





Mental distress and health-related quality of life among type 1 and type 2 diabetes patients using self-monitoring of blood glucose: A cross-sectional questionnaire study in Japan

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Keywords

Education, Health-related quality of life, Self-monitoring of blood glucose

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ABSTRACT

Aims/Introduction: The present multicenter, cross-sectional survey was initiated to evaluate self-monitoring of blood glucose (SMBG)-associated mental distress among patients with diabetes.

Materials and Methods: The survey was carried out in patients with type 1 diabetes and type 2 diabetes using SMBG recruited from 42 medical institutions. Profiles of Mood States 2 and diabetes therapy-related quality of life questionnaires were used to evaluate mood status and health-related quality of life. Two original questionnaires were also developed to evaluate SMBG 'importance,' 'painfulness' and 'confidence' among patients, and to evaluate physician attitudes to SMBG use.

Results: Questionnaires from 517 type 1 diabetes and 1,648 type 2 diabetes patients showed that 46.0% of type 1 diabetes and 37.5% of type 2 diabetes patients reported 'painfulness,' and that these patients reporting 'painfulness' showed significantly higher Profiles of Mood States 2 scores, lower diabetes therapy-related quality of life scores and higher glycated hemoglobin compared with those not reporting 'painfulness,' whereas the number of their daily SMBG tests were comparable. Patients reporting 'painfulness' also reported that SMBG use was significantly less important. Whether or not patients recognized the importance of SMBG use was well correlated with the frequency of physicians checking patient diaries.

Conclusions: Type 1 diabetes and type 2 diabetes patients reporting 'painfulness' in SMBG use had more mental distress, lower health-related quality of life and higher glycated hemoglobin regardless of their number of daily SMBG tests. The importance of SMBG use was recognized less by patients experiencing pain, and the importance of SMBG use was recognized more in medical institutions in which physicians regularly checked SMBG diaries to provide meaningful feedback to patients in clinical settings.

INTRODUCTION

Diabetes is one of the most serious global health-related problems, and leads to life-threatening complications when not properly managed¹. Patients with diabetes should therefore receive integrated diabetes self-management education as well

[†]Positive SMBG study group investigators are in Appendix.

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as diabetes self-management support, such that they can maintain appropriate glycemic control². Self-monitoring of blood glucose (SMBG) is widely recognized as a major component of integrated diabetes self-management education. SMBG is established as a useful tool for guiding healthy diet and exercise, choosing antidiabetic drugs, and preventing hypoglycemia³. In particular, SMBG contributes to appropriate glycemic control among patients with type 1 diabetes and type 2 diabetes receiving insulin injections^{4,5}. However, SMBG burdens the patient with mental distress and lowers health-related quality of life (QOL) in some cases^{6–8}. Finger pricking-associated pain is one of the most obvious burdens of SMBG use, although few studies have investigated this issue⁹. Despite recent improvement in lancing devices that reduce the pain of finger pricking, it remains a major burden of overall diabetes management. To clarify this and search for effective remedies, we carried out a multicenter, cross-sectional survey among Japanese patients with diabetes and their physicians-in-charge.

METHODS

Study design and participants

The present study was a multicenter, cross-sectional survey carried out in 42 Japanese medical institutions between October 2016 and January 2017 (clinical trial registration number: UMIN000026761). The survey was carried out in accordance with the Declaration of Helsinki, and the Ethical Guidelines for Medical and Health Research Involving Human Subjects established by the Ministry of Education, Culture, Sports, Science and Technology and the Ministry of Health, Labor and Welfare of Japan. The protocol was approved by the Ethical Committees of the Japan Association for Diabetes Education and Care, as well as those of each participating institution. All personal information was anonymized before sending to the data managing center at Kansai Electric Power Medical Research Institute from each participating institution. Eligible patients included: (i) those with type 1 diabetes or type 2 diabetes aged ≥ 20 years and < 90 years; (ii) those using SMBG for ≥ 3 months; (iii) those capable of answering the questionnaires used in the present study; and (iv) those receiving insulin and/or glucagon-like peptide-1 receptor agonist, as SMBG is allowed for those using injectables under the Japanese national health insurance coverage. Patients were excluded if they were susceptible to dementia and/or psychological and/or psychiatric disorders, or if they were considered to be ineligible for this study by physicians-in-charge.

Data collection and analysis

Clinical data, such as anthropometric measures, duration of diabetes, duration of insulin and/or glucagon-like peptide-1 receptor agonist use, glycated hemoglobin (HbA1c), frequency and timing of SMBG measurements, and therapeutic options for diabetes were collected with the questionnaire for the doctors. To evaluate mood status and health-related QOL, study participants were asked to complete the Profiles of Mood States

questionnaire, 2nd edition, Adult-Short Japanese version (POMS2), which is an instrument for assessing the mood states of individuals aged ≥ 13 years; and the Diabetes Therapy-Related QOL (DTR-QOL) questionnaire, which is an instrument for assessing the influence of diabetes treatment on patient QOL regardless of treatment method^{10,11}. POMS2 consists of seven domains: Anger-Hostility (AH), Confusion-Bewilderment (CB), Depression-Dejection (DD), Fatigue-Inertia (FI), Tension-Anxiety (TA), Vigor-Activity (VA) and Friendliness (F). Total Mood Disturbance (TMD) was calculated according to the equation as follows: $TMD = AH + CB + DD + FI + TA - VA$. The T-score of each domain and TMD was calculated from a T-score conversion table¹⁰. A T-score of 50 points represents the average T-score for Japanese individuals. The DTR-QOL consists of the following four categories: D1, 'Burden on social activities and daily activities'; D2, 'Anxiety and dissatisfaction with treatment'; D3, 'Hypoglycemia'; and D4, 'Satisfaction with treatment.' Each score of the domain and the total score was converted to a scale of 0–100 as described elsewhere¹¹. To evaluate attitudes of physicians and patients on SMBG and SMBG use, the participants also were asked to complete an original SMBG questionnaire developed in this study which asks four questions using a 5-point Likert scale with responses ranging from 'very unlikely' (1) to 'very likely' (5): Q1 'How important is SMBG to you?'; Q2 'How painful is SMBG to you?'; Q3 'How confident are you to enter SMBG results correctly in your SMBG diary?'; and Q4 'Would you like to share your SMBG results with your physician?'. Physicians-in-charge were asked to complete another SMBG questionnaire developed in this study with four questions using a 5-point Likert scale with responses ranging from 'very unlikely' (1) to 'very likely' (5): QD1 'How much do you credit SMBG meter readings with accuracy?'; QD2 'How much do you think SMBG readings reflect patients' self-management behavior?'; QD3 'How accurately do you think patients report SMBG readings?'; and QD4 'Do you check patients' SMBG diary regularly?'. Our questionnaires allow linking each individuals only to medical institution and not to physicians; thus, scores of QD1 to QD4 are expressed as the average scores of physicians in each medical institution for analysis.

Statistical analysis

Data are expressed as the median (interquartile range) unless otherwise stated. To compare the scores obtained from the questionnaires between two groups (i.e., type 1 diabetes vs type 2 diabetes; group A vs group B; group C vs group D; and group E vs group F), data were analyzed with the Mann-Whitney *U*-test. To assess the correlation between the scores obtained from Q1 to Q4 and from QD1 to QD4, Spearman's rank correlation coefficient was used. All statistical analyses were carried out using SPSS version 24.0 (SPSS Inc., Chicago, IL, USA). Statistical significance was set at $P < 0.05$.

RESULTS

Valid responses were obtained from 2,253 patients. Of them, 52 patients with other diabetes types and 36 with unknown diabetes types were excluded from the current analysis. The remaining 517 type 1 diabetes and 1,648 type 2 diabetes patients were subjected to further analysis (Table 1). Figure 1 shows the results of POMS2 and DTR-QOL questionnaires. All POMS2 scores in type 1 diabetes and type 2 diabetes did not differ substantially from those of general Japanese individuals¹¹. There were no significant differences between type 1 diabetes and type 2 diabetes except in AH ($P = 0.024$) and TA ($P = 0.003$). All DTR-QOL scores were comparable with previous studies carried out in Japanese type 1 diabetes and type 2 diabetes patients receiving insulin injections^{12,13}. Type 1 diabetes showed lower scores in D1, 'Burden on social activities and daily activities' ($P < 0.001$); D2, 'Anxiety and dissatisfaction with treatment' ($P < 0.001$); D3, 'Hypoglycemia' ($P < 0.001$); D4, 'Satisfaction with treatment' ($P < 0.001$); and total score ($P < 0.001$).

Figure 2 shows the results of the SMBG questionnaire developed by the current study. In Q2 'How painful is SMBG to you?', 39.8% of type 1 diabetes and 46.4% of type 2 diabetes patients responded 'very unlikely' or 'unlikely,' and 46.0% of type 1 diabetes and 37.5% of type 2 diabetes patients responded 'likely' or 'very likely.' To analyze possible associations of experience of pain with health-related QOL, the results of POMS2 and DTR-QOL were compared in two groups: group A, those responding 'very unlikely' and 'unlikely,' and group B, those

responding 'likely' and 'very likely' in Q2 'How painful is SMBG to you?'. Group A showed a significantly lower POMS2 total mood disturbance score in type 1 diabetes and type 2 diabetes patients (Figure 3a). Group A also showed a higher DTR-QOL total score in type 1 diabetes and type 2 diabetes patients. HbA1c was significantly lower in group A than in group B in both type 1 diabetes and type 2 diabetes patients (Figure 3c), suggesting that mood status and health-related QOL affect glycemic control. Interestingly, the frequency of SMBG testing reported by patients did not differ between the two groups both in type 1 diabetes and type 2 diabetes (Figure 3d). Group A showed significantly higher scores in Q1 'How important is SMBG to you?' compared with group B in both type 1 diabetes and type 2 diabetes patients (Figure 3e). These results suggest that SMBG-associated pain might influence patient appreciation of the importance of SMBG use. In Q1 'How important is SMBG to you?', 93.0% of type 1 diabetes and 84.8% of type 2 diabetes patients responded 'likely' or 'very likely' (group C), and 3.7% of type 1 diabetes and 6.7% of type 2 diabetes patients responded 'very unlikely' or 'unlikely' (group D). Group C showed lower scores in Q2 'How painful is SMBG to you?' compared with group D in both type 1 diabetes and type 2 diabetes (Figure 3f), although the results of the POMS2 total score (group C 47.8 ± 9.1 and group D 49.7 ± 9.4 , $P = 0.3287$ in type 1 diabetes patients, group C 47.1 ± 8.2 and group D 47.7 ± 8.4 , $P = 0.5010$ in type 2 diabetes) and DTR-QOL total score (group C 60.7 ± 16.2 and group D 61.0 ± 17.4 , $P = 0.7381$ in type 1 diabetes patients,

Table 1 | Characteristics of study participants

	Type 1 diabetes	Type 2 diabetes
<i>n</i> (male/female)	517 (234/282)	1,648 (982/659)
Age (years)	50 (40–65)	66 (57–72)
BMI (kg/m ²)	22.4 (20.5–24.9)	24.8 (22.3–27.8)
Duration of diabetes (years)	13.5 (6.0–22.0)	15.0 (10.0–23.0)
Duration of insulin use (years)	12.0 (5.0–20.0)	6.0 (3.0–11.0)
HbA1c (%)	7.7 (7.0–8.4)	7.4 (6.8–8.0)
Frequency of SMBG instructed by doctors (times/day)	3 (3–4)	2 (2–3)
Frequency of SMBG performed by patients (times/day)	3 (2–4)	2 (1–3)
Type of injection(s)		
Basal and bolus combination, <i>n</i> (%)	436 (84.3)	484 (29.4)
Basal only, <i>n</i> (%)	11 (2.1)	418 (25.4)
Bolus only, <i>n</i> (%)	23 (4.4)	56 (3.4)
Mix, <i>n</i> (%)	19 (3.7)	306 (18.6)
Continuous subcutaneous insulin infusion, <i>n</i> (%)	11 (2.1)	0 (0.0)
GLP-1 receptor agonist, basal and bolus combination, <i>n</i> (%)	0 (0.0)	32 (1.9)
GLP-1 receptor agonist and basal combination, <i>n</i> (%)	0 (0.0)	147 (8.9)
GLP-1 receptor agonist and bolus combination, <i>n</i> (%)	0 (0.0)	3 (0.2)
GLP-1 receptor agonist and mix combination, <i>n</i> (%)	0 (0.0)	23 (1.4)
GLP-1 receptor agonist, <i>n</i> (%)	0 (0.0)	157 (9.5)
Others	17 (3.3)	22 (1.3)

Data are shown as the median (interquartile range). Others include patients whose type of injections were unknown. BMI, body mass index; GLP-1, glucagon-like peptide-1; HbA1c, glycated hemoglobin; SMBG, self-monitoring of blood glucose.

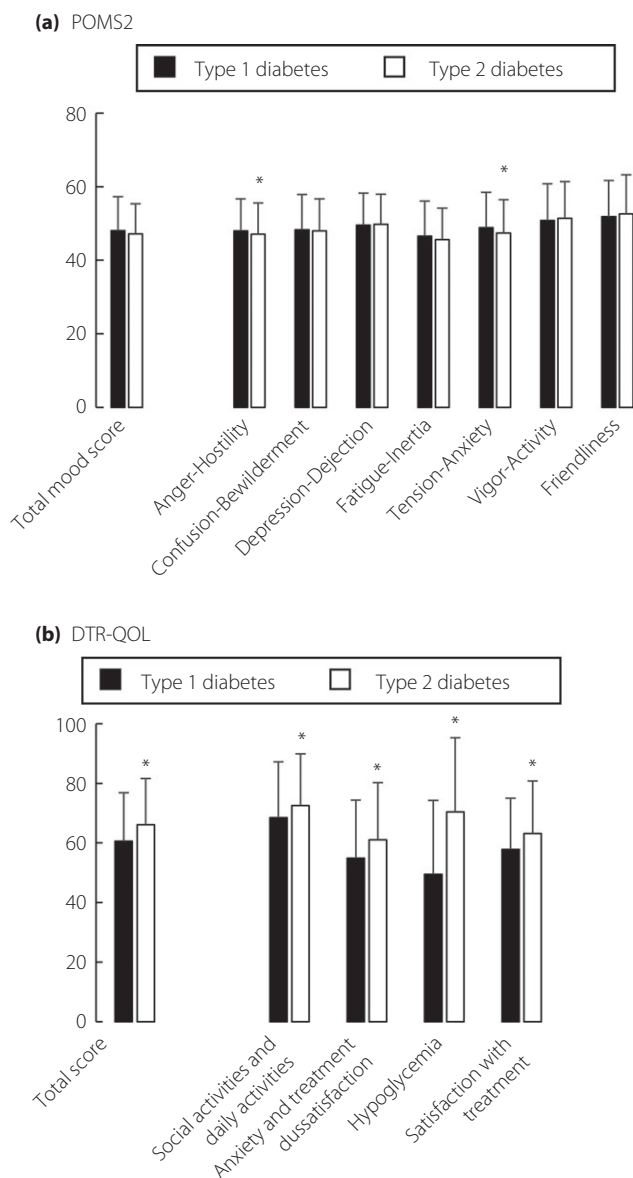


Figure 1 | Results of (a) Profiles of Mood States questionnaire, 2nd edition, Adult-Short Japanese version scores and (b) Diabetes Therapy-Related Quality of Life scores in type 1 diabetes (black bar) and type 2 diabetes (white bar) patients are shown. Values are mean \pm standard error of the mean. * $P < 0.05$ (vs type 1 diabetes).

group C 67.7 ± 14.7 and group D 70.5 ± 17.3 , $P = 0.0551$ in type 2 diabetes patients) were comparable in the two groups. In addition, scores in Q2 'How painful is SMBG to you?' were weakly, but significantly, associated with scores in Q1 'How important is SMBG to you?' (type 1 diabetes $r = -0.165$, $P < 0.01$; and type 2 diabetes $r = -0.230$, $P < 0.01$).

We also investigated possible interactions between attitudes of patients and physicians-in-charge to SMBG use, as it is likely that structured education on SMBG and regular checks of

SMBG results by physicians-in-charge might increase patients' understanding of the importance of carrying out SMBG testing, thereby reducing the burden of SMBG-associated pain. In Q4 'Would you like to share your SMBG results with your physician?', 9.5% of type 1 diabetes and 10.0% of type 2 diabetes patients responded 'very unlikely' or 'unlikely,' and 68.5% of type 1 diabetes and 65.5% of type 2 diabetes patients responded 'likely' or 'very likely.' As shown in Figure 4, POMS2 total mood disturbance score and DTR-QOL total score did not differ between group E, those responding 'very unlikely' and 'unlikely,' and group F, those responding 'likely' and 'very likely' in Q4 'Would you like to share your SMBG results with your physician?'. Importantly, scores in Q4 'Would you like to share your SMBG results with your physician?' were associated with the scores in Q1 'How important is SMBG to you?' (type 1 diabetes $r = 0.328$, $P < 0.01$; and type 2 diabetes $r = 0.368$, $P < 0.01$), Q3 'How confident are you to enter SMBG results correctly in your SMBG diary?' (type 1 diabetes $r = 0.387$, $P < 0.01$; and type 2 diabetes $r = 0.439$, $P < 0.01$) and age (type 1 diabetes $r = 0.253$, $P < 0.01$; and type 2 diabetes $r = 0.368$, $P < 0.01$), but not with HbA1c and duration of diabetes, as well as POMS2 total score or DTR-QOL total score. We then turned to physicians' attitudes on SMBG and SMBG use. Valid responses were obtained from 137 physicians (91 diabetes specialists certified by the Japan Diabetes Society and 46 non-certified physicians) in the 42 medical institutions. Figure 5 shows results of the SMBG questionnaire for physicians developed by the current study. Notably, in QD4, 'Do you check patients' SMBG diary regularly?', 97.9% of the doctors answered that they were 'likely' or 'very likely' to check patients' SMBG diary regularly. To understand possible impacts of physician behavior on patient attitude to SMBG and SMBG use, associations of QD1-QD4 with results of the SMBG questionnaire for patients, as well as POMS2 and DTR-QOL scores, were investigated. Significant associations were found with QD4 scores and Q1 'How important is SMBG to you?' ($r = 0.311$, $P < 0.05$) and those of Q4 'Would you like to share your SMBG results with your physician?' ($r = 0.344$, $P < 0.05$; Figure 6).

DISCUSSION

The present multicenter, cross-sectional study shows that type 1 diabetes and type 2 diabetes patients with SMBG-associated pain have a lower mood state, lower health-related QOL, higher HbA1c and they appreciate the importance of SMBG use less, regardless of their frequency of daily SMBG testing. The present study also shows that patients who appreciate the importance of SMBG use are more willing to share their SMBG results with their physicians, and that patients realize the importance of conducting SMBG testing and sharing SMBG results with their physicians more when their physicians regularly check patient SMBG results.

The average POMS2 TMD scores of type 1 diabetes and type 2 diabetes patients in the current study did not differ from

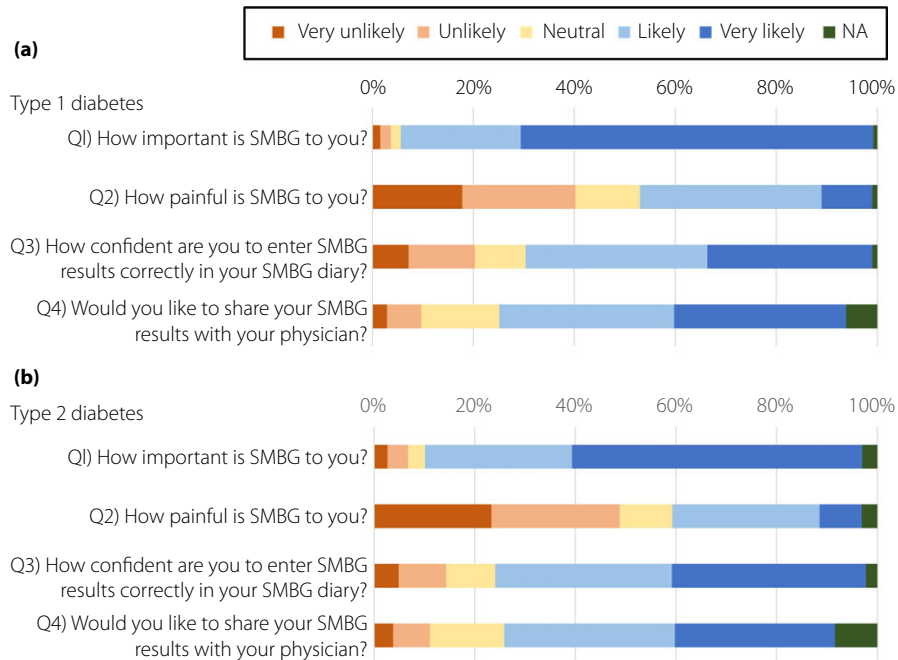


Figure 2 | Results of the original self-monitoring of blood glucose (SMBG) questionnaire from patients with (a) type 1 diabetes ($n = 517$) and (b) type 2 diabetes ($n = 1,648$). Each questionnaire was answered by using a 5-point Likert scale from '1: very unlikely' to '5: very likely', or not answered (NA).

the average scores of Japanese individuals, suggesting that diabetes and/or SMBG use does not affect patient mood status. However, AH and TA scores were slightly, but significantly, lower in type 1 diabetes patients, possibly due to the more frequent hypoglycemia in type 1 diabetes patients. Although the frequency and severity of hypoglycemia in each patient was not assessed in the current study, type 1 diabetes patients had lower DTR-QOL scores than type 2 diabetes patients regardless of insulin injection type; and the AH and TA scores were weakly, but significantly, associated with DTR-QOL scores (Figure S1). In the present study, the scores of total and each DTR-QOL category were comparable with those of previous studies carried out in Japanese type 1 diabetes and type 2 diabetes patients receiving insulin injections^{12,13}. Importantly, the treatment satisfaction-related score was relatively high in the present study population, possibly because most participants consulted regularly with Japan Diabetes Society-certified diabetes specialists.

The present results suggest that SMBG-associated pain generates a negative impact on diabetes management overall, which might be furthered by patients' lack of appreciation of the importance of SMBG use. It has been found that the number of finger pricks required for a SMBG reading is associated with patient fear of insulin injection and SMBG use¹⁴. As it has been shown that SMBG use provides substantial clinical benefits when SMBG is implemented by well-trained healthcare professionals in a structured fashion¹⁵ and structured education on SMBG by well-trained healthcare professionals might well reduce the number of finger pricks required for an SMBG

reading, such training clearly would be beneficial. In addition, SMBG-associated pain might be reduced by patients' better appreciation of the importance of SMBG use when they receive structured education on SMBG and regular checks of SMBG results from well-trained healthcare professionals. Indeed, the present study shows that patients who realize the importance of carrying out SMBG testing are more willing to share SMBG results with their physicians, and that patients realize the importance of carrying out SMBG testing and sharing SMBG results with their physicians more when physicians regularly check patients' SMBG results to provide meaningful feedback. Previous studies have shown that appropriate SMBG use under instructions from healthcare professionals improved glycemic control and well-being in type 1 diabetes patients¹⁶ and also in non-insulin treated type 2 diabetes patients^{17,18}, whereas others have failed to show significant benefits^{19,20}. As the present study shows that physicians' regular check of patients' SMBG results affects patients' attitude to SMBG use, sharing SMBG results between patients and healthcare professionals could play a critical role in making better use of SMBG to improve glycemic control in type 1 diabetes and type 2 diabetes patients. Thus, it would be interesting to test in prospective, randomized, controlled trials whether modalities to facilitate SMBG data sharing between patients and healthcare professionals could improve glycemic control in type 1 diabetes and type 2 diabetes patients.

There were two major limitations to this study. First, 'painful' in the current questionnaire could mean emotional

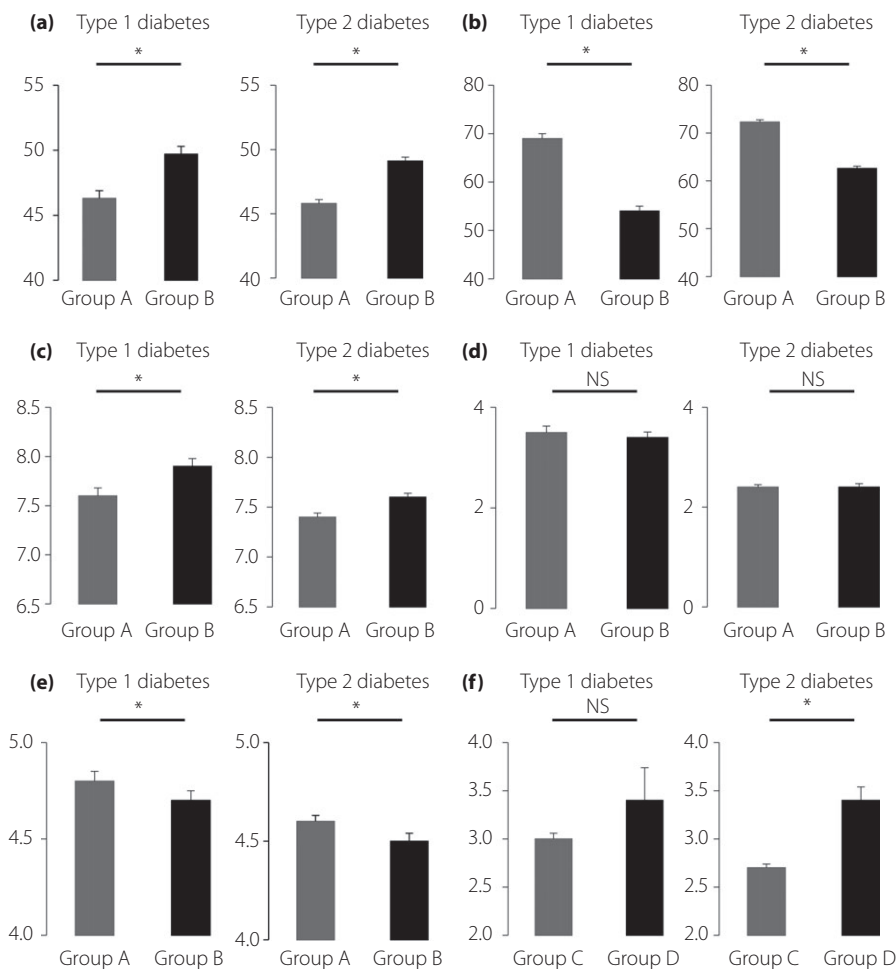


Figure 3 | Comparisons of various parameters between patients answering, 'very unlikely' or 'unlikely' (group A) and those answering 'likely' or 'very likely' (group B) in Q2 'How painful is SMBG to you?'. Parameters include (a) total mood disturbance scores in Profiles of Mood States questionnaire, 2nd edition, Adult-Short Japanese version, (b) total scores in Diabetes Therapy-Related Quality of Life, (c) glycated hemoglobin, (d) frequency of self-monitoring of blood glucose (SMBG) testing and (e) scores in Q1 'How important is SMBG to you?'. (f) Comparisons of scores in Q1 'How important is SMBG to you' between patients answering 'likely' or 'very likely' (group C) and those answering 'very unlikely' or 'unlikely' (group D) in Q2 'How important is SMBG to you?'. Data are shown as mean \pm standard error of the mean. * $P < 0.05$. NS, not significant.

burden rather than somatic pain, which could underlie higher negative mood disturbance and lower QOL with similar SMBG frequency. However, insofar as 'painful' was construed as emotional burden by study participants, improved SMBG data sharing between patients and healthcare professionals would more readily improve patients' appreciation of the importance of SMBG. Second, we could not correlate physicians' attitudes on SMBG and SMBG use with each patient, because all personal information of each patient and physician was anonymized before it was sent from each participating institute.

In conclusion, the current questionnaire-based survey shows that type 1 diabetes and type 2 diabetes patients experiencing SMBG-associated pain have more mental distress, lower health-related QOL and higher HbA1c; they also appreciate the

importance of SMBG use less, regardless of their number of daily SMBG tests. The current study also shows that patients who realize the importance of SMBG testing are more willing to share their SMBG results with their physicians, and that patients realize the importance of carrying out SMBG testing and sharing SMBG results with their physicians more when physicians regularly check patients' SMBG results to provide meaningful feedback in clinical settings.

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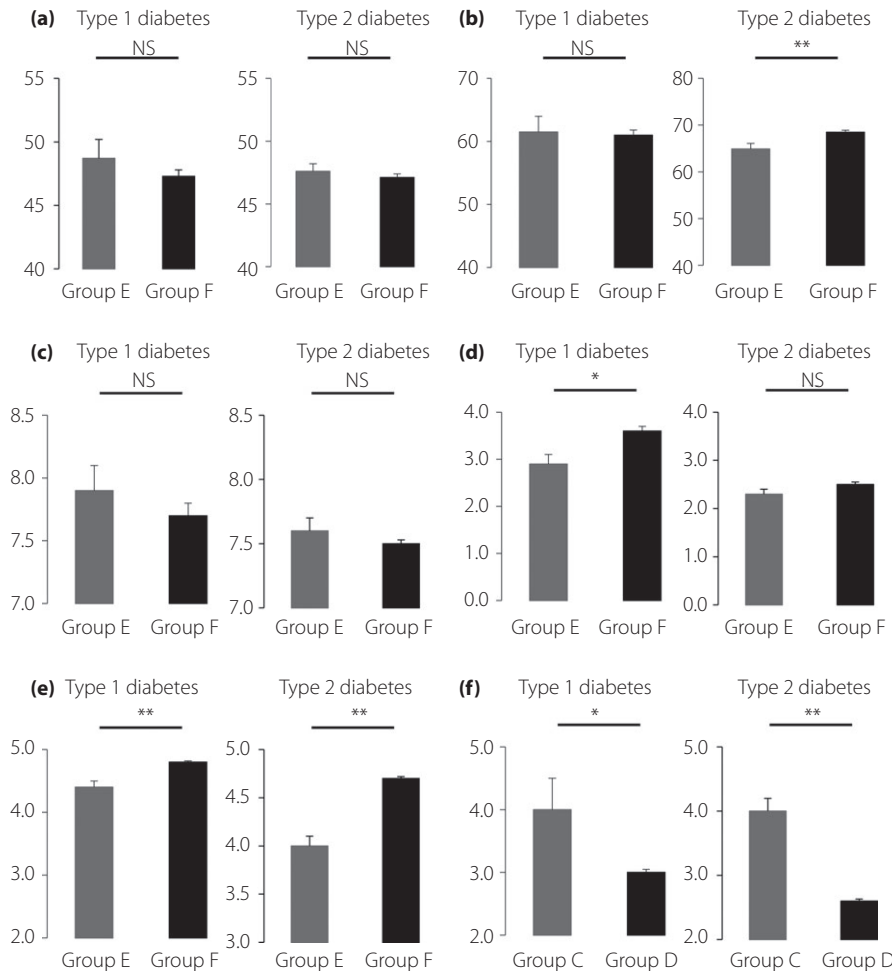


Figure 4 | Comparisons of various parameters between patients answering, 'very unlikely' or 'unlikely' (group E) and those answering 'likely' or 'very likely' (group F) in Q4 'Would you like to share your SMBG results with your physician?'. Parameters include (a) total mood disturbance scores in Profiles of Mood States questionnaire, 2nd edition, Adult-Short Japanese version, (b) total scores in Diabetes Therapy-Related Quality of Life, (c) glycated hemoglobin, (d) frequency of SMBG, self-monitoring of blood glucose (SMBG) testing and (e) scores in Q1 'How important is SMBG to you?'. (f) Comparisons of scores in Q1 'How important is SMBG to you' between patients answering 'likely' or 'very likely' (group C) and those answering 'very unlikely' or 'unlikely' (group D) in Q4 'Would you like to share your SMBG results with your physician?'. Data are shown as mean \pm standard error of the mean. * $P < 0.05$, ** $P < 0.01$. NS, not significant.

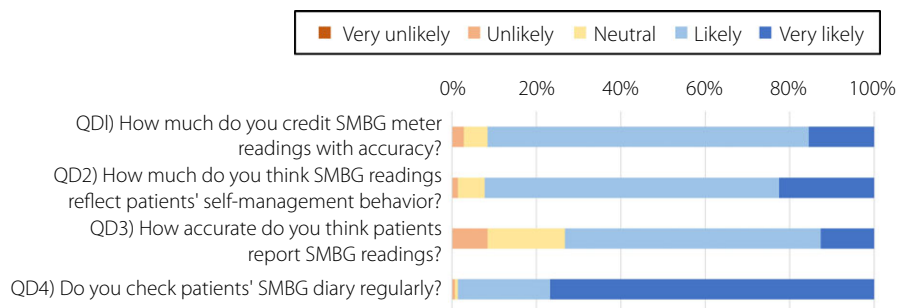


Figure 5 | Results of the original self-monitoring of blood glucose (SMBG) questionnaire from 137 physicians-in-charge in the 42 participating medical institutions. Each questionnaire was answered by using a 5-point Likert scale from '1: very unlikely' to '5: very likely.'

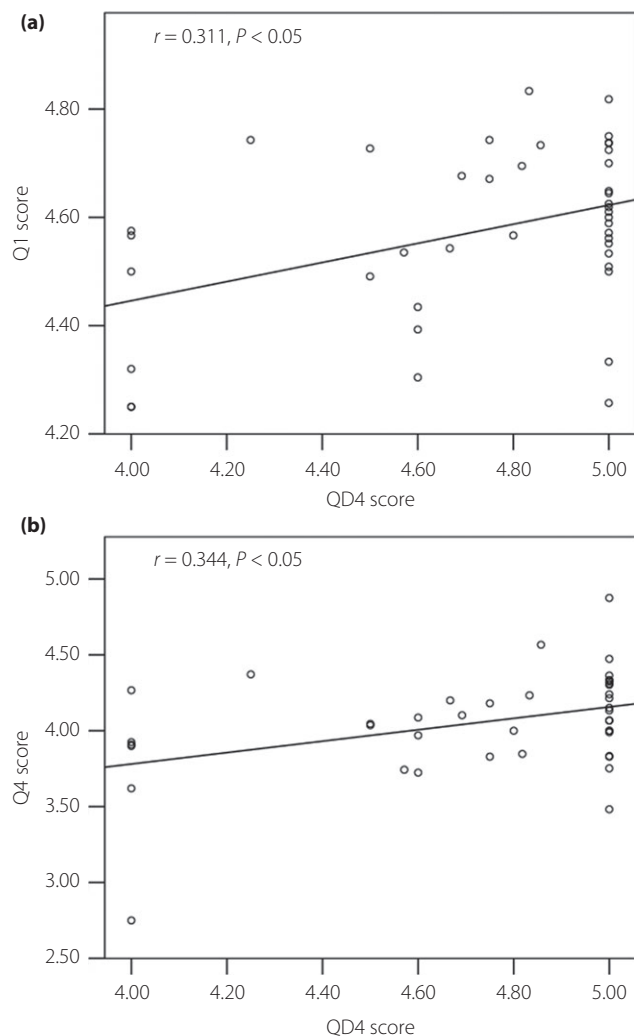


Figure 6 | Association of (a) the score of QD4 'Do you check patients' SMBG diary regularly?' with the score of Q1 'How important is SMBG to you?' ($r = 0.311$, $P < 0.05$) and that of (b) Q4 'Would you like to share your SMBG results with your physician?' ($r = 0.344$, $P < 0.05$). SMBG, self-monitoring of blood glucose.

DISCLOSURE

D Yabe received consulting or speaker fees from MSD K.K. and Novo Nordisk Pharma Ltd. D Yabe also received clinically commissioned/joint research grants from MSD K.K., Ono Pharmaceutical Co. Ltd., Novo Nordisk Pharma Ltd., Arklay Co. Ltd., Takeda Pharmaceutical Company Limited and Terumo Corporation. Y Hamamoto received consulting or speaker fees from Novo Nordisk Pharma Ltd. T Kurose received consulting or speaker fees from Sanofi K.K. T Kurose also received clinically commissioned/joint research grants from the Japan Vascular Disease Research Foundation. T Osonoi received consulting or speaker fees from Sanwa Kagaku Kenkyuso Co., Ltd., Novo Nordisk Pharma Inc., Astellas Pharma Inc., Tanabe Mitsubishi Co., Ltd. and Takeda Pharmaceutical Company Limited. T

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SUPPORTING INFORMATION

Additional Supporting Information may be found in the online version of this article:

Figure S1 | Hypoglycemia-related Diabetes Therapy-Related Quality of Life (DTR-QOL) scores in type 1 and type 2 diabetes patients in the current study.

APPENDIX

Positive SMBG study group investigator

Positive SMBG study group investigators: Masatomo Sekiguchi (Sapporo-Kosei General Hospital, Sapporo, Japan), Norihiko Hirota (Hakodate Medical Association Hospital, Hakodate,