RESEARCH PAPER

Assessment of Medication Adherence and Comorbidities on Health Related Quality of Life of Covid Recovered Diabetes Patients

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ABSTRACT

Type 2 Diabetes Mellitus (T2DM) is a common chronic condition with serious health risks, including heart disease, kidney damage, and vision problems. The COVID-19 pandemic has further exposed the vulnerability of T2DM patients, making post-recovery care even more challenging. This study examined the demographic, clinical, and treatment aspects of T2DM patients recovering from COVID-19, focusing on factors affecting blood sugar control, medication adherence, and coexisting conditions. A cross-sectional observational study was conducted over 18 months, involving 350 T2DM patients from a tertiary care hospital's outpatient department. Data were collected through patient interviews, medical records, and lab results, and then analyzed using IBM SPSS Version 26 and AMOS. Results showed that most patients were middle-aged or older, with a high prevalence of obesity, hypertension, and heart disease. Blood sugar control was poor, with an average HbA1c of 8.31%, and 30.3% of patients had significantly high levels. While most followed their prescribed medications, 32% were non-adherent. These findings highlight the need to address obesity, comorbidities, and medication adherence in post-COVID diabetes care. Targeted interventions, integrated care strategies, and lifestyle changes are essential to improving long-term outcomes and reducing the healthcare burden for these patients.

Keywords: Type 2 diabetes mellitus, COVID-19 recovery, glycemic control, medication adherence, comorbidities, obesity, hypertension, cardiovascular diseases.

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INTRODUCTION

Type 2 Diabetes Mellitus (T2DM) is a common chronic metabolic disorder and a major global health challenge. It is marked by insulin resistance and poor glucose metabolism, leading to high blood sugar levels and an increased risk of complications like heart disease, kidney damage, and vision problems. With a global prevalence of 9.3%, T2DM is rising due to aging populations, unhealthy lifestyles, and increasing obesity rates.The management of T2DM typically involves pharmacological interventions, lifestyle modifications, and continuous monitoring of glycemic control to prevent complications and improve quality of life [1-9].

In the wake of the COVID-19 pandemic, there has been an increased focus on the impact of the virus on individuals with pre-existing conditions such as T2DM. The pandemic has highlighted the vulnerability of diabetic patients to severe COVID-19 outcomes, and the recovery phase has presented additional challenges in managing the disease. Despite the growing body of research on the intersection between diabetes and COVID-19, there remains a gap in understanding the specific patterns of diabetes management and treatment adherence in the post-COVID recovery phase [10-14].

This study aims to explore the demographic, clinical, and treatment characteristics of T2DM patients recovering from COVID-19, focusing on factors that impact glycemic control, medication adherence, and comorbidities. By validating a new scale and examining the socio-medical factors influencing

disease outcomes, this research seeks to contribute valuable insights that can help guide healthcare interventions and strategies to optimize the management of T2DM in the post-COVID era. Through this study, we aim to better understand the unique challenges faced by diabetic patients during recovery, ultimately improving patient outcomes and reducing the burden on healthcare systems [15-19].

METHODOLOGY

Study Site

The study was conducted at the outpatient departments (OPD) of the Department of Endocrinology and the Department of Medicine at a tertiary care hospital in South India.

Study Design

This was a cross-sectional observational study conducted over a period of 18 months, from October 2022 to April 2024. The study aimed to validate a scale through cross-sectional analysis.

Study Population

The study population comprised patients with Type 2 Diabetes Mellitus who visited the OPD of the Department of Endocrinology and the Department of General Medicine.

Subject Selection

Patients were selected based on defined inclusion and exclusion criteria.

Inclusion Criteria

- Patients diagnosed with T2DM with disease onset of at least one year and currently receiving a pharmacological regimen for their condition.
- Individuals who are at least 18 years of age, possess clear consciousness and understanding, can effectively communicate with the researcher either in writing or verbally, and are able to provide informed consent.
- Individuals who are willing and able to participate in the study.

Exclusion Criteria

- Pregnant and lactating mothers.
- Patients with a history of depression or other psychiatric disorders.
- Patients with dementia or psychosis, as these conditions may affect their ability to provide informed consent, understand study procedures, or comply with study requirements.
- Patients who experienced a significant unpleasant event, such as the death of a relative, within the prior three months, as this may impact their emotional state and ability to participate.
- Patients unable to cooperate or act autonomously.

Sample Size

For cross-cultural scale adaptation, sample size requirements for credible factor analysis are as follows: 200 is considered "average," 300 "excellent," 500 "very good," and 1000 "perfect." Additionally, a person-to-item ratio of 10:1 is deemed adequate for analysis.

Using the current prevalence of T2DM of 9.3%, with a 95% confidence interval and an 8.5% absolute error, the minimum required sample size was calculated to be 414 for effective subgroup analysis. Considering human and material constraints, the final sample size was set at 350 participants.

Source of Data

Data were collected through patient history interviews, OPD case sheets with medication charts, and laboratory examination results. A specially designed data collection form was utilized to record the data.

Data Analysis

The data analysis was conducted using IBM SPSS (Statistical Package for Social Sciences) Version 26 and SPSS AMOS, with the significance level set at $P < 0.05$.

Descriptive Analysis

Descriptive statistics were used to summarize sociodemographic and clinical characteristics. Normally distributed continuous variables were reported as means with standard deviations (SD), while non-normally distributed variables were expressed as medians with interquartile ranges (25th and 75th percentiles). Categorical variables were presented as counts and percentages.

Validity Assessment

Content Validity: Content validity was assessed using the Content Validity Index (CVI), where experts rated each item on a scale of 1 to 4. The Scale-level CVI (S-CVI) was computed by averaging Item-level CVIs (I-CVI), with recommended thresholds of S-CVI > 0.90 and I-CVI > 0.78.

Construct Validity: Exploratory Factor Analysis and Confirmatory Factor Analysis were used to assess the latent structure of the C-DDS17 scale. Bartlett's test and the Kaiser-Meyer-Olkin test checked data

suitability for factor analysis. A KMO value above 0.90 was considered excellent.

Convergent Validity: Convergent validity was evaluated using inter-scale correlations and the Average Variance Extracted (AVE), with AVE values greater than 0.50 indicating satisfactory validity.

Discriminant Validity: Discriminant validity was confirmed when squared correlations (SCs) between paired constructs were lower than the AVE of individual constructs.

Reliability Assessment

Internal consistency was assessed using Cronbach's alpha and corrected item-total correlation coefficients. Reliability was categorized as follows:

- Cronbach's alpha < 0.40: Unreliable
- 0.40–0.59: Less dependable
- 0.60–0.79: Reliable
- 0.80–1.00

RESULTS AND DISCUSSION

Social History of Patients

The study also assessed the social habits of participants, including smoking, alcohol consumption, and tobacco chewing. The majority of participants (88.0%) reported never smoking, while 10.0% were regular smokers and 1.7% had quit smoking (Table 1).

Table 1: Proportion of smoking patients

Smoking	Frequency	Percentage
Regularly	35	10.0
Never	308	88.0
Occasionally Irregularly	1	0.3
Quit	6	1.7
Total	350	100.0

Similarly, the majority of participants abstained from alcohol (79.4%), while a small proportion reported regular drinking (7.4%) (Table 2).

Table 2: Proportion of alcohol drinking patients

Drinking	Frequency	Percentage
Regularly	26	7.4
Never	278	79.4
Occasionally Irregularly	40	11.4
Quit	6	1.7
Total	350	100.0

Regarding tobacco use, 86.9% of participants had never chewed tobacco, while 10.6% chewed tobacco regularly, and 2.6% had quit chewing tobacco (Table 3).

Table 3: Tobacco chewing

Tobacco chewing	Frequency	Percentage
Regularly	37	10.6
Never	304	86.9
Quit	9	2.6
Total	350	100.0

Treatment Patterns and Medication Adherence

In terms of treatment, 75.1% of patients were prescribed oral agents, 19.4% received a combination of insulin and oral agents, and 5.4% received insulin alone (Table 4).

Table 4: Distribution of patients based on type of treatment

Type of treatment	Frequency	Percentage
Oral agents	263	75.1
Insulin	19	5.4
Insulin + oral	68	19.4

The majority of patients (41.1%) were on 3-4 medications, followed by 30.6% on 1-2 medications, and 28.3% on 5 or more medications (Table 5).

Table 5: Distribution of patients according to number of medications prescribed

No. of medicines	Frequency	Valid Percent
1-2	107	30.6
3-4	144	41.1
>=5	99	28.3
Total	350	100.0

Medication adherence was reported to be high, with 68.0% of patients adhering to their prescribed regimens (Table 6).

Table 6: Distribution of patients according to adherence

Adherence	Frequency	Percentage
Yes	238	68.0
No	112	32.0
Total	350	100.0

Glycemic Control (HBA1c)

The average HbA1c level in the sample was 8.31% (SD = 1.94), with a median of 7.80% and shown in Table 7. The Kolmogorov-Smirnov and Shapiro-Wilk tests showed a significant deviation from normality ($p < 0.01$), suggesting that most patients had poor blood

sugar control. Glycemic control also varied notably between those on insulin therapy and those on oral medications. Insulin therapy patients had better glycemic control over the oral therapy patients.

Table 7: Descriptive statistics of HBA1c values

Descriptive statistics for HBA1C		Statistic	Std. Error
Mean		8.3113	.10565
95% Confidence Interval for Mean	Lower Bound	8.1035	
	Upper Bound	8.5191	
5% Trimmed Mean		8.1769	
Median		7.8000	
Std. Deviation		1.97661	
Minimum		4.60	
Maximum		15.80	
Interquartile Range		2.50	
Skewness		1.053	.130
Kurtosis		.750	.260
Kolmogorov-Smirnov(sig)		.120(0.000)	
Shapiro Wilk		.918(0.000)	

A large proportion of patients had poor control (30.3%), while 25.7% had great control and 24.6% had good control. Only 3.4% of patients achieved excellent control (Figure 1 & Table 8).

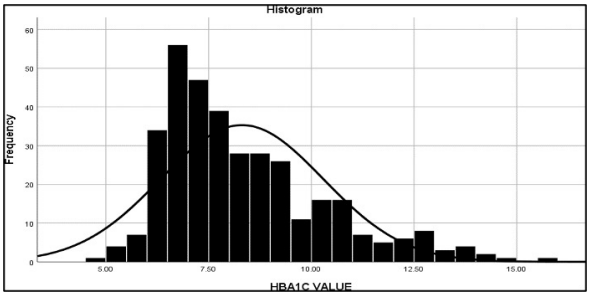

Figure 1: Histogram with normal curve of HBA1c values

Table 8: Disease control across patients

Disease control (HBA1c)	Frequency	Percentage
Excellent control (<6)	12	3.4
Great control (6-7)	90	25.7
Good control (7-8)	86	24.6
Fair control (8-9)	56	16.0
Poor control (>9)	106	30.3

Comorbidities

Of the 350 patients, 62.6% had at least one comorbidity. The most common comorbidities included hypertension and cardiovascular diseases. Thirty-eight percent of patients had one comorbidity, while 20.3% had two comorbidities (Table 9 and 10).

Table 9: Distribution of patients based on comorbidities

Comorbidities	Frequency	Percentage
Yes	219	62.6
No	131	37.4
Total	350	100.0

Table 10: Distribution of patients according to no. of comorbidities

No. of comorbidities	Frequency	Percentage
0	131	37.4
1	136	38.9
2	71	20.3
3	11	3.1
4	1	.3
Total	350	100.0

The results of this study provide crucial insights into the demographic, anthropometric, clinical, and treatment characteristics of diabetes patients recovering from COVID-19. The sample's skewed age distribution, with a high prevalence of individuals aged 51–70 years, is consistent with the higher prevalence of renal impairment and comorbidities such as hypertension and cardiovascular diseases in middle-aged and elderly populations. This underscores the need for targeted healthcare strategies to address these at-risk groups [20].

The notable male predominance (69.1%) in this study suggests potential gender-specific risk factors for renal impairment and variations in healthcare-seeking behavior between men and women. Furthermore, the high prevalence of overweight and obesity (46.6%) underscores the need to address obesity as a key modifiable risk factor for diabetes complications and inadequate glycemic control. The BMI distribution also pointed to a higher occurrence of obesity among females, further emphasizing the need for gender-specific interventions [21].

The substantial proportion of patients reporting comorbidities (62.6%) emphasizes the complex clinical management of diabetes in this cohort.

Hypertension and cardiovascular diseases are commonly associated with diabetes and renal impairment, making integrated care for managing these comorbidities essential. The suboptimal glycemic control observed in a significant portion of the sample, with a high mean HBA1c value of 8.31%, underscores the challenge of achieving optimal diabetes management, especially in the post-COVID recovery phase [22].

Regarding treatment, the high percentage of patients receiving oral agents (75.1%) and combination therapies (19.4%) reflects the standard treatment approach for diabetes, with insulin usage being less frequent (5.4%). Despite this, a majority of patients adhered to their prescribed regimens, which is encouraging and suggests that efforts to improve patient education and simplify medication regimens have been effective. However, the study also highlights the need for continuous efforts to improve adherence, particularly among the 32% of non-adherent patients [23].

The observed male predominance (69.1%) is in line with research indicating that men may have a higher risk of diabetes-related complications due to differences in healthcare-seeking behavior and biological susceptibility [24]. The higher obesity rate among female's further supports findings that gender-specific interventions are crucial for effective diabetes management.

The presence of comorbidities in 62.6% of participants aligns with studies highlighting the frequent coexistence of hypertension and cardiovascular diseases in diabetic populations [25]. Given the well-established link between these conditions and renal impairment, integrated care models remain essential for improving patient outcomes. Furthermore, the suboptimal glycemic control observed in this study (mean HbA1c: 8.31%) is comparable to previous reports emphasizing the challenge of achieving optimal blood sugar levels in post-COVID diabetes patients [26-27].

CONCLUSIONS

This study highlights key clinical and treatment characteristics of T2DM patients in the post-COVID recovery phase. The high prevalence of obesity, hypertension, and cardiovascular diseases underscores the need for integrated care strategies. Poor glycemic control (mean HbA1c: 8.31%) and a 32% non-adherence rate emphasize the importance of personalized treatment plans and adherence-support programs. Clinically, these findings stress the need for targeted interventions in glycemic control, comorbidity management, and lifestyle modifications. Future research should focus on multidisciplinary approaches, digital health tools, and long-term metabolic effects of COVID-19 to enhance diabetes care and outcomes.

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ETHICS APPROVAL

This study was approved by Swecha Indenpendent Ethics Committee (Ref number:10/2022) and this study enrolled and approved by CTRI

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AUTHORS CONTRIBUTION

All the authors have equal contribution in the preparation of manuscript.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest regarding the publication of this manuscript.

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