INTERMITTENTLY SCANNED CONTINUOUS GLUCOSE MONITORING FOR TYPE 1 DIABETES

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Abstract: BACKGROUND

In persons with type 1 diabetes and high glycated hemoglobin levels, the benefits of intermittently scanned continuous glucose monitoring with optional alarms for high and low blood glucose levels are uncertain.

Keywords: Type 1 Diabetes,In a parallel-group, multicenter, randomized, controlled trial .involving participants with type 1 diabetes and glycated hemoglobin levels between 7.5% and 11.0%, we investigated the efficacy of intermittently scanned continuous glucose monitoring as compared with participant monitoring of blood glucose levels with fingerstick testing. The primary outcome was the glycated hemoglobin level at 24 weeks, analyzed according to the intention-to-treat principle. Key secondary outcomes included sensor data, participant-reported outcome measures, and safety.

RESULTSA

Total of 156 participants were randomly assigned, in a 1:1 ratio, to undergo intermittently scanned continuous glucose monitoring (the intervention group, 78 participants) or to monitor their own blood glucose levels with fingerstick testing (the usual-care group, 78 participants). At baseline, the mean (±SD) age of the participants was 44±15 years, and the mean duration of diabetes was 21±13 years; 44% of the participants were women. The mean baseline glycated hemoglobin level was 8.7±0.9% in the intervention group and 8.5±0.8% in the usual-care group; these levels decreased to 7.9±0.8% and 8.3±0.9%, respectively, at 24 weeks (adjusted mean between-group difference, −0.5 percentage points; 95% confidence interval [CI], −0.7 to −0.3; P<0.001). The time per day that the glucose level was in the target range was 9.0 percentage points (95% CI, 4.7 to 13.3) higher or 130 minutes (95% CI, 68 to 192) longer in the intervention group than in the usual-care group, and the time spent in a hypoglycemic state (blood glucose level, <70 mg per deciliter [<3.9 mmol per liter]) was 3.0 percentage points (95% CI, 1.4 to 4.5) lower or 43 minutes (95% CI, 20 to 65) shorter in the intervention group. Two participants in the usual-care group had an

episode of severe hypoglycemia, and 1 participant in the intervention group had a skin reaction to the sensor.

CONCLUSIONS

Among participants with type 1 diabetes and high glycated hemoglobin levels, the use of intermittently scanned continuous glucose monitoring with optional alarms for high and low blood glucose levels resulted in significantly lower glycated hemoglobin levels than levels monitored by fingerstick testing.

The development of continuous glucose monitoring systems (either intermittently scanned systems or real-time systems) has enabled the monitoring of glucose levels without fingerstick testing. Studies have been needed to assess the efficacy of intermittently scanned continuous glucose monitoring with optional alarms for high and low blood glucose levels in persons with type 1 diabetes, particularly in those with high glycated hemoglobin levels and a risk of complications who would benefit the most from decreased glycemia. In the FLASH-UK trial, we aimed to determine whether the use of intermittently scanned continuous glucose monitoring with optional alarms, as compared with traditional monitoring of blood glucose levels with the use of fingerstick testing, would reduce glycemia and increase treatment satisfaction over a 24-week period in persons with type 1 diabetes and high glycated hemoglobin levels.

Methods

TRIAL DESIGN AND OVERSIGHT

We conducted an open-label, parallel-group, multicenter, randomized, controlled trial at seven specialist diabetes clinics and one primary care center in the United Kingdom. The device manufacturer played no part in the design, funding, or conduct of the trial. The trial was conducted in accordance with the principles of the Declaration of Helsinki, and oversight was provided by the trial steering committee and an independent data monitoring committee. The protocol, available with the full text of this article at NEJM.org, was approved by the Greater Manchester West Research Ethics Committee. The trial protocol has been published previously.

The first author and the ninth through the twelfth authors vouch for the accuracy and completeness of the data and for the fidelity of the trial to the protocol. All the authors made the decision to submit the manuscript for publication.

PARTICIPANTS

Participants who were at least 16 years of age and who had had type 1 diabetes for at least 1 year and a glycated hemoglobin level of 7.5 to 11.0% while receiving either continuous subcutaneous insulin infusion or multiple daily injections were eligible. Key exclusion criteria were the current use of real-time continuous glucose monitors or intermittently scanned continuous glucose monitoring for more than 4

weeks within the previous 12 weeks, pregnancy or planned pregnancy, and complete loss of awareness of hypoglycemia, as judged by the investigators. Full inclusion and exclusion criteria are provided in the supplementary appendix , available at NEJM.org. All the participants received oral and written information about the trial before they provided written informed consent.

TRIAL PROCEDURES

Participants were randomly assigned in a 1:1 ratio to undergo intermittently scanned continuous glucose monitoring or to monitor their own blood glucose levels with the use of fingerstick testing. Randomization was performed with a Web-based system (Sealed Envelope) that used stochastic minimization to balance treatment assignments according to trial center, category of baseline glycated hemoglobin level (7.5 to 9.0% or >9.0 to 11.0%), method of treatment (multiple daily injections or continuous subcutaneous insulin infusion), previous participation in a structured education program regarding diabetes (yes or no), and current use of a bolus calculator (yes or no).

The device used in the intervention group was the FreeStyle Libre 2 (Abbott Diabetes Care) intermittently scanned continuous glucose monitor with optional alerts. This device met the safety, health, and environmental protection requirements in the European Union and had received Conformité Européenne (CE) marking. The glucose sensor was worn on the arm for 14 days. A handheld reader, mobile telephone application (app), or both displayed current and historical glucose data and provided optional alarms at glucose thresholds that were set by the user. Participants in the usual-care (control) group continued to monitor their own blood glucose levels with the use of fingerstick testing. All trial devices were provided to the participants free of charge.

The trial included six visits for participants in the intervention group and seven visits for those in the usual-care group (see the supplementary appendix). Owing to the coronavirus disease 2019 (Covid-19) pandemic, trial visits were conducted either in person or by means of telephone, text messaging, or the Internet. Before randomization, all the participants underwent blinded continuous glucose monitoring with the use of a FreeStyle Libre Pro continuous glucose monitoring device for 10 to 14 days. Participants in the usual-care group attended an additional visit at 22 weeks to have another continuous glucose monitoring sensor fitted to obtain blinded data. This sensor was worn at 22 to 24 weeks to allow for a comparison of blinded sensor data with data in the intervention group. Education about the use of sensor data and glucose data obtained by fingerstick testing and about treatment was provided to both groups at randomization and at 4 and 12 weeks. Additional information about how the participants could use glucose data according to their assigned treatment is provided in the supplementary appendix .

The glycated hemoglobin level was measured at screening and at 12 and 24 weeks locally with the use of a method that was recommended by the International Federation of Clinical Chemistry and Laboratory Medicine and consistent with the guidelines of the National Glycohemoglobin Standardization Program. Participants who were receiving care through telemedicine performed a capillary test at home with the use of a glycated hemoglobin kit (TDL TINY). The capillary blood sample was then mailed to the Doctors Laboratory and was analyzed with the use of the Tosoh G8 HPLC Analyzer system, which had previously been shown to be similar to interlaboratory methods; in one study involving 240 participants, the percentage of participants with glycated hemoglobin levels within 5% of venous levels ranged from 96 to 99%. LibreView software was used to download sensor data.

OUTCOMES

The primary outcome was the glycated hemoglobin level at 24 weeks after randomization. Prespecified secondary outcomes included the glycated hemoglobin level at 12 weeks and the percentage of participants with a glycated hemoglobin level of 7.0% or less, the percentage of those with a glycated hemoglobin level of 7.5% or less, and a reduction in the glycated hemoglobin level of at least 0.5 percentage points or at least 1.0 percentage point at 12 weeks and 24 weeks. Prespecified outcomes based on sensor data and calculated over the last 2 weeks of follow-up included the percentage of time that the sensor glucose measurement was in the target range of 70 to 180 mg per deciliter (3.9 to 10.0 mmol per liter), the duration of hypoglycemia and hyperglycemia, the mean glucose level, and glucose variability.

Outcome questionnaires that were completed by the participants at baseline and at the end of the trial included the following: the Type 1 Diabetes Distress Scale (T1-DDS) questionnaire the Diabetes Fear of Injecting and Self-Testing Questionnaire, Fear of Self-Injection component (D-FISQ FSI) the Diabetes Eating Problem Survey–Revised (DEPS-R)the Diabetes Treatment Satisfaction Questionnaire (DTSQ), with scores ranging from 0 to 36 and higher scores indicating greater satisfaction the Patient Health Questionnaire 9-item version (PHQ-9); and the Glucose Monitoring Satisfaction Survey (GMSS), with scores ranging from 1 to 5 and higher scores indicating greater satisfaction with glucose monitoring.Further details regarding these questionnaires and secondary outcome measures are provided in the supplementary appendix .

References

1. B.X Shagazatova,, Endocrinology’
2. S.I Ismailov,, Endocrinology’
3. Mark S. New York: Thieme Medical Publishers. 7 2010. Greenberg. ,, A guide to neurosurgery
4. Internet networks.
5. Causes of diabetes
6. Types of diabetes