DOI: 10.7860/JCDR/2026/80321.23174

Original Article

Internal Medicine Section

Assessment of Glycaemic Control and its Association with Quality of Life in Patients of Diabetes Mellitus: A Cross-sectional Study

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ABSTRACT

Introduction: Incidence of Diabetes Mellitus (DM) is rising in India. Uncontrolled diabetes is a harbinger of potential life-threatening complications. In recent years, focus has shifted to achieving adequate glycaemic control in order to prevent the complications of Diabetes. Adequate glycaemic control significantly reduces diabetes-related complications. Good glycaemic control should therefore lead to better Quality of Life (QoL) in Diabetes patients.

Aim: To assess whether glycaemic control has any relationship with QoL as assessed by the World Health Organisation (WHO) Quality of Life Brief Version (WHOQoL-BREF) Questionnaire.

Materials and Methods: This cross-sectional study was conducted at the Department of Medicine, ESI Postgraduate Institute of Medical Sciences and Research, Basaidarapur, New Delhi, India, from July 2022 to December 2023, in which 140 subjects satisfying inclusion and exclusion criteria were recruited. Patients were subjected to Serum HbA1c estimation and based on HbA1c values, the subjects were divided into good glycaemic control group (satisfying ADA glycaemic goal of HbA1c <7%, n=55) and poor glycaemic control group (not satisfying ADA glycaemic goal and HbA1c ≥7%, n=85). The patients were then administered QoL questionnaire devised by WHOQoL-BREF evaluating four key domains of life i.e., physical, psychological, social relationships and environmental and the QoL scores for each domain were calculated for each patient. Thereafter, the QoL scores in all four domains of both good and poor glycaemic control were compared and correlation was assessed using Pearson's correlation coefficient.

Results: A total of 140 patients were enrolled in the study with a mean age of 55.32±5.9 years. The proportion of male patients was slightly less as compared to female patients of Diabetes Mellitus (46.4% vis a vis 53.6%). The QoL of good glycaemic control group was significantly higher in all four domains viz., p-values was <0.001 for physical, and for psychological, social and environmental domain it was p-value ≤0.001 as compared to the poor glycaemic control group. QoL scores in all four domains showed a statistically significant negative correlation with HbA1c (all p-value<0.05), with correlation coefficients ranging from -0.181 to -0.417.

Conclusion: In the present study, majority of the diabetic patients had poorly controlled diabetes. The level of glycaemic control has a weak to moderate negative correlation with QoL and good glycaemic control is associated with better QoL as compared to poor glycaemic control group.

Keywords: Blood glucose, Glycated haemoglobin, Health-related quality of life, Hyperglycaemia

INTRODUCTION

Diabetes mellitus is a lifestyle-related disorder which has reached epidemic proportions worldwide due to the dietary and lifestyle practices prevalent in today's fast paced life. India is significantly affected by this global trend and is poised to be the diabetes capital of the world with more than a 100 million diabetes patients estimated to be living in India [1]. The disease has been known to affect many organs of the body and has multiple known complications leading to huge morbidity and mortality burden [2].

In order to reduce the potentially high morbidity and mortality burden and the resultant treatment costs of diabetes mellitus, ensuring adequate control of the disease is of fundamental importance. Presently, the prominent markers of glycaemic control are Glycated Haemoglobin (HbA1c) and Time In Range (TIR), a parameter derived from Continuous Glucose Monitoring (CGM). HbA1c is a form of haemoglobin that is non enzymatically linked to glucose and contains beta-N-1-deoxy fructosyl haemoglobin as component [3]. It reflects the average blood glucose level during the preceding three months. HbA1c is currently considered as the primary measure to guide glucose management and is a vital risk marker for complications of diabetes while the TIR is still evolving in terms of accuracy and affordability of CGM devices. Guidelines are in place to define the treatment targets of which glycaemic control as measured by glycated haemoglobin is a prominent one. The American Diabetes Association (ADA) recommends achieving a goal of HbA1c level less than 7% without significant hypoglycaemia for adult population [4].

Attainment of adequate glycaemic control in diabetic patients has been proven in multiple studies to have a significant beneficial effect on potential life-threatening complications of diabetes [5]. However, in addition to physical illness, diabetes can have a significant impact on social and psychological well-being and overall QoL. It is one of the chronic illnesses that exerts great psychological strain, with psychosocial factors influencing almost every facet of the disease and its management [6]. Therefore, the question of whether adequate glycaemic control with resultant beneficial effect on life threatening complications finally translates into better QoL in diabetic patients becomes pertinent and needs evaluation.

The QoL has become a key goal of contemporary health care and can be an important measure of the impact a disease has on an individual's life. It is often confused with standard-of-living. However, standard-of-living refers to the possession of wealth or material goods whereas QoL is a holistic concept which addresses many aspects of health. It has been defined by WHO as an individual's

perception of their position in life in the context of culture and value system in which they live and relation to their goals, expectations, standards, and concerns [7]. It is regarded as a comprehensive idea that takes into account several facets of health. There are multiple tools available for assessment of QoL like McGill QoL Expanded Questionnaire (MQoL-E), Health-related Quality Of Life (HRQoL) and the WHOQoL-BREF Questionnaire [8-10].

The WHOQoL-BREF Questionnaire is a valid, authentic and relatively easy to administer tool developed by WHO and is, therefore, one of the most widely used and accepted tools for studying the QoL. It includes 26 items contains two items for the overall QoL and general health and 24 items covering four qualities of life domains consisting of physical, social, psychological and environmental domains [7,10,11].

While there are multiple studies in medical literature which have evaluated the QoL in DM patients and have demonstrated deleterious effects of diabetes on QoL, the studies evaluating relationship between glycaemic control and QoL are limited [12,13]. Few studies have addressed the question of whether adequate glycaemic control translates into better QoL in diabetic patients and have been conducted mostly in western world and there is a wide variation in the tools employed for the assessment of QoL [14,15]. Hence, the present study was conducted to assess whether glycaemic control has any relationship with QoL as assessed by the WHOQoL-BREF questionnaire.

MATERIALS AND METHODS

This cross-sectional study was conducted at the Department of Medicine, ESI Postgraduate Institute of Medical Sciences and Research, Basaidarapur, New Delhi, India, in which 140 subjects were recruited from July 2022 to December 2023. Ethical clearance was taken from the Institutional Ethics Committee (vide IEC approval no. ESIPGIMSR-IEC/2022019).

Inclusion criteria: The study included patients aged ≥18 years or older attending the Medicine Outpatient Department (OPD) and Diabetes clinic who had DM diagnosed as per the ADA criteria [4] irrespective of their duration of illness or treatment.

Exclusion criteria: Patients with other chronic medical or surgical illnesses, those who required immediate hospitalisation for a serious illness or suffering from any chronic debilitating disease, Patients receiving corticosteroids or any psychotropic drugs or suffering from any co-morbid psychiatric illness and pregnant female were excluded from the study.

Sample size calculation: The sample size was calculated by the formula

$n=z^2pq/d^2$ where,

z is 1.96 with a confidence interval of 95%,

p is the prevalence of good glycaemic control among diabetes patients (8.2% rounded-off to 9%) [16],

q is 1-p, and

d is the precision limit or proportion of sampling error as 5%. The sample size was calculated to be 126 patients. A total of 140 patients were enrolled in the study. Considering the study duration and patient flow, it was decided to recruit all available subjects sequentially till the sample size of 140 subjects was reached.

Study Procedure

All diagnosed patients of DM attending the medicine OPD and diabetes clinic satisfying the inclusion and exclusion criteria were included in the study after obtaining their consent. Thereafter, demographic data like age, gender and educational status was recorded and a detailed history and examination was done.

Measurement of serum parameters: Patients were subjected to certain biochemical tests like Fasting Blood Sugar (FBS), Post Prandial Blood Sugar (PPBS) and HbA1C. After 12 hours of overnight fasting and two hours postprandial blood samples were collected from all the participants for measuring biochemical parameters. The samples were immediately centrifuged at 3000 rpm for five minutes and serum was separated. The sera were stored at -20°C until assayed. Patients were subjected to serum HbA1c estimation by High Performance Liquid Chromatography (HPLC).

Thereafter based on the HbA1c values, the subjects were divided into good glycaemic control group (satisfying ADA glycaemic goal of HbA1c <7%) and poor glycaemic control group (not satisfying ADA glycaemic goal and HbA1c ≥7%) [4].

Assessment of Quality of Life (QoL)

The patients were then administered QoL questionnaire devised by WHOQoL-BREF evaluating four key domains of life i.e., Physical, Psychological, Social, Relationships and Environmental and QoL scores for each domain were calculated out of total score of 20. The WHOQoL-BREF questionnaire contains 26 items of satisfaction. Out of these 26 items, two items are concerned with an individual's overall perception of QoL and health and they are scored on Likert scale from 1 to 5 in a positive direction i.e., higher score indicates better status. The remaining 24 items are divided into four domains: Physical health with seven items covers pain, energy, sleep, mobility, daily activities, dependence on medication, and work capacity with higher scores implying better physical functioning and independence; Psychological health consists of six items including positive/negative feelings, self-esteem, body image, spirituality, and cognitive functions indicating emotional well-being; social relationships domain consists of three items assessing personal relationships, social support, and sexual activity and environment domain includes eight items encompassing financial resources, safety, healthcare access, home environment, opportunities for leisure, and access to information. Each item is rated on a 5-point Likert scale. Domain scores are scaled in a positive direction (i.e., higher scores denote higher QoL. Raw domain scores for each patient for the WHOQoL were transformed to a 4-20 score according to guidelines and a mean QoL domain score of 12.0 is considered as the scale midpoint where QoL is judged to be neither good nor poor [7,10,11].

STATISTICAL ANALYSIS

The mean QoL scores of each domain of the two groups were then compared and evaluated using appropriate statistical tests. Categorical variables were presented in numbers and percentage (%) and continuous variables were presented as mean±SD. Quantitative variables were compared using t-test for normally distributed data. Correlation was assessed using the Pearson's correlation coefficient. A p-value of <0.05 was considered statistically significant. The data was entered in MS Excel spread sheet and analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0. Conclusions and inferences were drawn based on the findings of the statistical tests.

RESULTS

The baseline characteristics of study population are shown in [Table/Fig-1]. As depicted, a total of 140 patients were enrolled in the study with a mean age of 55.32±5.9 years. The proportion of male patients was slightly less as compared to female patients of DM with 65 (46.4%) males vis a vis 75 (53.6%) females. On overall assessment of glycaemic control, it was found that the mean HbA1c value was 7.74%±1.5% indicating suboptimal glycaemic control of DM. The average overall QoL grade of diabetes patients stood at 2.27±0.48 out of maximum score of 5 implying that most of the patients viewed their QoL to be poor. Similarly, most of the patients were dissatisfied by their health status as their average grade stood at 2.16±0.51 out of maximum score of 5.

S. No.	Parameters		No. of patients (n)	Mean±SD
1.	Age (years)		140	55.32±5.9
2.	Gender	Male	65 (46.4%)	--
		Female	75 (53.6%)	
3.	HbA1c (percentage)		140	7.74±1.5
4.	Overall Quality Of Life (QoL)		140	2.27±0.48
5.	Overall satisfaction with health		140	2.16±0.51
6.	Good glycaemic control (HbA1c <7%)		55 (39.3%)	6.47±0.25
7.	Poor glycaemic control (HbA1c ≥7%)		85 (60.7%)	8.56±1.46

[Table/Fig-1]: Baseline characteristics of study population.

Furthermore, as seen in [Table/Fig-1], the distribution of patients into good glycaemic control (achieving ADA glycaemic target of HbA1C <7%) and poor glycaemic control groups (HbA1C ≥7%) revealed that out of a total of 140 patients of DM, only 55 (39.3%) patients were maintaining good glycaemic control. Majority of the patients 85 (60.7%) were unable to achieve the target glycaemic control.

The characteristics of good and poor glycaemic control group patients of DM are compared in [Table/Fig-2]. It is amply clear from the table that while good and poor glycaemic control groups were similar in term of age and gender composition, there was statistically significant difference in the two groups in terms of mean HbA1c level, FBS and PPBS. Good glycaemic control group patients had significantly lower values of Mean HbA1c, FBS, PPBS, as compared to poor glycaemic control group (p-value <0.001).

Parameters	Good glycaemic control group (HbA1c <7)	Poor glycaemic control group (HbA1c ≥7)	p-value unpaired t-test
Mean age (in years)	55.87±6.149	54.96±5.764	0.377
Number of males	27 (49.1%)	38 (44.7%)	0.611*
Number of females	28 (50.9%)	47 (55.3%)	
Mean HbA1c (%)	6.47±0.248	8.565±1.465	<0.001
FBS (mg/dL)	135.64±24.66	169.13±28.20	<0.001
PPBS (mg/dL)	187.73±25.55	214.72±43.06	<0.001

[Table/Fig-2]: Characteristics of good and poor glycaemic control group patients of DM.
Categorical variables: Chi-square test; Continuous variables: unpaired t-test

As can be inferred from [Table/Fig-3], the QoL of good glycaemic control group was significantly higher in all four domains viz., p-value was <0.001 for physical and for psychological, social and environmental domain p-value were ≤0.001 as compared to the poor glycaemic control group. It can also be seen that in the good glycaemic control group, best QoL scores were obtained in the social domain followed closely by environmental, psychological and physical domains.

Unpaired t-test				
	Group	N	Mean±SD	p-value
WHOQoL-BREF Physical domain score	Good Glycaemic control (HbA1c<7)	55	14.89±3.629	<0.001
	Poor glycaemic control (HbA1c ≥7)	85	12.25±3.602	
WHOQoL-BREF Psychological domain score	Good glycaemic control (HbA1c<7)	55	15.29±4.126	0.001
	Poor glycaemic control (HbA1c ≥7)	85	12.93±3.951	
WHOQoL-BREF Social domain score	Good glycaemic control (HbA1c<7)	55	16.13±3.707	0.001
	Poor glycaemic control (HbA1c ≥7)	85	13.91±3.832	
WHOQoL-BREF Environmental domain score	Good glycaemic control (HbA1c<7)	55	15.56±4.045	<0.001
	Poor glycaemic control (HbA1c ≥7)	85	11.31±4.044	

[Table/Fig-3]: Quality of Life (QoL) of good vs poor glycaemic control groups.

The correlation between WHO QoL scores of all four domains and glycaemic control (HbA1c) and it can be inferred from the table that the QoL in all four domains was significantly negatively correlated with glycaemic control with strength of correlation being moderately negative in physical and environmental domains and weakly negative in psychological and social domains are depicted in [Table/Fig-4].

Pearson's correlation			
Parameters		Glycaemic control (HbA1c)	Interpretation
WHOQoL-BREF Physical domain score	Pearson's correlation	-0.417	Moderately negative
	Sig. (2-tailed)	<0.001	significant
	N	140	
WHOQoL-BREF Psychological domain score	Pearson's correlation	-0.181	Weakly negative
	Sig. (2-tailed)	0.033	significant
	N	140	
WHOQoL-BREF Social domain score	Pearson's correlation	-0.225	Weakly negative
	Sig. (2-tailed)	0.007	significant
	N	140	
WHOQoL-BREF Environmental domain score	Pearson's correlation	-0.330	Moderately negative
	Sig. (2-tailed)	<0.001	significant
	N	140	

[Table/Fig-4]: Correlation of Glycaemic control (HbA1c) with Quality of Life (QoL).

DISCUSSION

The present study demonstrated that a majority of patients had poor glycaemic control, and QoL scores across all domains were significantly lower in patients with higher HbA1c levels. The health consequences of diabetes in Asian countries are overwhelming as compared to western countries due to the strong genetic predisposition and early onset of diabetes and India is not aloof from this phenomenon [17]. Studies conducted till date do not report any clearcut age or gender predilection for diabetes but the disease prevalence has been observed to increase with advancing age [18-20]. This is in agreement with the results obtained in present study where the Mean±SD age of patients was 55.32±5.9 years with no particular gender bias and the number of female patients (53.6%) was comparable to that of males (46.4%).

It has also been found in many studies that most patients are not able to achieve adequate glycaemic control as assessed by HbA1c levels despite availability and access to latest treatments and monitoring devices [21-23]. In one such study by Borgharkar SS and Das SS from western India, more than 75% patients of diabetes type 2 were found to have HbA1c levels more than 7% and only a meagre 23% patients achieving adequate glycaemic control [22]. Similar results were obtained in the multicentric Indian Council of Medical Research – India Diabetes (ICMR-INDIAB) study phase I study which reported a greater proportion of patients with poor glycaemic control with mean HbA1c of 9.1% (76 mmol/mol) [23]. Most of such studies found that presence of co-morbid conditions like obesity and hypertension, longer duration of diabetes, and multiple number of therapies were the factors significantly associated with poor glycaemic control [22-24]. Another plausible reason for poor glycaemic control could be poor clinical adherence and scarce availability of glucose monitoring devices among patients. Results obtained in present study were broadly in agreement with previous studies [22,23] with majority of the patients having poor glycaemic control (more than 60%) with mean HbA1c level of 7.7%. Poor metabolic control seen in most studies can be attributed to a number of plausible causes, prominent among them being lack of funding for diabetic healthcare and patients' ignorance of diabetic self-care [25].

However, in present study the percentage of patients achieving adequate glycaemic control (39.3%) was higher than that found in previous studies [22,23]. The probable explanation could be better availability of antidiabetic drugs and blood glucose monitoring devices to patients at current study centre.

In addition to physical illness, diabetes can have a significant impact on social and psychological well-being and overall QoL. With respect to QoL assessment using WHOQoL-BREF, it was found that the good glycaemic control patients had significantly better QoL in all four domains ($p \leq 0.001$). Further analysis revealed significantly negative correlation between HbA1c and all four domains of QoL. Similarly negative correlation was observed in another study from Central America in all domains of WHO QoL ($r=-0.205$, $p<0.05$) [26]. Comparable conclusions were also drawn in a study conducted in Malaysia [27], which demonstrated that glycaemic control has an impact on QoL, although they used a different tool (Short Form 36) for QoL assessment and had a similar sample size of 150. Similar findings were also observed in a Thai study that employed the WHO-QoL BREF tool and inferred that compliance with dietary control, exercise, and medication use were positively associated with QoL in DM patients [28]. These studies also showed that inadequate glycaemic control increased the frequency of hyperglycaemic symptoms, which in turn affected the patient's QoL, highlighting the significance of symptoms in determining a person's QoL.

The observed association between glycaemic control and QoL may also be mediated through diabetes-related complications, which are known to adversely impact multiple domains of life. The strong association between glycaemic control and diabetes complications has already been documented in the landmark UK Prospective Diabetes Study which concluded that reduction in the average yearly values of HbA1c by 1% reduces the risk of microvascular complications, peripheral vascular disease, heart attack and stroke by 37%, 43%, 14% and 12% respectively [29]. It has been reported in another study that diabetes complications such as neuropathy (40%) and retinopathy affected physical and psychological domains of QoL while erectile dysfunction which is observed in diabetic males adversely affected the psychological domain of QoL [25]. Furthermore, it was reported in a study that the QoL decreased in relation to the number of diabetes related complications among patients of both type 1 and 2 diabetes [30].

Thus, on the basis of results obtained in the study and in consonance with other studies, it is amply clear that glycaemic control has a significant relationship with QoL in DM patients and the QoL of patients with good glycaemic control is significantly better than those with poor glycaemic control.

Limitation(s)

In the present study, long-term follow-up of patients to see the impact of strategies or treatment modalities aimed at achieving glycaemic target (HbA1c <7 %) in patients with poor glycaemic control could not be done. This may be become a part of future studies which may help in further analysing the impact of achieving good glycaemic control on QoL which in turn could be an important predictor of future cardiovascular events in patients of DM. Moreover, this being a single centre study can potentially limit the generalisability of the findings. Another key limitation of the study is that study was conducted in tertiary care referral hospital and may represent serious cases in the spectrum of the disease and hence the QoL scores may have been adversely affected. Therefore, large scale community based studies can be undertaken to further analyse the relationship between glycaemic control and QoL in DM patients.

CONCLUSION(S)

Most diabetic patients have poorly controlled diabetes and are not able to achieve glycaemic control despite having access to quality healthcare. The level of glycaemic control has a weak to moderate negative correlation with QoL and a poor glycaemic control is associated with poorer QoL. Thus there is a need to further strengthen the healthcare systems with a focus on creating awareness and motivation among diabetic patients of the importance and benefits of achieving adequate glycaemic control. The present study demonstrated a significant relationship between glycaemic control and QoL in patients with diabetes mellitus. These results obtained in the present study will pave the way for inclusion of QoL as a part of routine clinical assessment of diabetes patients in existing guidelines and policies for better management of DM.

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PLAGIARISM CHECKING METHODS: [Jain H et al.]
- Plagiarism X-checker: May 25, 2025
- Manual Googling: Mar 17, 2026
- iThenticate Software: Mar 19, 2026 (1%)

ETYMOLOGY: Author Origin

EMENDATIONS: 6

AUTHOR DECLARATION:
- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. NA

Date of Submission: **May 03, 2025**
Date of Peer Review: **May 30, 2025**
Date of Acceptance: **Mar 21, 2026**
Online Ahead of Print: **Mar 27, 2026**
Date of Publishing: **May 01, 2026**