

Flash Glucose Monitoring (FGM) Can Contribute Better Glucose Variability and Treatment Satisfaction

Hiroshi Bando*

Tokushima University / Medical Research

Abstract

For adequate diagnosis and treatment for diabetes, there have been Self-Monitoring of Blood Glucose (SMBG), Continuous Glucose Monitoring (CGM) and Flash Glucose Monitoring (FGM). By applying FreeStyle Libre, many patients with diabetes mellitus have obtained better glucose variability. FGM can also contribute treatment satisfaction, which is evaluated by Diabetes Treatment Satisfaction Questionnaire (DTSQ) and Diabetes Therapy-Related Quality of Life (DTR-QOL) questionnaire. A report for patients with Type 2 Diabetes Mellitus (T2DM) showed that FGM continuation for 3 months contributed significant reduction of HbA1c and successive 3 months without FGM revealed stable HbA1c value, suggesting clinical psychological effect of FGM.

Keywords: Flash glucose monitoring; Self-monitoring of blood glucose; FreeStyle Libre; Type 2 diabetes mellitus; Diabetes treatment satisfaction questionnaire; Diabetes therapy-related quality of life questionnaire

Abbreviations

FGM: Flash Glucose Monitoring; SMBG: Self-Monitoring of Blood Glucose; T2DM: Type 2 Diabetes Mellitus; DTSQ: Diabetes Treatment Satisfaction Questionnaire; DTR-QOL: Diabetes Therapy-Related Quality of Life Questionnaire

Introduction

There has been the challenging situation of increasing obesity and aging population [1]. Consequently, the incidence of diabetes mellitus has been increasing worldwide [2,3]. Authors and collaborators have continued diabetic practice and research including continuous glucose monitoring (CGM) and Flash Glucose Monitoring (FGM) [4,5]. Several reports are observed concerning CGM, FGM and Self-Monitoring of Blood Glucose (SMBG), which indicate the development of diabetic research [6]. As FGM, FreeStyle Libre has been prevalent for some years. It has been applied for Type 1 diabetes mellitus (T1DM) and Type 2 diabetes mellitus (T2DM).

There was an observational study from regional diabetes database [7]. Subjects were 128 T1DM patients and HbA1c was checked 0,3,6,12 months after using FGM system. On 6 months, FGM group showed significant decrease of HbA1c (8.0-7.6%, $p=0.00$), whereas SMBG group showed unchanged (7.9-7.9%, $p=0.66$). Thus, to change from SMBG to FGM contribute improvement of glucose variability for T1DM.

By applying FreeStyle Libre Flash Glucose Monitoring (FSL-FGM),

***Corresponding Author:** Dr. Hiroshi Bando, Shikoku Division of Integrative Medicine Japan (IMJ), Nakashowa 1-61, Tokushima 770-0943, Japan. Email id:

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many diabetic patients have obtained better glucose variability. Then, what is the factors predicting HbA1c reduction? The research showed that 860 patients (average 46.7 years old) had baseline HbA1c 8.1%, in which 75% was type 1 DM [8]. Associated with FGM, HbA1c reduction more than 0.5% for 6 months was 22% of them. They showed median HbA1c reduction at 6 and 12 months was -0.82%. After multivariable regression analysis with several factors, SF-12 physical and mental component scores, baseline HbA1c was only significant different factor ($p<0.001$, $R^2 = 0.240$). Thus, only high HbA1c at baseline would predict significant improvement of HbA1c during FGM application.

Clinical efficacy of FGM was found in comparison with FGM and SMBG in patients with type 2 diabetes mellitus (T2DM) [9]. The research was RCT study for 24 weeks with multi-center study from 5 hospitals. The subjects were selected T2DM patients with 20-69 years old with HbA1c 7.5-8.4%. Subjects ($n=100$) were divided into two groups, which were FGM group and SMBG group. Both groups were educated to adjust their lifestyles to achieve pre-prandial blood glucose <130 mg/dL and postprandial blood glucose <180 mg/dL. Each group was provided with the intervention for 12 weeks. After that, without the intervention, the HbA1c status on 24 weeks were investigated. They did not receive FGM or SMBG from 13-24 weeks [9].

Main outcome included the changes in HbA1c at 24 weeks [9]. Second outcomes included BMI, BP, fasting plasma glucose, lipid profile and uric acid. Furthermore, diabetes treatment satisfaction questionnaire (DTSQ) was studied at 0 and 12 weeks. As a result, HbA1c changes at 12 weeks were -0.43% vs -0.30% in FGM ($n=48$) vs SMBG ($n=45$) group. However, HbA1c changes persisted at 24 weeks in only FGM group (-0.46%). The FGM group was 0.29% superior to SMBG group ($p=0.014$).

When investigating in detail points, FGM group showed improvement and significant difference between the groups for mean glucose value, Time In Range (TIR) and Time Above Range (TAR) [9].

Furthermore, FGM group showed the improvement of the Coefficient of Variation (CV), Mean Amplitude of Glycemic Excursions (MAGE) exceeding the standard deviation, and daily difference in blood glucose (MODD). These factors had significant differences between both groups. The result suggested that FGM suppressed mean blood glucose levels, diurnal blood glucose fluctuations, and daily disparities. As to the changes in DTSQ, only FGM group showed significant elevation from 26.5 to 29.9 points. On the other hand, SMBG group showed no changes. These results suggested that diabetic patients may improve and regulate their lifestyle inspired from the continuous glucose data of GFM. These beneficial changes were probably continued in the latter 12 weeks. The continuation of adequate diet habit seems to be rather difficult. For example, the Dietary Intervention Randomized Controlled Trial (DIRECT) showed the regain of the body weight in T2DM patients [10].

Formerly, SMBG was introduced to medical practice by the method of pricking the fingers. After that, FGM was evaluated for the beneficial effect of reducing frequency of hypoglycemia in RCT study [11]. FGM could also improve HbA1c values for T1DM in several investigations [12-14]. Furthermore, FGM was evaluated to be superior to SMBG in reducing the episode of hypoglycemia [15], and HbA1c value in T2DM patients with insulin treatment [16,17].

A recent report showed the efficacy of FGM. Subjects were 94 T2DM adult patients treated with basal-bolus insulin therapy [18]. After the application of FreeStyle Libre, they showed improved glycemic variability as follows: time period of glucose within normal range + 1.7 hours/day, hyperglycemia period -1.6 hours/day, HbA1c -0.4% (each $p < 0.0001$). Treatment satisfaction by DTSQ showed improved values increasing 11.8 points [19].

From the view point of satisfaction for FGM, a report was observed for patients with T1DM [20]. The protocol included 0,4,12 weeks evaluation by two questionnaires. One is the DTSQ with eight questions such as satisfaction with current treatment, flexibility, convenience, understanding of diabetes, recommend treatment to others, willingness to continue [21,22]. Another is Diabetes Therapy-Related Quality of Life (DTR-QOL) questionnaire with 29 items for 4 groups, such as burden on social activities and daily activities, anxiety and dissatisfaction with treatment, hypoglycemia, and satisfaction with treatment [23]. The results showed the significant improvement of HbA1c ($p=0.002$) and the percentage of time within the target glucose range ($p=0.016$), burden in social activities ($p=0.024$) and treatment satisfaction ($p=0.007$). Thus, FGM contributed to glucose variability and patient satisfaction in T1D patients.

Conclusion

FGM has been known for its usefulness of prompt grasping the current blood glucose level. A new report shows the characteristic point that the experience of FGM can contribute the better glucose variability after discontinuation of FGM for months. The main cause seems to be due to understanding the relationship between detail fluctuation of glucose and daily life style in each subject. Furthermore, GGM may

give each patient treatment satisfaction, which can make the patient continue better diabetic control with adequate lifestyle for long.

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