Relation between Quality of Sleep Habits and Glycemic Control among Insulin Dependent Diabetes Mellitus Patients

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Abstract:

Background: Type I diabetes mellitus (TIDM) is an emerging public health issue; in which the relation between quality of sleep (QoS) and glycemic control is inconsistent; where inadequate or poor QoS is associated with higher glycosylated hemoglobin (HbA1c) levels and greater glycemic variability. Conversely, altered glucose metabolism may affect sleep quality, suggesting a bidirectional relationship between QoS and DM control. Aim of the study: Assess the quality of sleep habits among TIDM patients and to assess the relation between quality of sleep habits and glycemic control among type I insulin dependent diabetes mellitus patients. Design: A descriptive correlational research design was used to conduct this study. Setting: The present study was conducted at: the Inpatient Medical Department and Medical Outpatient Clinic at Matrouh General Hospital affiliated to Directorate of Health Affairs in Matrouh. Subjects: A convenience sample of 120 adult patients with type I diabetes mellitus were recruited in the current study. Three tools were utilized for data collection; namely: The Bio-sociodemographic and Clinical Data Structured Interview Schedule, Parameters for Glycemic Control Sheet and The Pittsburgh Sleep Quality Index (PSQI). Results: More than half of the studied patients suffered from poor QoS ranged from moderate to moderate severe difficulties in all area of sleep quality. In addition, a significant relation was declared between the global PSQI components score and the HbA1C level in the baseline and second researcher's assessment. In conclusion: the TIDM patients are more susceptible to poor sleep quality being obviously linked with poor glycemic control. **Recommendation:** Increase diabetic patients' awareness about the importance of following proper sleep quality practices in association with sustaining their glycemic

Key words: Quality of Sleep Habits, Glycemic Control, Insulin Dependent, Diabetes Mellitus.

Introduction

In 2019, nearly 463 million individuals globally were anticipated to have diabetes. While in Egypt, being one of the top five world's countries in terms of the number of adults diagnosed with diabetes ranging between 20-79 years. Researches have revealed that; the prevalence of DM in Egypt in 2019 was estimated 8.9 million cases (Saeedi et al., 2019 and Saeedi et al., 2020).

Type I diabetes mellitus (TIDM) is a chronic autoimmune diseases resulting in pancreatic beta-cell destruction and insulin deficiency. It occurs at any age, but usually occurs in young 30 years; in which the body produces very little or no insulin (**Hinkle et al., 2018**).

Recent researches have declared a bidirectional relation between quality of sleep (QoS) and glycemic control in DM patients (Perez et al., 2018; Frye et al., 2019; Monzon et al., 2019). Where, sleep is a

fundamental biological process, playing a key role in maintaining both physical and mental wellbeing. However, most healthy adults need to sleep seven to nine hours per night; which in turn has modulatory effects on glucose homeostasis. During sleep leptin hormone is secreted acting as a satiety moderator balancing the need for food intake and energy consumption (Ojile, 2017; Friedman, 2019). Thus, sleep deprivation induces leptin hypersecretion; which increases carbohydrates intake, predisposing to obesity, and increasing the susceptibility to DM (Kanda et al., 2016; Friedman, 2019).

In patients with DM studies illustrated that; the impact of sleep behavior on requires metabolic states investigations; as less sleeping hours at night, sleep loss and sleep disturbances are detrimental to metabolic function and glucose intolerance (Larcher et al., 2015; Von Schnurbein et al., 2018). Evidences shows that; symptoms associated with TIDM, such thirst. nocturia, glucose as extreme excursions, and mood alterations, may interfere with QoS contributing to sleep fragmentation affecting patients' healthrelated quality of life (QoL) (Aleem et al., 2018; Macaulay et al., 2020). Nurses play an important role in the diagnosis and treatment of sleep and the improvement of QoS. Where, educating diabetic's healthy lifestyle and sleep hygiene practices is extremely important in DM. (Lawler et al., 2019)

Based on this debate, the researcher found it necessary to investigate and add a building block in the nursing science regarding the relation between QoS habits and glycemic control among insulin-dependent diabetes mellitus patients.

Aims of the study

This study aims to:

1. Assess the quality of sleep habits among type I diabetes mellitus patients.

2. Assess the relation between quality of sleep habits and glycemic control among insulin dependent diabetes mellitus patients.

Research questions:

- 1. What is the quality of sleep habits among insulin dependent diabetes mellitus patients?
- 2. What is the relation between quality of sleep habits and glycemic control among insulin dependent diabetes mellitus patients?

Materials and Method:

Materials

Research Design: A descriptive correlational research design was used to conduct this study.

Setting: The present study was carried out at: the inpatient Medical Department and Medical Outpatient Clinic at Matrouh General Hospital; affiliated to Directorate of Health Affairs in Matrouh governorate.

Subjects: A convenience sample of 120 adult patients (18-60 year) with type I diabetes mellitus who were presented to the above mentioned setting; were comprised the study subjects. They were enrolled based on Epi info-7 programme using the following parameters: The estimated sample size:120 patients, Expected frequency:50%, Acceptable error:10%, Confident coefficient:99% and Minimum sample size:37 patients.

Patients participating in the study had met the following *inclusion criteria*: Free from psychological disorders (stress-anxiety), have controlled associated chronic conditions, i.e. hypertension, respiratory disorders ...etc., and patients are not receiving anti-histamines or allergy medications.

Tools of the study: Three tools were utilized by the researcher for data collection; in order to fulfill the study aim.

Tool (I): Bio-sociodemographic and Clinical Data Structured Interview Schedule. This tool was developed by the researcher based on review of relevant literature (Gozashti et al., 2016; Al-Humairi & Hassan, 2018; Sakamoto et al., 2018), and was used to collect the sociodemographic and clinical data of TIDM patient. It was composed of two parts:

Part I: Socio-demographic data: This part included data related to patients': age, gender, marital status, area of residence, level of education, occupation and income.

Part II: Clinical data: This part was used to collect data about: patient's diagnosis, number of years with diabetes, patient's health history which was divided into: Associated diseases such as: hypertension, kidney, respiratory, or heart disease. retinopathy, neuropathy, cancer cerebrovascular accident. Medications which contained items related to; prescribed medications such as: type of insulin, dose and frequency of insulin; and over the counter medications which included: diuretics, antiarrhythmic, beta blockers, corticosteroids and analgesics.

Tool (II): Parameters for Glycemic Control Sheet: This tool was developed by the researcher based on reviewing of relevant literature (Beck et al, 2017; Frye et al., 2019; Pinto et al., 2020), and was used to assess the studied patients' blood glucose level. It was composed of five parameters namely; fasting blood glucose level (FBG), random blood glucose level (RBG), glycosylated hemoglobin level measurement (HbA1C), as well as signs and symptoms of hyperglycemia and hypoglycemia occurrence.

Tool III: Pittsburgh Sleep Quality Index (PSQI): This tool was adopted from Buysse et al., 1989; and consisted of 24 questions; from which 19 are self-rated questions aimed to assess QoS habits during the last month in relation to seven components namely: subjective sleep quality, sleep latency, sleep

duration, habitual sleep efficiency, sleep disturbances, consumption of sleep medication, and daytime dysfunction each of which has a range of "zero-3 points". Where, a score of "zero indicates no difficulty", while a score of "3 indicates severe difficulty".

However; the researcher of the current study has developed her own sub-scaling scoring system to be more specified when describing patient's sleep quality as follows. "Zero" indicates "No difficulties", "1-5" indicates "Mild difficulties in all areas", "6-10" indicates "Moderate difficulties in all areas", "11-15" indicates "Moderate severe difficulties in all areas" and "21" indicates "Severe difficulties in all areas of sleep quality". It also included "5" questions which were rated by the bed partner or roommate (if available).

Method

- An official permission to collect data was obtained from Research Ethical Committee of the Faculty of Nursing, University of Alexandria, the responsible authorities (director) of the Matrouh General Hospital, in addition to the director of the outpatient clinic of diabetes after explanation of the aim of the study.
- Tools I and II were developed and translated into Arabic language by the researcher, while; tool III was adopted from Buysse et al., 1989, and its Arabic version was adopted from Suleiman et al., 2010.
- The developed tools were submitted to a jury of five experts in the Medical-Surgical Nursing field; and based on their advices necessary modifications were done.
- Reliability of the tools I & III was identified using Cronbach Coefficient Alpha test, it was estimated (α =0.708) (α =0.757); respectively.

- A pilot study was conducted on 10% of the study patients to test the feasibility, and clarity of the study tool.
- The data collection was initiated covering a period of 9 months (from March to December 2021).
- The total subjects were randomly enrolled consisting of 120 adult TIDM patients who met the study's inclusion criteria. They were interviewed twice at the Inpatient Medical Departments and Medical Outpatient Clinic.
- Patients interviews were conducted by the researcher utilizing tool I, II and III at the above mentioned setting to collect patient's sociodemographic and clinical data, assess their blood glucose level, and assess patient's quality of sleep habits during the last month; respectively.
- The researcher used finger pricking to attain blood spots in the (ACCU CHECK) Blood-Glucose Meters to measure F.B.G and R.B.G levels required in tool II in both first and second interview.
- In addition the researcher withdrew blood samples from each studied patient; and kept them in their specialized test tubes for not more than three hours for correct HbA1C result.
- Then the researcher sent it to "Alosra lab" located at Matrouh governorate which is an external private lab, for estimating the glycosylated hemoglobin (HbA1C) score; for not a routine test in Matrouh General Hospital.
- In relation to signs and symptoms related to glucose variability; the researcher performed physical examination twice through individualized meetings; to collect data, as well as ask patients about any signs and symptoms of hypoglycemia or hyperglycemia.
- The duration for collecting each tool's data took approximately from 15-20

minutes. The researcher compared between patient's first and second month's data.

Ethical Considerations

Informed written consent was obtained from each patient participating in the study after explanation of the study aims. Each patient had the right to withdraw at any time without any drawbacks. Patient privacy and the ethics in conducting the research was assured, also confidentiality and anonymity of the collected data was ascertained for each patient.

Statistical Analysis

Data were analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp) (Qualitative data were described using number and percent. Quantitative data were described using range (minimum and maximum), mean, standard deviation, median and Significance of the obtained results was judged at the 5% level.

Results

Figure 1: Shows Frequency Distribution of the Diabetic Patients according to their Sociodemographic and Clinical Data.

Regarding sociodemographic data; more than one third of the patients (43.3%) were in the age group between 35<45 years, (55.8%) were females. Almost an equal proportion (27.5%, 26.7%) were illiterate and university education; respectively. Additional clinical data revealed that; approximately half of patients (49.2%) were ranging from 1-less than 5 years with diabetes, more than half of patients (57.5%) had Hypertension, 12.5% of patients received Corticosteroids, and more than half of diabetic patients were on Mixtard insulin representing (52.5%), with Mean \pm SD of insulin dose 33.84 ± 10.86 on frequency of two to three times per day, followed by Lantus 41.7% with Mean \pm SD of insulin dose

 14.70 ± 6.73 on the frequency of one to two times per day.

Table 1: Shows Comparison between Baseline and Second Assessment Data of the Glycemic Control Parameters among the Diabetic Patients.

According to fasting blood glucose level: in the baseline assessment more than one third (35.8%) of studied patients had value of 120 - less than 250mg/dl, while in the second assessment, 44.2% of patients had value 120 - less than 250mg/dl. Regarding the random blood glucose level, in the baseline assessment more than half (54.2%) of patients value of 200-260mg/dl, had approximately two thirds of diabetic patients 65.0% had value 200 - 260mg/dl in the second assessment. Concerning to HbA1C, in the baseline assessment 45.0% of patients had value of more than or equal 8%, while in the second assessment; 47.5% of them had value more than or equal 8%.

Concerning to the presence of signs and symptoms of hyperglycemia, the majority of patients (90.8%) had tachycardia, followed by 88.3%, 42.5%, 37.5%, with thirst, general weakness, abdominal pain, in baseline second assessments; the and respectively. As regards to the total classifications of hvperglycemia manifestations, in baseline assessment more than half of diabetic patients (52.5%) had moderate hyperglycemia, while 51.75% of diabetic patients had moderate hyperglycemia the second assessment.

Regarding to the **presence of signs** and symptoms of hypoglycemia it was noticed that, in the baseline assessment the majority of diabetic patients (87.5%) had headache, followed by 71.7%, 60.8%, 58.3%, with anxiety, visual disturbance, sweating; respectively. While in the second assessment; 88.3% of patients had headache followed by 71.7%, 61.7%, 57.5%, with anxiety, visual disturbance, sweating; respectively. Also

related to the **total classifications of hypoglycemia manifestations;** in baseline assessment about two third of diabetic patients (55.8%) had moderate hypoglycemia, while 56.7% of patients had moderate hypoglycemia in the second assessment.

This table shows that there was no statistical significant difference between both baseline and second assessments regarding diabetic patients' glycemic control parameters; except, for FBG and RBG levels representing MH 4.822*, 4.213* at P 0.001*, 0.013*; respectively.

Table 2: Shows Comparison between Baseline and Second Assessment Data of the Global Pittsburgh Sleep Quality (PSQI) Components Score among the Diabetic Patients.

Regarding the global score of PSQI in the baseline assessment; less than half of patients (40.0%) had moderate severe difficulties, followed by one third with moderate difficulties, and one quarter (25.0%) had severe difficulties in all areas of sleep quality; respectively. Furthermore in the second assessment one month thereafter; less than half of the patients (43.3%) had moderate difficulties in all areas of sleep quality, followed by two fifth had moderate severe difficulties, while 40.0%, and 10.8% of patients had severe difficulties; respectively.

A statistical significant difference was declared between the baseline and second assessments at (P=< 0.001*), with a total Mean \pm SD percent score representing 58.85 \pm 18.10 and 50.82 \pm 15.99; respectively.

Table 3: Relationship between Global Pittsburgh Sleep Quality Index Components Score and Glycemic Control Parameters among Baseline and Second Assessment.

In relation to glycated hemoglobin HbA1C it was noticed that; in the baseline assessment about two fifth of the patients

(40.0%) had mild difficulties PSQI score illustrated by normal glycemic control (HbA1C= 4%- less than 6%). While in the second assessment 61.5% of diabetic patients who had severe difficulties in PSQI score represented by poor glycemic control (HbA1C= 8% or more).

As regard **fasting blood glucose level** in the baseline assessment; more than half of studied patients (60.0%) and all the diabetic patients (100.0%) had mild difficulties PSQI score illustrated by high blood glucose level 120—less than 250 mg/dl. Concerning **random blood glucose level** in the baseline assessment the majority of the diabetic patients (80.0%) and all the diabetic patients (100.0%) had mild difficulties PSQI score represented by sever high blood glucose 200—260 mg/dl.

Regarding total classifications of hyperglycemia manifestations the baseline assessment more than half of the studied diabetic patients (60.0%) had mild difficulties PSQI score were suffering from moderate hyperglycemia, while in the second assessment 55.8% of the studied patients who had moderate difficulty PSQI score were suffering from moderate hyperglycemia. Concerning total classifications hypoglycemia manifestations it was noticed that, more than half of the studied patients who had moderate difficulties PSQI score were suffering from moderate hypoglycemia in the baseline and second assessment 64.9%, 65.4%; respectively.

This table clarified a statistically significant relation between global PSQI components score and HbA1C in the baseline

This result is supported by **Turin et al., (2021)** who reported that; the majority of their studied patients had poor glycemic control. Also, they mentioned that diabetic patients need to improve their QoS, QoL and adhere to routine management of diabetes care. Thus, these patients must have adequate

and second assessment represented by p=0.008*, 0.029*; respectively.

However, no statistically significant relation between global score of Pittsburgh sleep quality index components and other glycemic control parameters was declared.

Discussion:

Type I diabetes mellitus is an emerging global issue; in which the relationship between sleep quality and glycemic control in TIDM is inconsistent. Where, inadequate or poor quality sleep is associated with higher HbA1c levels and greater glycemic variability suggesting a bidirectional relationship between sleep and glycemic control (Farooque et al., 2020; Suteaua et al., 2020; Malone et al., 2021).

In the present study variation was noticed in glycemic control parameters (fasting blood glucose, random blood glucose) during the base line and second assessment; reflecting alteration of all glycemic control parameters linked with repeated attacks of hypo and hyperglycemia. Also, there were an observed variation in subjective sleep quality, sleep duration, habitual sleep efficiency and sleep disturbances between the baseline and second data of the research assessment; where more than half of studied patients suffered from poor QoS ranged from moderate to moderate severe difficulties in all area of sleep quality. In addition, there were a significant relation between the global PSQI components score and the HbA1C level in the baseline and second researcher's assessment.

knowledge and taught to use effective QoL practices to improve the factors affecting their self-care management and controlling their blood glucose level. Also **Griggs etal.**, (2020) reported that; there was an association between glucose variability and sleep disruptions in TIDM patient. On the other

hand this finding contradicts the study by **Lee et al.,(2017)** who reported that; there were no significant association between HbA1C and sleep disturbance. Moreover **Tan et al.,(2018)** stated that; no association between sleep duration and HbA1C levels.

The present study showed also, a statistically significant relation between "global Pittsburgh sleep quality index components score and glycosylated hemoglobin (HbA1C)" in the baseline and second assessments. The reason from the researcher point of view might be related to; the fact that DM symptoms or complications such as nocturia, polyuria, diabetic neuropathy, neuropathy pain, and depression, all of which can affect QoS causing sleep disturbance. This explains why the researcher conducted the evaluation for HbA1C twice over a two-month period rather than just once.

Conclusion:

In the present study variation was noticed in glycemic control parameters during the baseline and second assessment; reflecting alteration of all glycemic control parameters. Also, there were a variation in subjective sleep quality, sleep duration, habitual sleep efficiency and sleep disturbances between the baseline and second data of the research assessment; where more than half of studied patients suffered from poor OoS ranged from moderate to moderate severe difficulties in all area of sleep quality. In addition, there were a significant relation between the global PSQI components score and the glycemic parameter HbA1C level in the baseline and second researcher's assessments.

This finding also agrees with **Rose et al., (2021)** who stated that; diabetes and sleep disturbance are closely associated with each other. However, this finding is contradicted with **Narisawa et al., (2017)** who declared that; HbA1c was not associated with sleep disturbance or insomnia in TIDM patients.

Nevertheless, the relation between poor QoS and glycemic control in TIDM is complex and bidirectional; where poor sleep quality is associated with suboptimal glycemic control parameters namely: HbA1C; thus sleep optimization can improve glycemic control. Where, sleep assessment among patients with TIDM must be performed being one of the vital diabetic medical and nursing management.

Recommendations:

- 1. Diabetic patients' should be involved in diabetes control program concerning: compliance with medical regimen, importance of periodical follow up, diet, exercise, warning signs of hypoglycemia or hyperglycemia and daily healthy sleep habits; which should initiated as early as possible to improve patient's QoL.
- 2. Health care facilities have to organize workshops for nurses about type of insulin, and the effect of over countered medications on QoS among diabetic patient.
- Nurses should be aware of the consequences and the measures to control poor QoS as well as the poor glycemic control on their patients' health and QoL.

Figure 1: Frequency Distribution of the Diabetic Patients according to their Sociodemographic and Clinical Data.

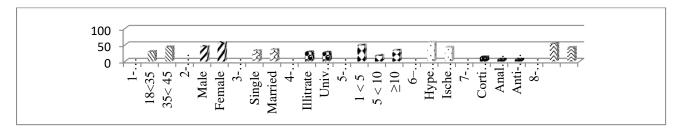


Table (1): Comparison between Baseline and Second Assessment Data of the Glycemic Control Parameters among the Diabetic Patients (n=120)

Glycemic control parameters		eline sment	Second as	ssessment	Test of sig.	р	
	No.	%	No.	%			
1-Fasting blood glucose (mg/dl)							
a) 50 < 60mg/dl (hypoglycemia)	13	10.8	6	5.0			
b) 60 <120 mg/dl (euglycemia)	39	32.5	28	23.3	MH= 4.822*	0.001*	
c) 120 < 250 mg/dl (high blood glucose level)	43	35.8	53	44.2	MH= 4.822	0.001	
d) ≥ 250mg/dl(hyperglycemia)	25	20.8	33	27.5			
2-Random blood glucose (mg/dl)							
a) 100< 150 mg/dl (normal blood glucose level)	19	5.8	11	9.2			
b) 150 <200 mg/dl(high blood glucose level)	36	30.0	31	25.8	MH=	0.013^{*}	
c) 200 – 260 mg/dl(severe high blood glucose level)	65	54.2	78	65.0	4.213*		
3-Glycosylated hemoglobin level measurement (HbA1C)							
a) 4% < 6% (normal glycemic control)	19	15.8	17	14.2			
b) 6% < 8% (good glycemic control)	47	39.2	46	38.3	MH= 2.784	0.369	
c) 8% or more (poor glycemic control)	54	45.0	57	47.5			
4-Presence of signs and symptoms of hyperglycemia							
a) Tachycardia	109	90.8	109	90.8	McN	1.000	
b) Thirst	106	88.3	106	88.3	McN	1.000	
c) General weakness	51	42.5	51	42.5	McN	1.000	
d) Abdominal pain	45	37.5	45	37.5	McN	1.000	
e) Loss of appetite	41	34.2	41	34.2	McN	1.000	
f) Dry mouth	39	32.5	39	32.5	McN	1.000	
g) Confusion	39	32.5	39	32.5	McN	1.000	
h) Dyspnea	38	31.7	38	31.7	McN	1.000	
i) Polyuria	37	30.8	37	30.8	McN	1.000	
j) Vomiting	36	30.0	36	30.0	McN	1.000	
k) Dry skin	27	22.5	24	20.0	McN	0.453	
1) Fruity odor on the breath	14	11.7	14	11.7	McN	1.000	
Total classifications of hyperglycemia manifestations	2.4	20.2	2.5	20.2			
a) Mild hyperglycemia (1-3)	34	28.3	35	29.2	100	0.754	
b) Moderate hyperglycemia (4-6)	63	52.5	62	51.7	MH = 4.500	0.564	
c) Severe hyperglycemia q(≥7)	23	19.2	23	19.2			
5-Presence of signs and symptoms of hypoglycemia	105	07.5	106	00.2	MAY	1.000	
a) Headache	105 86	87.5 71.7	106	88.3 71.7	McN McN	1.000 1.000	
b) Anxiety c) Visual disturbances	86 73	60.8	86 74	61.7	McN McN	1.000	
d) Inability to concentrate	70	58.3	69	57.5	McN	1.000	
e) Sweating	50	36.3 41.7	50	41.7	McN	1.000	
f) Lethargy	51	42.5	51	42.5	McN	1.000	
g) Restlessness	46	38.3	45	37.5	McN	1.000	
h) Weakness	44	36.7	44	36.7	McN	1.000	
i) Hunger	43	35.8	42	35.0	McN	1.000	
j) Tremulousness	40	33.3	40	33.3	McN	1.000	
k) Palpitations	36	30.0	36	30.0	McN	1.000	
Nausea& vomiting	7	5.8	7	5.8	McN	1.000	
m) Seizures	4	3.3	4	3.3	McN	1.000	
Total classifications of hypoglycemia manifestations					-		
a) Mild hypoglycemia (1-3)	20	16.7	20	16.7		0.317	
b) Moderate hypoglycemia (4-6)	67	55.8	68	56.7	MH=2.500		
c) Severe hypoglycemia (≥7)	33	27.5	32	26.7	WIII-2.500		

^{*:} Statistically significant at $p \le 0.05$

MCN: McNemar Test

MH: Marginal Homogeneity Test

Table (2): Comparison between Baseline and Second Assessment Data of the Global Pittsburgh Sleep Quality (PSQI) Components Score among the studied Diabetic Patients (n=120)

CILLING I I I I I I I I I I I I I I I I I I	Baseline	assessment	Second	assessment	T		
Global Pittsburgh sleep quality index score	No.	%	No.	%	Test of sig.	p	
a) No difficulty (zero)		-	-	-			
b) Mild difficulty (1-5)	5	4.2	7	5.8	MH= 174.000*	<0.001*	
c) Moderate difficulty(6 - 10)	37	30.8	52	43.3	174.000		
d) Moderate severe difficulty (11 - 15)	48	40.0	48	40.0			
e) Severe difficulty (16 - 21)	30	25.0	13	10.8			
Total score Mean ±SD.	12.36 ±3.80		10.68 ±3.36		t=6.323*	<0.001*	
Total Percent score Mean ±SD.	58.85	±18.10	50.82	±15.99			

Table (3): Relationship between Global Pittsburgh Sleep Quality Index Components Score and Glycemic Control Parameters among Baseline and Second Assessment. (n = 120)

						Global	Pittshu	rah Slee	n anality	v score (PSOI)											
	Global Pittsburgh Slee Baseline assessment						Second assessment															
Glycemic control parameters	Mild difficulty (1 - 5) (n = 5)		Moderate difficulty (6 – 10) (n = 37)		Moderate severe difficulty (11 – 15) (n = 48)		Severe difficulty (16 – 21) (n = 30)		Mild difficulty (1 - 5) (n = 7)		Moderate difficulty (6 – 10) (n = 52)		Moderate severe difficulty (11 – 15) (n = 48)		Severe difficulty (16 – 21) (n = 13)							
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%						
Fasting blood glucose level (mg/dl) a) 50<60 mg/dl	-	1	2	5.4	4	8.3	7	23.3	_	-	1	1.9	5	10.4	-							
b) 60<120 mg/dl c) 120<250 mg/dl d) ≥ 250mg/dl	2 3 -	40.0 60.0	18 13 4	48.6 35.1 10.8	12 18 14	25.0 37.5 29.2	7 9 7	23.3 30.0 23.3	- 7 -	100.0	13 26 12	25.0 50.0 23.1	12 16 15	25.0 33.3 31.3	3 4 6	23.1 30.8 46.2						
2/MC \											14 (22)	0.064										
χ ² (^{MC} p)		14.316(0.084)								ı		14.633(0.064)	I	1							
2-Random blood glucose level (mg/dl)																						
a) 100< 150 mg/dl b) 150 <200 mg/dl c) 200 - 260 mg/dl	1 - 4	20.0	6 11 20	16.2 29.7 54.1	6 16 26	12.5 33.3 54.2	6 9 15	20.0 30.0 50.0	- - 7	- 100.0	3 13 36	5.8 25.0 69.2	6 14 28	12.5 29.2 58.3	2 4 7	15.4 30.8 53.8						
$\gamma^2(^{MC}p)$		3,239(0,793)							100.0	50	6.062(30.3	,	33.0							
3- Glycosylated hemoglobin				0.207(0.770)							0.002(
level measurement (HbA1C)																						
a) 4% < 6% b) 6% < 8% c) 8% or more	2 2 1	40.0 40.0 20.0	11 13 13	29.7 35.1 35.1	6 17 25	15.5 35.4 52.1	- 15 15	50.0 50.0	1 5 1	14.3 71.4 14.3	13 17 22	25.0 32.7 42.3	2 20 26	4.2 41.7 54.2	1 4 8	7.7 30.8 61.5						
$\chi^2(\mathbf{p})$	15.857*(MCp= 0.008*)							13.325*(MCp=0.029*)														
4-Total classifications of hyperglycemia manifestations					•								Î									
a) Mild (1-3) b) Moderate (4-6) c) Severe (≥7)	2 3	40.0 60.0	11 22 4	29.7 59.5 10.8	15 22 11	31.3 45.8 22.9	6 16 8	20.0 53.3 26.7	2 3 2	28.6 42.9 28.6	15 29 8	28.8 55.8 15.4	13 26 9	27.1 54.2 18.8	5 4 4	38.5 30.8 30.8						
$\chi^2(^{MC}\mathbf{p})$	5.295 (0.492)						4.094 (0.669)															
5-Total classifications of hypoglycemia					/																	
manifestations																						
a) Mild (1-3) b) Moderate (4-6) c) Severe (≥7)	3 2	60.0 40.0	5 24 8	13.5 64.9 21.6	8 24 16	16.7 50.0 33.3	4 17 9	13.3 56.7 30.0	3 1 3	42.9 14.3 42.9	7 34 11	13.5 65.4	7 26	14.6 54.2	3 7 3	23.1 53.8						
c) Severe (≥ 7) $\chi^2(^{MC}\mathbf{p})$	7.445 (0.250)						3	42.9	11	21.2 15 31.3 3 23.1 8.599 (0.165)												

χ²: Chi square test

MC: Monte Carlo

^{*:} Statistically significant at $p \le 0.05$

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