust insulin dose. Individuals with type 2 diabetes had a mean age of 57 years, had been diagnosed 9 years previously, were overweight (mean body mass index of 30.2 kg/m^2) and had a mean A1C of 136% of the ULN.

Frequency of monitoring and reporting

In period 1, a total of 1597 and 1330 results were collected from the memory of BG meters for type 1 and type 2 patients, respectively, and were compared with 1613 and 1674 logbook values. In period 2, 1419 and 1061 results were collected from BG meters for type 1 and type 2 patients, respectively, and compared with 1377 and 1412 logbook values (Table 2).

Table 2. Accuracy of SMBG entries and reliability of reporting

	Type 1		*Type 2*	
	Period 1	**Period 2**	**Period 1**	**Period 2**
Meter results, n	1597	1419	1330	1061
Frequency of monitoring, mean±SE	2.1±0.2/day*	3.4±0.2/day	3.7±0.3/week	2.9±0.3/week
Logbook entries, n	1613	1377	1674	1412
Frequency of reporting, mean±SE	2.2±0.2/day*	3.4±0.2/day	4.7±0.3/week	3.9±0.3/week
Accuracy of SMBG entries, %				
Clinically accurate	49†	93	76	72
Modified	6†	2	3	3
Phantom	44†	5	21	25
Omission	45†	8	N/A	N/A
Reliability of reporting, %				
Very reliable	67	53	51	59
Fairly reliable	20	33	31	17
Unreliable	13	13	18	24
Mean BG, mmol/L‡				
Clinically accurate	8.7±0.5	9.6±1.3	8.0±1.5	8.3±1.5
Phantom	8.8±0.30	8.2±0.39	9.0±0.90	8.4±0.50
Omission	8.7±0.30	10.9±0.42	N/A	N/A

*p<0.05 (period 1 vs. period 2)
†p<0.001 (period 1 vs. period 2 for type 1)
‡Mean BG: mean of clinically accurate logbook values (≤15% difference from meter memory) vs. mean of phantom (in logbook but not in meter) and omitted values (in meter but not reported in logbook)

BG = blood glucose
N/A = not applicable
SE = standard error
SMBG = self-monitoring of blood glucose

Although patients with type 1 diabetes were asked to perform SMBG at least 4 times daily throughout the study, they actually monitored only 2.1 times per day and reported 2.2 times per day in period 1 (Table 2). There was, however, a significant ($p<0.05$) increase in the mean frequency of monitoring and reporting in period 2, to 3.4 times per day.

Individuals with type 2 diabetes were asked to perform SMBG ~4.7 times per week; in fact, they monitored 3.7 times per week in period 1 but reported that they had monitored 4.7 times per week. Contrary to that of individuals with type 1 diabetes, the monitoring and reporting behaviour of individuals with type 2 diabetes tended to deteriorate by period 2, to 2.9 and 3.9 times per week, respectively.

Accuracy of logbook entries and reliability of reporting

The accuracy of SMBG entries and reliability of reporting for patients with type 1 and type 2 diabetes are reported in Table 2.

Overall

Inaccuracies consisted mainly of phantom and omitted values for type 1 patients and phantom values for type 2 patients. Over time, there tended to be fewer phantom values (5% in period 2 vs. 44% in period 1) and omissions (8% in period 2 vs. 45% in period 1) reported by type 1 patients ($p<0.001$). The accuracy of values reported by type 2 patients remained similar in the 2 periods. Despite the inaccuracies, patients did not appear to report values that significantly altered (i.e. improved or worsened) their clinical profile. The mean±SE for phantom and omitted values was not significantly different from that of accurately reported logbook values (Table 2).

Relationships among variables

Individuals with type 1 diabetes who were classified as being very and fairly reliable in their reporting monitored significantly more frequently (3.0±0.2 times/day) than those who were classified as unreliable in their reporting (1.1±0.3 times/day) ($p=0.001$). Similar findings were observed in individuals with type 2 diabetes: those considered very and fairly reliable also monitored significantly more frequently (7.1±0.6 times/week) than individuals classified as unreliable (3.3±0.6 times/week) ($p=0.003$).

There was no significant relationship between frequency of monitoring and glycemic control for either group.

However, there was a significant relationship between accuracy of reporting and glycemic control in type 1 patients in period 1 only ($p=0.005$), whereby those who were considered to be very ($n=10$) and fairly ($n=3$) reliable had significantly better control, as assessed by A1C (106±4.1% [ULN] and 111±10.9% ULN, respectively, $p=0.006$) than subjects who were considered unreliable ($n=2$) (150±8.0%). This pattern was also observed in period 2 (NS), but no improvement was seen compared with period 1. No such relationship was found in individuals with type 2 diabetes.

Predictors of accuracy

Individuals with type 1 diabetes considered to be very reliable perceived themselves as having a better quality of life and were more confident in adjusting their insulin (self-efficacy) than those considered to be unreliable ($p<0.05$). Individuals with type 2 diabetes who were unreliable in their reporting appeared to have more diabetes-related worries (quality of life) than those considered very or fairly reliable (NS). Data related to these psychosocial measures are presented elsewhere (8,9).

DISCUSSION

Our study revealed that there continues to be a significant problem with respect to the accuracy and reliability of reporting SMBG results. Although the majority of values (>70%) were accurately reported by period 2 in both groups, only 49% of values were accurately reported in period 1 by individuals with type 1 diabetes undergoing intensive management. This level is much lower than that reported in previous studies: ~74% of the results were accurately reported by type 1 subjects in the first study ever done (2); 77% were accurately reported by type 1 subjects treated with continuous insulin infusion or insulin pump therapy (3) and 63% of results were accurately reported in subjects with gestational diabetes (5). However, the proportion of values that were accurately reported markedly improved in period 2 in individuals with type 1 diabetes, reaching a higher level (93%) than that reported in previous studies (2-6). The explanation for this improvement is likely increased awareness of the meter-downloading process. This is similar to what has been previously reported: accuracy improved to a level of 99% when subjects were aware of the presence of the meter memory (6). With respect to those with type 2 diabetes, the proportion of accurate results was similar to those found in previous studies (2-6).

With respect to the reliability of reporting by patients, only slightly more than 50% of patients were very reliable in their reporting over the 2 periods assessed for type 1 (67% and 53%, respectively) and type 2 patients (51% and 59%, respectively). Moreover, a significant proportion of patients (13% of type 1 and 24% of type 2) remained unreliable in their reporting over time. Like the study by Mazze and colleagues (6), which assessed accuracy under conditions of awareness of the meter memory, we did find a difference in the pattern of accuracy over time in individuals with type 1 diabetes, but not in those with type 2. In both populations, the most common types of errors were phantom rather than modified values. This is similar to what has previously been reported in the literature (2-6). These results could not be explained by the use of another BG meter; only 2 patients with type 1 diabetes mentioned having used another meter, and this was a rare occurrence.

Individuals in both groups (especially type 1 in period 1 and type 2 in both periods) tended to "add" values (phantoms). We hypothesize that this occurred, particularly in those testing less often, as an attempt to "fill up" logbooks and thus satisfy healthcare providers. This problem is not unique to diabetes: it has been demonstrated in other populations, such as children with asthma (15). The cost of testing was not a factor in our study, as test strips were provided free of charge. Whatever the reason, this practice did not result in a significant alteration of patients' clinical profiles. More importantly, most logbook errors did not represent attempts to present a more favourable clinical profile, as the mean BG level of the phantom values did not significantly differ from the mean values that were accurately reported. This finding is similar to what has been previously reported in all (3-6) but 1 study (2).

Although there was a significant relationship between frequency of monitoring and reliability of reporting, there was no significant relationship between frequency of monitoring and glycemic control in either group. This finding is in agreement with 1 of 3 recent survey studies that examined frequency of SMBG obtained via questionnaire in type 2 diabetes (16-18). In one of the studies, a higher frequency of SMBG was associated with better glycemic control only in those subjects who were able to adjust insulin doses; no relationship was found in the other patients, irrespective of the kind of treatment (16). Another study (17) had completely contrary results: a higher frequency of SMBG was associated with a higher proportion of insulin-treated patients with poor glycemic control (17). The latest of the studies found no association between testing frequency and glycemic control (18). One potential confounding variable in these studies may be the accuracy and reliability of SMBG reporting, which could not be assessed given the nature of the study designs. Although autonomy with respect to self-adjustments of therapy is encouraged in all patients with diabetes, especially those treated with insulin, we do not feel this was a major factor in explaining the lack of relationship between SMBG frequency and glycemic control. A more probable explanation may be related to the limitations of conventional methods of SMBG, which may not adequately assess 24-hour glycemic excursions (19); this can only be done with continuous glucose monitoring, which is now available (20).

Contrary to previous studies (2,6), we did find a significant relationship between reliability of reporting and glycemic control in individuals with type 1 diabetes, whereby those who were more reliable in their reporting tended to have better glycemic control. This finding may be a reflection of more precise adjustments of therapy by the clinician for those who presented accurate logbooks. However, although the level of accurately reported values increased over time ($p<0.001$), there was no significant improvement in glycemic control. This may be partially explained by the fact that the reliability of subjects did not change significantly over time, especially the proportion of unreliable subjects, which remained the same over the 2 periods. The absence of a relationship between reliability of reporting and glycemic control in individuals with type 2 diabetes may be related to the fact that the mean of the phantom values was not significantly different from the mean of the meter values, thereby not modifying the clinician's periodic treatment adjustments.

Individuals who were unreliable in their reporting tended to worry more about their diabetes; were less satisfied and less confident with their diabetes self-care management; and had poorer glycemic control. The causal direction and reason(s) for these relationships, however, remains to be clarified.

Only slightly more than half of patients in both groups were considered to be very reliable in their reporting. This signals that there is still a problem with respect to reliability of reporting, even more than a decade after initial studies in this area. Since clinicians rely on the results of SMBG to make management decisions, the use of the memory capacity of BG meters as a more reliable source of data may help prevent inadequate adjustments of therapy. However, further research in this regard is warranted. As well, it is important to remind patients of the importance of keeping accurate logbooks and to identify those individuals who may be less reliable in their reporting, as this may help to focus interventions on those who may be less satisfied and less confident with their diabetes self-care management.

Potential limitations of this study exist. As is the case with previous studies, patients in this study were not told exactly how their meter-downloaded information would be used. As well, the characteristics/behaviour of individuals who participate in studies may be slightly different from those who do not. It is possible that the findings obtained in this study, as well as other studies, may actually underestimate the problem at hand.

CONCLUSIONS

We strongly recommend that clinicians use the memory capacity of BG meters, in addition to logbooks, as part of routine clinical care of all adult patients with diabetes mellitus. Further research related to the accuracy of SMBG reporting is encouraged in other populations, especially in children with diabetes, as no studies, to our knowledge, have been conducted in this group. Use of continuous BG monitoring will also be of benefit for determining the adequacy and efficacy of SMBG.

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AUTHOR DISCLOSURES

No duality of interest declared.

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