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Article

The Impact of Sleep Quality on Glycemic Control in Type 1 Diabetes: A Retrospective Study in Cohort Using Advanced Technological Devices

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Abstract: *Introduction/Aim:* Type 1 Diabetes (T1D) challenges glycemic control, with sleep disturbances affecting insulin sensitivity and glucose variability. This study aims to assess sleep quality in T1D patients and its impact on glycemic outcomes, particularly at bedtime. *Methods:* This retrospective observational study, conducted at an Italian clinical center, included T1D patients using Medtronic devices. Sleep quality was assessed using the Italian version of the *Pittsburgh Sleep Quality Index* (PSQI), and glycemic outcomes were analyzed with CGM data. Statistical comparisons were made using descriptive statistics and non-parametric tests. *Results:* Of 45 patients, 4 were excluded, leaving 41 for analysis. The mean PSQI score was 6.0 ± 4.1 , with 36.6% showing poor sleep quality. No significant differences in age, sex, BMI, or diabetes duration were found. Poor sleepers had higher *Time in Elevated Glycemic Range 2* (TAR2) ($6.3 \pm 6.2\%$) compared to good sleepers ($4.1 \pm 5.0\%$). During bedtime hours, poor sleepers showed significantly higher TAR2 ($6.7 \pm 7.2\%$ vs. $3.3 \pm 6.2\%$, $p = 0.013$). *Conclusions:* Improving sleep quality may boost glycemic control and prevent nocturnal hyperglycemia. Future research should focus on sleep interventions in diabetes care.

Keywords: Type 1 diabetes; technological device; Sleep Quality; Cohort Study

1. Introduction

Diabetes is one of the most significant global public health challenges [1–3]. The World Health Organization (WHO) estimates that over 460 million people are affected by this condition, with predictions for exponential growth in the coming decades, largely driven by changes in dietary and lifestyle habits [4–10]. While Type 1 Diabetes (T1D) is less prevalent than Type 2 Diabetes (T2D), it remains a major concern, particularly among younger populations, due to its chronic nature and the therapeutic challenges it entails [11–15]. The epidemiology of diabetes, both nationally and globally, highlights an increasing burden on healthcare systems, exacerbated by factors such as aging populations, rising obesity rates, and the growing prevalence of sedentary lifestyles [16–18]. Although T2D affects a larger number of people worldwide, T1D presents unique challenges that require specific and innovative therapeutic approaches, particularly given its increasingly complex

and technologically advanced management [19–21]. Diabetes management, especially for T2D, has made significant strides in recent decades, with a decisive shift toward personalized therapeutic strategies supported by increasingly sophisticated devices [22,23]. Among these innovations, the introduction of continuous glucose monitoring (CGM) systems and insulin pumps (IP) has marked a major step forward in achieving more precise glycemic control and improving the quality of life for patients [24,25]. For individuals with T1D, who must manage daily insulin doses to maintain stable blood sugar levels, the introduction of technologies such as CGM, IP, and "smart pens" has been a crucial advancement [26–28]. These devices not only enhance glycemic control but also help reduce the emotional and psychological burden associated with diabetes management—a key aspect that should never be underestimated in the overall, holistic management of T1D patients [29,30]. In recent years, increasing attention has been given to the relationship between sleep and glycemic regulation in individuals with T1D [31]. Sleep disturbances, such as reduced duration or poor-quality sleep, are common among T1D patients and can negatively impact glycemic control [32]. Sleep deprivation, for instance, may alter insulin sensitivity and increase glycemic variability, making it more challenging to maintain stable blood glucose levels both during the day and overnight. In particular, poor sleep quality can lead to greater glucose fluctuations, increasing the risk of hypoglycemia or hyperglycemia [33]. These issues are especially significant for T1D patients, who must manage insulin on a daily basis to maintain stable glucose levels [31–33]. While technologies such as continuous glucose monitoring (CGM) and insulin pumps (IP) have improved glycemic control, they do not always fully compensate for the negative effects of disturbed sleep [34]. Recent studies suggest that optimizing sleep quality could be an important strategy to improve glycemic control in T1D patients, particularly in paediatric population [35,36]. However, integrating sleep management with the use of technological devices remains a challenge, and further investigation is needed to better understand how sleep quality may influence long-term glycemic regulation, particularly during the night [31–34]. In this context, our study aims to support new research on this topic and expand the debate on an extremely crucial aspect of T1D management, particularly through modern technological tools that are now common in all chronic diseases in general [37].

Aims

Primary

The primary objectives of this analysis were to characterize the sleep quality of patients with T1D based on their Italian version of Pittsburgh Sleep Quality Index (PSQI) [38] (Supplementary File 1) scores and compare patient characteristics between groups.

Secondary

Compare glycemic outcomes during the 30 days preceding the PSQI assessment between groups, as primary objective but considering bedtime hours only.

2. Materials and Methods

2.1. Study Design

A single-center retrospective observational clinical study was conducted at the Diabetes and Nutrition Clinic of the tertiary hospital in Ast Fermo (Italy). The STROBE checklist was adopted for study reporting (Supplementary File 2) [39,40].

2.2. Ethical Considerations

The study was conducted in full compliance with the ethical principles outlined in the Declaration of Helsinki and in accordance with institutional and national research ethics guidelines. Ethical approval was granted by the Institutional Review Board of Ast Fermo (INF 03/2024, date March 3, 2024). All participants provided informed consent for the collection and use of their data.

2.3. Sample and Criteria

Patients using Medtronic Smart MDI (Simplera™ + InPen™) [<https://www.medtronic-diabetes.com/en-gb/SmartMDI>] or the MiniMed™ 780G system [<https://www.medtronicdiabetes.com/products/minimed-780g-insulin-pump-system>] were included in the study. The sample was selected for convenience at the recruiting center. All subjects meeting the criteria outlined below were included in the observation. To minimize potential confounding factors related to overall glycemic response, the exclusion criteria were carefully structured to ensure a valid interpretation of the collected data. The statistical methods employed, as described below, were chosen to best support the generalization of the results.

Inclusion criteria were: T1D diagnosis, male or female, aged ≥ 18 years, therapy requirement determined by the physician's judgment, at least 70% sensor usage during the 30 days prior to the PSQI assessment, and provision of signed informed consent.

Exclusion criteria included: refusal to consent to data use, presence of concomitant or suspected malignant diseases, pregnancy or breastfeeding, recent acute illnesses (within 3 months of enrollment) excluding viral illnesses, renal impairment (eGFR < 60 mL/min), severe liver failure, congestive heart failure (NYHA class IV), proliferative diabetic retinopathy, cholelithiasis, chronic or ongoing acute pancreatitis, and adherence to a ketogenic diet or other nutritional interventions considered supplementary therapeutic treatments.

2.4. Endpoints

Description of patients' sleep quality in terms of PSQI score, analyzed both as a continuous variable and as categorical (PSQI ≤ 5 , PSQI > 5). Statistical comparison between groups based on age, gender, T1D duration, Body Mass Index (BMI), smoking status, and type of diabetes management device used. Statistical comparison of glycemic outcomes between groups was performed, including:

- a. Sensor Glucose (SG) mean, Standard Deviation (SD), and Coefficient of Variation (CV);
- b. Time Below Range level 2 (TBR2): percentage of time spent below 54 mg/dL;
- c. Time Below Range level 1 (TBR1): percentage of time spent between 54-69 mg/dL;
- d. Time Below Range (TBR): percentage of time spent below 70 mg/dL;
- e. Time In Range (TIR): percentage of time spent within 70-180 mg/dL;
- f. Time Above Range level 1 (TAR1): percentage of time spent between 181-250 mg/dL;
- g. Time Above Range level 2 (TAR2): percentage of time spent above 250 mg/dL;
- h. Time Above Range (TAR): percentage of time spent above 180 mg/dL.

2.5. Statistical Analysis

2.5.1. General Methodology

Descriptive statistics were used to summarize results. These include mean and SD, minimum, maximum, and median with InterQuartile Range (IQR) for continuous variables and counts and percentages for categorical variables. Summary statistics were reported with maximum two decimals, as appropriate. Bar charts were produced to visually represent some of the results. Continuous variables were compared between groups using the Wilcoxon rank-sum test, while categorical variables were compared using Fisher's exact test. All tests were two sided and p-values < 0.05 were considered statistically significant. SAS software, version 9.4, (SAS Institute Inc., Cary, NC, USA) was used to perform all statistical analyses.

2.5.2. Data Analysis

All data were collected by the physicians from device data files, CareLink™ reports [39], clinical records and other relevant sources, and shared through Excel spreadsheet using the SharePoint platform. Raw CGM data were utilized to calculate glycemic outcomes, as detailed in the next section.

2.5.3. Derived Variables

The Medtronic CGM systems track SG levels throughout the day and night and measures SG (mg/dL) at regular intervals, as frequently as every 5 minutes. Thus, 288 measurements are taken daily for a patient who keeps the system on all the time. The following Table 1 summarizes the criteria that were used to derive glycemic outcomes from CGM data:

Table 1. Criteria that were used to derive glycemic outcomes from CGM data.

Variable	Derivation for a given period
Sensor usage (%)	(Number of CGM measurements / (Number of minutes in the period of interest / 5) * 100
SG mean, SD, and CV	Mean, SD, and CV of CGM measurements
TIR metrics	(Number of CGM measurements in the range of interest / Number of CGM measurements) * 100

Legend. SG: sensor glucose; SD: standard deviation; CV: Coefficient of Variation; TIR: Time-in-range; CGM: continuous glucose monitoring.

2.5.4. Bedtime Hours

Bedtime hours refer to the range of hours from when a patient goes to bed to when they get up in the morning. To analyze glycemic outcomes based solely on bedtime hours, a patient-specific time range was determined. This range was established by reviewing the patient’s responses to the PSQI questions about the usual time they went to bed and got up during the past month.

2.5.5. Handling of Missing Data and Outliers and Validation Requirements

Potential outliers were retained in the analysis, and no imputation methods were applied to handle missing data. To ensure accuracy and reliability, all analyses were independently reviewed and validated by a second statistician.

3. Results

3.1. Patient Disposition

Out of the 45 patients considered, 4 were excluded from the analysis due to using the sensor for less than 70% of the time during the 30 days preceding the PSQI assessment. Consequently, the results presented in this manuscript refer to the remaining 41 subjects.

3.2. Sleep Quality

The mean PSQI score was 6.0 ± 4.1, and 15 (36.6%) patients had a PSQI score greater than 5, indicating poor sleep quality [41] (Table 2).

Table 2. Sleep quality in T1D patients.

	Summary Statistic	Total (N = 41)
PSQI	Available Measures (%)	41 (100.0%)
	Mean ± SD	6.0 ± 4.1
	Median (IQR)	4.0 (3.0-8.0)

Min-Max		1.0 - 17.0
Sleep quality		
Poor sleepers (PSQI greater than 5)	% (n/Available Measures)	36.6% (15/41)
Good sleepers (PSQI lower or equal to 5)	% (n/Available Measures)	63.4% (26/41)

Legend. PSQI: Pittsburgh Sleep Quality Index; SD: standard deviation; IQR: InterQuartile Range.

3.3. Patient Characteristics

Table 3 shows patient characteristics, comparing poor and good sleepers. No statistically significant differences were observed for the variables examined. Patients’ mean age was approximately 52 years in both groups. The proportion of females was equal to 46.7% (7/15) among poor sleepers, and 38.5% (10/26) among good sleepers. Poor sleepers had a shorter mean diabetes duration (19.2 ± 12.0 yrs.) compared to good sleepers (28.8 ± 15.1 yrs.). The mean BMI was 25.0 ± 4.1 kg/m² in the entire cohort (poor sleepers: 25.6 ± 3.6 kg/m²; good sleepers: 24.6 ± 4.4 kg/m²). Most patients (68.3%) used the MiniMed™ 780G system, with a higher proportion among good sleepers (73.1%) than poor sleepers (60.0%).

Table 3. Patient characteristics by sleep quality.

	Summary Statistic	Total (N = 41)	Poor sleepers (N = 15)	Good sleepers (N = 26)	p-value
Age (yrs.)	Available Measures (%)	41 (100.0%)	15 (100.0%)	26 (100.0%)	0.850
	Mean ± SD	51.9 ± 11.6	52.2 ± 12.3	51.7 ± 11.5	
	Median (IQR)	51.0 (43.0-63.0)	51.0 (43.0-63.0)	50.5 (42.0-64.0)	
	Min-Max	26.0 - 72.0	26.0 - 72.0	29.0 - 70.0	
Female	% (n/Available Measures)	41.5% (17/41)	46.7% (7/15)	38.5% (10/26)	0.745
Diabetes duration (yrs.)	Available Measures (%)	39 (95.1%)	15 (100.0%)	24 (92.3%)	0.058
	Mean ± SD	25.1 ± 14.6	19.2 ± 12.0	28.8 ± 15.1	
	Median (IQR)	25.0 (14.0-34.0)	17.0 (10.0-32.0)	27.0 (21.5-37.0)	
	Min-Max	1.0 - 61.0	1.0 - 40.0	5.0 - 61.0	
BMI (kg/m²)	Available Measures (%)	39 (95.1%)	15 (100.0%)	24 (92.3%)	0.516
	Mean ± SD	25.0 ± 4.1	25.6 ± 3.6	24.6 ± 4.4	
	Median (IQR)	24.9 (21.7-28.7)	24.9 (23.0-28.7)	24.6 (20.7-28.6)	
	Min-Max	18.0 - 32.4	19.8 - 32.2	18.0 - 32.4	
Smoking habit					
Current smoker	% (n/Available Measures)	22.5% (9/40)	26.7% (4/15)	20.0% (5/25)	0.204
Former smoker	% (n/Available Measures)	15.0% (6/40)	26.7% (4/15)	8.0% (2/25)	
Non-smoker	% (n/Available Measures)	62.5% (25/40)	46.7% (7/15)	72.0% (18/25)	
Device					
MiniMed™ 780G	% (n/Available Measures)	68.3% (28/41)	60.0% (9/15)	73.1% (19/26)	0.492
Medtronic Smart MDI	% (n/Available Measures)	31.7% (13/41)	40.0% (6/15)	26.9% (7/26)	

Legend. BMI: Body Mass Index; SD: standard deviation; IQR: InterQuartile Range.

3.4. Glycemic Outcomes

Table 4 shows the glycemic outcomes of the cohort during the 30-day period preceding the PSQI assessment and Figure 1 represent average TIR, TBR and TAR during bedtime hours in the 30 days preceding PSQI assessment by sleep quality. No statistically significant differences were observed between good and poor sleepers. Average SG mean and SD were 153.9 ± 18.3 mg/dL and 47.4 ± 10.7 mg/dL for the entire sample, respectively. Average CV was within the recommended target of ≤ 36% ² in both groups (poor sleepers: 31.2 ± 5.6%; good sleepers: 30.4 ± 4.6%). The mean TIR for the entire sample was 72.0 ± 11.5%, meeting the recommended target of > 70% ². Poor sleepers demonstrated slightly lower TIR (70.0 ± 13.1%) compared to good sleepers (73.2 ± 10.6%). The mean TBR for the entire sample was 1.7 ± 2.4%, well within the target of < 4% ², with TBR2 also meeting the recommended target of < 1% (0.3 ± 0.7%). However, the mean TAR for the entire sample was 26.2 ± 12.3%, slightly exceeding the target of < 25%. Poor sleepers exhibited higher TAR (28.5 ± 14.0%) than good sleepers (24.9 ± 11.3%). The mean TAR2 was 6.3 ± 6.2% for poor sleepers, exceeding the recommended target of < 5%, while was 4.1 ± 5.0% for good sleepers [41].

Table 4. Glycemic outcomes during the 30 days preceding PSQI assessment by sleep quality.

	Summary Statistic	Total (N = 41)	Poor sleepers (N = 15)	Good sleepers (N = 26)	p-value
SG mean (mg/dL)	Available Measures (%)	41 (100.0%)	15 (100.0%)	26 (100.0%)	0.310
	Mean ± SD	153.9 ± 18.3	157.5 ± 20.4	151.8 ± 17.1	
	Median (IQR)	150.7 (142.0-168.6)	159.0 (142.0-172.4)	149.0 (142.0-162.9)	
	Min-Max	117.0 - 197.5	120.8 - 194.5	117.0 - 197.5	
SG SD (mg/dL)	Available Measures (%)	41 (100.0%)	15 (100.0%)	26 (100.0%)	0.228
	Mean ± SD	47.4 ± 10.7	49.4 ± 12.1	46.3 ± 9.8	
	Median (IQR)	44.9 (40.0-51.4)	49.5 (42.5-53.5)	42.1 (39.9-48.9)	
	Min-Max	29.9 - 81.2	29.9 - 81.2	35.3 - 77.3	
SG CV (%)	Available Measures (%)	41 (100.0%)	15 (100.0%)	26 (100.0%)	0.598
	Mean ± SD	30.7 ± 5.0	31.2 ± 5.6	30.4 ± 4.6	
	Median (IQR)	30.2 (27.3-32.4)	30.6 (26.1-33.6)	29.2 (27.3-31.7)	
	Min-Max	21.6 - 44.8	23.2 - 44.8	21.6 - 43.6	
TBR2 (%)	Available Measures (%)	41 (100.0%)	15 (100.0%)	26 (100.0%)	0.250
	Mean ± SD	0.3 ± 0.7	0.2 ± 0.3	0.4 ± 0.8	
	Median (IQR)	0.1 (0.0-0.3)	0.0 (0.0-0.4)	0.1 (0.0-0.3)	
	Min-Max	0.0 - 3.9	0.0 - 1.0	0.0 - 3.9	
TBR1 (%)	Available Measures (%)	41 (100.0%)	15 (100.0%)	26 (100.0%)	0.167
	Mean ± SD	1.4 ± 1.9	1.3 ± 2.1	1.5 ± 1.7	
	Median (IQR)	0.8 (0.2-1.7)	0.4 (0.1-1.4)	1.0 (0.4-2.0)	
	Min-Max	0.0 - 7.5	0.0 - 6.9	0.0 - 7.5	
TBR (%)	Available Measures (%)	41 (100.0%)	15 (100.0%)	26 (100.0%)	0.137
	Mean ± SD	1.7 ± 2.4	1.5 ± 2.4	1.9 ± 2.4	
	Median (IQR)	0.9 (0.2-2.1)	0.5 (0.1-1.8)	1.1 (0.5-2.3)	
	Min-Max	0.0 - 11.4	0.0 - 7.5	0.0 - 11.4	
TIR (%)	Available Measures (%)	41 (100.0%)	15 (100.0%)	26 (100.0%)	0.473

	Mean ± SD	72.0 ± 11.5	70.0 ± 13.1	73.2 ± 10.6	
	Median (IQR)	73.3 (65.0-81.7)	70.3 (59.3-81.9)	75.5 (68.4-81.7)	
	Min-Max	43.5 - 92.7	43.5 - 92.7	44.9 - 85.8	
TAR1 (%)	Available Measures (%)	41 (100.0%)	15 (100.0%)	26 (100.0%)	0.490
	Mean ± SD	21.3 ± 7.9	22.2 ± 9.2	20.8 ± 7.2	
	Median (IQR)	21.3 (15.7-26.9)	23.2 (16.3-30.5)	21.2 (15.7-25.9)	
	Min-Max	5.3 - 36.2	5.3 - 36.2	6.7 - 34.2	
TAR2 (%)	Available Measures (%)	41 (100.0%)	15 (100.0%)	26 (100.0%)	0.120
	Mean ± SD	4.9 ± 5.5	6.3 ± 6.2	4.1 ± 5.0	
	Median (IQR)	2.6 (1.4-6.5)	5.1 (1.7-8.4)	2.4 (1.0-4.9)	
	Min-Max	0.1 - 20.7	0.1 - 20.3	0.1 - 20.7	
TAR (%)	Available Measures (%)	41 (100.0%)	15 (100.0%)	26 (100.0%)	0.365
	Mean ± SD	26.2 ± 12.3	28.5 ± 14.0	24.9 ± 11.3	
	Median (IQR)	23.7 (17.2-35.0)	29.7 (17.9-40.5)	23.6 (16.9-31.0)	
	Min-Max	5.4 - 56.1	5.4 - 56.1	7.3 - 54.9	

Legend. SG: Sensor Glucose; SD: standard deviation; IQR: InterQuartile Range; Min-Max: minimum-maximum; CV: Coefficient of Variation; TBR2: Time Below Range level 2; TBR1: Time Below Range level 1; TBR: Time Below Range; TIR: Time In Range; TAR1: Time Above Range level 1; TAR2: Time Above Range level 2; TAR: Time Above Range.

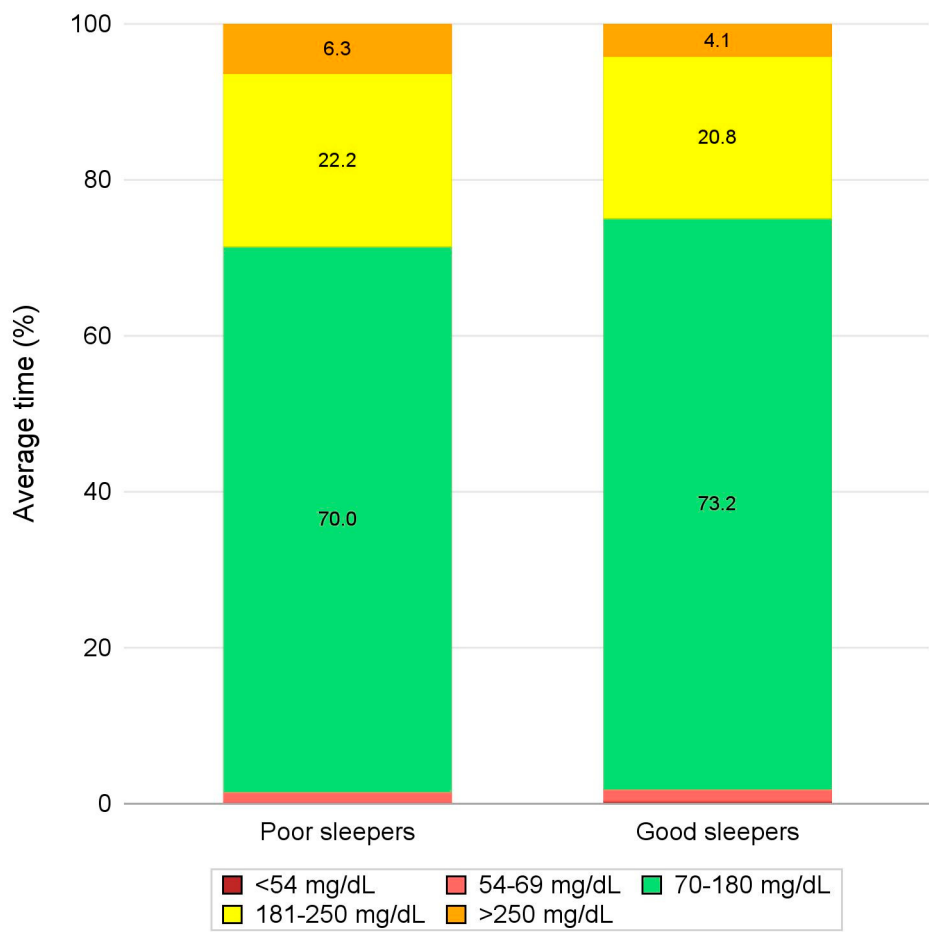


Figure 1. Average TIR, TBR and TAR in the 30 days preceding PSQI assessment by sleep quality.

3.5. Glycemic Outcomes during Bedtime Hours

Table 5 shows the glycemic outcomes of the patients during the 30 days preceding the PSQI assessment, considering bedtime hours only and average TBR, TIR and TAR values during bedtime hours are shown in **Error! Reference source not found.** Bedtime hours were defined for each patient based on the PSQI responses as outlined in section 0. Poor sleepers had an average number of bedtime hours of 7.3 ± 1.3 per night, while this figure was 7.6 ± 1.0 for good sleepers.

Mean TAR2 was significantly higher in poor sleepers compared to good sleepers ($6.7 \pm 7.2\%$ vs. $3.3 \pm 6.2\%$, $p = 0.013$), with median values of 4.9% and 1.1%, respectively. No other statistically significant differences were observed.

Table 5. Glycemic outcomes during bedtime hours in the 30 days preceding PSQI assessment by sleep quality.

	Summary Statistic	Total (N = 41)	Poor sleepers (N = 15)	Good sleepers (N = 26)	p-value
SG mean (mg/dL)	Available Measures (%)	41 (100.0%)	15 (100.0%)	26 (100.0%)	0.379
	Mean $\pm$ SD	153.0 $\pm$ 22.5	157.5 $\pm$ 24.5	150.5 $\pm$ 21.3	
	Median (IQR)	147.5 (141.0-164.5)	150.5 (142.0-174.0)	147.1 (135.3-161.0)	
	Min-Max	121.3 - 213.9	121.3 - 204.5	122.0 - 213.9	
SG SD (mg/dL)	Available Measures (%)	41 (100.0%)	15 (100.0%)	26 (100.0%)	0.113
	Mean $\pm$ SD	44.1 $\pm$ 12.6	48.1 $\pm$ 13.5	41.7 $\pm$ 11.6	
	Median (IQR)	41.4 (35.5-49.8)	49.8 (34.4-54.9)	40.1 (35.5-45.8)	
	Min-Max	26.8 - 84.6	27.8 - 72.9	26.8 - 84.6	
SG CV (%)	Available Measures (%)	41 (100.0%)	15 (100.0%)	26 (100.0%)	0.091
	Mean $\pm$ SD	28.7 $\pm$ 5.9	30.6 $\pm$ 7.3	27.5 $\pm$ 4.8	
	Median (IQR)	28.3 (24.2-31.6)	29.9 (24.2-35.0)	28.0 (23.7-29.5)	
	Min-Max	17.4 - 42.5	17.4 - 42.5	19.0 - 39.6	
TBR2 (%)	Available Measures (%)	41 (100.0%)	15 (100.0%)	26 (100.0%)	0.977
	Mean $\pm$ SD	0.3 $\pm$ 0.8	0.3 $\pm$ 0.7	0.3 $\pm$ 0.9	
	Median (IQR)	0.0 (0.0-0.1)	0.0 (0.0-0.1)	0.0 (0.0-0.2)	
	Min-Max	0.0 - 4.2	0.0 - 1.9	0.0 - 4.2	
TBR1 (%)	Available Measures (%)	41 (100.0%)	15 (100.0%)	26 (100.0%)	0.691
	Mean $\pm$ SD	1.2 $\pm$ 2.2	1.5 $\pm$ 3.1	1.0 $\pm$ 1.5	
	Median (IQR)	0.5 (0.0-1.2)	0.4 (0.0-0.9)	0.6 (0.0-1.4)	
	Min-Max	0.0 - 9.9	0.0 - 9.9	0.0 - 5.5	
TBR (%)	Available Measures (%)	41 (100.0%)	15 (100.0%)	26 (100.0%)	0.711
	Mean $\pm$ SD	1.5 $\pm$ 2.8	1.8 $\pm$ 3.8	1.4 $\pm$ 2.2	
	Median (IQR)	0.5 (0.0-1.3)	0.4 (0.0-1.0)	0.6 (0.0-1.7)	
	Min-Max	0.0 - 11.8	0.0 - 11.8	0.0 - 9.5	
TIR (%)	Available Measures (%)	41 (100.0%)	15 (100.0%)	26 (100.0%)	0.163
	Mean $\pm$ SD	73.7 $\pm$ 15.7	69.6 $\pm$ 16.9	76.0 $\pm$ 14.9	
	Median (IQR)	77.3 (66.8-85.3)	71.0 (60.1-84.2)	78.7 (70.3-86.5)	
	Min-Max	32.6 - 95.3	37.8 - 95.1	32.6 - 95.3	
TAR1 (%)	Available Measures (%)	41 (100.0%)	15 (100.0%)	26 (100.0%)	0.636

	Summary Statistic	Total (N = 41)	Poor sleepers (N = 15)	Good sleepers (N = 26)	p-value
	Mean ± SD	20.2 ± 10.8	21.8 ± 12.7	19.2 ± 9.6	
	Median (IQR)	19.1 (12.1-26.2)	19.5 (12.1-30.1)	17.9 (12.1-24.0)	
	Min-Max	3.8 - 53.6	3.8 - 53.6	4.6 - 43.6	
	Available Measures (%)	41 (100.0%)	15 (100.0%)	26 (100.0%)	
TAR2 (%)	Mean ± SD	4.6 ± 6.7	6.7 ± 7.2	3.3 ± 6.2	0.013
	Median (IQR)	1.8 (0.5-5.6)	4.9 (1.4-10.6)	1.1 (0.5-2.8)	
	Min-Max	0.0 - 27.7	0.3 - 27.7	0.0 - 27.3	
	Available Measures (%)	41 (100.0%)	15 (100.0%)	26 (100.0%)	
TAR (%)	Mean ± SD	24.8 ± 16.0	28.5 ± 17.7	22.6 ± 14.9	0.310
	Median (IQR)	20.6 (13.2-33.2)	24.5 (13.5-39.9)	19.8 (12.6-27.0)	
	Min-Max	4.1 - 65.0	4.1 - 61.2	4.7 - 65.0	
	Available Measures (%)	41 (100.0%)	15 (100.0%)	26 (100.0%)	

Legend. SG: Sensor Glucose; SD: standard deviation; IQR: InterQuartile Range; Min-Max: minimum-maximum; CV: Coefficient of Variation; TBR2: Time Below Range level 2; TBR1: Time Below Range level 1; TBR: Time Below Range; TIR: Time In Range; TAR1: Time Above Range level 1; TAR2: Time Above Range level 2; TAR: Time Above Range.

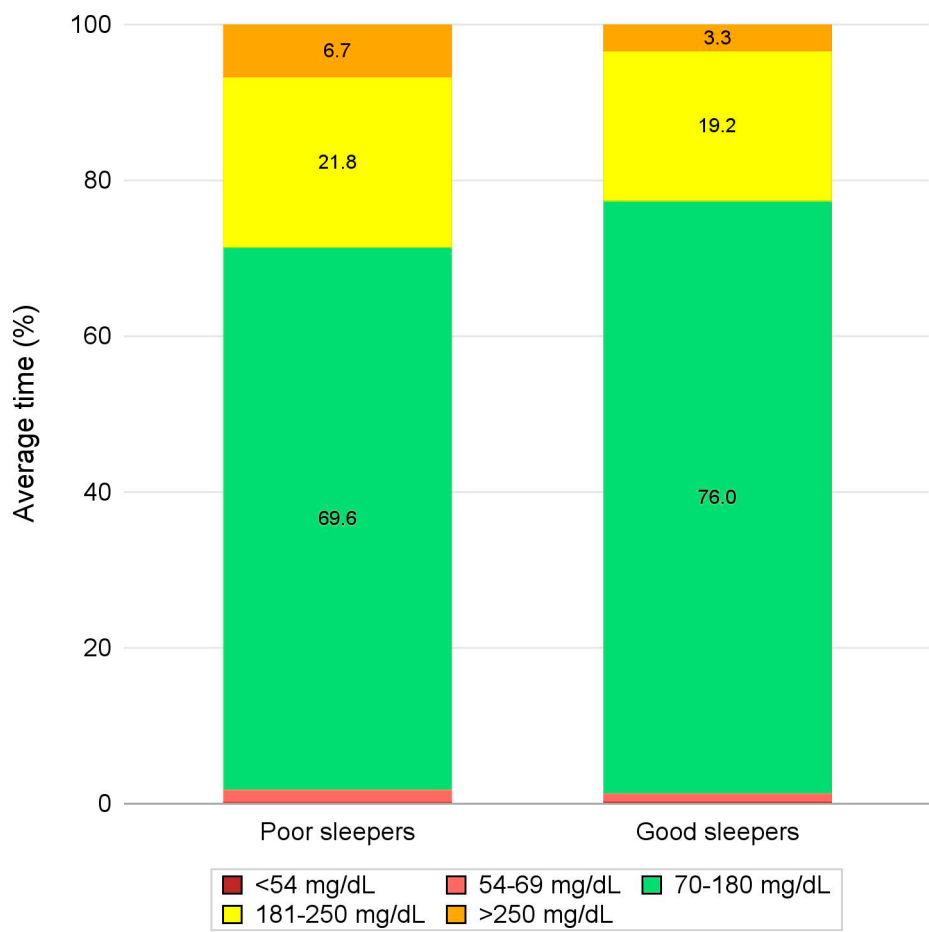


Figure 2. Average TIR, TBR and TAR during bedtime hours in the 30 days preceding PSQI assessment by sleep quality.

4. Discussion

This analysis included 41 T1D patients treated with either the Medtronic Smart MDI system (Simplera™ + InPen™) or the MiniMed™ 780G system, undergoing a PSQI assessment and reaching a sensor use of at least 70% of the time during the 30 days preceding the assessment. A total of 15 (36.6%) patients had a PSQI score greater than 5, indicating poor sleep quality. No statistically significant differences were observed between good and poor sleepers in terms of age, sex, BMI, diabetes duration, smoking habit, device used for diabetes management, and glycemic outcomes during the 30 days preceding the PSQI assessment. However, when restricting the evaluation of the glycemic outcomes to the bedtime hours only, the mean TAR2 (> 250 mg/dL) was significantly higher in poor sleepers compared to good sleepers ($6.7 \pm 7.2\%$ vs. $3.3 \pm 6.2\%$, $p = 0.013$), with median values of 4.9% and 1.1%, respectively. This finding is in line with previous studies, which have highlighted how poor sleep quality negatively affects glycemic control in patients with type 1 diabetes. Therefore, monitoring sleep quality could be a useful intervention to optimize glycemic control, particularly during nighttime hours, and prevent episodes of hyperglycemia. Our results also align with a recent study conducted by Passanini et al., [43] which analyzed the use of the MiniMed™ 780G system for the treatment of type 1 diabetes. In this study, the use of an insulin delivery system, also the MiniMed™ 780G, led to improvements in both glycemic control and sleep quality, while also reducing the psychological distress associated with diabetes. Although both studies agree on the importance of sleep quality for glycemic control, there are differences in the details. Our study primarily focused on the effect of sleep quality on TAR2 and showed a significant difference between patients with good and poor sleep quality, while Passanini et al.'s study highlighted how the use of the MiniMed™ 780G was associated with a reduction in severe hypoglycemia and an improvement in time in the target glycemic range (TIR), without detecting a significant increase in TAR. This suggests that advanced devices like the MiniMed™ 780G may offer additional benefits, improving both glycemic control and sleep quality, with potential positive implications for overall diabetes management. Moreover, the results of our study are also consistent with another study [44], who observed a correlation between poor sleep quality and greater nocturnal glycemic variability, measured both by standard deviation (SD) and coefficient of variation (CV). Specifically, nights with poor sleep quality were associated with greater glycemic variability, emphasizing how sleep quality negatively impacts glycemic stability during the night. Again, our study confirms the importance of monitoring sleep quality to optimize nocturnal glycemic control in patients with type 1 diabetes. On the other hand, the study conducted by Martin-Nemeth et al. [45] explored the role of fear of hypoglycemia (FOH) as a factor contributing to poor sleep quality in patients with type 1 diabetes. Anxiety related to the risk of hypoglycemia could therefore be an additional factor to consider in the management of sleep quality and, consequently, in improving glycemic control. Indeed, our study did not directly explore this aspect, but it is important to highlight how psychological factors such as FOH may interact with sleep quality and negatively impact glycemic control. In another study [46] was found that poor sleep quality, measured by PSQI, was associated with higher levels of HbA1c and less optimal glycemic management. Additionally, several factors affecting sleep quality were identified, such as pain, coughing, snoring, and the inability to maintain continuous sleep, all of which were significantly correlated with poorer glycemic control. These factors may represent additional issues that negatively influence glycemic management in patients with type 1 diabetes, as seen in our study. Finally, a recent study [47] examined the effect of seasonal transitions on sleep quality and glycemic parameters in patients with type 1 diabetes treated with continuous glucose monitoring (CGM) systems. Although no significant changes in sleep quality were observed, the study found a deterioration in glycemic parameters, with an increase in GMI and a reduction in time in the target glycemic range (TIR) during seasonal changes. This suggests that, in addition to sleep quality, environmental factors such as seasonal changes may negatively influence glycemic control. Our results, which highlight the impact of sleep quality on glycemic control, fit into this broader context, emphasizing the importance of monitoring multiple factors, including seasonal ones, for optimal management of type 1 diabetes.

4.1. Limitations

This analysis was conducted on a selected set of patients, and given the retrospective observational nature of the data, selection bias may be present. Furthermore, the available patient characteristics were limited, potentially excluding factors that could influence sleep quality. Future analyses incorporating a broader range of patient characteristics and a larger sample size, allowing for covariate adjustment, are recommended to generate more robust evidence.

5. Conclusions

This research contributes to a deeper understanding of the link between sleep quality and glycemic control in patients with type 1 diabetes, highlighting the need to consider sleep quality as a modifiable factor that can positively influence glycemic management and potentially prevent episodes of nocturnal hyperglycemia. The study underscores the critical role of sleep quality in glycemic control, showing that poor sleep quality is associated with a higher time spent in the TAR2 during the night. Although no significant differences were observed between patients with good and poor sleep quality regarding age, sex, BMI, or diabetes duration, the findings suggest that monitoring sleep quality could be an effective strategy for optimizing glycemic control, particularly during nighttime, and preventing hyperglycemic episodes. Furthermore, this research enhances our understanding of the relationship between sleep and glycemic control, emphasizing that sleep quality should be viewed as a modifiable factor. When properly managed, it can positively influence glycemic stability and reduce the risk of long-term complications. Psychological and environmental factors, alongside physiological ones, seem to play an important role in both sleep quality and glycemic management, indicating that a holistic approach to diabetes care should address these aspects. Future research should focus on exploring specific interventions aimed at improving sleep quality as a strategy to optimize glycemic control and reduce the risk of long-term complications.

Supplementary Materials: The following supporting information can be downloaded at the website of this paper posted on Preprints.org, 1. Italian version of Pittsburgh Sleep Quality Index (PSQI); 2. STROBE Statement—checklist.

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