

Receiving Insulin Therapy in Type 2 Diabetes Mellitus Patients Hypoglycemia After 15 Minutes in the Event of the Suitability of Blood Glucose

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Abstract

This study is a non-synchronized design single group study to determine whether 15 minutes is appropriate for re-treatment of hypoglycemia after measuring the blood glucose levels at 15 min, 30 min, and 45 min, after dosing 15 g of simple carbohydrates during hypoglycemia in patients with Type 2 Diabetes Mellitus using a specified glucometer. The study was conducted in 30 adult patients with Type 2 diabetes mellitus who were hospitalized as in-patients at the Internal Medicine of Endocrinology of one general hospital in Seoul to get insulin therapy (15 men, 15 women). The collected data was analyzed using PASW statistics 18 program. General characteristics of subjects were analyzed with frequency and percentage. The blood glucose level comparison each time was analyzed by using Repeated measured ANOVA. Upon any incidence of hypoglycemia, 175 cc of orange juice (equivalent to 15 g of simple carbohydrates) was given to patients whose blood glucose were ≤ 70 mg / dL or patients who meet the Whipple triad, and the blood glucose levels were measured using a specified glucometer respectively at 15 min, 30 min, and 45 min intervals after drinking the juice. These blood glucose levels were then compared at each time interval (Korean Diabetes Association (KDA) Treatment Guideline for Diabetes, 2011). Upon the incidence of hypoglycemia in patients with Type 2 diabetes mellitus who are currently under insulin therapy, each blood glucose level measured at 15 min, 30 min, and 45 min intervals after taking 15 g of simple carbohydrates using a specified glucometer was studied. The blood glucose level measured at 30 minutes after taking simple carbohydrates had shown also statistically significant increase from the blood glucose level at the time of hypoglycemia ($p < .001$). However, when comparing glucose levels measured at 15 min ($p = .001$) and at 30 min ($p < .001$) after taking simple carbohydrates, from the glucose level at the time of hypoglycemia, the glucose level measured at 30 min after taking after taking simple carbohydrates was significantly increased. Thereby, it is suggested to measure the glucose level at 30 min, not at 15 min after taking simple carbohydrates when considering incidences of hypoglycemia in in patients with Type 2 diabetes mellitus who are currently under insulin therapy.

Keywords: Insulin therapy, Type 2 Diabetes mellitus, Hypoglycemia, Blood glucose

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1. Introduction

1.1. The Needs of Study

Diabetes mellitus (hereinafter referred to as DM) is a metabolic disease that is difficult to cure completely. The World Health Organization (WHO) estimated that prevalence of DM in 1995 was 4.0%, but expected to increase to 5.4% by 2015. In Korea, the prevalence of DM in 2009 was reported as 10% [1].

However, circumstantially, diabetes management rate is very low, considering the rapidly increasing rates of morbidity and mortality of DM [2]. In addition to such rapid increase in the morbidity of DM, there is a notably increasing population of elderly patients with DM because of increasing life expectancy. However, there is not enough effective regulation of blood glucose levels, while incessant self-management and social support are continuously in demand.

Strict glucose control is essential to reduce the morbidity and mortality of diabetic patients. However, incidences of severe hypoglycemia are increasing during insulin therapy for strict blood glucose control. Hypoglycemia is the most common complication in patients who get insulin injections. According to the report of Diabetes Control and Complication Trial (Hereinafter DCCT) in 1993[3], maintaining blood glucose to normal or nearly normal levels using active insulin treatment in patients with DM would be effective for delaying the development and progression of diabetic retinopathy, nephropathy, and neuropathy [4]. However, in actual application, the hypoglycemia induced by strict blood glucose control became clinically problematic as it had increased the frequency of hypoglycemia by 3 times greater [5].

Therefore, the more strictly blood glucose level is being regulated, the lower the blood glucose control targets, the higher the frequency of hypoglycemia is. In addition, more than 90% of patients with DM being treated with insulin reported they had experienced hypoglycemia, with the frequency of symptomatic hypoglycemia known to be at least once a week in average among those under conventional insulin treatment, and at least twice a week in average among those under active insulin treatment [6].

Hypoglycemia is presented with various symptoms, with change in consciousness being the most common among them. Other complications include increasing prevalences of a variety of diseases such as seizures accompanied by injury, and even damage to sensory detection of low blood sugar. Sometimes in rare and severe cases, even hemiplegia or sudden death could happen. Therefore, above all, appropriate training on detecting the symptoms and management of hypoglycemia in diabetic patients is important. In particular, the in-patient regulation of hypoglycemia and insulin treatment in hospitals for blood glucose management is extremely important to diabetic patients, since the method of hypoglycemia regulation has a significant effect on insulin therapy.

In Korea, the Korea Diabetes Association recommends measuring blood glucose levels at 15 minutes after taking 15 g of carbohydrate when checking for hypoglycemia in patients with DM [7].

However, since it was not possible to find the ground for re-measurement of blood glucose levels at 15 min after the incidence of hypoglycemia, each hospital has different recommended re-measurement time including 15 minutes, 20 minutes, or 30 minutes. At the moment, education on the correct re-measurement time for blood glucose levels after the occurrence of hypoglycemia has not been properly conducted. There has been a study in pediatric patients with type 1 Pediatric Diabetes Mellitus in 2011 [8,9], for re-measurement of blood glucose level at 2 min, 5 min, 10 min, and at 15 min after intake of 0.3 g/ carbohydrate/ kg, however, such study was not conducted in Korea in the past, so that there is actually no paper or study on change of the blood glucose level at 15 minutes after the administration of simple carbohydrates.

In this study, we wanted to identify whether the time to recover from hypoglycemia

had any association with the measurement of the blood glucose level at 15 min after in patients with Type 2 DM, and to apply the outcome to nursing practice to make it more effective.

1.2. Objectives

The objectives of this study is to determine whether re-treatment is required by re-testing the blood glucose level at 15 min after the incidence of hypoglycemia, and to scientifically verify the appropriate time of recovery from hypoglycemia after intake of 15 g of carbohydrate, in addition to conducting education on the correct time of hypoglycemia management in patients with Type 2 DM [10].

The details of study objectives are:

- 1) To measure blood glucose levels at 15 min, 30 min, and 45 min after intake of carbohydrates using a specified glucometer upon the occurrence of hypoglycemia in patients with Type 2 DM undergoing the insulin treatment, and to confirm the appropriateness of 15 min as the proper time for retreatment of blood sugar level after intake of carbohydrate at the time of hypoglycemia.

1.3. Definitions

1. Hypoglycemia

Hypoglycemia is defined as having blood glucose levels below 70 mg/dL [7], and when Whipple triad is observed.

* Whipple triad

- 1) These are symptoms known or likely to be caused by hypoglycemia
- 2) Low plasma glucose is measured
- 3) Hypoglycemic symptoms recover to normal when glucose is injected

2. Simple carbohydrate 15 g

Simple carbohydrates are sugars that are quickly metabolized when taken by the body, and which raise blood glucose levels as its mechanism. In this study, the food applying to simple carbohydrate is established as 175 cc of orange juice [7].

2. Study Methods

2.1. Study Design

This study is designed as a non-synchronized single group study in patients with Type 2 Diabetes Mellitus, to determine whether 15 min after intake of simple carbohydrate upon any incidence of hypoglycemia is an appropriate time for re-treatment of blood glucose levels by measuring blood glucose levels at 15 min, 30 min, and 45 minutes after intake of carbohydrate <Figure 1>

	Hypo glycemia occurrence	Treatment	After simple carbohydrate 15minutes	After simple carbohydrate 30minutes	After simple carbohydrate 45minutes
Exp.	Ye1	X	Ye2	Ye3	Ye4

Ye1, Ye2, Ye3, Ye4: Blood glucose check

X: 15g of simple carbohydrate was given to the patient
 (175 cc of orange juice)

Figure 1. Research Design

2.2. Selection of Study Population and Target Group Recruitment

The study was conducted in adult patients with Type 2 diabetes mellitus who were hospitalized as in-patients at the Internal Medicine of Endocrinology of one general hospital in Seoul to get insulin therapy, from October 2, 2013 to March 15, 2014.

Prior to data collection, the study obtained the approval of the IRB of the Investigational Institution. Sufficient information about the purpose of the study was provided to potential participants. After being informed that participation in this study is absolutely voluntary and that their information shall remain confidential, study participants personally signed the informed consent forms.

The sample size was calculated as 23 subjects using G-POWER 3.1.7 program, with established conditions including the test power as .8, the effect size as .5, and the significance level as .5 [11]. 30 subjects were selected in consideration of the dropout rate, but without any drop-out case, 30 subjects were included in the final analysis.

The detailed inclusion criteria of subjects are as follows:

- 1) Patients with Type 2 Diabetes Mellitus at the age ≥ 19 years old, and who are able to communicate.
- 2) In-patients currently undergoing insulin treatment who had signed forms and given their informed consent to this study upon admission to the hospital.
- 3) Patients with Type 2 Diabetes Mellitus who are not pregnant, breastfeeding, or are not accompanied with chronic wasting disease, azotemia, chronic renal diseases, or cerebral diseases.

2.3. Study Flow

1. Hypoglycemia is defined as having blood glucose levels below 70 mg/dL [7], and when Whipple triad is observed.
2. When an incidence of hypoglycemia occurs in a subject, let the subject drink 175 cc of orange juice, which is equivalent to 15 g of simple carbohydrate [7]. Afterward, measure blood glucose levels applicable at 15 min, 30 min, and 45 minutes respectively using a specified glucometer (Responsible nurse shall personally supply simple carbohydrate and measure blood glucose levels).
3. Compare blood glucose levels by each time interval.

2.4. Data Analysis Method

The collected data was analyzed using PASW statistics 18 program.

1. General characteristics of subjects were analyzed with frequency and percentage.
2. The blood glucose level comparison at each time interval was analyzed using Repeated measured ANOVA.

3. Study Results

3.1. General Characteristics of Subjects

Subjects accounted for the most proportion was 46.7% at the age under 60, and the ratios of men and women were the same. As for the diagnosis of diabetes mellitus, those with preexisting diabetes mellitus accounted for 86.7% of the subjects, and those taking the regular insulin accounted for 86.7%, which was a large proportion. Whether or not taking diabetes medication also showed the same percentage of 50% <Table. 1>.

Table 1. Homogeneity of Characteristics

(N= 30)

Characteristics	Categories	N	%
Age	60≥	14	46.7
	61~69	9	30
	70≤	7	23.3
Gender	Male	15	50
	Female	15	50
DM Diagnostic Status	New diagnostic	4	13.3
	Existing diagnostic	26	86.7
Short-acting insulin Use or not	Use	26	86.7
	Unused	4	13.3
Whether diabetes PO medication	Taking	15	50
	Does not taking	15	50

3.2. Differences of Changes in the Blood Glucose Levels by Time

When measuring the changes in blood glucose levels over time, the blood glucose level measured at the time of hypoglycemia was (M = 62.60), while the blood glucose level at 15 min after intake of simple carbohydrates was (M = 100.36), at 30 minutes after intake of simple carbohydrates was (M = 116.00), and at 45 min after intake of simple carbohydrates was (M = 110.50), showing there were changes in the blood glucose level over time (F=20.373, p< .001). When conducting a comparative analysis between the time intervals, the results as presented in <Figure 2> showed that the blood glucose level at the time of hypoglycemia and the blood glucose level at 15 minutes after intake of simple carbohydrates (p = .001) had shown statistically significant increases.

Also, when comparing the blood glucose level at the time of hypoglycemia and the blood glucose level at 30 min after intake of simple carbohydrates (p<.001), both had shown statistically significant increases. However, when comparing the blood glucose level at the time of hypoglycemia to the blood glucose levels at 15 min (p = .001) and at 30 min after intake of simple carbohydrates (p<.001), the blood glucose level measured at 30 min after intake of simple carbohydrates was significantly increased against the level at 15 min <Table 2>.

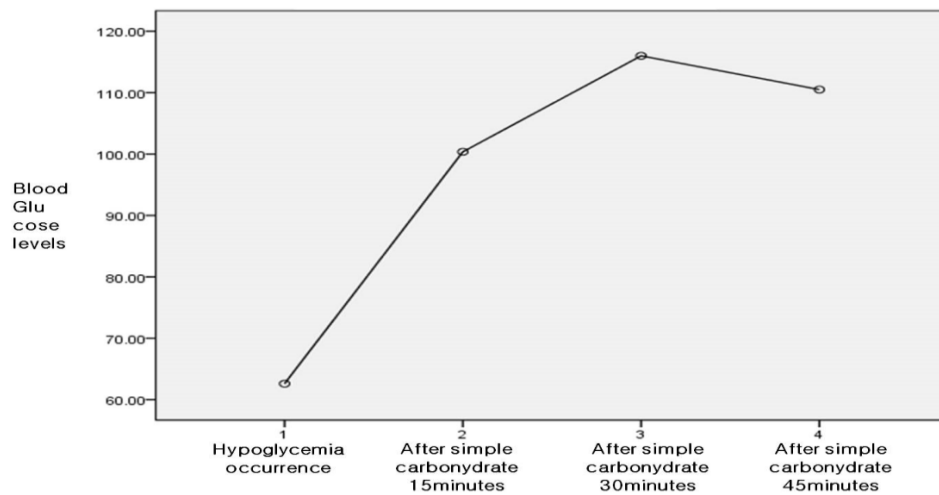


Figure 2. Time-Dependent Changes in Blood Glucose Level

Table 2. Time-Dependent Changes in Blood Glucose Level (N=30)

	Hypo glycemia occurrence	After simple carbohydrate 15minutes	After simple carbohydrate 30minutes	After simple carbohydrate 45minutes	F	P
	M±SD	M±SD	M±SD	M±SD		
	62.60±1.16	100.36±9.67	116.00±8.73	110.50±8.68		
	p =.001		p <.001			
	p <.001			p=.001		
Blood glu cose levels	p <.001				20.373	p <.001

4. Discussion

This study was designed with limits on the study topic as the nurses in the Internal Medicine of Endocrinology had doubts about the appropriateness of measuring the blood glucose level at 15 min after intake of simple carbohydrates at incidences of hypoglycemia in patients with Type 2 Diabetes Mellitus who were under the insulin treatment in clinical settings [12].

Research on the risk of hypoglycemia and the food to take upon an incidence of hypoglycemia has been performed actively, however, a study on the time required for the normalization of blood glucose levels was not conducted as this has only been dependent on the Korean Diabetes Association (KDA) [7] Treatment Guideline for Diabetes.

In clinical settings particularly, the blood glucose level was measured only once at 15 min after intake of simple carbohydrates in accordance with the above Treatment Guideline, and according to the blood glucose level only, the medical staff determined the dosage of regular insulin to be administered to the subjects. Therefore, the determination of the correct time to re-measure the blood glucose level after intake of simple carbohydrates in the event of hypoglycemia should be also an important treatment method for hypoglycemia [13].

Additionally, the treatment for hypoglycemia is considered as having uttermost importance not only for hospitals, but also for patients with diabetes mellitus who are receiving the insulin treatment in the community [14].

5. Conclusion and Recommendations

The study is intended to present research-related questions about the nursing problems found in clinical settings, and to attempt an experimental study in order to solve those problems by studying the nursing actions being conducted without any doubt, so as to establish the source data for correct nursing interventions on patients with hypoglycemia [15].

This study was designed as a non-synchronized single group study on 15 male and 15 female patients with Type 2 Diabetes Mellitus who were hospitalized as in-patients at the Internal Medicine of Endocrinology of one general hospital in Seoul, to get insulin therapy from October 2, 2013 to March 15, 2014.

The objective of this study was to measure blood glucose levels using a specified glucometer at each time interval of 15 min, 30 min, and 45 minutes respectively after intake of 15 g of carbohydrate, in order to determine whether 15 min after intake of simple carbohydrate is an appropriate time for re-treatment of blood glucose levels in the event of hypoglycemia in the patients with Type 2 diabetes mellitus who are receiving insulin treatment.

The collected data from 15 male patients and 15 female patients with Type 2 Diabetes Mellitus who are receiving insulin treatment was analyzed using PASW statistics 18 program. General characteristics of subjects were analyzed with frequency and percentage. The difference of changes in the blood glucose level over time was analyzed using repeated measured ANOVA.

The results of this study are as follows:

1) When studying blood glucose levels measured using a specified glucometer at each time interval of 15 min, 30 min, and 45 min respectively after intake of 15 g of simple carbohydrates in the event of hypoglycemia in patients with Type 2 diabetes mellitus who are receiving insulin treatment, it was found that the blood glucose level at the time of hypoglycemia and the blood glucose level at 15 min after intake of simple carbohydrates ($p=.001$) had shown statistically significant increases.

Also, the blood glucose level at the time of hypoglycemia and the blood glucose level at 30 min after intake of simple carbohydrates ($p<.001$) had shown statistically significant increases as well. However, when comparing the blood glucose level at the time of hypoglycemia to the blood glucose levels at 15 min ($p = .001$) and at 30 min after intake of simple carbohydrates ($p<.001$), the blood glucose level measured at 30 min after intake of simple carbohydrates was significantly increased compared to the level at 15 min.

From the results of this study, it was confirmed that in the event of hypoglycemia in patients with Type 2 diabetes mellitus who are receiving insulin treatment, it is much more desirable to let them take 15 g of simple carbohydrates and to measure the blood glucose level at 30 min after intake of simple carbohydrates, rather than at 15 min [16,17].

With the aforementioned results, we would like to make recommendations as follows:

- 1) It is recommended to re-measure the blood glucose level at 30 min after the intake rather than at 15 min after intake of 15 g of simple carbohydrates in the event of hypoglycemia in patients with Type 2 diabetes mellitus who are receiving insulin treatment [18].
- 2) Since this study was conducted in patients who were in-patients at the Internal Medicine of Endocrinology in one hospital located in Seoul, it is not ideal to generalize the study results. Therefore, further study on a bigger number of subjects

- is recommended covering more diversified regions [18].
- 3) It is recommended to conduct any further study by separating the subjects who are taking the regular insulin and the subjects who are not, by separating the subjects who are taking oral hypoglycemic agents and by classifying the types of oral hypoglycemic agents [18].

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