A cross-sectional study of the relationship between quality of life and sleep quality in Japanese patients with type 1 diabetes mellitus

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Abstract. This study aimed to reveal the relationship between quality of life (QOL) and sleep quality in patients with type 1 diabetes mellitus (T1DM). Overall, 202 patients with T1DM were registered in our study, and 192 were eligible for analysis. Baseline characteristics and laboratory values were determined. Patients completed the Japanese versions of the Pittsburgh Sleep Quality Index (PSQI) and Diabetes Therapy-Related QOL (DTR-QOL) questionnaires. We investigated the relationship between the global PSQI and DTR-QOL total scores by using linear regression analysis. In univariate regression analysis, DTR-QOL total scores were associated with body mass index, alcohol consumption, hypertension, hemoglobin A1c (HbA1c), and global PSQI score (all \( p \)-value <0.05) but not with sleep duration. When the association between PSQI subscales and DTR-QOL total scores was examined, DTR-QOL total scores were significantly related to subjective sleep quality and daytime dysfunction. In a multivariate regression analysis, the global PSQI score was negatively related to DTR-QOL total scores. Patients with an HbA1c concentration \( \geq 8.0\% \) had significantly lower DTR-QOL total scores. We revealed a relationship between QOL and sleep quality in T1DM patients and showed that the relationship between QOL and PSQI subscales in T1DM patients may be different from that in patients with type 2 diabetes mellitus. Assessing and managing sleep quality may be necessary for patients with diabetes to improve QOL.

Key words: Type 1 diabetes mellitus, Quality of life, Sleep quality

DIABETES MELLITUS (DM) adversely affects the physical and psychological status and social functioning of patients, resulting in a decreased quality of life (QOL). QOL has been reported to be worse in a group of patients with type 1 diabetes mellitus (T1DM) that maintained a hemoglobin A1c (HbA1c) concentration of approximately 9% than that in a group that maintained an HbA1c concentration of approximately 7% [1]. In patients with type 2 diabetes mellitus (T2DM), insufficient blood glucose control was reported to be related to a poor QOL [2, 3]. Since the evaluation of QOL depends on the subjectivity of the patient, its assessment requires measurement and quantification using scales with reliability and validity that have been confirmed by econometric methods and statistical analysis.

Currently, there is no consistent, approved definition of QOL; however, a consensus describes QOL as a multifaceted concept that includes physical, psychological,
and social aspects and is evaluated based on a subjective judgment by the patient [4]. In Japan, the Japanese version of the Diabetes Therapy-Related QOL (DTR-QOL) questionnaire [5] was developed as a tool for assessing the QOL of diabetic patients. This questionnaire has proven to be sufficiently reliable and quantitatively valid, and it can be used to assess patient QOL and treatment satisfaction in various DM therapies.

Recently, it has been reported that there is a relationship between sleep quality and DM. In a previous meta-analysis of sleep quality in T1DM patients, it was reported that HbA1c was significantly higher in a poor self-reported sleep quality group than in a good sleep quality group [6]. In a study that used the Pittsburgh Sleep Quality Index (PSQI) [7, 8], insufficient sleep quality was found in 55% of patients with T2DM [9]. We also reported that sleep quality in patients with T2DM was worse in the group with an HbA1c concentration ≥7.9% [10]. These findings indicate that DM and sleep quality are related, regardless of whether the patient has T1DM or T2DM.

Poor sleep quality is significantly related to worse European Quality of Life-5 Dimensions Questionnaire (EQ-5D), Diabetes Quality of Life (DQOL) measure, 36-item Short-Form Health Survey (SF-36), and Diabetes Specificity Quality of Life Scale (DSQL) scores in patients with T2DM [2, 9, 11]. It has been reported that sleep disorders may cause poor psychosocial outcomes [12] in children and adolescents with T1DM, and it has been suggested that daytime sleepiness may decrease Quality of Life Youth Version (DQOL-Y) scores [13]. However, since the relationship between QOL and sleep quality in adult patients with T1DM was not reported, this study aimed to clarify this relationship.

Materials and Methods

Patients

We registered patients with T1DM from the multicenter SOREKA study (UMIN000014318) as well as additional patients with T1DM who visited Yokohama City University Medical Center. This study has the same protocol as the SOREKA study except that it is limited to patients with T1DM, and the eligibility and exclusion criteria are the same [10]. We recruited participants between July 2014 and June 2018.

Ethical considerations

The protocol for this study was approved by the Yokohama City University Certified Institutional Review Board (UMIN000025654). Informed consent was obtained from all participants. This study adhered to the principles of the 2013 Declaration of Helsinki.

Data collection

Participants completed questionnaires regarding their demographic characteristics, medical history, and health-related habits. The PSQI questionnaire, DTR-QOL questionnaire, and blood and urinalysis data were collected within 1 month of registration. We measured HbA1c concentration by using high-performance liquid chromatography and measured blood glucose by using the glucose oxidase method.

PSQI questionnaire

As in our previously reported SOREKA study [10], the PSQI questionnaire was used to evaluate sleep quality, and the definitions of subscales (C1-C7) were the same. Higher global PSQI scores indicated poorer sleep quality.

DTR-QOL questionnaire

The DTR-QOL questionnaire included 29 questions. Responses to each question were scored on a scale of 1 to 7, and the sum of the scores for each question was converted to a scale of 0 to 100 to be evaluated as the DTR-QOL total score. The higher the DTR-QOL total score, the better the patient’s QOL. The DTR-QOL is divided into four factors: Factor 1 is the burden on social activities and daily life, Factor 2 is the anxiety and dissatisfaction with treatment, Factor 3 is hypoglycemia, and Factor 4 is satisfaction with treatment.

Statistical analysis

Results are presented as median (25 ± 75% interquartile range [IQR]) or as numbers with percentages. We first performed univariate analysis, adding all variables with p-value <0.05 to multivariate linear regression analyses with age, sex, body mass index (BMI), HbA1c, and global PSQI score. We divided the patients into two groups: those with an HbA1c concentration <8% and those with an HbA1c concentration ≥8%, since insufficient glycemic control is defined by the Japanese Diabetes Association as an HbA1c concentration ≥8%. BMI was categorized according to the World Health Organization general population BMI classification, divided into three groups with divisions at 18.5 and 25 kg/m². In the multivariate linear regression analysis sample, 105 patients had an HbA1c concentration of <8%, 85 had an HbA1c concentration of ≥8%, 22 had a BMI of <18.5 kg/m², 137 had a BMI between 18.5 and 25 kg/m², and 31 had a BMI of ≥25 kg/m². The two-sided p-value <0.05 was defined as statistically significant. If the variance inflation factor exceeded 10.0, multicollinearity was considered. Stata version 16.1 for Windows (Stata Corporation, College Station, TX, USA) was used to perform all statistical analyses.
Results

Baseline characteristics
A total of 202 patients were enrolled between July 2014 and June 2018. Of these, ten were excluded because their PSQI or DTR-QOL questionnaire data were not available. Consequently, we included 192 participants in our analysis. Their median age was 55 years (IQR, 43–65 years); median BMI, 21.7 kg/m² (IQR, 19.9–23.8 kg/m²); and median HbA1c concentration, 7.8% (IQR, 7.0%–8.8%). The proportions of different DM complications (microangiopathy and macroangiopathy) were assessed using the same definitions as in the SOREKA study [10]: neuropathy (32%), retinopathy (19%), grade 3 or higher nephropathy (4.7%), and macroangiopathy (7.3%). The median global PSQI score was 6 (IQR, 4–7.5) (Table 1).

Associations between global PSQI score and DTR-QOL total scores
In a univariate regression analysis, the DTR-QOL total score was significantly associated with BMI, alcohol consumption, hypertension, HbA1c, and global PSQI score, while sleep duration was not associated with DTR-QOL total scores (Table 2). We performed a multivariate regression analysis using age, sex, BMI, HbA1c, and global PSQI score, and the above factors that were found to be significantly associated in Table 2 were used as adjustment factors; the results are shown in Table 3. Table 3 shows that patients with a higher global PSQI score had significantly lower DTR-QOL total scores. Moreover, it shows that patients in the HbA1c ≥8.0% group had significantly lower DTR-QOL total scores than those in the <8.0% group.

Association of glycemic control and DTR-QOL subscale with global PSQI score
Table 4 shows that the global PSQI score was significantly associated with DTR-QOL Factor 1 (burden on social activities and daily activities) and DTR-QOL Factor 2 (anxiety and dissatisfaction with treatment) but not with HbA1c and DTR-QOL Factor 3 (hypoglycemia).

Associations between PSQI subscale and DTR-QOL total scores
Table 5 shows that the DTR-QOL total scores were significantly associated with C1 (subjective sleep quality) and C7 (daytime dysfunction).

Discussion
In this study, we showed that adult patients with T1DM who had high global PSQI scores had significantly lower DTR-QOL total scores, and patients with an HbA1c concentration ≥8.0% had significantly lower DTR-QOL total scores than those with an HbA1c concentration <8.0%. To the best of our knowledge, this is the first report on QOL and sleep quality in adults with T1DM.

The relationship between sleep quality and QOL has been reported in several studies. For instance, in a study of the general population in South Korea, the EQ-5D was lower in the group with poor sleep quality than in the group with good sleep quality [14]. In a study evaluating global PSQI score and SF-36 in patients with moderate to very severe chronic obstructive pulmonary disease, worse sleep quality was associated with lower QOL [15]. Likewise, in a report of patients with gynecologic cancer, poor sleep quality was associated with decreased QOL as assessed by the Functional Assessment of Cancer Therapy-General (FACT-G) [16]. The relationship between QOL and sleep quality has also been reported in several studies in patients with T2DM. Poor sleep quality has been related to worse EQ-5D scores [11]. In a study of 300 patients with T2DM examining the association between global PSQI score and DQOL and SF-36 scores, poor sleep quality was correlated with worse DQOL and
SF-36 scores [9]. In a report examining the association between global PSQI and DSQL scores, poor sleep quality was related to worse DSQL scores [2]. As described above, previous studies have shown a relationship between QOL and global PSQI score in patients with T2DM and other diseases, as well as in the general population, and QOL was significantly lower when sleep quality was poor. In this study, a higher global PSQI score was related to lower DTR-QOL total scores. Although this study investigated the relationship between QOL and global PSQI score in adults with T1DM, the results were similar to those of previous studies in patients with T2DM and other diseases, as well as in the general population, suggesting that there is a relationship

### Table 2
Univariate linear regression analysis of baseline characteristics, global PSQI score, and DTR-QOL total scores

|                         | B     | 95% confidence interval | p-value |
|-------------------------|-------|-------------------------|---------|
| Age (years)             | 0.12  | –0.055–0.30             | 0.17    |
| Sex                     | –4.5  | –9.69–0.62              | 0.085   |
| Body mass index (kg/m²) | 1.1   | 0.24–1.9                | 0.011   |
| Estimated duration (years) | 0.13  | –0.15–0.41              | 0.36    |
| Current smoker          | 2.5   | –3.4–8.5                | 0.84    |
| Alcohol consumption     | 5.6   | 0.42–10.7               | 0.034   |
| Hypertension            | 5.9   | 0.29–11.4               | 0.039   |
| Dyslipidemia            | –2.3  | –7.7–3.0                | 0.39    |
| HbA1c (%)               | –2.4  | –3.9–0.89               | 0.002   |
| Insulin total daily dose (IU/kg/day) | –2.5  | –11.5–6.6              | 0.59    |
| Neuropathy              | –3.2  | –8.7–2.4                | 0.26    |
| Retinopathy             | –3.4  | –10.0–3.2               | 0.31    |
| Nephropathy             | –9.8  | –22.0–2.3               | 0.11    |
| Macroangiopathy         | –0.03 | –10.0–9.9               | 0.995   |
| Global PSQI score       | –1.5  | –2.4–0.66               | 0.001   |
| Sleep duration          | 2.0   | –0.39–4.5               | 0.10    |

*B*, partial regression coefficient; PSQI, Pittsburgh Sleep Quality Index; DTR-QOL, Diabetes Therapy-Related Quality of Life; HbA1c, hemoglobin A1c.

### Table 3
Multivariate linear regression analysis of clinical variables, global PSQI score, and DTR-QOL total scores

|                         | B     | 95% CI | β      | p-value |
|-------------------------|-------|--------|--------|---------|
| Age (years)             | 0.05  | –0.14–0.24 | 0.043 | 0.58    |
| Sex                     | –2.7  | –7.9–2.5 | –0.075 | 0.31    |
| BMI (kg/m²)             |       |         |        |         |
| <18.5                   | 1.0   | Reference | Reference | Reference |
| 18.5–25                 | 9.1   | –0.5–18.7 | 0.19   | 0.063   |
| ≥25                     |       | Reference |       |         |
| HbA1c (%)               |       |         |        |         |
| <8.0                    | –7.9  | Reference | –12.8–2.9 | –0.22  |
| ≥8.0                    | 2.5   | –2.8–7.8 | 0.069  | 0.35    |
| Alcohol consumption     | 3.6   | –2.5–9.8 | 0.093  | 0.25    |
| Hypertension            |       |         |        |         |
| Global PSQI score       | –1.5  | –2.4–0.66 | –0.24  | 0.001   |

*B*, partial regression coefficient; β, standardized partial regression coefficient; CI, confidence interval; PSQI, Pittsburgh Sleep Quality Index; DTR-QOL, Diabetes Therapy-Related Quality of Life; BMI, Body mass index; HbA1c, hemoglobin A1c.
between QOL and global PSQI score in patients with T1DM.

The association between diabetes-specific QOL and components of the PSQI differed between the results of this study and those of a previous study on T2DM [2]. The results of this study showed that C1 (subjective sleep quality) and C7 (daytime dysfunction due to excessive daytime sleepiness [17]) were associated with diabetes-specific QOL, whereas in the study on patients with T2DM, C1 (subjective sleep quality), C2 (sleep latency), C4 (habitual sleep efficiency), and C5 (sleep disturbance) were associated with diabetes-specific QOL [2]. It has been reported that increased subjective complaints of daytime sleepiness may decrease the DQOL-Y score in children and adolescents with T1DM [13]. When assessing sleep stages by polysomnography, non-rapid eye movement was divided into three stages, including N1, N2, and N3 [18], and a high percentage of time spent in stage N2 was reported to be associated with daytime sleepiness [13]. A study comparing adult patients with T1DM and healthy subjects also reported a higher percentage of stage N2 to be associated with daytime sleepiness [19], and it is possible that QOL may be reduced in adult patients with T1DM due to excessive daytime sleepiness. In addition, the total sleep time, time spent awake after sleep onset, and sleep onset latency in patients with T1DM did not differ from those in healthy subjects [19]. This suggests that C2 (sleep latency), C4 (habitual sleep efficiency), and C5 (sleep disturbance) are less likely to be affected in patients with T1DM. In contrast, no significant difference was noted in the percentage of stage N2 associated with daytime sleepiness in a study comparing healthy subjects and patients with T2DM using polysomnography, unlike in patients with T1DM [20]. Furthermore, patients with T2DM have been found to have more nighttime sleep deprivation than excessive daytime sleepiness [17]. These results suggest that C7 may be less affected in patients with T2DM and may not be associated with QOL. In both T1DM and T2DM, sleep quality and QOL are related, although the components of the PSQI that affect QOL may be different. Further studies on the relationship between the components of the PSQI and QOL are necessary to gather more information.

We revealed that QOL was worse in patients with an HbA1c concentration ≥8.0%. A previous study on T1DM reported a poor QOL in a group of patients with an HbA1c concentration of approximately 9% compared with that in a group with an HbA1c concentration of approximately 7%, suggesting poor QOL in the group with insufficient glycemic control [1]; this result is consistent with the findings of the present study. Previous studies have reported that HbA1c was not associated with global PSQI score in T1DM, which is consistent with the results of the present study [21-23]. However, a meta-analysis on T1DM reported that individuals with good sleep quality had significantly lower HbA1c than those with poor sleep quality [6]. This difference may be
because some of the studies integrated into the meta-analysis used measures of sleep quality other than the PSQI.

We showed that no association was found between sleep duration and DTR-QOL total scores. In a study of patients with T1DM in which objective sleep duration was assessed using actimetry, the DQOL score was not significantly different between shorter sleepers (<6.5 h) and longer sleepers (>6.5 h) [24]. Although the current study subjectively assessed sleep duration, the results were similar to those of previous studies [24], suggesting that the relationship between sleep duration and QOL may be poor in patients with T1DM. Since the previous study [24] was not performed with QOL as the primary outcome, future studies that objectively examine the relationship between sleep duration and QOL, using QOL as an outcome, are considered necessary.

This study has some limitations. First, we could not confirm causality due to the cross-sectional nature of the study. Second, the majority of patients with sleep-related breathing disorders report poor sleep quality [25]. However, this study did not use polysomnography to assess these diseases. It can also be mentioned that the PSQI questionnaire produces only subjective data as opposed to objective data. Third, hypoglycemia was not assessed in this study. Although a previous study reported that hypoglycemia may reduce QOL [26], a recent systematic review found that hypoglycemia is not associated with diabetes-specific QOL [27]. Therefore, the impact of not assessing hypoglycemia on the results of this study was considered to be negligible because this study assessed diabetes-specific QOL. In addition, in this study, DTR-QOL Factor 3 assessed subjective hypoglycemia but was not associated with global PSQI score, suggesting that unassessed hypoglycemia had little impact. Finally, depression has been associated with lower QOL [28]. During this study, depressive symptoms were not investigated; nevertheless, this would have little impact on the results of this study because none of the included patients had a history of depression.

In conclusion, in this study, we investigated the relationship between QOL and sleep quality in T1DM patients. The results suggest that, like T2DM, T1DM may be associated with worse QOL if sleep quality deteriorates. Assessing and managing sleep quality may be necessary for patients with DM to improve QOL.

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Author Contributions

M.I. collected the data and contributed to the discussion and wrote the manuscript. T.Y. conceptualized and collected the data, contributed to the discussion, and revised the text. R.S., K.T., J.S., M.S., E.S., S.T., M.K., T.A., T.K., Y.Y., U.O., T.I., and A.T. collected data. K.K. and Y.T. edited and approved the final manuscript.
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