

INPLASY PROTOCOL

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Effect of different continuous glucose monitoring durations on glycemic control in Diabetes: A Systematic Review With Meta-analysis of Randomized Controlled Trials

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Review question / Objective: P:Patients diagnosed with type 1 or type 2 diabetes mellitus; I:Continuous blood glucose monitoring system was used in the intervention group; C:Routine nursing or self-monitoring of blood glucose was used in the control group; O:Outcome indicators include HbA1c, time in range, time below range(TBR), time above range(TAR) and mean glucose(MG) level; S:Randomized controlled trial(RCT).

Condition being studied: At present, there is no new evidence-based basis for the application effect of continuous glucose monitoring in different duration of use. The purpose of this systematic review is to supplement the shortcomings of existing studies and analyze the differences of blood glucose control effects of CGM in patients with type 1 and type 2 diabetes mellitus for different durations, so as to provide a basis for its clinical application.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 22 November 2021 and was last updated on 22 November 2021 (registration number INPLASY2021110080).

INTRODUCTION

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METHODS

Participant or population: Patients diagnosed with type 1 or type 2 diabetes mellitus.

Intervention: Continuous blood glucose monitoring system was used in the intervention group.

Comparator: Routine nursing or self-monitoring of blood glucose was used in the control group.

Study designs to be included: Randomized controlled trial(RCT).

Eligibility criteria: Inclusion criteria: (1)Study type: randomized controlled trial; (2)Patients diagnosed with type 1 or type 2 diabetes mellitus; (3)Continuous blood glucose monitoring system was used in the intervention group,Routine nursing or self-monitoring of blood glucose was used in the control group. (4)Outcome indicators include HbA1c, time in range(TIR: usually refers to the duration of personal blood glucose within 70-180mg/dL[12]), time below range(TBR), time above range(TAR) and mean glucose(MG) level. Exclusion criteria: (1) Gestational diabetes study; (2)Self-control study; (3)Conference literature and abstracts; (3)Full-text literature could not be obtained.

Information sources: Electronic databases, contact with authors, trial registers, or grey literature.

Main outcome(s): In this study, changes in HbA1c and TIR were used as the primary outcome indicators. TBR, TAR and mean glucose level were statistically analysed as secondary outcome indicators.

Quality assessment / Risk of bias analysis: The method of quality assessment in primary studies: the generation of random sequences, the concealment of the allocation of random schemes, the blind method to the implementers and participants of the study, the blind method to the evaluators of the results, the integrity of the outcome index data (loss of follow-up), the possibility of selective reporting of research results and other sources of bias.

Strategy of data synthesis: When TIR, TBR and TAR are reported as hours or percentage of time in 24 hours in the included studies, conversions in minutes will be performed. When HbA1c and MG are reported as mmol/L in the included studies, conversions in mg/dL will be performed so that a uniform unit of measurement will be used for all included studies. When the data included in the study were reported as median and quartile spacing, the mean and standard deviation were estimated by a modified data transformation method. The mean difference (MD) was used as the effect index to analyze the statistics of the measurement data, and the 95%CI was provided. Heterogeneity was analyzed by χ^2 test, the test level was set to $\alpha = 0.10$, statistical heterogeneity was evaluated by I^2 , $P > 0.10$ and $I^2 < 50\%$ indicated that there was no heterogeneity, which was analysed using a fixed-effects model; $P \leq 0.10$ and $I^2 \geq 50\%$ indicated heterogeneity, which was analysed using a random-effects model. Review Manager5.4 was used for meta-analysis and Egger test in Stata16 software was used to evaluate the publication bias. All the statistical data were tested by bilateral test, and differences were considered statistically significant at $P < 0.05$.

Subgroup analysis: The use effect of CGM was analyzed by subgroups in time periods. defining $\leq 16w$ as short-term use

duration and >16 was long-term use duration to explore the effect of CGM use duration on participants' glycemic control. Richard measured HbA1c at the mid-week return visit at week 16, so to ensure that all study data were fully utilised, week 16 was set as the cut-off value in this study.

Sensitivity analysis: Sensitivity analyses of HbA1c, TIR, TBR, TAR and MG were performed using Stata software.

Country(ies) involved: China.

Keywords: Blood glucose monitoring; Diabetes; Implantable CGM system; Continuous blood glucose monitoring; Intervention effect; Meta-Analysis.

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