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Rapid Efficacy of Low Carbohydrate Diet for Diabetic Patient by Use of FreeStyle Libre

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Abstract

In recent years, continuous glucose monitoring (CGM) has been introduced and used in clinical diabetic research. Authors have investigated research about Low Carbohydrate Diet (LCD) and Calorie Restriction (CR) and developed medical and social LCD movement through Japan LCD Promotion Association (JLCDPA). In this study, a case with remarkable improving effect for change from CR to LCD is presented using CGM. The case is 41 years-old female with type 2 diabetes mellitus (T2DM). She was newly diagnosed as T2DM with HbA1c 11.0%, glucose >400 mg/dL, BMI 26.0, AST 30 IU/mL, Hb 16.3 g/dL. She was given CR meal with 60% carbohydrate on day 1 to 4, and LCD meal with 12% carbohydrate on day 5 to 7. Daily profile of blood glucose showed 200-400 mg/dL in day 1-4, 160-240 mg/dL on day 5 and 110-150 mg/dL on day 7. FreeStyle Libre (Abbott, USA) has been valid and useful medical apparatus for monitoring the the detailed fluctuation of blood glucose. Blood glucose value was immediately decreased just after starting LCD, and the short-term effect of the LCD was found. These results would become basal and reference data and contribute to the development of future research.

Keywords: FreeStyle libre; Continuous glucose monitoring; Low carbohydrate diet; Glucose variability; Japan LCD promotion association; Calorie restriction

Abbreviations: CGM: Continuous Glucose Monitoring; LCD: Low Carbohydrate Diet; T2DM: Type 2 Diabetes Mellitus; CR: Calorie Restriction; JLCDPA: Japan LCD Promotion Association.

Introduction

In recent years, the adequate treatment and management for diabetes has become an important problem in medical practice and research [1]. Observing the diabetic situation in the world, the prevalence of diabetes has been increasing year by year [2]. Among them, diet therapy is the fundamental therapy for diabetes, and various dietary therapies have been reported so far [3]. They include variety types of diet, such as low-carbohydrate diet, low-fat diet, vegetarian diet, high protein diet, Mediterranean dietary pattern, Paleolithic diet, low-glycemic index/load diet.

Including these reports and related papers, the comparison with CR or LCD has been often investigated, when adequate diabetic nutrition has been discussed [4]. Historically, CR has been known for standard diabetic nutritional therapy. However, LCDs Bernstein and colleagues have introduced and started LCD in early period [5]. Afterwards, the efficacy of LCD has been reported by the investigators of Dietary Intervention Randomized Controlled Trial (DIRECT) Group and others [6,7]. Thus, the diet method of LCD has been spread in European and North American countries [8].

In Japan, Ebe et al. firstly reported the medical application of LCD [9]. After that, the authors have reported markedly high value of blood ketone bodies in fetuses, placenta, neonates, and pregnant women and discussed the physiological role of ketone bodies [10]. Following this, we have continued clinical research on LCD for obesity, diabetes, pregnant women, and various subjects [11,12]. Several reports have been found about the clinical effectiveness of LCD [13,14].

Through continuing such our clinical studies, we experienced a case with T2DM in which continuous glucose monitoring (CGM). Two dietary regimens, CR and LCD were obtained and the detail glucose variability was elucidated. The detail of them would be described in this report.

Case Presentation

History of present illness

The patient enrolled in this study was 41 years-old female. She has unremarkable past history or family history. She developed the symptom of urinary incontinence for several days and consulted our clinic. Urinalysis showed turbidity of the urine and increased WBC suggesting urinary tract infection and cystitis. Furthermore, it showed highly elevated glucose concentration and elevated protein, and elevated occult blood, which strongly suggests the presence of diabetes mellitus.

The patient was checked the routine examination of diabetes. Postprandial blood glucose was more than 400 mg/dL, and HbA1c value was 11.0%. She was diagnosed as type 2 diabetes mellitus (T2DM) and was started to be given further evaluation for diabetes mellitus.

Physicals and basal tests

On the first visit for the outclinic, her physicals was unremarkable, and negative for vitals, heart, lung, abdomen and neurological findings. Her body mass index (BMI) was 26.0 kg/m^2. Chest X-ray and Electrocardiogram (ECG) were unremarkable.

Biochemistry

The Data of the fundamental blood tests were revealed in the following: AST 30 IU/mL, ALT 33 IU/mL, AlP 350 IU/mL (104-338), total protein 7.6 g/dL, T-Bil 0.3 mg/dL, D-Bil 0.1 mg/dL, BUN 12 mg/dL, Cre 0.5 mg/dL, Na 135 mEq/L, K 3.9 mEq/L, Cl 98 mEq/L, T-Cho 204 mg/dL, complete blood count; RBC 518 × 10^4/μl, Hb 16.3 g/dL, MCV 92 fL, WBC 12,250/μl, Fe 81 μg/dL, ferritin 105 ng/mL (5-157).

Research Methods and Progress

In current study for blood glucose fluctuation, we used recently-introduced apparatus, FreeStyle Libre [15]. It has been reliable apparatus for Continuous Glucose Monitoring (CGM) worldwide [16]. It has been produced by Abbott Diabetes Care Inc. and been prevalent in recent years [17].

Authors have investigated nutritional therapy using Low Carbohydrate Diet (LCD) and also Calorie Restriction (CR) for years. We have certain protocol for research meal for LCD and CR. CR has 60% of carbohydrate in calorie ratio, which is the standard Japanese meal for diabetes by Japan Diabetes Association [18]. On the other hand, LCD meal was selected 12% of carbohydrate in calorie ratio, which has been called as super-LCD. It is from standard LCD meal by Ebe et al. in Japan LCD Promotion Association (JLCDPA). In current study, we have provided the patient the following standard protocol for CR and LCD meals in our investigation:

- The patient has her regular meal as CR diet from day 1 to day 4,
- The meal time is regular at 0800h, 1200h and 1800h,
- She has super-LCD meal from day 5 to day 7,
- Daily profile of blood glucose was studied from day 1 to day 7.

The result of CGM by FreeStyle Libre for glucose variability was shown in Figure 1. Daily profile of blood glucose from day 1 to day 4 showed almost between 200 mg/dL to 400 mg/dL. For these period, patient has CR meal. After that, she has changed to LCD meal from day 5 to day 7. Blood glucose value has decreased around 160 mg/dL to 240 mg/dL abruptly on day 5. Successively, blood glucose ranged about from 110 mg/dL to 150 mg/dL on day 7.

Discussion and Conclusion

CGM has been developed by medical and engineering inspection techniques, and one of the CGM, FreeStyle Libre has been gained its validity and credibility so far [19]. In particular, it was to reduce the incidence of hypoglycemia in type 1 diabetes that CGM seemed to be clinically very effective. In the DIAMOND Randomized Clinical Trial, a result of HbA1c with low hypoglycemia was obtained [20]. It is also applied to the patients with type 2 diabetes and other situations, and it has been evaluated the usefulness of obtaining the glucose variability [21]. For the development of CGM, Food and Drug Administration (FDA) approved the management decisions about the insulin dose from obtained CGM values [22].

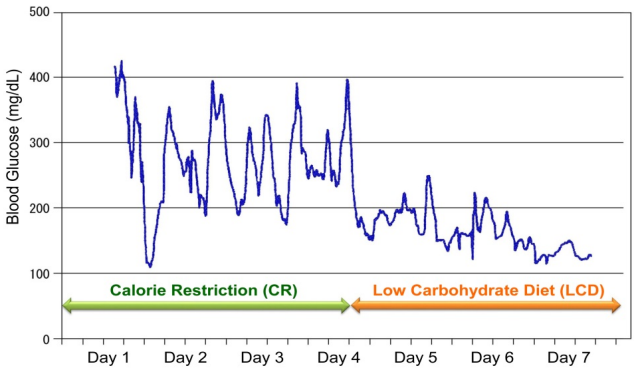

Figure 1: Daily profile of blood glucose from day 1 to 7 using CGM, Calorie restriction (CR) in day 1 to day 4, Low carbohydrate diet (LCD) in day 5 to day 7.

Concerning the technical aspect of CGM, Updike et al. reported formerly [23]. Successively, the electrodes were improved for converting blood glucose level into electric signals. Then some CGM experimental trials were shown [24]. The guideline of CGM was shown by Clinical and Laboratory Standards Institute (CLSI) [25]. Further, lots of research have been found concerning international standardization. They include mean absolute relative deviation (MARD) and precision absolute relative difference (PARD) [26,27]. FreeStyle Libre (Abbott, USA) has been evaluated for useful examination tool for CGM with sensor-based method for glucose monitoring [28].

Historically, authors and co-researcher have developed LCD in Japan. Dr. Ebe initiated and reported LCD in Japan and continued medical practice of LCD [9]. We have also established the Japan LCD Promotion Association (JLCDPA) and developed LCD movement with books, seminars and reports in medical societies for years [11].

As a matter of fact, the author previously had diabetes sustaining the HbA1c value more than 9%. At that time, I have obtained the medical information for LCD and tried and continued LCD. Then, successfully, weight reduction of 15 kg were found. Furthermore, HbA1c value decreased to 5%, and both high blood pressure and fat liver were all relieved. According to this dramatic change and remarkable effect, the author has decided to apply LCD in the field of obstetrics and gynecology (OB/GYN) [11]. After that, the author have applied LCD to gestational diabetes mellitus, diabetic pregnant woman management, and infertility treatment in OB/GYN, and showed breakthrough results until now [29]. We have reported clinical studies in several medical association, and developed LCD socially with some textbooks.

Concerning this activity for developing LCD, it is true that there were moderate objections at the beginning. However, medical misunderstanding has been gradually smaller about LCD and hyperketonemia, leading to widespread of LCD.

At present, several incorrect explanations have been found in two points. One is the content ratio of carbohydrates with respect to carbohydrate restriction. In our research protocol, 12%, 26% and 40% of carbohydrates are defined as super LCD, standard LCD, petite LCD respectively [30]. In general medical research field, however, the standard of carbohydrate inclusion in LCD is not determined.

Therefore, there are many papers under different conditions, and various evaluations are observed [4]. Another problem is that there are several situations concerning hyperketonemia, such as three typical situations. They are:

- Pathological cases of diabetic coma,
- Insufficient calorie intake and/or dehydration,
- Fat in the body has been burning due to carbohydrate restriction.

Medical physicians and staffs tend to be confused concerning these situations [31,32].

Current data can be analyzed in detail. As to the blood glucose between preprandial and postprandial blood glucose from day 1 to day 4, it increased from about 190 mg/dL to 390 mg/dL with approximately rise in 200 mg/dL. It has been considered as a standard that an increase of 3 mg/dL is observed after ingestion of 1 g of carbohydrate. Consequently, blood glucose seemed to be increased due to ingestion of about 70 g of carbohydrate. Moreover, it is inferred that intake of the same amount of carbohydrates on day 2, 3, and 4 resulted in almost similar daily fluctuation of blood glucose.

On the other hand, when LCD meal was administered from day 5 to day 7, the difference between preprandial and postprandial glucose was less than 60 mg/dL. It is inferred that approximately 20 g of carbohydrate was contained in each meal. Further, the difference before and after the meal decreased from day 5, day 6 to day 7. The fluctuation range of blood sugar on day 7 were smaller from 110 mg/dl to 150 mg/dL, which is almost the same level as that in normal people. Thus, it is suggested that the LCD can lower blood glucose variability from the first day, with remarkable efficacy for decreasing blood glucose [33].

In summary, we could monitor the detailed fluctuation of blood glucose by using CGM, when diet was changed from CR to LCD. As a result, the blood glucose was immediately decreased just after starting LCD, and the short-term effect of the LCD was proved. These results will become basal and reference data and contribute to the development of future research.

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