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MEAN NOCTURNAL BLOOD GLUCOSE LEVELS AMONG DIABETICS IN A TERTIARY HEALTHCARE CENTER: A CROSS-SECTIONAL STUDY

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Abstract

Background: Diabetes is a pandemic disease with high prevalence, and long-term control is essential to prevent complications. HbA1c was initially proposed as a standard for monitoring diabetes; however, it has limitations. This study investigated the mean nocturnal blood glucose levels among patients with diabetes in a tertiary healthcare center. **Materials and Methods:** This cross-sectional descriptive study included 134 participants who were previously diagnosed with diabetes and were currently admitted to Thoothukudi Medical College and Hospital for various complications for two months from May to June 2023. This study used Accu-Chek Performa to obtain nocturnal blood glucose samples from 134 participants who met the inclusion criteria. The mean nocturnal blood glucose levels were studied and compared in accordance with the participant's demographic factors, whether they were on oral antidiabetics or insulin, and the development of specific complications due to diabetes mellitus. Statistical analysis was performed using Python v3.12.2 with additional packages for analysis. **Result:** Out of 71 male participants with the age average of 57.84 ±11.40 and 63 female participants with the average age of 57.4 ± 11.42 from the southern parts of Tamil Nadu, a high percentage had at least one associated complication and more than half developed at least two complications due to diabetes mellitus. There was an association between sex of the participant and nocturnal glucose level changes, with no significant difference in levels observed between the groups. Insulin therapy was associated with higher nocturnal glucose level changes compared to oral hypoglycaemic agents. There was no significant association between the mean nocturnal blood glucose levels and the development of complications in patients with diabetes, as indicated by the paired t tests. However, there was a substantial difference in the mean nocturnal blood glucose values of individual groups with complications, paving the way to the idea that different complications develop at different threshold levels of blood glucose dysregulation. **Conclusion:** This study explored the relationship between mean nocturnal blood glucose levels, and variables such as age, sex, type of treatment, and microvascular and macrovascular complications in patients with diabetes admitted to GTKMCH. A statistically significant association between mean nocturnal blood glucose levels, and complication categories was absent. Further studies with higher power need to be done to identify effects of smaller size. Continuous glucose monitor is a better modality for the measurement of newer diabetic indices than glucometers. The findings emphasize this fact.

INTRODUCTION

Diabetes is a non-communicable disease pandemic that ranks among the top 10 causes of mortality.[1] Worldwide, with 537 million diagnosed diabetics age group–20-69. The count is 74 million in India, and the age-adjusted prevalence is 9.6%.[2] Diabetic control indices are an evolving topic of interest in the medical community. First HbA1c was proposed as a standard of care testing for diagnosing and monitoring Type II diabetes mellitus. HbA1c was used as an index for long-term control (3 months) because RBCs have a rough lifespan of 110 days.[3]

HbA1c variability in terms of covariance and mean values has been used to evaluate control and predict complications.[4,5] Increased HbA1c variability is closely associated with diabetic peripheral neuropathy in patients with type II diabetes mellitus. It was also associated with cardiovascular complications regardless of glycaemic control in the short term.[6] The mean HbA1c level and its standard deviation were found to be associated with deteriorating renal function in patients with type II diabetes and were also associated with increased mortality.[7] First, it was implemented in existing forms of blood glucose measurement indices, such as fasting glucose levels, 2-hour measurements etc.[8]

Continuous glucose monitoring systems enable short-term glycaemic variability on a scale of minutes possible.[9] Continuous glucose monitoring (CGM) technology, introduced in 2000, enables 24/7 blood glucose monitoring using subcutaneous sensors with error range of ±10% Challenges include sensor lifespan and cost, which limit their usage in developing countries. Continuous glucose monitoring empowers individuals to manage diabetes independently, with glycaemic variability monitoring crucial for optimal care. The importance of glycaemic control in reducing complications was underscored by landmark studies, such as Diabetes Control and Complications Trial for type 1 diabetes,[10] and The UK Prospective Diabetes Study for type 2 diabetes.[11,12] The major advantages of point-of-care testing can be understood by accessibility of the population to medical devices for continuous glucose monitoring and expenses incurred.

Devices used for measuring capillary blood glucose are expected to have a deviation of less than 0.83 mmol/L from actual glucose levels for readings under 5.5 mmol/L. For higher glucose levels, accuracy is generally within ±20%.[13] Recent studies have indicated that outcomes in critically ill patients are improved when blood glucose levels are maintained in the euglycemic range, reiterating the fact that the progression of complications or comorbid illnesses associated with diabetes can be effectively suppressed with tighter glycaemic control.[14-16]

Sasaki et al proposed the concept of β cell mass and its exhaustion leading to type II diabetes and basing its management on measures of β cell mass as an index.[17] Since CGMs are still distant in the future for developing countries and comes with its own set of disadvantages- including that it measures blood glucose levels in the interstitial fluid before it enters the blood allowing discrepancies, the high cost and sophistication of sensors and machines being a hindrance to new patients and elderly.

HbA1c has long been the go-to for deciphering long-term glucose control, but it falls short when it comes to capturing short-term fluctuations and nocturnal glucose patterns—factors that are increasingly recognized as crucial in diabetes management and development of complications. Continuous glucose monitoring (CGM) could provide a more cost effective increase in Quality adjusted life years,[18] but its high cost and limited accessibility make it a challenge, especially in developing countries. We lack a clear understanding of how nocturnal glucose levels influence the development of both microvascular and macrovascular complications. Most studies have concentrated on HbA1c and daytime measurements, missing the potential effects of night time glucose levels. This study seeks to fill that gap by exploring how mean nocturnal glucose levels relate to factors like age, sex, and treatment type, and by comparing the effectiveness of nocturnal blood glucose monitoring using a glucometer than with traditional measures like HbA1c.[19-21]

This study aimed to explore the relationship between mean nocturnal blood glucose levels and age, sex, type of treatment received, and development of microvascular and macrovascular complications in patients with diabetes admitted to the GTKMCH to support the benefits of continuous glucose monitoring even in type 2 diabetes and to discuss the potential implications and efficacy compared to other widely accepted measures such as HbA1c.

MATERIALS AND METHODS

This cross-sectional descriptive study included 134 participants who were previously diagnosed with diabetes and were currently admitted to Thoothukudi Medical College and Hospital for various complications for two months from May to June 2023. After obtaining approval from the Institutional Ethics Committee [IEC Ref.No 04/2023-29], informed consent was obtained from all participants who met the inclusion criteria. A semi-structured pre-test questionnaire was administered during an interview with patients in the local language, following which nocturnal blood glucose samples were obtained by Accu-Chek Performa at hourly intervals starting at midnight and going on up to 5 AM, FBS, and PPBS samples.

Inclusion Criteria

Patients diagnosed with complications secondary to type 2 diabetes mellitus, such as diabetic retinopathy, diabetic foot ulcer, cardiovascular disease, cerebrovascular accident, and diabetic nephropathy as their primary complication were included in the study.

Exclusion Criteria

Participants younger than 20 years and older than 69 years and those on corticosteroids, immunosuppressants, atypical antipsychotics, thiazide diuretics, non-selective beta-blockers, or any other medication known to interfere with blood glucose levels were excluded from the study.

Accu-Chek Performance Working Principles and Standards.

The Accu-Chek Performa glucose meter utilizes an electrochemical method where glucose dehydrogenase converts glucose into gluconolactone with the aid of modified pyrroloquinoline quinone (PQQ) as a cofactor. This modification of PQQ helps reduce interference from substances like maltose. The meter measures the resulting electrochemical current, which correlates with the glucose concentration in the blood sample. The parameters in the reference study done in Denmark are accuracy and precision as end points and variability. The device demonstrated strong precision with a repeatability coefficient of variation (CV) between 2.9% and 4.1%, meeting the quality standards for accuracy. For glucose levels below 10 mmol/L, the meter's results were in agreement with the comparison method. For levels above 10 mmol/L, a consistent deviation of -0.5 mmol/L was noted. The device fulfilled ISO 15197 standards, with satisfactory user-friendliness and an error rate below 2%.[22]

Statistical analysis

Data entry was consolidated in Microsoft Excel, and processing and statistical analysis of the participants were performed using Python v3.12.2, with statistical packages such as SciPy and NumPy. Statistical significance was set at $p < 0.05$, with a 95% confidence interval and an alpha of 0.05.

RESULTS

Based on the study criteria, 134 participants were enrolled. 71 of the 134 participants were male (52.5%), and the remaining 63 were female (46.6%). The mean age of patients was 57.4 years (SD= 11.3) and the mean duration of diabetes illness was 7.14 years (SD=7.53). Most of the patients had poor glycaemic control, with a mean FBS value of 200 mg/dl and PPBS value of 283 mg/dl. The mean of all individual nocturnal blood glucose values was 213.8 mg/dl with a standard deviation of 25.9 [Table 1].

Table 1: Mean and SD of glucose measurements, serum sodium and serum potassium of participants at particular intervals.

(According to time)	Mean ± SD
12 am	235.87 ± 98.61
1 am	220.67 ± 93.74
2 am	207.46 ± 82.75
3 am	199.15 ± 84.22
4 am	195.85 ± 76.55
5 am	196.51 ± 80.06
FBS	200.00 ± 75.52
PPBS	283.31 ± 92.23
Sodium	138.33 ± 3.87
Potassium	4.07 ± 0.58

Table 2: Mean nocturnal blood glucose values according to demographic factors

		Total participants (N)	Mean nocturnal blood glucose value (mean ± SD)	P value
Gender	Female	63	211.74 ± 78.00	0.751
	Male	71	207.73 ± 68.01	
Type of treatment	Insulin	18	240.22 ± 84.47	0.054
	Oral hypoglycaemics	116	204.87 ± 69.83	

Independent sample t-tests were performed to compare mean nocturnal blood glucose levels between genders and across treatment types. The analysis revealed no significant difference in blood glucose levels between male and female participants, suggesting that gender does not influence nocturnal glucose levels in this sample. Similarly, the comparison between participants using insulin therapy and those on oral hypoglycemic agents showed no statistically significant difference. Although the difference approached significance, further investigation is necessary to decipher any possible trend, if any. [Table 2].

In the demographic study, most of the patients were on oral hypoglycaemic agents, with some of them on insulin. Of the 134 participants, 108 (80.5%) had at least one associated complication and 73 (54.4%) developed at least two complications [Table 3].

Table 3: The mean nocturnal blood glucose values in diabetic patients with specific complications

Type of complication	Total participants (N)	Mean nocturnal blood glucose value	P value
Hypertension	67	203.96 ± 74.49	0.369
Cerebrovascular accident	20	202.52 ± 69.68	0.637
Coronary artery disease	40	200.48 ± 73.63	0.344
Foot ulcer	14	243.50 ± 79.38	0.065
Infections	46	222.17 ± 73.70	0.149
CKD	20	212.60 ± 77.21	0.843

Independent and paired sample t-tests were analyzed to determine if associations existed between the type of complication and mean nocturnal blood glucose levels. The independent sample t-tests showed no statistically significant differences in mean nocturnal blood glucose levels among participants with different complications such as hypertension, cerebrovascular accident (CVA), coronary artery

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disease (CAD), infections, foot ulcers, or chronic kidney disease (CKD). Participants with foot ulcers had the highest mean blood glucose levels, band yet the p-value did not reach statistical significance. (p = 0.065)

In the paired sample t-tests, most comparisons between complications did not yield significant differences. However, a statistically significant difference was observed between participants with CVA and those with foot ulcers (p = 0.040). Other comparisons showed no significant associations, with p-values consistently above the threshold for significance of 0.05. The given findings suggest that mean nocturnal blood glucose levels are not strongly associated with specific complications, apart from the isolated significant difference between CVA and foot ulcers.

A weak negative correlation between serum sodium (R=-0.083 p value = 0.332) and potassium (CR= -0.106 ; p value = 0.234) with Mean nocturnal blood glucose levels was seen but this was not statistically significant.

DISCUSSION

The aim of this study was to explore the therapeutic significance of using newer indices for the management of diabetes mellitus including mean nocturnal blood glucose levels. They may help us to titrate the dosage of anti diabetic medication and outline management in a shorter time period especially in patients with diabetes related complications or those admitted in intensive cares who require precise glucose management. Diabetes is a ongoing pathological process which should be curtailed as soon as possible to avoid complications.[23] The changes in mean blood glucose levels occur in a shorter time-frame and nighttime levels are not affected by caloric intake although hepatic glucose production and the last meal before sleep can be a confounding factors.[24]

A statistically significant difference in nocturnal mean blood glucose levels of people categorized under different complications of Diabetes Mellitus is absent. However, this may be attributed to the numerous confounders and low power of study.

Among the microvascular complications, diabetic foot accounted for 10.4% and nephropathy accounted for 14.9%. A significant correlation between the duration of diabetes (12±2.7 years), average level of HbA1c (7.9%±1.3%) and development of diabetic nephropathy has been shown in type 2 diabetes mellitus.[25]

A statistically insignificant weak negative correlation was seen between serum sodium and potassium with mean nocturnal blood glucose levels. This could indicate dilution of blood sugar concentration due to higher levels of electrolytes.

The mean blood glucose have already been shown to correlate with changes in HbA1c,[26] and HbA1c is shown to correlate with long term complications of diabetes. Thus using mean blood glucose levels for guiding diabetic management may provide better control than HbA1c or single glucose values like fasting plasma glucose.[27] Kilpatrick et al,[28] showed that in the intensively treated arm of Diabetic Control Complications Trial, there was lower mean plasma glucose (mean was taken from 8 measurements done throughout the day) than the conventionally treated arm for the same level of HbA1c. This could indicate diabetic control measures being reflected in mean plasma glucose much faster than HbA1c.

HbA1c(8-11%) values, foot hygiene and duration of diabetes also correlated with diagnosis of diabetic foot in a meta-analysis.[29] An increasing trend in the HbA1c levels and microvascular complications can be noted. A similarity in the progression of mean nocturnal blood glucose levels among the complication categories obtained in the study can be recognized though.

The weak negative correlation between electrolytes and HbA1c was reported by Lengeiya F et al., though only the correlation with calcium and sodium were statistically significant.[30] The statistically insignificance may be attributed to the confounding factors and low sample population reducing the power of the study.

This study was based on CBG findings because according to Pichon-Riviere A et al., the cost effectiveness threshold for India is $190–$3249 USD.[31] The cost effectiveness threshold is the amount of money a decision maker is willing to spend on a unit of health outcome. According to WHO-CHOICE, any intervention that is less than 3 times the GDP per capita can be considered cost effective. The GDP per capita of India is 2484.8 USD as of 2023 according to World Bank. The Continuous glucose monitoring systems were found to be cost effective in a systematic analysis but based on threshold from 45,000 to 175,000 USD.[32] This is significantly higher than the same in India and is a barrier to its widespread use in India. The flash glucose monitoring utilizing similar mechanism as CGM is found to be more cost effective in type I diabetes mellitus and insulin dependent type 2 diabetes mellitus than traditional glucometer in Chinese population.[33] A similar cost effectiveness study in the Indian population might change and improve diabetic management.

Studies by Olateju et al,[34] and Kotwal et al,[35] outline the analytical and pre-analytical variability of using GDH glucometers, emphasizing the need to address the following limitations or utilize better methods of continuous and flash glucose monitoring.

Study limitations

Since the study was done using a Cartridge based glucometer in a selected population, this cannot be generalized to population in which continuous glucose monitoring is the standard of care, which is not the case in our population. The study was done in a hospitalized population and bias in the distribution of complications can be noted. The study cannot be generalized to population who do not have symptoms and complications severe enough to be hospitalized. The complications and comorbidities of each patient may have a confounding effect on the blood glucose measurements. The data was recorded via a questionnaire which implicates a recall bias. Due to small sample size, the power of the study is reduced.

CONCLUSION

The study concluded that there was no significant association between mean nocturnal blood glucose levels, and complications of diabetes mellitus. This result may be attributed to the use of glucometer in this study. Glucometer do not provide a consistent and optimal way to measure blood sugar indices of short time frame. Continuous glucose monitoring is the better modality for such indices. Further studies with much larger sample size and power with mean blood glucose levels as the endpoint need to be done to prove its potential as a better measure for strict diabetic control than long term goals like HbA1c.

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