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Relation Between Quality Of Sleep Habits And Glycemic Control Among Insulin Dependent Diabetes Mellitus Patients

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Abstract:
Type I diabetes mellitus is an emerging public health issue. The relationship between sleep quality and glycemic control in TIDM is inconsistent; that inadequate or poor quality sleep is associated with higher HbA1c levels and greater glycemic variability. Conversely, altered glucose metabolism may affect sleep quality, suggesting that; there is a bidirectional relationship between sleep and DM. Aim of the study: Assess the quality of sleep habits among type I diabetes mellitus patients and assess the relation between quality of sleep habits and glycemic control among insulin dependent diabetes mellitus patients. 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 [1]Clinic at Makkah hospitals, Saudi Arabia. Subjects: A convenience sample of 120 adult patients (18-60 year) with type I diabetes mellitus. Three tools were utilized by the researcher for data collection. Bio-sociodemographic and Clinical Data Structured Interview Schedule, Parameters for Glycemic Control Sheet and Pittsburgh Sleep Quality Index (PSQI). Results: The result of the present study revealed that more than half of studied patients suffered from poor QoS ranged from moderate to moderate sever 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. Conclusion: This study concluded that IDDM patients are more susceptible to poor sleep quality even it linked with poor glycemic control.

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

Introduction:

Diabetes mellitus (DM) is a universal health condition; that influences not only the individual's health, but also causes work boundaries as well as diminished quality of life

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(QoL) index, and life expectancy **(Alam., 2020).** In 2019, 463 million individuals were anticipated to have diabetes **(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 & Cheever., 2018)**.

Researchers reported that; the presence of interacting factors which markedly affect the glycemic control in diabetic patients; one of these factors is the quality of sleep (QoS). Furthermore, recent researches declared a bidirectional relation between sleep and glycemic control in patients with DM **(Monzon et al., 2019; Perez et al., 2018; Frye et al., 2019).**

Sleep is a fundamental biological process that has been associated with the physiological, psychological, and neurological systems of well beings; it plays a key role in maintaining our physical and mental health. Generally, most healthy adults need to sleep seven to nine hours per night. The sleep state itself has modulatory effects on glucose homeostasis. Leptin hormone also is secreted during sleep by the fat cells in adipose tissue and acts as a satiety moderator balancing out the need for food intake and energy consumption **(Corbalán-Tutau et al., 2014; Kanda et al., 2016; Ojile., 2017; Friedman., 2019).**

Sleep deprivation induces hypersecretion of leptin; which inturn increases food intake, especially carbohydrates, that can predispose or aggravate to obesity. On the other hand; obesity increases susceptibility to DM **(Kanda et al., 2016; Ojile., 2017; Friedman., 2019).**

In patients with DM, the impact of sleep behavior on metabolic states requires further investigations; because these patients with less sleeping hours at night were reported to have poor glycemic control. Experimental studies illustrated that; sleep loss and sleep disturbances are detrimental to metabolic function and may predispose to obesity or glucose intolerance **(Vargas et al., 2014; Larcher et al., 2015; Von Schnurbein et al., 2018).**

Nevertheless; the bidirectional DM and sleep relation appears if; the compromised sleep quality interrupts sufficient glycemic control, producing hypoglycemia, hyperglycemia and metabolic syndrome; affecting these individuals health-related QoL. Evidences shows that; symptoms associated with TIDM, such as thirst, nocturia, extreme glucose excursions, and mood alterations, may interfere with sleep quality contributing to sleep fragmentation **(Surani et al., 2015; Aleem et al., 2018; Macaulay et al., 2020)**.

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

Aim of the study:

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:

3. What are the quality of sleep habits among insulin dependent diabetes mellitus patients?

4. What are the relation between quality of sleep habits and glycemic control among insulin dependent diabetes mellitus patients?

Methodology:

Materials

Research 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 Makkah hospitals, Saudi Arabia.

Subjects:
A convenience sample of 120 adult patients (18-60 year) with type I diabetes mellitus presented to the above mentioned setting; comprised the study subjects. They were enrolled in the study based on Epi info-7 programme using the following parameter:

1. The estimated sample size:120 patients
2. Expected frequency:50%
3. Acceptable error:10%
4. Confident coefficient:99%
5. Minimum sample size:37 patients

Patients participating in the study met the following inclusion criteria:

1. Free from psychological disorders(stress-anxiety),
2. Have controlled associated chronic conditions, i.e. hypertension, respiratory disorders …etc.
3. 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 **(Borel et al., 2013; 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 and 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, anti-arrhythmic, 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, random blood glucose level, glycated hemoglobin measurement (HbA1C), signs and symptoms of hyperglycemia occurrence, as well as signs and symptoms of hypoglycemia occurrence.

Tool III: Pittsburgh Sleep Quality Index (PSQI): This tool was adopted from **Buysse et al., 1989;** it consisted of 24 questions; from which 19 are self-rated questions aimed to assessing quality of sleep habits during the last month only 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. It also included "5" questions are rated by the bed partner or roommate (if one is available).

1- Self-rated questions:

A. **Subjective sleep quality:** It was assessed through asking the patient one question **(question number 6)** about "How would rate their sleep quality overall", responses were rated from "zero to 3" .
B. **Sleep latency:** This was collected by the researcher through asking the patient two questions: the first one is **(question number 2)** about "How long does it usually take to fall asleep each night", which was rated from "zero to 3" and each response. While the second question was **(question number 5A)**, that was directed to ask patient about "How often have you had trouble sleeping because you cannot get to sleep within 30 minutes", that similarly was rated from "zero to 3". After that; the results of the two questions **(2& 5A)** have been added and summed together to be assigned a score for sleep latency.
C. **Sleep duration:** It was assessed through asking the patient one question **(question number 4)**, about "How many hours of actual sleep did he/she get at night" patients responses were rated from "zero to 3".
D. **Habitual sleep efficiency:** This was examined by asking the patients three questions. Firstly the researcher asked the patient **(question number 1)** about "When have you usually gone to bed at night", and documented the bedtime. Then the researcher asked the patient "When have you usually gotten up in the morning", and calculated the number of hours spent in bed by writing the getting up time; which is related to **(question number 3).** After that the patient was asked about "How many hours of actual sleep did you get at night" where the patients wrote the number of hours slept at night; that was related to **(question number 4).** Thereafter the researcher calculated habitual sleep efficiency by dividing the number of hours the patients actually slept on the number of hours spent in bed; multiplied in 100 to represent score in percentage. (Number of hours actually slept / number of hours spent in bed) × 100 = habitual sleep efficiency (%).
E. **Sleep disturbances:** This component was assessed through asking the patients nine questions namely; **(questions from 5b to 5j)**, which regarding "How often have they had trouble sleeping because of "waking up in the middle of the night or early morning", "have to get up to use the bathroom", "cannot breathe comfortably", "cough or snore loudly", "feel too cold", "feel too hot", "had bad dreams", "have pain" and "Other reasons, describing how often during the past month have he/she had trouble sleeping because of this". These nine questions responses were rated from "zero-3". Thereafter these nine questions scores were added and summed to be rated from "zero-3".

F. **Use of sleeping medication:** This item's data was collected through asking **(question number 7)** to the patient regarding "How often has he/she taken medicine (prescribed or "over the counter") to help your sleep". Each response was rated from "zero-3".
G. **Day time dysfunction:** This item's data was collected through asking two questions **(question number 8 & 9).** As regard to **(question number 8)** that where the researcher asked the patient about "How often has he/she had trouble staying awake while driving, eating meals, or engaging in social activity?"**.** The question response was rated from "zero-3. While **(question number 9)** namely, "How much trouble has it been for him to keep up enough enthusiasm to get things done?". Each response for this question was rated from "zero-3. Then the researcher added the scores of both (questions 8 and 9) to estimate a total day time dysfunction assigned score; which was rated from "zero-3.

2- Bed partner or roommate questions: If the patients had a roommate or bed partner, they were asked five questions about how often in the past month the patient has had loud snoring, long pauses between breaths while asleep, legs twitching or jerking while you sleep, episodes of disorientation or confusion and other restlessness while your sleep. Each response was rated from "zero-3".

The global Scoring System for (PSQI): The Pittsburgh Sleep Quality Index (PSQI) contains 24 questions; Only the self-rated questions were included in the study. As mentioned; the 19 self-rated items were combined to form seven components scores, each of which has a range of "zero-3 points". In all cases, a score of "zero indicates no difficulty", while a score of "3 indicates severe difficulty". The seven components scores were then added to yield "One global score", with a range of "0-21 points", where:

- "zero" indicates "No difficulty", and
- "21" indicating "Severe difficulties in all areas".

-Finally; "the global Pittsburgh Sleep Quality Index (PSQI) score" was estimated through adding; the seven components scores together. However; the researcher of the current study has developed her own subsceling 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 sever difficulties in all areas" and
- "21" indicates "Severe difficulties in all areas".

Method

Written Approval:

An official permission to collect data was obtained from ethical research committee

Tool development:

Tool I was developed and translated into Arabic language by the researcher based on a review of the relevant literature to collect data about the patient's socio-demographic,

as well as clinical data. As well; the **tool II** which aimed to collect data about the patient's blood glucose level as well as signs and symptoms of glucose variability; it was developed and translated into Arabic language by the researcher based on a review of the relevant literature. Moreover; **tool III** was adopted from **Buysse et al., 1989**, and its Arabic version was adopted from **Suleiman et al., 2010.**

Testing of content validity:

The developed tools were submitted to a jury of five experts in the field, to assure the content validity, completeness and clarity of items, appropriateness of translations and applicability.

Reliability testing:

The study tool II was tested for its reliability on a sample of 10% of patients using Alpha Cronbach's statistical test for measuring the internal consistency of tool's items.; the correlation coefficient was (α=0.708), so it was reliable. Secondly Pittsburgh Sleep Quality Index tool III English version by **Buysse et al., 1989** internal consistency of items was (0.83), indicating high correlation and statistically reliable. While tool III Pittsburgh Sleep Quality Index (PSQI) was reassessed for items' internal consistency using Alpha Cronbach's statistical test (=0.757) due to the researcher modification of the scoring system.

Pilot study:

Before conducting the actual study, a pilot study was carried out on 10% of the study patients (12 patients) in the both the Medical Departments and Medical Outpatient Clinic at Makkah Hospital; to ascertain the clarity and applicability of the study tools and to identify obstacles that may be faced during data collection. However; these patients were not included within the actual study subjects. Based on the findings of the jury's comments and the pilot study; some questions of the tools were clarified, others were added and others were omitted.

Data collection:

The data collection was initiated covering a period of 9 months (from March 2022 to December 2022).

Steps of the study:

1. The total subjects were randomly enrolled consisting of 120 adult TIDM patients who met the study's inclusion criteria. they were interviewed twice as follows: The first interview was conducted at the Inpatient Medical Departments, however, if patients were not accessible in the Inpatient Department it was conducted at the Medical Outpatient Clinic. While the second interview took place at the Medical Outpatient Clinic; one month thereafter.

2. Patients both interviews was conducted by the researcher (individually in a separate meetings room) utilizing tool I, II and III at the above mentioned setting to collect patient's bio-sociodemographic data, assess their blood glucose level, and assess patient's quality of sleep habits during the last month; respectively.

3. In the first interview data collection started by reviewing patient's records using **tool I**, in the morning shifts to collect patient's bio-sociodemographic data if the patient was hospitalized in the Inpatient Medical Departments; or by face to face meeting asking

questions to the patient and their family; if the patients were met at the Medical Outpatient Clinic.

4. However, the researcher collected the necessary data included in **tool II** as follows:

   - 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 result.

   - Then the researcher sent it to the lab for estimating the glycosylated hemoglobin (HbA1C) score.

   - 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.

5. Moreover in both first and second interviews; the researcher asked each patient about quality of sleep domains in **tool III**. The duration for collecting each tool's data took approximately from 15-20 minutes. Moreover; if the patient has a roommate or bed partner, the researcher asked him/ her five questions in the PSQI about "How often in the past month the patient has had sleeping trouble". In addition the researcher was available for extra 10-15 minutes to clarify any patients and family questions.

6. The researcher pact with the patient about the importance and the date for attending one month thereafter to assess patient's glycemic control parameters and quality of sleep.

7. Moreover, the researcher took patient's phone number and connected with each patient the day before the scheduled time to confirm the second interview date.

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

Ethical Considerations:

Informed written consent was obtained from patients participating in the study after explanation of the study aims. Each patient had the right to withdraw at any time for the study without any drawbacks. Patient privacy was assured and the purposes of the study were explained to all the studied patients stressing confidentiality and anonymity of the collected data for each patient was ascertained and assuring the ethics in conducting the research. This helped to ensure their cooperation and gaining the confidence.

Statistical Analysis:

- After data collection, data was coded and transferred into a specially designed format so as to be suitable for computer feeding. Following data entry, checking and verification processes were carried out to avoid errors during data entry.

- Data were fed to the computer and analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp) (Qualitative data were described using number and percent. Kolmogorov-Smirnov test was used to verify the normality of distribution 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:

Table 1: Frequency Distribution of the Diabetic Patients According to their Sociodemographic Data (n=120)

Regarding **age**, it was noticed that, more than one third of the patients (43.3%) were between 35<45 years, while 29.2% were in the age group (18<35) years, and only 27.5 % were in the age group 45≤60 years. In relation to **gender** it was found that, more than half of the diabetic patients (55.8%) were females. When considering **marital status**, diabetic patients the highest percentages were married represented by 35%, followed by single (31.7%). Concerning the **educational level** it was evident that, almost an equal proportion of the diabetic patients (27.5%, 26.7%) were illiterate and university education; respectively.

In relation to patients' **income** it was found that, the majority of the diabetic patients had enough income representing (98.3%). While concerning **area of residence** it was found that, more than half of patients lived in rural area (56.7%). Regarding **occupation**, about two thirds were not working (61.7%), while 26.0% were self-employed.

Additional data were revealed that; in relation to **number of years with diabetes** it was noticed that, approximately half of patients (49.2%) were ranging from 1-less than 5 years, while 33.3% were in the diabetic patients (equal or more than 10 years), and only17.5% were ranging from 5-less than 10 years; with a Median of 6.0 years. Concerning patients' **health history related to associated diseases** it was observed that, more than half of patients (57.5%) had Hypertension, followed by had 42.5% Ischemic heart disease, and almost an equal proportion 39.2% & 38.3% had Retinopathy and Respiratory disease; respectively.

In relation to patients' **health history of over the counter medications**, it was found that 12.5% of patients takes Corticosteroids and equal proportion 5.8% Antiarrhythmic and Analgesics; respectively. Concerning **prescribed medication** it was found that, more than half of diabetic patients were on Mixtard representing (52.5%), with Mean ± SD of insulin dose 33.84 ± 10.86 on frequency of two to three times per day, followed by Lantus 41.7% with Mean ± SD of insulin dose 14.70 ± 6.73 on frequency of one to two times per day; and Apidra insulin 29.2% with Mean ± SD of insulin dose 34.06 ± 15.67 on frequency of two to three times per day; respectively.

Sociodemographic data	No.	%
1-Age (years)		
18<35	35	29.2
35< 45	52	43.3
45≤60	33	27.5
2-Gender		
Male	53	44.2
Female	67	55.8
3-Marital status		
Single	38	31.7

Married	42	35.0
Divorced	17	14.2
Widow	23	19.2
4-Level of education		
Illitrate	33	27.5
Primary	14	11.7
Preparatory	18	15.0
Secondary	23	19.2
University	32	26.7
5-Income		
Enough	118	98.3
More than enough	2	1.7
High	0	0.0
6-Area of residence		
Urban	68	56.7
Rural	52	43.3
7-Occupation		
No work	74	61.7
Self-empolyment	33	27.5
Employee	13	10.8

Table (2): Comparison between Baseline and Second Assessment Data of the Glycemic Control Parameters among the Diabetic Patients (n = 120)

According to **fasting blood glucose level** it was observed that, in the baseline assessment more than one third of diabetic patients 35.8% had value of 120 less than 250mg/dl, followed by 32.5%, 20.8% with value of 60-less than 120 mg/dl and equal or more 250mg/dl; respectively. While regarding the second assessment, 44.2% of patients had value 120-less than 250mg/dl followed by 27.5%, 23.3% representing equal or more 250mg/dl and 60-less than 120mg/dl; respectively.

Regarding to **random blood glucose level** it was noticed that, in the baseline assessment more than half of diabetic patients 54.2% had value of 200-260mg/dl, followed by 30.0%, 5.8% with value of 150-less than 200mg/dl and 100-less than 150mg/dl; respectively. While regarding the second assessment, approximately two thirds of diabetic patients 65.0% had value 200-260mg/dl, followed by 25.8%, 9.2% representing 150-less than 200mg/dl and 100-less than 150mg/dl; respectively.

Concerning to **glycated hemoglobin HbA1C** it was observed that, in the baseline assessment 45.0% of diabetic patients had value of more than or equal 8%, followed by 39.2%, 15.8% with value of 6%-less than 8% and 4%-less than 6%; respectively. While in the second assessment, 47.5% of diabetic patients had value more than or equal 8% followed by 38.3%, 14.2% representing 6%-less than 8% and 4%-less than 6%.

Concerning to the **presence of signs and symptoms of hyperglycemia** it was observed that, the majority of diabetic patients (90.8%) had tachycardia, followed by 88.3%, 42.5%, 37.5%, 34.2%, 32.5%, 31.7%, 30.8%, 30.0% with thirst, general weakness, abdominal pain, loss of appetite, dry mouth, confusion, dyspnea, polyuria, and vomiting with an equal proportion in the baseline and second assessment ; respectively. As regards to **the total classifications of hyperglycemia manifestations** it was showed that, in baseline assessment more than half of diabetic patients (52.5%) had moderate hyperglycemia, followed by 28.3%, 29.2% with mild hyperglycemia and severe hyperglycemia; respectively. While regarding the second assessment 51.75% of diabetic patients had moderate hyperglycemia followed by 29.2%, 19.2% with mild hyperglycemia and severe hyperglycemia; respectively.

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%, 41.7%, 42.5%, 38.3%, 36.7%, 35.8%, 33.3%, 30.0% with anxiety, visual disturbance, sweating, lethargy, restlessness, weakness, hunger, tremulousness and palpitations; respectively. While regarding the second assessment 88.3% of diabetic patients had headache followed by 71.7%, 61.7%, 57.5%, 41.7%, 42.5%, 37.5%, 36.7%, 35.0%, 33.3%, 30.0% with anxiety, visual disturbance, sweating, lethargy, restlessness, weakness, hunger, tremulousness and palpitations; respectively.

Moreover, related to the **total classifications of hypoglycemia manifestations** it was observed that, in baseline assessment about two third of diabetic patients (55.8%) had moderate hypoglycemia, followed by 27.5%, 16.7% with severe hypoglycemia and mild hypoglycemia; respectively. While regarding second assessment 56.7% of diabetic patients had moderate hypoglycemia followed by 26.7%, 16.7 with sever hypoglycemia and mild hypoglycemia; respectively.

This table shows that there was no statistical significant difference between both baseline and second assessment regarding diabetic patients glycemic control parameters; except, fasting blood glucose and random blood glucose levels representing MH 4.822 , 4.213 at P 0.001, 0.013; respectively.

Glycemic control parameters	**Baseline assessment**		**Second assessment**		**Test of sig.**	**p**
	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		
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= 4.213*	0.013*

c) 200 – 260 mg/dl(severe high blood glucose level)	65	54.2	78	65.0		
3-Glycated hemoglobin 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
l) Fruity odor on the breath	14	11.7	14	11.7	McN	1.000
Total classifications of hyperglycemia manifestations						
a) Mild hyperglycemia (1-3)	34	28.3	35	29.2		
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						
a) Headache	105	87.5	106	88.3	McN	1.000
b) Anxiety	86	71.7	86	71.7	McN	1.000
c) Visual disturbances	73	60.8	74	61.7	McN	1.000
d) Inability to concentrate	70	58.3	69	57.5	McN	1.000

e) Sweating	50	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
l) 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	MH=2.500	0.317
b) Moderate hypoglycemia (4-6)	67	55.8	68	56.7		
c) Severe hypoglycemia (≥7)	33	27.5	32	26.7		

Table (3): Comparison between Baseline and Second Assessment Data of the Global Pittsburgh Sleep Quality (PSQI) Components Score among the Diabetic Patients (n = 120)

Regarding the global score of PSQI it was noticed that, in the baseline assessment less than half of diabetic patients (40.0%) had moderate severe difficulties in all areas of sleep quality (11-15), followed by one third of patients (30.8%) who had moderate difficulties in all areas of sleep quality (6-10), and one quarter (25.0%) who had severe difficulties in all areas of sleep quality (16-21); respectively.

Furthermore this table shows that, in the second assessment one month thereafter less than half of the patients (43.3%) had moderate difficulties in all areas of sleep quality (6-10), followed by two fifth had moderate severe difficulties in all areas of sleep quality (11-15), while 40.0%, and 10.8% of patients had severe difficulties in all areas of sleep quality (16-21); respectively.

As regards global score of Pittsburgh sleep quality index, this table clarifies a statistical significant difference between the baseline and second assessment at (P=< 0.001*), with a total Mean ± SD percent score in baseline and second assessment representing 58.85 ± 18.10 and 50.82 ± 15.99; respectively.

Global Pittsburgh sleep quality index score	**Baseline assessment**		**Second assessment**		**Test of sig.**	**p**
	No.	**%**	**No.**	**%**		
a) No difficulty (zero)	-	-	-	-	MH= 174.000*	<0.001*
b) Mild difficulty (1-5)	5	4.2	7	5.8		
c) Moderate difficulty(6 - 10)	37	30.8	52	43.3		

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 (4): Relation between Global Pittsburgh Sleep Quality Index Components Score and Glycemic Control Parameters among Baseline and Second Assessment.

It was noticed that, in the baseline assessment about two fifth of the diabetic 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** it was observed that, in the baseline assessment more than half of diabetic 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** it was noticed that, 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** it was observed that, in the baseline assessment more than half of the diabetic patients (60.0%) had mild difficulties PSQI score was severing from moderate hyperglycemia, while in the second assessment 55.8% of diabetic patients who had moderate difficulty PSQI score was suffering from moderate hyperglycemia.

Concerning **total classifications of hypoglycemia manifestations** it was noticed that, more than half of the diabetic patients had moderate difficulties PSQI score was suffering from moderate hypoglycemia in the baseline and second assessment 64.9%, 65.4%; respectively. This table clarified that there were statistically significant relation between global Pittsburgh sleep quality index components score and glycated hemoglobin (HbA1C) in the baseline and second assessment represented by p=0.008*, 0.029*; respectively.

This table clarified that, there were no statistically significant relation between global score of Pittsburgh sleep quality index components and other glycemic control parameters namely; total classifications of hyperglycemia manifestations, total classifications of hypoglycemia manifestations, fasting blood glucose level and random blood glucose level.

Glycemic control parameters	**Global Pittsburgh Sleep quality score (PSQI)**															
	Baseline assessment								**Second assessment**							
	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	-	-	2	5.4	4	8.3	7	23.3	-	-	1	1.9	5	10.4	-	-
b) 60<120 mg/dl	2	40.0	18	48.6	12	25.0	7	23.3	-	-	13	25.0	12	25.0	3	23.1
c) 120<250 mg/dl	3	60.0	13	35.1	18	37.5	9	30.0	7	100.0	26	50.0	16	33.3	4	30.8
d) ≥ 250mg/dl	-	-	4	10.8	14	29.2	7	23.3	-	-	12	23.1	15	31.3	6	46.2
□□²(MCp)	**14.316(0.084)**								**14.633(0.064)**							
2-Random blood glucose level (mg/dl)																
a) 100< 150 mg/dl	1	20.0	6	16.2	6	12.5	6	20.0	-	-	3	5.8	6	12.5	2	15.4
b) 150 <200 mg/dl	-	-	11	29.7	16	33.3	9	30.0	-	-	13	25.0	14	29.2	4	30.8
c) 200 – 260 mg/dl	4	80.0	20	54.1	26	54.2	15	50.0	7	100.0	36	69.2	28	58.3	7	53.8
□²(MCp)	**3.239(0.793)**								**6.062(0.371)**							
3- Glycated hemoglobin measurement (HbA1C)																
a) 4% < 6%	2	40.0	11	29.7	6	15.5	-	-	1	14.3	13	25.0	2	4.2	1	7.7
b) 6% < 8%	2	40.0	13	35.1	17	35.4	15	50.0	5	71.4	17	32.7	20	41.7	4	30.8
c) 8% or more	1	20.0	13	35.1	25	52.1	15	50.0	1	14.3	22	42.3	26	54.2	8	61.5
□²(p)	**15.857*(MCp= 0.008*)**								**13.325*(MCp=0.029*)**							
4-Total classifications of hyperglycemia manifestations																
a) Mild (1-3)	2	40.0	11	29.7	15	31.3	6	20.0	2	28.6	15	28.8	13	27.1	5	38.5
b) Moderate (4-6)	3	60.0	22	59.5	22	45.8	16	53.3	3	42.9	29	55.8	26	54.2	4	30.8
c) Severe (≥7)	-	-	4	10.8	11	22.9	8	26.7	2	28.6	8	15.4	9	18.8	4	30.8
□²(MCp)	**5.295 (0.492)**								**4.094 (0.669)**							
5-Total classifications of hypoglycemia manifestations																
a) Mild (1-3)	3	60.0	5	13.5	8	16.7	4	13.3	3	42.9	7	13.5	7	14.6	3	23.1

b) Moderate (4-6)	2	40.0	24	64.9	24	50.0	17	56.7	1	14.3	34	65.4	26	54.2	7	53.8
c) Severe (≥7)	-	-	8	21.6	16	33.3	9	30.0	3	42.9	11	21.2	15	31.3	3	23.1
$\square^2$(^{MC}p)	**7.445 (0.250)**								**8.599 (0.165)**							

Table (5): Relation between Diabetic Patients' Sociodemographic Data and Mean ± Standard Deviation of the Pittsburgh Sleep Quality Index Global Score (n = 120)

This table revealed that, there were a significant relation between age, level of education and income with mean ± standard deviation global score of Pittsburgh sleep quality index in the baseline assessment representing by P= 0.015, 0.001*, <0.001*; respectively. Moreover this table clarified that, there was significant relation between age and level of education with mean ± standard deviation global score of Pittsburgh sleep quality index in the second assessment representing by P= 0.027*, 0.029*; respectively.

Sociodemographic data	**Baseline assessment**			**Second assessment**		
	Global PSQI Score Mean ± SD.	**Test of Sig.**	**p**	**Global PSQI Score Mean ± SD.**	**Test of Sig.**	**p**
1-Age (years)						
18 < 35	10.94 ± 3.56	F= 4.337*	0.015*	10.09 ± 2.93	F= 3.725*	0.027*
35 < 45	12.56 ± 3.53			10.23 ± 3.32		
45≤ 60	13.55 ± 4.09			12.0 ± 3.56		
2-Gender						
Male	12.51 ± 3.67	t= 0.386	0.700	10.77 ± 3.36	t= 0.285	0.776
Female	12.24 ± 3.93			10.60 ± 3.38		
3-Marital status						
Single	11.82 ± 3.52	F= 0.824	0.483	10.66 ± 3.07	F= 0.741	0.529
Married	12.64 ± 3.97			10.74 ± 3.68		
Divorced	11.76 ± 3.78			9.71 ± 3.29		
Widow	13.17 ± 3.97			11.30 ± 3.30		
4-Level of education						
Illitrate	12.97 ± 3.78	F= 5.089*	0.001*	10.82 ± 3.34	F= 2.813*	0.029*
Primary	12.36 ± 3.08			11.43 ± 3.03		
Preparatory	14.17 ± 2.75			11.67 ± 3.27		

Secondary	13.26 ± 4.06			11.43 ± 3.45		
University	10.06 ± 3.55			9.09 ± 3.12		
5-Income						
Enough	12.40 ± 3.82	t= 6.818*	<0.001*	10.72 ± 3.37	t= 1.137	0.258
More than enough	10.0 ± 0.0			8.00 ± 1.41		
High	-			–		
6-Area of residence						
Urban	12.49 ± 3.96	t= 0.417	0.677	10.85 ± 3.41	t= 0.662	0.509
Rural	12.19 ± 3.61			10.44 ± 3.30		
7-Occupation						
No work	12.0 ± 3.68	F= 0.920	0.401	10.46 ± 3.08	F= 1.376	0.257
Self-empolyment	13.06 ± 3.93			9.92 ± 4.29		
Employee	12.62 ± 4.21			11.45 ± 3.52		

Table (6): Relation between Diabetic Patients' Clinical Data and their Mean ± Standard Deviation of the Pittsburgh Sleep Quality Index Global Score (n=120)

Regarding **number of years with diabetes**, this table shows high statistical significant relation between number of years with diabetes and Mean ± SD global score of PSQI in the baseline and second assessment where (P= <0.001*,<0.001*); respectively. As regards **Patient health history** of Associated diseases, this table reveals statistical significant relation between hypertension, respiratory disease, retinopathy, and Mean ± SD global score of PSQI in the baseline assessment where (P= 0.001*, <0.001*, 0.026*); respectively. While there was significant relation between respiratory disease, retinopathy, hypertension and Mean ± SD global score of PSQI in the second assessment where (P=0.003*, 0.007*, 0.034*); respectively.

According to **over-the counter medication**, this table clarifies a statistical significant relation between corticosteroids, anti-arrhythmic, analgesics, diuretics, and Mean ± SD global score of PSQI in the baseline assessment where(P= <0.001*, 0.002*, 0.002*, 0.021*); respectively. While there was significant relation between diuretics, anti-arrhythmic, analgesics and Mean ± SD global score of PSQI in the second assessment where (P=0.001*, 0.001, 0.001); respectively.

In relation to **Prescribed medication**, this table indicates statistical significant relation between insulin mixtard, teujeo, apidra, novorapid and Mean ± SD global score of PSQI in the baseline assessment where (P= <0.001*, <0.001*, 0.008*, 0.009*); respectively. While there was significant relation between mixtard, levemir, apidra, teujeo, novorapid and Mean ± SD global score of PSQI in the second assessment where (P=<0.001*, 0.001*, 0.006*, 0.016*, 0.037*,); respectively.

Clinical data	Baseline assessment	Second assessment

	(Global PSQI Score) Mean ± SD.	Test of Sig.	p	(Global PSQI Score) Mean ± SD.	Test of Sig.	p
8-Number of years of diabetes						
a) 1 < 5	10.81 ± 3.65	F= 14.997*	<0.001*	9.51 ± 2.76	F= 12.204*	<0.001*
b) 5 < 10	12.33 ± 3.15			10.29 ± 3.47		
c) ≥10	14.65 ± 3.19			12.60 ± 3.32		
9-Patient health history **A-Associated diseases**						
a) Hypertension	13.32 ± 3.66	t=3.355*	0.001*	11.23 ±3.37	t=2.144*	0.034*
b) Renal disease	11.78 ± 3.25	t=0.807	0.421	9.96 ±2.77	t=1.143	0.256
c) Ischemic heart disease	12.61 ± 4.0	t=0.617	0.539	10.98 ±3.53	t=0.855	0.394
d) Neuropathy	12.0 ± 3.98	t=0.621	0.536	10.84 ± 3.10	t=0.331	0.741
e) Retinopathy	13.32 ± 3.83	t=2.260*	0.026*	11.70 ± 3.23	t=2.762*	0.007*
f) Respiratory disease	14.30 ± 2.91	t=5.121*	<0.001*	11.83 ± 3.07	t=3.063*	0.003*
g) Cerebrovascular accident	13.69 ± 2.70	t=1.975	0.059	10.75 ± 3.79	t=0.096	0.924
h) Cancer	13.57 ± 2.99	t=0.869	0.387	10.43 ± 2.82	t=0.199	0.842
B-Medications **B1-Over-the counter medication**						
a) Diuretics	17.33 ± 1.53	t=2.338*	0.021*	16.67 ± 1.53	t=3.253*	0.001*
b) Corticosteroids	9.40 ± 2.77	t=4.206*	<0.001*	9.47 ± 2.50	t=1.497	0.137
c) Anti-arrhythmic	16.14 ± 2.19	t=4.459*	0.002*	14.86 ± 2.73	t=3.557*	0.001*
d) Analgesics	16.14 ± 2.19	t=4.459*	0.002*	14.86 ± 2.73	t=3.557*	0.001*
e) Beta blockers	7.0	–	–	11.0	–	–
B2-Prescribed medication						
a) Apidra	10.94 ± 3.75	t=2.685*	0.008*	9.29 ± 2.44	t=3.484*	0.001*
b) Mixtard	13.59 ± 3.35	t=3.944*	<0.001*	11.71 ± 3.49	t=3.755*	<0.001*
c) Lantus	12.16 ± 3.52	t=0.481	0.631	10.38 ± 3.02	t=0.812	0.418
d) Tresiba	12.31 ± 3.28	t=0.051	0.960	10.85 ± 3.29	t=0.194	0.847

e) Teujeo	8.27 ± 3.32	t=3.965*	<0.001*	8.36 ± 3.04	t=2.444*	0.016*
f) Humalog	12.20 ± 3.96	t=0.095	0.925	11.20 ± 1.79	t=0.356	0.723
g) Novorapid	9.77 ± 4.07	t=2.667*	0.009*	8.85 ± 3.72	t=2.109*	0.037*
h) Humulin NPH	15.00 ± 2.00	t=1.221	0.224	12.67 ± 2.31	t=1.041	0.300
i) Levemir	11.19 ± 3.67	t=1.328	0.187	8.56 ± 2.56	t=2.778*	0.006*
j) Basaglar	13.75 ± 2.99	t=0.743	0.459	12.25 ± 2.06	t=0.954	0.342

Discussion:

Type I diabetes mellitus is an emerging public health issue being the most common endocrinal and metabolic chronic disorder; showing remarkable incidence variations in different parts of the world. It is also known as insulin-dependent diabetes mellitus and juvenile diabetes. **(El Fathi et al., 2020; Chachar, Ashfaq, Bader-u-Nisa, Ahmed, Ahmed, & Ibrahim, 2021).**

The relationship between sleep quality and glycemic control in TIDM is inconsistent; that inadequate or poor quality sleep is associated with higher HbA1c levels and greater glycemic variability. Conversely, altered glucose metabolism may affect sleep quality, suggesting that; there is a bidirectional relationship between sleep and DM **(Farooque, Herekar, Iftikhar, & Patel, 2020; Malone et al., 2021; Suteaua et al., 2020).** Therefore, this study was carried out to assess the quality of sleep (QoS) among TIDM and the relation between QoS habits and glycemic control among insulin dependent diabetes mellitus patients; in both the inpatient medical department and the medical outpatient clinic of Makkah Hospital.

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 sever 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.

this result is supported by **Birhanu et al., (2020); Dedefo, Abate, Ejeta, & Korsa, (2020); Ji, Wang, & Saylor, (2021); Turin, & Radobuljac, (2021)** who reported that; the majority of their studied patients had poor glycemic control also, they mentioned that patients need to improve their QoS and QoL and adherence to routine management of diabetes care. Thus, the patients must have adequate knowledge and use effective QoL education to improve the factors affecting their self-care management and controlling their blood glucose level.

This finding was agreed with **Griggs, Redeker, Crawford, & Grey, (2020)** who reported that; TIDM patient there was associated between glucose variability and sleep disruptions. In addition **Cobry, Hamburger, & Jaser, 2020; Morrow et al., (2020)** stated that; the insufficient sleep occurs secondary to diabetes-related disturbances, including fear

of hypoglycemia, nocturnal glucose monitoring, hypoglycemia, and device alarms. On the other hand this finding contradicts the study by **Lee, Ng, & Chin, (2017)** who reported that; there 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 glycated 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.

this finding agrees with **Cho, 2020 and Rose et al., (2021)** who stated that; diabetes and sleep disturbance are closely associated with each other, that uncontrolled diabetes level causes sleep disturbances, and conversely sleep disturbances induce high blood glucose; which can lead to vicious cycles of diabetes and sleep disturbances. This finding is contradicted by **Narisawa et al., (2017)** who stated that; HbA1c was not associated with sleep disturbance or insomnia in TIDM patients.

Moreover, a significant relation was noticed between age, level of education as a sociodemographic characteristics and PSQI score during the baseline and second assessment. As regards the relation between clinical data and PSQI score during the baseline and second assessment, significant relation was notices regarding years of DM, presence of associated diseases (hypertension, retinopathy, and respiratory diseases), use of over countered medications (diuretics, corticosteroids, ant arrhythmias and analgesics) and prescribed medications as Apidra, Mixtard, Teujeo, Novorapid and Levemir.

These result is approved by **Lee, Ju, Lee, Kim, Hong, & Choi, (2020)** who reported that; illiteracy, low income, and unemployment in both males and females were associated with poor QoS. Also congruent with **Pérez-Fuentes, Molero Jurado, Simón Márquez, & Gázquez Linares, (2019)** who reported a relationship between diabetic patients sleep quality and age, marital status, eating behavior, physical exercise, emotional intelligence, and self-esteem.

This finding is congruent with **Lee et al., (2020)** who illustrated that; smoking, high-risk drinking, diabetes, hypertension, non-participation in walking, and obesity, in addition to poor mental health as perceived poor health status, stress, depressive symptoms, and subjective cognitive decline were associated with poor QoS in both males and females. Also **Dutta, Ghosh, & Ghosh, (2022)** who stated that; Poor PSQI scores was associated with increasing severity of diabetic retinopathy. However this finding is not congruent with **Morjaria, Alexander, Purbrick, Safa, Chong, & Wulff., (2019)** who stated that; no significant difference between PSQI scores in their diabetic retinopathy patients and controlled group.

Moreover as regards to **"over-the counter medications"**, The study results are not in agree with **Banda, Muungo, & Lambwe, (2020)** who stated that; diuretic don't affect the quality and duration of sleep. While agree with **Cole., (2020)** who stated that; sleep disruption is caused by exogenous administration of steroids anti-inflammatory and analgesics.

Whereas in relation to **"prescribed medications"**, the results may be due to poor QoS associated with poor glycemic control, increased insulin resistance and thus induces high insulin requirements. These results agree with **Chontong, Saetung, & Reutrakul, (2016)** who reported that; sleep variability affects glycemic control and insulin requirement in TIDM.

Furthermore, Relations between poor QoS and glycemic control in TIDM are complex and bidirectional; where poor sleep quality are associated with suboptimal glycemic control parameters namely HbA1C; thus sleep optimization will improve glycemic control. Where sleep assessment among patients with TIDM must to be performed being one of the vital diabetes medical and nursing management.

Conclusion and recommendations:

In the present study variation was noticed in glycemic control parameters during the base line 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 QoS ranged from moderate to moderate sever 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.

Based on the findings of the study, the researcher proposed the following recommendations

1. Increase diabetic patients' awareness about the disease and the importance of following proper sleep quality practices in glycemic control; through developing and applying educational sessions.
2. All 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.
3. Organize workshops and courses for nurses about the effect of over countered medications and type of insulin on sleep quality for diabetic patient.
4. Nurses should be aware of the consequences and the measures to control poor QoS and poor glycemic control on their patients.

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