International Journal of Pediatrics and Genetics

Vol. 4 No. 01 (2026)
ISSN: 2995-5483

Continuous Glucose Monitoring Versus Finger-Prick Self-Monitoring For Pediatric Glycemic Control: A Prospective Randomized Comparative Study

Samer Hussein Jasim
Baghdad welfare children hospital

Abstract: Background: Continuous glucose monitoring (CGM) has been more and more encouraged in children and adolescents with type 1 diabetes due to its capacity to offer more glycemic indicators, such as Time in Range (TIR), than traditional ones, such as glycated hemoglobin (HbA1c). The comparative data at resource settings variable however are sparse.

Aim: To compare the effectiveness of CGM versus finger-prick self-monitoring of blood glucose (SMBG) in improving glycemic control among pediatric patients with type 1 diabetes.

Methods: A 28-week randomized controlled study was carried out at Baghdad Welfare Children Hospital on 120 children and adolescents (617 years) with type 1 diabetes. The participants were randomly divided into CGM (n = 60) and SMBG (n = 60). The first consequence was TIR change (70180 mg/dL). HbA1c, time above range (TAR), time below range (TBR), glycemic variability, and frequency of hypoglycemia were the secondary outcomes. ANCOVA adjustment and multivariate regression modelling were used in analyses.

Findings: CGM was much higher in TIR at 24 weeks than SMBG (+8.4% vs +2.1%; mean difference 6.3, 95% CI 2.939.67; p < 0.001). The difference was also significant after adjustment (adjusted mean difference 5.5, p = 0.001). The CGM group had a reduction of HbA1c of −0.65% compared to SMBG of -0.18% (adjusted difference -0.46, p=0.001). Another significant reduction of TAR (−7.2 vs -1.9, p = 0.003) and TBR (−0.9 vs -0.2, p = 0.02), symptomatic hypoglycemia (1.5 vs 2.3 events/month, p = 0.01), and glycemic variability was also noted in CGM. The results of multivariate regression supported CGM as a predictor of HbA1c reduction independently (B = -0.46, p = 0.001).

Conclusion: CGM showed statistically and clinically significant better results compared to the performance of finger-prick monitoring in enhancing pediatric glycemic control. The findings suggest the use of CGM as a more desirable method of monitoring in children and adolescents with type 1 diabetes.

Key words: Continuous glucose monitoring, pediatric diabetes, Time in Range, HbA1c, glycemic variability.

1. Introduction

Type 1 diabetes mellitus (T1DM) is a chronic endocrine disorder characterized as one of the most prevalent chronic diseases in children and adolescents worldwide, and increased cases of the disorder have been reported in various parts of the world. It is essential to reach optimal glycemic control in

childhood to avoid not only the acute complications, including severe hypoglycemia and diabetic ketoacidosis (DKA) but also the blunt impact of microvascular and macrovascular complications in the long term, as well (1). Nevertheless, because of hormonal fluctuations in children and adolescents, random food intake, and physical activity and psychosocial issues, which influence adherence, it is especially difficult to stabilize the glucose level of pediatric patients (2).

Historically, the self-monitoring of blood glucose (SMBG) by capillary finger-prick testing has been used to monitor the glycemic in children with diabetes. Though SMBG shows instantaneous glucose measurements, it cannot show glycemic trends, nocturnal hypoglycemia, postprandial changes, and glycemic variability between measurements (3). Moreover, adherence, quality of life, and psychological well-being of both children and their caregivers may be adversely impacted by the burden of conducting the tests through finger-prick tests that are frequent (4).

Continuous glucose monitoring (CGM) has become a disruptive technology in the management of diabetic children. CGM systems enables almost continuous monitoring of interstitial glucose, trend arrows, hypo- and hyperglycemia alerts, ambulatory glucose profile (AGP) reports, with which insulin adjustments can be made (5). In comparison to SMBG, CGM allows measuring more than glycated hemoglobin (HbA1c) such as Time in Range (TIR, 70180 mg/dL), Time Below Range (TBR), Time Above Range (TAR), and glycemic variability (6).

International consensus recommendations have highlighted the clinical significance of TIR and TIR >70, TBR <4 and TAR <25 were established as pediatric targets (6). TIR has been demonstrated to be associated with HbA1c and is emerging as a significant outcome that is indicative of actual glycemic exposure in the real world (6). Based on this, it is now recommended by both the American Diabetes Association (ADA) and the International Society for Pediatric and Adolescent Diabetes (ISPAD) to consider the option of CGM at the time of diagnosis or as soon as possible in the lives of children and adolescents with T1DM who are safe to use the device with supervision (1,2).

Randomized controlled trials have shown that the use of CGM has been accompanied by tremendous changes in glycemic results as compared to SMBG. CGM use in a multicenter randomized clinical trial in adolescents and young adults with T1DM led to a larger decrease in HbA1c levels when compared with the standard monitoring (−0.37, p=0.01) over 26 weeks (7). Furthermore, systematic reviews and meta-analyses have reliably demonstrated that CGM enhances HbA1c, augments TIR by about 6-10 percent as well as decreases hypoglycemia in contrast to standard monitoring approaches (8,9). The latter, namely real-time CGM (rtCGM), seems to offer even more advantages with regard to alarm functionalities and predictive alarms (9).

Although there is strong evidence of the effectiveness of CGM, access, cost, and device adherence disparities, and healthcare infrastructure disparities could affect actual effectiveness, especially in resource-sensitive environments. Also, comparative studies that directly compare CGM with structured SMBG in children population are also significant to inform clinical policy and tailor care.

Consequently, the current clinical trial will attempt to compare the efficacy of continuous glucose monitoring to that of finger-prick self-monitoring in enhancing glycemic control in children and adolescents with diabetes in terms of clinically meaningful outcomes such as Time in Range, HbA1c reduction, frequency of hypoglycemia, and glycemic variability.

2. Methodology

2.1 Study Design and Setting

The study was aimed at comparing the effectiveness of continuous glucose monitoring (CGM) and finger-prick self-monitoring of blood glucose (SMBG) in enhancing glycemic control in patients with type 1 diabetes mellitus (T1DM) with children. The research was conducted at Baghdad Welfare Children Hospital, a Baghdad tertiary level pediatric referral center that deals with specialized endocrinology and diabetes services in Baghdad, Iraq. The patient population served by the hospital is massive (urban and peri-urban) as well as pediatric and has specific outpatient diabetes clinics with

organized follow-up and insulin change protocols. The research involved a 13 months period (February 2024 to March 2025) comprising of recruitment, intervention and follow up.

2.2 Study Population

The participants considered in the study were children and adolescents of age 6 to 17 years with the diagnosis of type 1 diabetes mellitus with at least six months of disease before the time of enrolment. The inclusion criteria included participants who were undergoing intensive insulin therapy, be it multiple daily injections or insulin pump therapy, and have a baseline HbA1c of 7.0-11.5. Patients had to possess one caregiver who can assist patients with glucose monitoring and the use of devices. The exclusion criteria were the presence of other major chronic diseases that may have interfered with glycemic control, diabetic ketoacidosis in the past four weeks before the time of recruitment, frequent severe cases of hypoglycemia, skin conditions that could not accommodate sensor placement, and non-adherence to follow-up appointments.

2.2.1 Sample Size Determination

The calculation of sample size was based on a minimum clinical meaningful difference of 5% in Time in Range (70180mg/dl) between groups at 28 weeks assuming a standard deviation of 10, 80 power and 0.05 alpha. On the premise of these assumptions, there was a need of at least 54 participants in each group. Each arm was enrolled with 60 participants thus bringing the total sample to 120 patients to offset a 10 percent rate of drop outs.

2.3 Randomization and Allocation

Computer-generated block randomization with variable block sizes was used to assign eligible participants randomly 1:1 to both the CGM group and the SMBG group. Sequentially numbered opaque sealed envelopes that were prepared by an independent research coordinator ensured allocation concealment. Owing to the type of intervention, the participants and clinicians could not be blinded but laboratory staff performing the analysis of HbA1c values were blinded to the group assignment.

2.4 Intervention Procedures

Participants assigned to CGM group were given a real time constant glucose monitoring tool, which is pediatrically approved. They were provided with a uniform education about sensor insertion, calibration (where necessary), interpretation of trend arrows, alarm settings both in case of hypoglycemia and hyperglycemia and utilization of ambulatory glucose profile reports. Parents were taught data upload and review when going to the clinic.

The subjects of the SMBG group were still using the traditional capillary glucose measurements with glucometer and had at least four to seven tests of the finger-prick daily, including fasting and pre- and post-meal and bedtime measurements. Both groups were given the same schedules of clinical follow-up and dose change of insulin according to the standard care of diabetes management protocols in hospitals by children.

2.5 Follow-Up and Data Collection

The participants were tracked to 24 weeks, with planned visits to the clinic at the baseline, 12 weeks, and 28 weeks. Clinical assessment was conducted at every visit, and the insulin regimens were reviewed and adherence evaluated. Standard laboratory assays certified by the National Glycohemoglobin Standardization Program (NGSP) were used to measure HbA1c. In the case of the CGM group, glucose parameters such as Time in Range (TIR), Time Below Range (TBR), Time Above Range (TAR), and coefficient of variation were derived out of the device reports. In the case of the SMBG group, the structured glucose records were assessed, and 14-day blinded CGM was conducted on baseline conditions and the week 28 to provide objective measurements of the TIR and associated parameters.

Symptomatic hypoglycemia, severe hypoglycemia (needed any kind of assistance) cases, and diabetic ketoacidosis were noted during the research period. The quality of life was measured with the help of a validated pediatric diabetes questionnaire that was administered at both the beginning of the study and the end of it.

2.6 Outcome Measures

The main one was the variation of Time in Range (70180 mg/dL) between baseline and 24 weeks. The HbA1c, TBR (<70 mg/dL), TAR (>180mg/dl), glycemic variability, frequency of hypoglycemia episodes, and diabetic ketoacidosis were all used as secondary outcomes.

2.7 Statistical Analysis

The SPSS version 27 was used to analyze data. Continuous variables were reported in mean and standard deviation and the categorical variables were reported in frequencies and percentages. Independent-samples t-tests were used to make between-group comparisons of normally distributed variables, and Mann Whitney U tests were done to make the between-group comparisons of non-normally distributed variables. Paired t-tests were used to test within-group changes. Chi-square or Fisher exact tests were applied to test the categorical outcomes. To measure primary outcome measures, analysis of covariance (ANCOVA) was conducted to correct baseline differences. A p-value of less than 0.05 was taken to be statistically significant and two tailed.

2.8 Ethical Considerations

The director of Health and the Ethical Committee of Baghdad Welfare Children Hospital gave the consent to the study protocol. Parents or the legal guardians provided informed consent in writing and when it was appropriate, consent was provided by the children. Patient information remained confidential and the subjects were given the option of dropping out of the process without influencing their regular medical treatment.

3. Results

The amount of randomized patients was 120 (CGM = 60, SMBG = 60). Follow-up after 28 weeks was done in 114 participants following attrition (n=6).

Table 1: Sociodemographic and Clinical Baseline Characteristics (N = 120)

Variable	CGM (n=60) Mean ± SD / n (%)	SMBG (n=60) Mean ± SD / n (%)	Test	Mean Difference	95% CI	p-value
Age (years)	12.5 ± 2.7	12.2 ± 2.8	t = 0.52	0.30	−0.84 to 1.44	0.61
Diabetes duration (years)	3.2 ± 1.6	3.0 ± 1.7	t = 0.61	0.20	−0.46 to 0.86	0.54
HbA1c (%)	8.7 ± 1.1	8.6 ± 1.0	t = 0.36	0.10	−0.29 to 0.49	0.72
Time in Range (%)	45.9 ± 11.8	46.3 ± 12.1	t = −0.15	−0.40	−4.68 to 3.88	0.88
Male, n (%)	31 (51.7%)	32 (53.3%)	χ^2 = 0.03	—	—	0.85
Female, n (%)	29 (48.3%)	28 (46.7%)				

There were no statistically significant differences in the baseline between the groups (p > 0.05), which means that randomization and comparability were achieved.

Table 2 Primary Outcome: Change in Time in Range (TIR) at 24 Weeks (N = 114)

Variable	CGM (n=57) Mean ± SD	SMBG (n=57) Mean ± SD	t-value	Mean Difference	95% CI	p-value
Baseline TIR (%)	45.9 ± 11.8	46.3 ± 12.1	—	—	—	—
Week 24 TIR (%)	54.3 ± 12.4	48.4 ± 11.6	2.97	5.90	1.96 to 9.84	0.004
Δ TIR (%)	+8.4 ± 9.2	+2.1 ± 8.5	3.71	6.30	2.93 to 9.67	<0.001

CGM led to statistically significant and clinically significant 6.3 per cent greater improvement in TIR than the SMBG (95% CI: 2.93–9.67).

Table 3: Secondary Glycemic Outcomes at 24 Weeks

Outcome	CGM Mean ± SD	SMBG Mean ± SD	t-value	Mean Difference	95% CI	p-value
Δ HbA1c (%)	−0.65 ± 0.68	−0.18 ± 0.59	−3.16	−0.47	−0.77 to −0.17	0.002
Δ TAR (%)	−7.2 ± 9.8	−1.9 ± 8.7	−2.98	−5.30	−8.82 to −1.78	0.003
Δ TBR (%)	−0.9 ± 1.5	−0.2 ± 1.3	−2.39	−0.70	−1.28 to −0.12	0.02
Coefficient of Variation (%)	34.2 ± 5.8	37.1 ± 6.3	−2.53	−2.90	−5.16 to −0.64	0.01

CGM markedly decreased HbA1c, exposure to hyperglycemia (TAR), exposure to hypoglycemia (TBR), and variability in glycemia as opposed to SMBG.

Table 4: Hypoglycemia and Safety Outcomes

Outcome	CGM (n=57)	SMBG (n=57)	Relative Risk	95% CI	p-value
Severe hypoglycemia, n (%)	2 (3.5%)	5 (8.8%)	0.40	0.08–1.94	0.24
Symptomatic hypoglycemia (events/month)	1.5 ± 1.0	2.3 ± 1.4	−0.80 (MD)	−1.41 to −0.19	0.01
DKA episodes, n (%)	1 (1.8%)	2 (3.5%)	0.50	0.05–5.26	0.56

CGM lowered symptomatic hypoglycemia rate substantially, whereas there was no significant difference in severe hypoglycemia rate and DKA rate between groups.

Table 5 Multivariate Linear Regression Analysis Predicting Change in HbA1c (Δ HbA1c)

Predictor	B	SE	β	95% CI	p-value
CGM group	−0.46	0.14	−0.32	−0.73 to −0.19	0.001
Baseline HbA1c	−0.41	0.08	−0.45	−0.57 to −0.25	<0.001
Baseline TIR	0.01	0.004	0.21	0.002 to 0.018	0.02
Age	0.02	0.02	0.07	−0.02 to 0.06	0.31
Diabetes duration	0.01	0.03	0.03	−0.05 to 0.07	0.74

When the variables of baseline HbA1c, baseline TIR, age, and duration of diabetes were controlled, CGM use still continued to predict higher HbA1c reduction (B = -0.46, p = 0.001).

This means that, among children taking CGM, there was an extra 0.46% decrease in HbA1c over SMBG regardless of other measurements in clinical variables.

Baseline HbA1c was the best predictor of improvement ($\beta = -0.45$, $p = 0.001$), indicating that patients with high baseline HbA1c had bigger improvements.

4. Discussion

The current randomized controlled trial has proved that the continuous glucose monitoring (CGM) was a more effective glycemic control over finger-prick self-monitoring of blood glucose (SMBG) in childhood patients with type 1 diabetes.

On the Time in Range (TIR), the CGM group gained more, +8.4% on average, than the SMBG group, +2.1% on average, with a between-group difference of 6.3% (95% CI: 2.93967). The clinically relevant increase in TIR has been defined as 5 per cent and has yielded better long-term outcomes (10). The noted increase is thus a pertinent therapeutic benefit.

The CGM group had an average reductions of HbA1c of -0.65, whereas the SMBG group had a decrease of -0.18. This degree of decrease is in line with prior randomized data. According to Laffel et al., CGM was associated with a -0.37 percent higher reduction in HbA1c in adolescents and young adults (11). In a similar fashion, Beck et al. showed that there was a reduction of HbA1c of -0.6% in CGM users relative to conventional monitoring (12).

Recent meta-analyses are also consistent with our findings. Seidu et al. have documented a pooled change in HbA1c of between -0.4- -0.6 percent in the users of CGM compared with the conventional monitoring (13). Zhou et al. also reported that real-time CGM had a better effect on TIR by about 68% than intermittently scanned CGM and SMBG (14). Our study showed an increase of +8.4% TIR and this value lies within the high-range value.

Exposure to hyperglycemia was greatly reduced in CGM and Time Above Range (TAR) was reduced by -7.2% more than SMBG (-1.9 0.003). These results are in line with combined data that show there is 5-8% reduction in TAR by using CGM (13,14).

CGM was also seen to have better results in hypoglycemia. The frequency of symptomatic hypoglycemia dropped to 1.5 + 1.0/month, as opposed to 2.3 + 1.4/month in SMBG ($p = 0.01$). Even though no statistically significant differences in severe hypoglycemia rates were found (3.5% vs 8.8%, $p = 0.24$), numerical data indicates the trend towards decreasing the burden of hypoglycemia by using CGM due to real-time notification and predictive alarms (12,15).

The glycemic variability was also better, and the coefficient of variation dropped to a 34.2 in CGM and to 37.1 in SMBG ($p = 0.01$). Oxidative stress and endothelial dysfunction have been associated with high levels of glycemic variability, which implies that CGM could have more metabolic benefits that are independent of HbA1c improvement (16).

Significantly, baseline HbA1c and baseline TIR were powerful predictors of results at follow-up, which implies that patients with worse baseline control are the ones that gain the most with CGM. Longitudinal studies reveal this observation with a higher HbA1c reduction in persons with higher baseline HbA1c during the initiation of CGM (17).

In general, the level of improvement in this Iraqi tertiary-care population of pediatrics is similar to those of large multicentric trials that are done in Europe and North America (11,14). This implies that CGM efficacy can be generalized in different health care environments in case of organized education and follow-up.

5. Conclusion

Persistent glucose monitoring (CGM) was better than self-monitoring using fingers in children with type 1 diabetes in enhancing glycemic control. CGM also considerably improved Time in Range (+8.4% vs +2.1%), and it lowered HbA1c (-0.65% vs -0.18%), with other improvements in

hyperglycemia exposure and symptomatic hypoglycemia over 24 weeks. These results justify the use of CGM as a better monitoring tool in children and adolescents in line with the current international guidelines.

References

1. Biester T, Danne T, Kapellen T, et al. ISPAD Clinical Practice Consensus Guidelines 2024: Diabetes technologies—Glucose monitoring. Pediatr Diabetes. 2024.
2. Battelino T, Danne T, Bergenstal RM, et al. Clinical targets for continuous glucose monitoring data interpretation: Recommendations from the International Consensus on Time in Range. Diabetes Care. 2019;42(8):1593–1603.
3. Miller KM, Foster NC, Beck RW, et al. Current state of glucose monitoring in youth with type 1 diabetes. Diabetes Technol Ther. 2020;22(S1):S1–S12.
4. Hilliard ME, Yi-Frazier JP, Hessler D, et al. Psychological burden of glucose monitoring in youth with type 1 diabetes. Diabetes Care. 2019;42(6):1009–1016.
5. Beck RW, Riddlesworth T, Ruedy K, et al. Continuous glucose monitoring versus usual care in patients with type 1 diabetes receiving multiple daily insulin injections: A randomized trial. N Engl J Med. 2017;376(16):1507–1516.
6. Laffel LM, Kanapka LG, Beck RW, et al. Effect of Continuous Glucose Monitoring on Glycemic Control in Adolescents and Young Adults With Type 1 Diabetes. JAMA. 2020;323(23):2388–2396.
7. Seidu S, Kunutsor SK, Cos X, et al. Efficacy and Safety of Continuous Glucose Monitoring and Intermittently Scanned Continuous Glucose Monitoring Compared With Usual Care: Systematic Review and Meta-analysis. Diabetes Care. 2024;47(1):169–179.
8. Zhou Y, Guo J, Luo Y, et al. Real-time versus intermittently scanned continuous glucose monitoring in type 1 diabetes: A systematic review and meta-analysis. Diabet Med. 2024;41:e15124.
9. Beck RW, Bergenstal RM, Riddlesworth TD, et al. Validation of Time in Range as an outcome measure for diabetes clinical trials. Diabetes Care. 2019;42(3):400–405.
10. Monnier L, Colette C, Owens DR. Glycemic variability: The third component of dysglycemia in diabetes. Diabetes Care. 2006;29(2):455–460.
11. Mann EA, Raghinaru D, Beck RW, et al. Early continuous glucose monitor use in children and adolescents with type 1 diabetes and association with glycemic outcomes. Diabetes Care. 2024;48(5):768–776.
12. American Diabetes Association Professional Practice Committee. Glycemic Targets: Standards of Care in Diabetes—2024. Diabetes Care. 2026;49(Suppl 1):S97–S110.
13. Danne T, Nimri R, Battelino T, et al. International consensus on use of continuous glucose monitoring. Diabetes Care. 2017;40(12):1631–1640.
14. Riddlesworth TD, Beck RW, Gal RL, et al. Optimal sampling duration for continuous glucose monitoring to determine glycemic metrics. Diabetes Technol Ther. 2018;20(4):314–316.
15. Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group. Continuous glucose monitoring and intensive treatment of type 1 diabetes. N Engl J Med. 2008;359(14):1464–1476.
16. Agiostratidou G, Anhalt H, Ball D, et al. Standardizing clinically meaningful outcome measures beyond HbA1c for type 1 diabetes. Diabetes Care. 2017;40(12):1622–1630.