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Artigo Original

Sleep Quality in Caregivers of Pediatric Patients with Type 1 Diabetes Mellitus: The Impact of Flash Glucose Monitoring Systems with Alarms

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A B S T R A C T

Introduction: Type 1 diabetes mellitus (T1DM) requires ongoing intensive management. Caregivers of pediatric patients assume a fundamental role in glucose monitoring, 24 hours per day, which may affect their sleep. We aimed to compare the sleep quality of principal caregivers of T1DM pediatric patients who use flash glucose monitoring system (FGMS) with and without alarms and assess its impact on metabolic control.
Methods: Observational and cross-sectional study of T1DM patients using an FGMS and a continuous subcutaneous insulin infusion device. The main caregiver's sleep quality was assessed through the Pittsburgh Sleep Quality Index (PSQI), and metabolic control was evaluated through the ambulatory glucose profile and HbA1c.
Results: Forty-two patients and their caregivers were included, 14 children and adolescents with an alarm and 28 controls. The PSQI score showed no significant differences in parental sleep quality between groups: a median of 6.5 (IQR 7) in the alarm group and 9 (IQR 5) in the control group, p=0.348. The characterization of metabolic control (adjusted for children's age and caregivers' educational qualifications) revealed mean values of time in range (TIR) 52.17% *vs* 42.60% (p=0.134), time below range (TBR) 1.56% *vs* 5.59% (p=0.014) and glucose coefficient of variation (CV) 35.36% *vs* 41.62% (p=0.004) in the group with and without alarm, respectively.
Conclusion: The use of alarms did not lead to a worse sleep quality or more nocturnal awakenings in caregivers of T1DM children. However, the alarms improved metabolic control by reducing TBR and glucose CV. Our results support using alarms in diabetes management without prejudice to the caregivers' sleep quality.

Qualidade do Sono dos Cuidadores de Doentes Pediátricos com Diabetes Mellitus Tipo 1: O Impacto dos Sistemas de Monitorização Flash da Glicose com Alarmes

R E S U M O

Introdução: A diabetes *mellitus* tipo 1 (DMT1) requer uma monitorização intensiva e contínua. Os cuidadores dos doentes pediátricos assumem um papel fundamental na monitorização da glicose, 24 horas por dia, o que pode afetar o seu sono. Este trabalho teve como objetivo comparar a qualidade do sono dos cuidadores de crianças e adolescentes com DMT1 que utilizam sistemas de monito-

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rização *flash* da glicose (MFG) com e sem alarmes, bem como avaliar o seu impacto no controlo metabólico.

Métodos: Estudo observacional, transversal e analítico de doentes pediátricos com DMT1 utilizadores de MFG e sob sistema de infusão subcutânea contínua de insulina. A qualidade do sono dos cuidadores principais foi avaliada através do *Pittsburgh Sleep Quality Index* (PSQI) traduzido e validado para português, e o controlo metabólico foi analisado através do perfil ambulatório de glicose e da HbA1c.

Resultados: Foram incluídos 42 doentes e respetivos cuidadores, 14 crianças e adolescentes com alarme e 28 controlos. O *score* total do PSQI não demonstrou diferenças significativas na qualidade do sono dos cuidadores entre os grupos: mediana de 6,5 (IQR 7) no grupo com alarmes e 9 (IQR 5) no grupo sem alarmes, p=0.348. A caracterização do controlo metabólico (ajustada para a idade dos doentes e habilitações literárias dos cuidadores) revelou valores médios de tempo no alvo de 52.17% *vs* 42.60% (p=0.134), tempo abaixo do alvo de 1.56% *vs* 5.59% (p=0.014) e coeficiente de variação de glicose de 35.36% *vs* 41.62% (p=0.004) no grupo com e sem alarmes, respetivamente.

Conclusão: A utilização de alarmes não condicionou mais despertares noturnos ou pior qualidade de sono dos cuidadores de crianças e adolescentes com DMT1. No entanto, a sua utilização associou-se a um melhor controlo metabólico, através da redução do tempo abaixo do alvo e do coeficiente de variação de glicose. Os nossos resultados apoiam a utilização de alarmes no tratamento e monitorização da DMT1, sem prejuízo da qualidade do sono dos cuidadores.

Introduction

Type 1 diabetes mellitus (T1DM) is one of the most frequent chronic diseases in childhood and adolescence, and its incidence has increased worldwide.[1,2] These patients need lifelong insulin treatment and adequate metabolic control to avoid complications. The daily management of diabetes includes frequent glucose monitoring, insulin administration, adequate diet and physical activity. Consequently, this constitutes a challenge for both patients and their caregivers and may cause significant psychological stress and negatively impact the family´s quality of life.[1,3,4]

In order to decrease the burden of T1DM management and facilitate glucose monitoring, different technologies have been developed. The flash glucose monitoring system (flash GMS) continuously measures the glucose levels in the interstitial fluid, although the results are known and recorded only if the patient or the caregiver actively scans the sensor.[3,5] The flash GMS offers more than just a glucose measurement, it also indicates glucose tendencies (through trend arrows) and provides an ambulatory glucose profile (AGP) after transferring the data from the sensor to the reader.

Some flash GMS may have programmed alarms when hypoglycemia or hyperglycemia are detected.[5,6] In Portugal, at the time of the study, the National Health Service only subsidized one flash glucose monitoring system, the FreeStyle Libre 1®, which does not allow alarm programming.

The flash GMS makes glucose monitoring easier and allows caregivers to monitor the levels overnight with reduced interruption of the patients' sleep.[5]

Caregivers of T1DM patients commonly fear nocturnal hypoglycemia, leading to more frequent glucose monitoring during nighttime. This nocturnal vigilance could cause an interruption and shorter duration of the caregivers' sleep, impairing their daily activities and well-being.[3]

Recent studies revealed that a significant percentage of the caregivers of children and adolescents with T1DM have poor sleep quality or a sleep duration below the recommended amount, mainly due to nighttime glucose monitoring and fear of hypoglycemia.[1,7]

However, there is still scarce evidence on the impact of alarms associated with flash GMS on the caregivers' sleep quality.[8] A recent systematic review evaluated the patient and/or parents' sleep quality in seven studies on real-time continuous glucose monitoring use in youth. In contrast, the results from its literature review highlighted the lack of data on the quality of sleep in pediatric patients using flash GMS.[9]

The aim of this study was to compare the sleep quality of the main caregiver of T1DM pediatric patients who use flash GMS with and without programmed alarms. Therefore, we also intended to assess the alarms' impact on metabolic control.

Material and Methods

1. Participants

The potential participants were voluntarily recruited at their pediatric endocrinology appointment on pediatric endocrinology clinic from the north of Portugal.

The participants were children or adolescents with T1DM using a continuous subcutaneous insulin infusion (CSII) device and a flash GMS (FreeStyle Libre 1® or FreeStyle Libre 2®).

In Portugal, when the study was carried out, only FreeStyle Libre 1® was state-subsidized. Thus, most patients using flash GMS had FreeStyle Libre 1®, and only a few patients/caregivers had decided for FreeStyle Libre 2®.

FreeStyle Libre® has been approved for children aged four years and older. However, scientific evidence showed its safety and accuracy in younger children. For this reason, this study also included children under four years old.[10,11]

The following exclusion criteria were applied: diagnosis or alteration of the insulin delivery system in the previous three months, multiple daily insulin injections therapy, and the use of the flash GMS for less than one month or irregular use (patients did not use it at least 70% of the time).

The selected participants were divided into two groups: patients using flash GMS with programmed alarms (FreeStyle Libre 2®) and another group using flash GMS without alarms (FreeStyle Libre 1®), the control group. In the alarm group, patients had hypoglycemia alarms set to values <70 mg/dL; in patients who had hyperglycemia alarms, they were set to values > 250 mg/dL.

2. Study Design

An observational, cross-sectional, and analytical study was carried out in March 2021 at the Pediatric Endocrinology and Diabetology Unit of Centro Hospitalar de Vila Nova de Gaia/Espinho, a Portuguese tertiary hospital located in an urban environment.

After obtaining written informed consent, an online questionnaire was applied to the main caregiver, including socio-demographic data (sex, age, education level, and professional status) and questions regarding to the personal/subjective perception of glucose monitoring and programmed alarms; impact on individual sleep quality. The Pittsburgh Sleep Quality Index (PSQI - validated version in Portuguese) was also applied to all participants. The PSQI is a 19-item self-rated questionnaire that evaluates sleep quality over the previous month. The 19 questions are categorized into seven components, graded from 0 to 3. The PSQI score, ranging from 0 to 21, results from the sum of these seven components. A PSQI score equal to or lower than five corresponds to good sleep quality, while higher scores indicate poor sleep quality.[12]

The flash GMS data (AGP) from the previous four weeks was downloaded at the medical appointment on the same day the questionnaire was answered. When the patient did not have an appointment scheduled during the study period, caregivers made the discharge remotely and sent it. The collected AGP parameters were mean interstitial glucose, time in range (TIR, 70-180 mg/dL), time above range (TAR, >180 mg/dL), time below range (TBR, <70 mg/dL), coefficient of variation (CV), estimated HbA1c, percentage of time flash GMS is active, and the number of daily readings.

Patients' demographic and clinical data (sex, age, date of diagnosis, onset of CSII, and last HbA1c value) were collected from the corresponding clinical file after parental/legal guardians' consent.

3. Statistical Analysis

Statistical analysis was performed using SPSS Statistics 27.0 (IBM Corp., Armonk, NY, USA), and MPLUS for the latent class analysis. A value of $p<0.05$ was considered statistically significant.

Continuous variables were summarized as mean and standard deviation (SD) or as median and interquartile range (IQR), according to the normal or non-normal data distribution, and compared using the Student t-test or the Mann-Whitney U test, respectively. The categorical variables were described as counts and proportions and compared using the Chi-square test.

To study the association between using an alarm device and the metabolic variables, generalized linear models were computed to provide adjusted means and respective 95% confidence intervals (CI). The adjusted model included the age of the participants and their parental education.

Correlations between PSQI and metabolic variables were analyzed using Spearmans correlation.

4. Ethics

The study protocol was reviewed and approved by the ethics committee of our institution. Participants and their parents/legal guardians, as applicable, gave written informed consent to participate in the study.

Results

1. Sample Characteristics

At the time of the study, 136 pediatric patients with T1DM were followed-up in our hospital center, 105 were using CSII.

Forty-two (42) patients with T1DM fulfilled the inclusion criteria and accepted to participate in the study; 14 used flash GMS with associated alarms, and 28 used the same system without any alarm (Table 1). The youngest patient was two years old, and the oldest was 17 years (mean age 8.6 ± 4.2 years in the alarm group and 11.2 ± 4.2 years in the control group, p=0.061). The diabetes duration ranged from 0.4 to 13.6 years (median 1.9 years in the alarm group (IQR = 5.0) *vs* 4.4 years (IQR = 5.7), p=0.165). The median duration of treatment with CSII was 1.8 years (IQR = 3.9) in the alarm group and 3.2 years (IQR = 2.8) in the control group (p=0.298).

Table 1. Sample characteristics

	Alarm (n=14)	No alarm (n=28)	*p*-value
Diabetic child/adolescent characteristics			
Sex			
Female	8 (57%)	9 (32%)	0.221
Male	6 (43%)	19 (68%)	
Age, in years [mean ± SD]	8.6 ± 4.2	11.2 ± 4.2	
< 5 years	3 (21%)	2 (7%)	0.061
5-9 years	5 (36%)	7 (25%)	
≥ 10 years	6 (43%)	19 (68%)	
Duration of T1DM, in years [median (IQR)]	1.9 (5.0)	4.4 (5.7)	0.165
Duration of CSII, in years [median (IQR)]	1.8 (3.9)	3.2 (2.8)	0.298
Parents/caregivers characteristics			
Gender			
Female	11 (79%)	25 (89%)	0.383
Male	3 (21%)	3 (11%)	
Age, in years [mean ± SD]	42.1 ± 3.7	41.6 ± 5.5	0.796
Academic qualification			
4th Grade	0 (0%)	2 (7%)	
6th Grade	0 (0%)	2 (7%)	0.522
9th Grade	1 (7%)	5 (18%)	
Secondary education	5 (36%)	7 (25%)	
University education	8 (57%)	12 (43%)	
Professional situation			
Presential work	4 (29%)	9 (32%)	
Remote work	8 (57%)	6 (21%)	0.163
Unemployed	1 (7%)	8 (29%)	
Sick leave	0 (0%)	2 (7%)	
Other	1 (7%)	3 (11%)	

SD, standard deviation; IQR, interquartile range; T1DM, type 1 diabetes mellitus; CSII, continuous subcutaneous insulin infusion therapy.

The caregivers' age ranged from 30 to 52 years old, and 86% were female. In the alarm group, the mean caregivers' age was 42.1 ± 3.7 years *vs* 41.6 ± 5.5 (p=0.796), 57% had a bachelors degree *versus* 43% (p=0.522), and, by the time of the study, 57% were working remotely from home *versus* 21% (p=0.163). Therefore, there were no statistically significant differences in the characteristics of the caregivers between the two groups.

2. Sleep Characteristics and Qualification

Most caregivers self-evaluated their sleep quality as "bad" or "very bad" in both groups (Table 2). A number of awakenings equal to or greater than three times per night was reported by 36% caregivers in the alarm group and 43% in the control group (p=0.744). In the alarm group, 79% believed that alarms interfered with their sleep quality.

In both groups, most caregivers had a PSQI score above 5, which means poor sleep quality. The percentage of PSQI >5 was 57% *vs* 75% (p=0.298), and the PSQI median score was 6.5 (IQR

Table 2. Sleep characteristics and qualification

	Alarm (n=14)	No alarm (n=28)	*p*-value
Number of awakenings per night for GM			0.744
None	1 (7%)	3 (11%)	
1 to 2 times	8 (57%)	13 (46%)	
3 to 4 times	3 (21%)	10 (36%)	
5 or more times	2 (14%)	2 (7%)	
Sleep quality self-classification			0.264
Very good	1 (7%)	0 (0%)	
Good	5 (36%)	11 (39%)	
Bad	7 (50%)	10 (36%)	
Very bad	1 (7%)	7 (25%)	
Sleep quality classification			0.298
Good Sleep Quality (PSQI ≤ 5)	6 (43%)	7 (25%)	
Poor Sleep Quality (PSQI > 5)	8 (57%)	21 (75%)	

GM, glucose monitoring.

7.0) *vs* 9.0 (IQR 5.0) in the alarm and control group (p=0.348), respectively. There was a high agreement between the sleep quality self-classification and the PSQI score (p<0.001). There were no significant differences between the two groups regarding the number of awakenings per night for glucose monitoring, sleep quality self-classification, and global PSQI score.

3. Metabolic Control

The statistical analysis for the metabolic control is presented in Table 3.

Mean interstitial glucose adjusted for childrens age and caregivers' educational qualifications was 182.13 mg/dL (95% CI 162.80-201.45) in the alarm group and 193.44 mg/dL (95% CI 180.84-206.04) in the control group (p=0.360).

The adjusted mean for TIR was 52.17% (95% CI 42.06-62.27) in the alarm group and 42.60% (95% CI 36.1-49.19) in the control group (p=0.134). The adjusted mean for TBR was 1.56% (95% CI -0.96-4.08) in the alarm group and 5.59% (95% CI 3.95-7.24) in the control group (p=0.0014). The alarm group had a lower glucose coefficient of variation (p=0.004). HbA1c measured at the last medical appointment was 7.93% (95% CI 7.30-8.56) in the alarm group and 7.59% (95% CI 7.16-8.03) in the control group (p=0.393).

In both groups, there was no statistically significant correlation between the PSQI score and TIR (R=0.026; p=0.874), and the same occurred with PSQI and HbA1c (R=-0.199; p=0.207).

In the alarm group, 100% defined alarms for hypoglycemia and 93% for hyperglycemia too. When questioned about the reasons for acquiring alarm devices, 21% answered that they feared hypoglycemia; 36% wanted to improve metabolic control; 43% said they needed to feel more secure about the diabetes treatment of their children.

Discussion

Glucose monitoring systems have known benefits in metabolic control, although they may include alarms that could interfere in the sleep of patients and caregivers.[8]

In our study, most caregivers self-rated their sleep quality as "poor" or "very poor." When assessed by the PSQI, the majority of caregivers (69%) met poor sleep quality criteria. About 40% reported three or more awakenings per night to monitor glucose.

These results are consistent with the ones described in the literature. Several studies have shown poor quality or shorter sleep duration in caregivers of T1DM patients.[1,7,13,14] For this reason, we consider it is essential to understand the impact of alarms on the caregivers' sleep. Whether they can worsen sleep quality due to more frequent nocturnal awakenings and consequently greater fragmentation of sleep, or if, on the opposite, caregivers feel more comfortable knowing the alarms will alert them about hypo and hyperglycemia, leading to better a sleep quality.

Most caregivers (79%) in the alarm group believed that alarms interfered with their sleep quality, but we did not find significant differences in sleep quality or the number of nocturnal awakenings between the two groups.

These results are in accordance with those presented by Franceschi *et al*, who also showed that the alarms do not worsen the duration and the quality of sleep. However, in the study by Franceschi *et al*, patients used Freestyle Libre 2® only for 14 days, therefore the authors hypothesized that more prolonged alarms use could improve the sleep duration and quality.[8] In our study, the alarms were used for longer than one month. Even so, we did not find a significantly better sleep quality in the alarm group compared to the control group, which does not support their hypothesis.

Our results showed that alarms did not affect caregivers' sleep, as the alarms neither worsened nor improved their sleep quality. That probably occurred because the poor sleep quality in caregivers of diabetic patients has a multifactorial etiology.

Emotional stress is frequent among caregivers of patients with T1DM, especially concerning hypoglycemia.[4,15] In our cohort with alarms, 64% of the caregivers mentioned they chose to use alarms because they feared hypoglycemia or needed more confidence in diabetes treatment. There is evidence that continuous glucose monitoring improves the psychological well-being of children with T1DM and their parents by reducing worrisome and fear of hypoglycemia.[4,15] Franceschi et al also reported an improvement in the quality of life perceived by parents using flash GMS with alarms.[8]

Regarding to metabolic control, previous studies have demonstrated an improvement with flash GMS.[16,17] Franceschi *et al* also

Table 3. Metabolic control characterization

	Alarm (n=14)		No alarm (n=28)		*p*-value
	Adjusted mean[a]	95% CI	Adjusted meana	95% CI	
HbA1c (%)	7.93	7.30-8.56	7.59	7.16-8.03	0.393
Mean glucose (mg/dL)	182.13	162.80-201.45	193.44	180.84-206.04	0.360
TIR (%)	52.17	42.06-62.27	42.60	36.01-49.19	0.134
TAR (%)	46.11	35.79-56.43	51.81	45.08-58.54	0.378
TBR (%)	1.56	-0.96-4.08	5.59	3.95-7.24	**0.014**
Glucose CV (%)	35.36	31.97-38.75	41.62	39.41-43.83	**0.004**

[a] Adjusted means for the age of the participants and parental education; TIR, time in range; TAR, time above range; TBR, time below range; CV, coefficient of variation; CI, confidence interval.

found an improvement in metabolic control after switching from FreeStyle Libre 1® to FreeStyle Libre 2®, which increased TIR by about 5% and reduced TBR and glucose CV.[8]

Our results did not show a significantly better TIR or HbA1c in the alarm group than in the control group. Nonetheless, we found that using alarms was associated with a lower glucose CV and TBR. Decreasing the TBR is an essential target in diabetes management, and according to Battelino *et al*, the primary goal for effective and safe glucose control is to increase the TIR while reducing the TBR.[18]

Thus, our study demonstrated that by reducing TBR, alarms are advantageous in glycemic control. These results are probably justified because all patients had established alarms for hypoglycemia and because of the younger age of this childrens group, which is usually associated with higher parental concern about hypoglycemia.

We hypothesized that the parents with the worst sleep quality were those more concerned and who frequently monitored glucose, and this could result in better metabolic control. Nevertheless, there was no significant correlation between the PSQI score and TIR or HbA1c.

Our study has the strengths of having a control group, using a validated questionnaire to assess sleep quality, and guaranteeing a simultaneous assessment of metabolic control and sleep quality. As previously mentioned, the use of FreeStyle Libre® in children under four years was based on scientific evidence of its safety and accuracy in this age group.[10,11]

However, this work also has some limitations, such as being a single-center study, having a small number of patients, assessing sleep and metabolic control only for one month, and not considering other factors like the use of psychotropic drugs or the existence of comorbidities/pathologies that may interfere with the caregivers' sleep quality. Besides, in the alarm group, sleep quality was not assessed before and after the alarm use onset in order to evaluate alarms' impact on sleep over time.

In Portugal, at the time of the study, only FreeStyle Libre 1® was state-subsidized, which justifies the small number of patients using alarms. The fact that FreeStyle Libre 2® was not subsidized is also a limitation, as it could be a confounding factor. Parents who purchased FreeStyle Libre 2® could be more concerned about preventing hypoglycemia and pursuing optimal glucose control, which could influence the metabolic control observed in the alarm group.

Longitudinal studies and a larger patient sample are needed to better understand the alarms' impact on sleep quality and metabolic control.

Conclusion

Our study showed that the alarms are not associated with worse sleep quality for caregivers, but they also did not improve sleep quality or reduce the number of nocturnal awakenings. On the other hand, the alarms improved metabolic control by significantly reducing the TBR and glucose CV. Therefore, our results support using alarms in diabetes management without prejudice to the caregivers; sleep quality.

Pediatric diabetes medical teams should be aware of caregivers' sleep disturbances to provide additional education and support in order to minimize this problem. Poor sleep quality has possibly a multifactorial cause, so other parameters, including emotional factors, must be considered and managed. This type of strategy will allow increasing caregivers' confidence and, at the same time, will promote the use of technological tools to improve glycemic control.

Contributorship Statement / Declaração de Contribuição:

ES and TL: Study conception and design, data collection, analysis and interpretation of results, draft manuscript preparation.
ACS: Analysis and interpretation of results.
CL: Study conception and design, data collection.
MAR, RAC and ALL: Study conception and design, interpretation of results, supervision.
All authors reviewed and approved the final version of the manuscript.

Responsabilidades Éticas

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Proteção de Pessoas e Animais: Os autores declaram que os procedimentos seguidos estavam de acordo com os regulamentos estabelecidos pela Comissão de Ética responsável e de acordo com a Declaração de Helsínquia revista em 2013 e da Associação Médica Mundial.
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