ATTD 2022 35

WHICH DETERMINES ISCGM SENSOR ACCURACY, PATIENT OR SENSOR ITSELF?

Soichi Takeishi, Tatsuo Inoue, and Ryogo Himori
Department of Diabetes, Inuyama Chuo General Hospital

Background

◆The mean absolute relative difference (MARD) for intermittently scanned CGM (isCGM) sensors has been reported to be approximately 11% [1]. However, 11% is a mean value, and the range of MARD has been reported to be 5–23% [1].

◆In clinical practice, isCGM sensors may have inter-individual variability in accuracy, which may be derived from patients or sensors themselves. Therefore, when MARD for a patient using isCGM is lower or higher than the reported value, it is difficult for patients to interpret whether the patient or the sensor itself affects the MARD. This interpretation may affect the subsequent motivation for self-monitoring of blood glucose (SMBG) . How MARDs vary between patients or between individual sensors is well unknown.

◆We studied regarding inter-individual variability of sensor accuracy for isCGM.

1. Bailey T, et al. Diabetes Technol Ther. 2015; 17:787-94.

Research design & Methods

◆This was a prospective observational study. Twenty outpatients with type 2 diabetes wore an isCGM (FreeStyle Libre) over 12 weeks using six sensors.

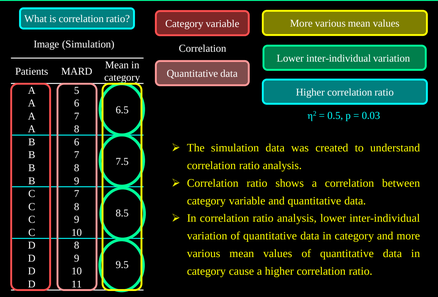
◆SMBG was performed once a day before breakfast using glucometers compliant with ISO15197:2013. Sensors where the MARD could be evaluated more than nine times were included in this study.

➢ Endpoints

◆Correlation between sensors (n = 6) and distribution of MARD (n = 6 × max 14) in each patient

◆Correlation between patients (n = 20) and distribution of MARD (n = 20 × max 84)

◆Correlation between sensors in all patients (n = 120) and distribution of MARD (n = 120 × max 14)



Result

Baseline characteristics

Characteristic	Values
N (Male / Female)	20 (13 / 7)
Age, years	66.4 ± 10.7
BMI, kg/m²	26.2 ± 5.5
HbA1c, %	8.2 ± 1.5
Mean of MARD, %	14.2 ± 5.3
SD of MARD, %	9.2 ± 5.1
Obtained MARD rate, %	89.8 ± 6.5
Overall MARD, %	14.3 ± 11.7

Data are shown as mean ± SD.

➢ For 17 out of 20 patients, the sensors significantly correlated with the distribution of MARD.

➢ The patients significantly correlated with the distribution of MARD.

➢ The sensors in all patients significantly correlated with the distribution of MARD.

Patients	MARD on Sensor 1	MARD on Sensor 2	MARD on Sensor 3	MARD on Sensor 4	MARD on Sensor 5	MARD on Sensor 6	Mean of MARD	η^2	p
A	5.0 ± 2.9	10.2 ± 7.0	19.8 ± 4.7	13.7 ± 6.2	15.3 ± 6.1	6.6 ± 4.1	11.8 ± 7.3	0.49	<0.001
B	7.3 ± 4.4	8.3 ± 6.4	14.2 ± 5.2	10.8 ± 4.8	6.3 ± 3.8	12.4 ± 4.5	9.8 ± 5.6	0.27	0.002
C	25.7 ± 13.9	14.8 ± 6.7	17.0 ± 6.7	20.6 ± 5.1	25.2 ± 7.1	17.6 ± 4.9	20.3 ± 8.9	0.22	0.005
D	7.8 ± 3.7	11.2 ± 9.9	5.2 ± 3.1	12.5 ± 7.2	5.8 ± 4.1	8.1 ± 6.0	8.3 ± 6.3	0.17	0.06
E	18.2 ± 4.4	15.6 ± 3.9	16.3 ± 4.2	19.3 ± 6.6	15.5 ± 3.5	14.4 ± 4.4	16.6 ± 4.8	0.13	0.06
F	30.9 ± 11.3	18.3 ± 6.4	18.8 ± 6.2	19.8 ± 4.3	23.5 ± 7.5	20.6 ± 9.5	22.0 ± 8.9	0.26	<0.001
G	11.4 ± 10.7	36.0 ± 24.0	12.4 ± 10.0	17.1 ±6.6	5.5 ± 4.4	13.0 ± 5.4	16.1 ± 15.4	0.41	<0.001
H	16.5 ± 5.2	11.9 ± 5.6	9.4 ± 8.3	12.6 ± 5.3	6.4 ± 5.3	6.0 ± 4.3	10.5 ± 6.7	0.33	<0.001
I	20.0 ± 5.6	6.8 ± 5.9	6.9 ± 4.6	18.0 ± 4.8	18.5 ± 7.1	15.4 ± 4.9	14.3 ± 7.7	0.51	<0.001
J	17.7 ± 12.3	13.9 ± 6.8	12.8 ± 6.6	7.7 ± 3.8	15.3 ± 7.4	6.7 ± 4.8	12.4 ± 8.4	0.23	0.003
K	12.4 ± 7.1	17.1 ± 5.9	5.4 ± 5.0	8.6 ± 6.0	5.6 ± 5.1	50.1 ± 60.8	16.1 ± 27.9	0.29	<0.001
L	7.8 ± 5.8	4.3 ± 3.1	8.2 ± 6.6	6.6 ± 4.2	8.5 ± 4.3	5.1 ± 5.3	6.8 ± 5.1	0.1	0.28
M	22.3 ± 4.4	22.5 ± 4.3	25.8 ± 4.3	32.8 ± 4.0	19.3 ± 4.3	21.5 ± 8.8	24.0 ± 6.8	0.43	<0.001
N	4.9 ± 3.4	5.8 ± 4.2	8.8 ± 7.6	5.1 ± 3.9	8.7 ± 4.9	2.9 ± 3.0	6.1 ± 5.1	0.16	0.02
O	15.0 ± 8.6	16.7 ± 10.0	27.8 ± 8.4	23.5 ± 11.0	21.1 ± 6.2	13.9 ± 7.3	19.4 ± 9.7	0.23	0.002
P	17.1 ± 13.6	12.3 ± 8.9	12.0 ± 8.7	31.8 ± 9.0	29.7 ± 9.2	30.9 ± 10.2	22.8 ± 13.0	0.44	<0.001
Q	19.2 ± 15.5	11.4 ± 7.5	10.8 ± 9.0	11.3 ± 7.7	7.8 ± 5.2	10.1 ± 8.8	11.9 ± 10.0	0.15	0.047
R	16.7 ± 8.1	5.5 ± 4.3	8.1 ± 6.1	6.6 ± 5.1	12.1 ± 6.0	7.1 ± 4.8	9.4 ± 6.9	0.32	<0.001
S	14.9 ± 10.5	12.3 ± 10.9	7.2 ± 6.0	5.2 ± 5.7	14.6 ± 6.2	17.2 ± 7.5	11.8 ± 8.8	0.25	0.001
T	16.7 ± 4.4	14.2 ± 5.4	4.7 ± 3.6	7.4 ± 5.2	26.0 ± 12.0	16.8 ± 6.4	14.2 ± 9.8	0.55	<0.001
η^2: correlation ratio							0.19	(P) η^2 (All S)	0.45
							<0.001	(P) p (All S)	<0.001

The η^2 and p values (η^2=0.19, p<0.001) show the correlation between patients and distribution of MARD (P).
The η^2 and p values (η^2=0.45, p<0.001) show the correlation between sensors in all patients and distribution of MARD (All S).

Discussion

➢ The reason why the overall MARD in the present study (14.3%) was slightly higher than the previously reported value (11%) [2] may be because elderly patients, whose skills, related to SMBG or attaching sensors, were low, may have been included relatively more in the present study. In this regard, these study results may be a bit exaggerated.

➢ Decreased sensor accuracy following consecutive low MARD is caused by the inter-individual variability in sensor accuracy. Consecutive low MARDs may reduce SMBG compliance. When sensor accuracy decreases following consecutive low MARD, decreased SMBG compliance due to low MARD may prevent an appropriate response for hypoglycemia or hyperglycemia.

- Table 2 shows that, in patient T, the MARD on sensor 5, following the MARD of 4.7% and 7.4% for sensors 3 and 4, respectively, was 26.0%. As in this case, if the patient interprets the low MARDs on sensors 3 and 4 as the accuracy derived from the patient, the motivation for SMBG may decrease, which may result in SMBG not being performed.
- Similarly, in patient K, the MARD on sensor 6, following the MARD of 5.4%, 8.6%, and 5.6%, for sensors 3, 4, and 5, respectively, was 50.1%. However, as in this case, the SG on sensor 6 shows obviously unnatural values compared to the SG on sensors 3–5; therefore, the patients can detect whether or not the sensor accuracy is low.
- A decrease in the accuracy to a degree where the patients are unable to detect whether the accuracy is low, may be a problem. When low MARD continues, patients should interpret the MARD as the MARD derived from the sensors themselves and not derived from patients, and patients should also admonish themselves by interpreting subsequent MARD to be high probabilistically.
- However, when high MARD continues, patients should not interpret subsequent MARD to be low probabilistically, because the MARD may be derived from patients.
- From the above, to admonish patients themselves, when low MARD continues, patients should interpret the MARD as that derived from the sensors themselves, and when high MARD continues, patients should interpret the MARD as that derived from patients.

➢ In addition, when we focused on the MARD variability within a sensor, for some sensors, the mean of absolute relative difference (ARD) and SD of ARD values were close. The MARD for the initial and closing days was slightly higher than that for the other days within two weeks [2]. This mainly affected the close values between the mean of ARD and SD of ARD. However, some high MARDs existed at random days.

- In particular, when the MARD within a sensor is approximately 10 ± 10 % included in Table 2, it may be difficult for the patient to trust the accuracy shown by the MARD practically.
- Patients should recognize that a low MARD does not always show subsequent low MARD within the same sensor.
- If patients recognize high MARD variability within a sensor, they must perform SMBG once a day, at least, and should perform frequent SMBG when patients doubt SG accuracy. However, both the sensor accuracy and SMBG accuracy should be considered.

➢ Any increase in the mean weekly MARD by 1% has been previously reported to be associated with a 0.35% decrease in adherence [3]. This previous study result can be interpreted as an indication that higher MARD reduces motivation for continuing CGM by reducing confidence. The present study shows that recognizing the possibility of MARD variability may prevent decreased motivation due to putting too much confidence in low MARD, in continuing SMBG. Thus, the previous report [3] supports the present study, in that glucose measurement adherence and MARD have causal relationships.

- Patients should pay attention to not only the MARD increase, but also the MARD variability.

2. Bailey T, et al. Diabetes Technol Ther. 2015; 17:787-94.
3. de Bock M, et.al. J Diabetes Sci Technol. 2016; 10:627-32.

Conclusion

➢Both the patient and sensor may affect the accuracy of the isCGM sensor.

Soichi Takeishi, MD;
E-mail: souichi19811225@yahoo.co.jp