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ORIGINALS

Continuous glucose monitoring on the perception of hypoglycemia in people with diabetes mellitus

Monitorización continua de glucosa en la percepción de la hipoglucemia en personas con diabetes mellitus

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ABSTRACT:
Introduction: Recurrent hypoglycemia increases the risk of developing asymptomatic hypoglycemia, which affects up to 40% of people with diabetes and leads to severe hypoglycemic episodes.
Objective: This study aimed to evaluate the effect of instant glucose monitoring on the perception of hypoglycemia in patients with type 1 diabetes mellitus.
Method: A 24-week quasi-experimental study was conducted at the Virgen del Rocío University Hospital involving 68 patients with type 1 diabetes with severe or asymptomatic hypoglycemia. The primary outcome was the change in Clark test score from baseline to 24 weeks after implementation of a flash glucose monitoring device (Free Style 2®, Abbott). Secondary outcomes included changes in glycemic data and factors influencing improved perception.
Results: The Clark test score decreased significantly, with a reduction in total hypoglycemic time. No significant changes were observed in time below or in range. Longer duration of diabetes was associated with a higher likelihood of persistent asymptomatic hypoglycemia.
Conclusions: Rapid glucose monitoring improved the perception of hypoglycemia and reduced hypoglycemic time and glycemic variability in patients with type 1 diabetes, although its impact on HbA1c and time in range was minimal.

Keywords: Type 1 Diabetes Mellitus; Hypoglycemia; Nurses; Continuous Glucose Monitoring.

RESUMEN:
Introducción: La hipoglucemia recurrente aumenta el riesgo de desarrollar hipoglucemia asintomática, que afecta hasta al 40 % de las personas con diabetes y conduce a episodios de hipoglucemia graves.
Objetivo: Este estudio tuvo como objetivo evaluar el efecto de la monitorización instantánea de la glucosa en la percepción de la hipoglucemia en pacientes con diabetes mellitus de tipo 1.
Método: Se realizó un estudio cuasiexperimental de 24 semanas en el Hospital Universitario Virgen del Rocío en el que participaron 68 pacientes con diabetes tipo 1 con hipoglucemia grave o asintomática. El resultado primario fue el cambio en la puntuación del test de Clark desde el inicio hasta las 24 semanas posteriores a la implementación de un dispositivo flash de monitorización de glucosa (Free Style 2®, Abbott). Los resultados secundarios incluyeron cambios en los datos glucémicos y factores que influyen en la mejora de la percepción.
Resultados: La puntuación de la prueba de Clark disminuyó significativamente, con una reducción en el tiempo total de hipoglucemia. No se observaron cambios significativos en el tiempo por debajo del rango o dentro del rango. Una mayor duración de la diabetes se asoció con una mayor probabilidad de hipoglucemia asintomática persistente.
Conclusiones: La monitorización rápida de la glucosa mejoró la percepción de la hipoglucemia y redujo el tiempo de hipoglucemia y la variabilidad glucémica en pacientes con diabetes tipo 1, aunque su impacto en la HbA1c y el tiempo en rango fue mínimo.

Palabras clave: Diabetes mellitus tipo 1; Hipoglucemia; Enfermeras; Monitoreo continuo de glucosa.

INTRODUCTION

Type 1 diabetes mellitus (T1D) accounts for 5-10% of all diabetes cases. It is characterized by an absolute deficiency of insulin due to autoimmune destruction of pancreatic β cells[1,2]. Hypoglycemia is the main barrier to achieving optimal control in patients with T1D[3]. Recurrent hypoglycemia is a risk factor for developing unawareness of hypoglycemia, a condition that affects up to 40% of patients with T1D, making it difficult for them to recognize symptoms, predisposing them to severe hypoglycemia[4–7].

Several structured therapeutic education programs have demonstrated a reduction in severe hypoglycemia and an improvement in hypoglycemic awareness[8,9]. However, continuous glucose monitoring (CGM) or flash glucose monitoring (FGM) systems, despite consistently demonstrating a reduction in severe hypoglycemia and glycated hemoglobin (HbA1c)[10–12], have not demonstrated benefits in the perception of hypoglycemia[10,11,13].

The Hypo COMPaSS study is the only study to date that evaluates the impact of technology on hypoglycemia awareness as its primary objective. This study showed a significant improvement in Gold test score at 24 weeks, but no difference between those using CGM, continuous subcutaneous insulin infusion (CSII), or both, compared to the group not using technology. However, adherence to the sensors was low (40% of patients used them less than 50% of the time), and all patients had received educational reinforcement about hypoglycemia[14].

The IN CONTROL study is a 16-week randomized crossover study comparing CGM use with capillary glucose monitoring in adults with T1D and hypoglycemia unawareness after a 6-week period of therapeutic education. CGM use was significantly associated with fewer episodes of severe hypoglycemia, but no change in hypoglycemia screening questionnaires[12].

In the HypoDE study, the use of CGM in adults with T1D and severe or asymptomatic hypoglycemia treated with multiple doses of insulin was associated with a reduction in the incidence of hypoglycemia events compared to the control group. The Clark test improved in both groups, but without significant differences between them[15].

It is also worth mentioning that, in addition to the type of diabetes, different clinical and demographic factors such as age, time of evolution of diabetes or presence of comorbidities, can influence the response to interventions such as FGM, especially in relation to the risk of severe hypoglycemia and the absence of perception of hypoglycemia[16].

However, there is little evidence on the impact of FGM on hypoglycemic awareness and its relationship to different clinical and demographic variables[17]. Therefore, the primary objective of the present study was to determine differences in Clarke test scores from baseline to 24 weeks after FGM implantation. Additionally, the possible association between clinical and demographic characteristics of patients and the presence of severe hypoglycemia or inadvertent hypoglycemia was explored.

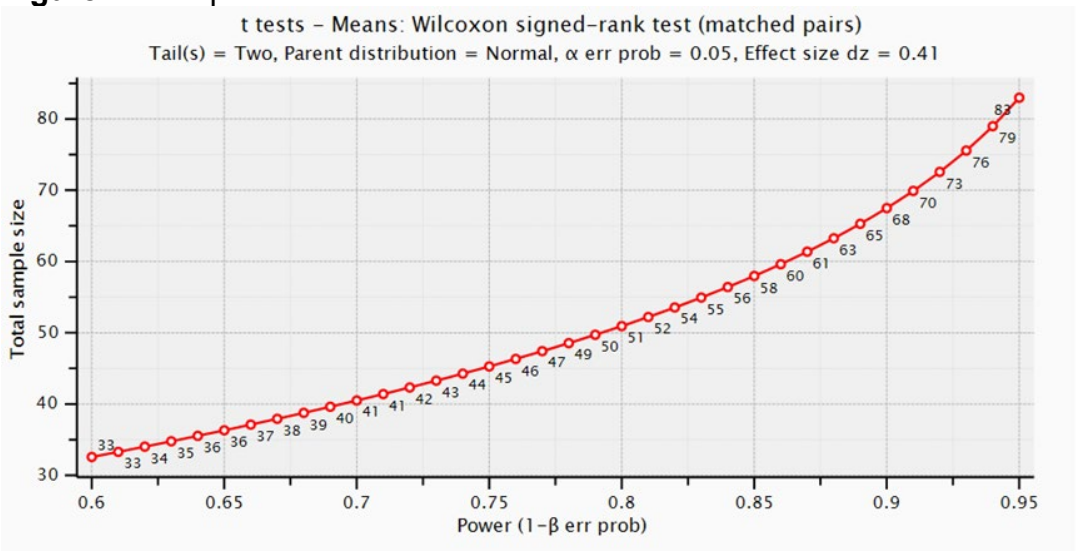
MATERIAL AND METHOD

A quasi-experimental study of a single group was carried out on an experimental basis, pre-post intervention[18], lasting 24 weeks, in a hospital in southern Spain.

Participants were selected from the total hospital population using sampling based on eligibility criteria[19]. Adults with T1D of more than 12 months' duration, with problematic hypoglycemia (unconscious or severe), treated with multiple daily insulin injections (MDI) or CSII were included. Patients who were already using CGM systems other than FGM were excluded as this would be implemented as part of the intervention during the study. Patients who were pregnant or planning to become pregnant were also excluded.

For a 95% confidence level, a 90% potency, and an effect size of 0.41, the sample size needed was 68 people. Figure 1 shows the calculations performed with the G-Power software version 3.1.9.7, along with different sample sizes for different test powers.

Figure 1. Sample size calculation



Source: Own elaboration with G-Power

The presence of inadvertent hypoglycemia was assessed using the validated Spanish version of the Clarke test at baseline and 24 weeks post-intervention. This instrument has an outstanding internal validity (Cronbach's alpha = 0.75). It measures the patient's awareness of hypoglycemic episodes, through eight questions that assess the ability to recognize hypoglycemic symptoms and the frequency with which they occur without noticeable symptoms. A score ≥4 indicates hypoglycemia unawareness (inadvertent hypoglycemia), while a score ≤2 indicates good knowledge or awareness of hypoglycemia[20]. Severe hypoglycemia was therefore defined as episodes of hypoglycemia that require assistance from another person for recovery, due to the presence of alterations in the level of consciousness[21].

The intervention that was carried out consisted of the implantation of a FreeStyle Libre 2® (Abbott) flash glucose monitoring sensor[22] preceded by a structured group education session, specifically designed to train patients in the safe and effective use of the device. This session, given before the implementation, lasted between 90 and 120 minutes depending on the number of attendees (between 3 and 6 per group), and included specific content such as the fundamentals of interstitial monitoring, indications of the FGM system, interpretation of trend arrows, criteria for rotation of insertion zones and use of the mobile application. The teacher presented the material through presentations, images, practice sensors and written materials, and assessed the understanding of the contents through interactive questions and direct observation of the insertion technique. Regarding the safety criteria, hygienic measures for the placement of the sensor, recommended anatomical areas and surveillance during the procedure were addressed, which was supervised by the personnel responsible for the session. Each participant performed their own sensor insertion under this supervision. Hypoglycemia and hyperglycemia alarms were set to <70 mg/dL and >250 mg/dL, respectively. No other therapeutic educational intervention was carried out prior to the implantation of the sensor. Perception of hypoglycemia was assessed using the Clarke test at baseline and after 24 weeks. Glycemic data were collected: time above range (TAR), time below range (TBR), time in range (TIR), coefficient of variability (CV) and glycated hemoglobin (HbA1c) at 4 and 24 weeks, considering only cases with sensor use greater than 70 %. Sociodemographic and clinical variables (age, gender, duration of diabetes, HbA1c, treatment, and comorbidities) were also collected prior to the intervention.

Regarding the statistical analysis, the total TBR (TBRT) was considered a non-normally distributed quantitative variable, so the Wilcoxon signed range test for related samples was used to calculate the sample size. Analyses were performed using R and SPSS version 28. Descriptive statistics included tables representing absolute and relative values for qualitative variables and measures of central tendency for quantitative variables.

For age and duration of diabetes, normality was checked using the Kolmogorov-Smirnov test. Inferential statistics involved a bivariate analysis using the Mann-Whitney test to compare age between groups and the Chi-square or Fisher's exact test for the relationship between qualitative variables. To identify predictors associated with post-intervention asymptomatic hypoglycemia, univariate and multivariate odds ratios (ORs) were determined by logistic regression. Statistical significance was established at a p-value < 0.05[23].

This study was conducted in accordance with the ethical standards set out in the Declaration of Helsinki. Potential participants were asked to accept informed consent for participation in the research and approval was obtained from the relevant ethics committee (ID: 0101-N-22).

RESULTS

During 2021, a total of 68 patients were recruited who met the pre-established eligibility criteria. The median age was 49 years (IQR 41–56), with a mean duration of diabetes of 23 years (IQR 14–31). 57.3% were women, 92.6% were on MDI treatment and 7.4% were using an insulin pump. In addition, 95.5% of participants had inadvertent hypoglycemia (Clarke test score ≥ 4), and 4.4% had had at least one episode of severe hypoglycemia in the previous 12 months. These sociodemographic and clinical characteristics were represented in Table 1.

Table 1: Sociodemographic and clinical characteristics

Variables	Median (IQR), or n (%)
Age	49 (41-56)
Gender (male/female)	29/39 (42,7-57,3).
Duration of diabetes (years)	23 (14-31)
HbA1c (%)	7,4 (6,6-8)
HbA1c (mmol/l/mol)	8,6 (7-10,1)
Insulin pump	5 (7,4)
MDI	63 (92,6)
High blood pressure	25 (36,8)
Dyslipidemia	32 (47,1)
Diabetic retinopathy	23 (33,8)
Nephropathy	8 (11,8)
Neuropathy	5 (7,4)
Coronary alterations	4 (5,9)
Peripheral arterial alterations	3 (4,4)
Cerebrovascular alterations	3 (4,4)
Inadvertent hypoglycemia (Clark ≥ 4)	65 (95,5)
Any severe hypoglycemia in the past 12 months	3 (4,4)

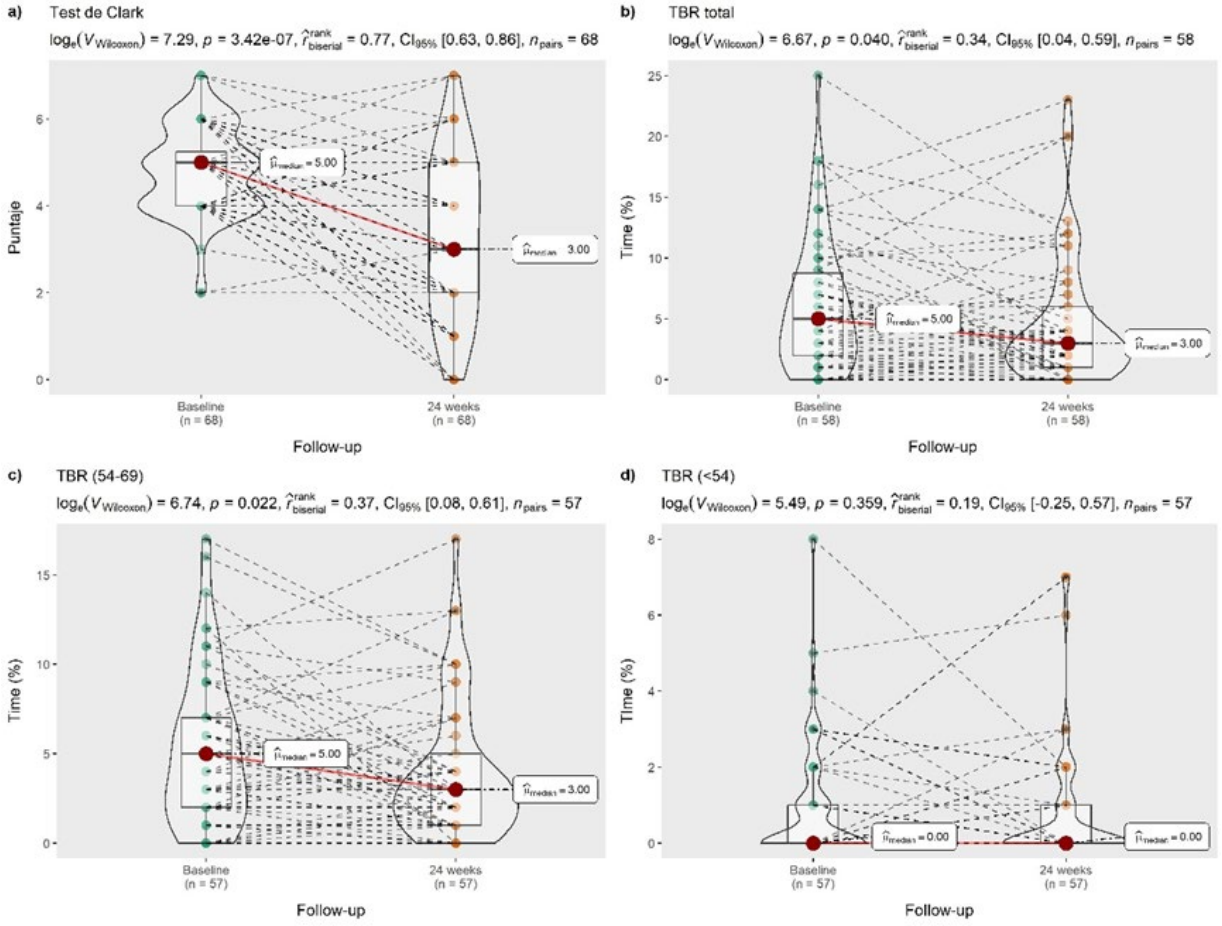
Source: Authors. n = 68

In accordance with the primary objective of the study, the impact of FGM use on hypoglycemic awareness was assessed. The score on the Clarke test dropped significantly after 24 weeks of intervention, from a median baseline of 5 (IQR 4-5) to 3 (IQR 2-5), with a $p < 0.001$. At the end of follow-up, 60% of patients had a score <2, indicating a better understanding of hypoglycemia.

Related glycemic parameters were also evaluated. Significant reductions were observed in TBRT, which decreased from 5% (IQR 2–10) to 3% (IQR 1–7), $p = .040$; and in the TBR (54-69 mg/dL), which was reduced from 5% (IQR 2–9) to 3% (IQR 1–6), $p = 0.022$. CV also decreased significantly, from 39% (IQR 34-42) to 35% (IQR 32-39),

p = 0.003. No significant differences were observed in TIR, TBR <54 mg/dL, or HbA1c. These changes were represented in Figure 2.

Figure 2. Comparison of baseline and 14-week Clark test score, TBRT, TBR (54-69 mg/dL), and TBR (<54 mg/dL)



Source: Own elaboration

In relation to the secondary endpoint, associations between clinical features and the presence of inadvertent hypoglycemia at the end of follow-up were explored. Duration of diabetes ≥23 years was significantly associated with asymptomatic hypoglycemia after the intervention (59.5% vs. 32.3%, p = 0.025), with an OR of 3.08 (95% CI: 1.13-8.36). Likewise, the presence of arterial hypertension was also associated with a higher frequency of inadvertent hypoglycemia at the end of the study (64.0% vs. 37.2%, p = 0.033), with an OR of 3.00 (95% CI: 1.08-8.36). These associations were shown in Table 2.

Table 2. Relationship between baseline clinical features of people with severe and/or inadvertent hypoglycemia and post-intervention hypoglycemia

Baseline clinical features	Post-intervention hypoglycemia		P-Value	OR (95%CI)
	Yes (Clark≥4) n (%)	No (Clark<4) n (%)		
Age (years)				
<50	18 (51,43)	17 (48,57)	0,457	1,44 (0,55-3,74)
≥50	14 (42,42)	19 (57,58)		
Diabetes Evolution (Years)				
≥23	22 (59,46)	15 (40,54)	0,025*	3,08 (1,13-836)**
<23	10 (32,26)	21 (67,74)		
Gender				
Male	12 (41,38)	17 (58,62)	0,418	0,67 (0,25-1,77)
Female	20 (51,28)	19 (48,72)		
High blood pressure				
Yes	16 (64,00)	9 (36,00)	0,033*	3,00 (1,08-8,36)*
No	16 (37,21)	27 (62,79)		
Dyslipidemia				
Yes	13 (40,63)	19 (59,38)	0,316	0,61 (0,23-1,60)
No	19 (52,78)	17 (47,22)		
Diabetic retinopathy				
Yes	13 (56,52)	10 (43,48)	0,264	1,78 (0,64-4,91)
No	19 (42,22)	26 (57,78)		
Nephropathy				
Yes	2 (25,00)	6 (75,00)	0,266	0,33 (0,06-1,79)
No	30 (50,00)	30 (50,00)		
Neuropathy				
Yes	2 (40,00)	3 (60,00)	1,000	0,73 (0,11-4,69)
No	30 (47,62)	33 (52,38)		
CV				
<36	11 (47,80)	12 (52,20)	0,746	1,18 (0,42-3,33)
≥40	17 (43,60)	22 (56,40)		
TBRT				
<5	12 (42,86)	16 (57,14)	0,741	0,84 (0,31-2,31)
≥5	16 (47,06)	18 (52,94)		
TBR (54-69 mg/dL)				
<4	11 (40,74)	16 (59,26)	0,539	0,73 (0,26-2,01)
≥4	17 (48,57)	18 (51,43)		
TBR (<54 mg/dL)				
<1	14 (38,89)	22 (61,11)	0,243	0,55 (0,20-1,52)
≥1	14 (53,85)	12 (46,15)		

Source: Authors. n = 68; *= statistical significance

In addition, multivariate analysis confirmed that duration of diabetes ≥23 years was an independent risk factor for inadvertent hypoglycemia at the end of follow-up (OR = 2.83;

95% CI: 1.01-7.90; p = 0.047), while arterial hypertension showed a non-significant trend (p = 0.062). These results were represented in Table 3.

Table 3. Multivariate analysis

Independent variables	B	P-Value	OR	95% CI-OR	
				Li	Ls
High blood pressure	1,01	0,062	2,73	0,95	7,87
Duration of Diabetes ≥ 23 Years	1,04	0,047*	2,83**	1,01	7,90

Source: Authors. n = 68; *=statistical significance; ** Li risk factor >1

DISCUSSION

The present study showed that implementation of FGM for 24 weeks was associated with significant improvement in awareness of hypoglycemia, as measured through the Clarke test. The median score dropped from 5 to 3, and at the end of follow-up, 60% of participants achieved a score below 2, suggesting a partial recovery of the ability to identify symptoms of hypoglycemia. Improvements were also observed in relevant glycemic indicators, such as TBRT, TBR 54–69 mg/dL, and CV. However, there were no significant changes in HbA1c, TIR, or TBR <54 mg/dL.

These findings contrast with the results of previous studies. Research such as IN CONTROL and HypoDE, focused on the use of CGM, documented a reduction in hypoglycemic events, but did not observe significant improvements in hypoglycemia screening questionnaires, such as the Clarke test[12,15]. A key difference from these studies lies in the objective of the present research, which was specifically designed to assess changes in hypoglycemic awareness, possibly contributing to the detection of effects that were not evident in studies with outcomes focused on biochemical or clinical parameters.

Importantly, in some of the comparative studies, participants received structured training on hypoglycemia, an intervention that likely improved awareness in all groups and reduced the ability to detect a differential effect attributed to the device[(12,15)]. In the present study, the use of FGM was accompanied by educational sessions that followed a different structure, which allows us to interpret the improvement in the perception of hypoglycemia as a potential effect of the continued use of the technology itself.

On the other hand, the results of the subgroup analysis identified that a duration of diabetes ≥23 years, as well as the presence of arterial hypertension, were associated with a higher probability of maintaining inadvertent hypoglycemia after the intervention. Although hypertension did not retain statistical significance in the multivariate model, prolonged disease duration was consolidated as an independent risk factor. These data suggest that some clinical profiles have a lower ability to recover from the perception of hypoglycemia[(24)], which could guide personalized decisions about the type and intensity of potential educational interventions required.

This study has some relevant limitations. The absence of a control group is noteworthy, which restricts the possibility of establishing firm causal relationships between the intervention and the changes observed[(18)]. Likewise, the pre-post design, although useful for evaluating intra-individual evolution, does not exclude the influence of other

factors such as the Hawthorne effect or spontaneous changes in self-management[25]. Finally, the 24-week follow-up does not allow us to determine whether the observed benefits are maintained in the long term[26].

Despite these limitations, the study has strengths that reinforce the importance of its findings. The use of a validated and widely recognized instrument such as the Clarke test has made it possible to guarantee the reliability of the results[20]. In addition, the analysis of clinical variables provided useful information for the identification of factors that may modify the response to the intervention. In addition, multivariate analysis is used to control for possible confounding factors, which gives greater strength to the identification of clinical variables associated with the persistence of hypoglycemia([27]).

The findings obtained have direct implications for clinical practice, especially in the context of care for people with T1D. FGM, beyond its glycemic control function, could play a relevant educational role as a tool that facilitates the understanding of glycemic behavior in relation to the patient's symptoms, habits and therapeutic decisions[28]. In addition, nurses can play a key role in identifying patients at increased risk of inadvertent hypoglycemia[29] and in promoting the appropriate and sustained use of FGM. Specifically, the Advanced Practice Nurse in Complex Treatments for Diabetes can facilitate technical training in the use of the sensor, promote adherence and reinforce the patient's autonomy in decision-making related to their self-care[30].

CONCLUSIONS

Continued use of FGM for 24 weeks was associated with a significant improvement in the perception of hypoglycemia in people with T1D, as well as a reduction in TBR and CV. These findings contrast with previous studies and could be explained by the specific focus of the present study. The identification of clinical factors associated with the persistence of inadvertent hypoglycemia, and the use of multivariate models for their analysis, reinforce the validity of the results. The active involvement of nurses is considered key to optimize the use of this technology and improve patient safety. However, more studies are needed to assess the impact of technology on recovery from hypoglycemia symptoms in people with inadvertent hypoglycemia.

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