Usability of early treatment intervention using personal continuous glucose monitor in hospitalized patients with type 2 diabetes

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Background

- It has been reported that outpatients with type 1 diabetes using real-time continuous glucose monitoring (rtCGM) reduce HbA1c more than those using self-monitoring of blood glucose (SMBG) [1].
- It is not well known whether inpatients with type 2 diabetes using rtCGM reduce HbA1c more than those using SMBG.

1. Šoupal J, et al. Diabetes Care. 2020; 43: 37-43.

Research design & Methods

- This is a prospective parallel-group comparative study.
- Sixteen patients with type 2 diabetes hospitalized for diabetes treatment were randomly allocated to 2 groups.
- In group 1, patients used personal continuous glucose monitor (CGM) [GUARDIAN CONNECT], and drug treatment intervention (DTI) is performed based on the sensor glucose levels (SG) in the rtCGM (CGM group).
- In group 2, patients used professional CGM (iPro2) and DTI is performed based on the capillary blood glucose levels (BG) measured using "glucometers that were compliant with ISO15197:2013 diagnostic test systems" ("GISO") [ACCU-CHEK Guide] (BGM group).
- In both groups, CGM was attached on the day of hospitalization (day 1) and used for 6 days.
- In group 1, all 288 SG were referenced for the intervention in real-time.
- In group 2, BG referenced for the intervention in real-time were measured at pre- and post-prandial time and bedtime (7 points) on days 2 and 5 and pre-prandial time and bedtime (4 points) on days 3 and 4.
- We preliminarily analyzed the 24-h SG of professional CGM (iPro2) for 150 patients with type 2 diabetes at our hospital to determine the target range for intervention using rtCGM to achieve both time-in-range (70–180 mg/dL) [TIR] > 70% and coefficient of variation [CV] < 36%.
- From this analysis, we determined the target range to achieve TIR>70% as "75–160 mg/dL" and that to achieve CV<36% as "within ± 30% of mean glucose levels".
- In both groups, DTI was performed each evening from day 2 to day 5 and each morning from day 3 to day 5 based on the DTI algorithm unified for each CGM group and BGM group, where the target range was used.

Drug treatment intervention algorism
➢CGM
Intervention at evening from day 2 to day 5 and morning from day 3 to day 5 (Intervention 1)
- SGs on CGM used to determine intervention: the previous intervention ~ just before intervention
① 160 mg/dL < peak glucose levels < 250 mg/dL and TIR (70-180) < 70%: 1 intervention unit (IU)
② 250 mg/dL < peak glucose levels and TIR (70-180) < 70%: 2 IU
③ Peak glucose levels < 75 mg/dL and TIR (70-180) < 70%: -1 IU
(If two out of three above conditions ("① and ③" or "② and ③") are applicable, interventions are performed for both conditions)
Intervention at morning from day 3 to day 5 (Intervention 2)
- SGs on CGM used to determine intervention: 0 AM on the previous day ~ 0 AM on the day
Deviation of more than ± 30% of 24-h mean glucose levels and CV > 36%: 1 IU
(If interventions 1 and 2 are duplicate, the optimal intervention is selected)
➢ BGM
Intervention at evening from day 2 to day 5 and morning from day 3 to day 5
- BGs used to determine intervention: the previous intervention ~ just before intervention
① 160 mg/dL < peak glucose levels < 250 mg/dL: 1 IU
② 250 mg/dL < peak glucose levels: 2 IU
③ Peak glucose levels < 75 mg/dL: -1 IU
(If two out of three above conditions ("① and ③" or "② and ③") are applicable, interventions are performed for both conditions)
◆IU
1 IU: long-action insulin 3 U, metformin (750 mg), α-GI, DPP-4 inhibitor, SGLT-2 inhibitor, glinide
2 IU: 1 IU × 2, ultra-rapid acting insulin 3 U × 3
Optimal interventions are selected from the above.
✓Intervention finish criteria
CGM: When both TIR (70-180) > 70% and CV < 36% are achieved on SGs from 0 AM on the previous day to 0 AM on the day, interventions are finished.
BGM: Even after all BGs before every meal and on bedtime from 0 AM on the previous day to 0 AM on the day become within 75-160 mg/dL, the interventions are maintained.

Fig. 1: Drug treatment intervention algorism
CGM, group of patients performing drug treatment intervention referring to real-time CGM; BGM, group of patients performing drug treatment intervention referring to capillary blood glucose levels in real-time; SGs, sensor glucose levels; TIR (70-180), time-in-range (70-180 mg/dL); CV, coefficient of variation; BGs, capillary blood glucose levels

➢ Primary endpoints

Duration needed to achieve both TIR>70% and CV<36% for patients in CGM group and those in BGM group

➢ Secondary endpoints

Intervention unit (IU) at each day and in total for patients in CGM group and those in BGM group

Sensitivity and specificity of "Both 'all 24-h SGs within 75-160 mg/dL' and 'all 24-h SGs within ± 30% of 24-h mean glucose levels'" ("Both 75-160 mg/dL and ±30% of the Mean") for both TIR>70% and CV<36% in "all 24-h SGs until the target achieving day for all patients in both CGM and BGM groups"

Results

Two patients in the BGM group were excluded from this study because they could not carry out the research protocol (CGM group: n=8, BGM group: n=6).

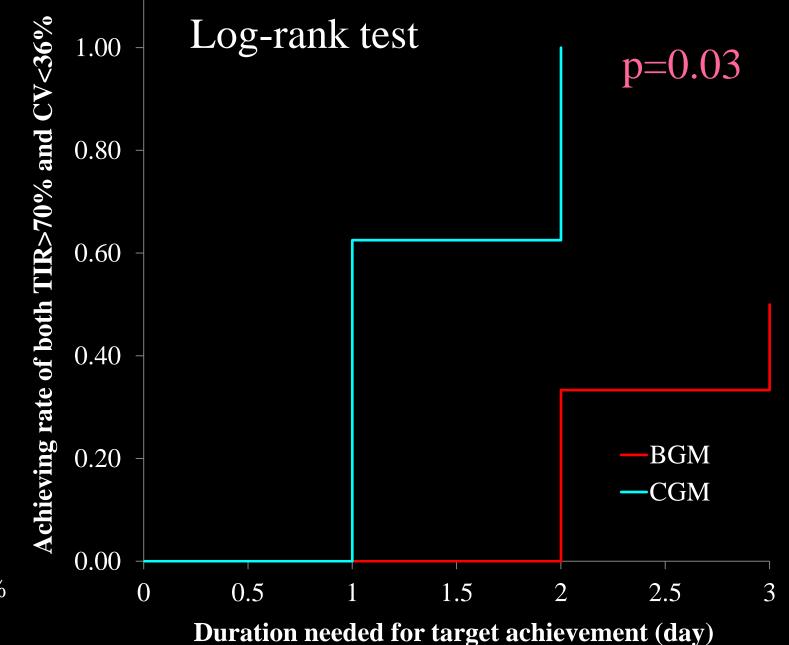| Characteristic	CGM	BGM
N (Male / Female)	8 (4 / 4)	6 (2 / 4)
Age, years	76.0 (70.0-84.0)	73.5 (63.8-75.0)
BMI, kg/m^2	23.0 (22.2-24.9)	19.3 (18.2-20.2)
HbA1c, %	9.0 (8.6-11.2)	9.1 (8.9-10.6)

Table 1: Baseline characteristics
Data are shown as median (interquartile range).
BMI, body mass index; HbA1c, hemoglobin A1c; CGM, group of patients performing drug treatment intervention referring to real-time CGM; BGM, group of patients performing drug treatment intervention referring to capillary blood glucose levels in real-time

Fig. 2: Duration needed to achieve both TIR>70% and CV<36%
p: Log-rank test

Intervention unit	CGM	BGM	p
Day 2	2 (1.8-2)	2 (2-2)	0.72
Day 3	1 (1-3.3)	4 (3.3-4)	0.08
Day 4	0 (0-2.3)	2.5 (2-3)	0.1
Day 5	0 (0-0)	1.5 (1-2)	0.005
Total	4 (2-6.5)	9.5 (9-10)	0.03

Table 2: Intervention unit at each day and in total
Data are shown as median (interquartile range).
p: Mann–Whitney U test

➢ Patients in the CGM group achieved both TIR>70% and CV<36% earlier than those in the BGM group (1.4 days vs. 2.7 days; p=0.03: Log-rank test).

Discussion

➢ The present study result suggest that, during hospitalization, DTI with reference to personal CGM may achieve both TIR>70% and CV<36% slightly earlier than that with reference to BGM. This result corresponds to the result in the previous report [1].

1. Šoupal J, et al. Diabetes Care. 2020; 43: 37-43.

➢ For the situation where rapid improvement of glycemic variability is needed, such as perioperative period, DTI using personal CGM may be effective.

➢ The results regarding IU may suggest that high quality intervention on day 2 due to reference to real-time CGM made the target achievement earlier than intervention using BGM despite equivalent IU on day 2, resulting in subsequent lower IUs for CGM group than those for BGM group.

➢ The sensitivity and specificity of Both 75-160 mg/dL and ±30% of the Mean for both TIR>70% and CV<36% may suggest that the target range determined by the preliminary analysis is appropriate.

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Conclusion

➢ During hospitalization, the DTI with reference to rtCGM may achieve both TIR>70% and CV<36% slightly earlier than that with reference to BGM.