

# Impact of SARS-CoV-2 Pandemic on Glycaemic Control, Metabolic Status, Treatment Adherence, Quality of Life in Diabetes Mellitus Patients in Tertiary Care Hospital of Eastern India

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## ABSTRACT

**Introduction:** Many medical and social challenges have been noticed during lockdowns and restrictions in the course of the COVID-19 pandemic. These restrictions had a profound impact on people's lifestyle and caused psychological distress. In the management of type 2 diabetes mellitus, lifestyle modifications, such as nutritional intervention and proper physical activity, are important aspects.

**Aims/objective:** To study the effect of lockdown or self-imposed restrictions due to pandemic on glycaemic control in diabetes mellitus patients and the possible determinants, including diet, sleep, physical activity, psychological status and adherence to treatment.

**Materials and method:** A comparative analysis of the glycaemic status and metabolic parameters (such as random blood glucose, glycated haemoglobin, weight, hypoglycaemia and lipid profile), lifestyle and psychological changes and treatment adherence was done in 103 patients. Retrospective pre-lockdown data was collected from the clinical records and interviews (offline, online or by telephone). Prospective lockdown/restrictions data was questionnaire based. Chi-square test was used to analyse categorical data and ANOVA for continuous data.

**Results:** The majority of patients were in the age group of 40-60 years. Most of them reported disturbance in their adherence to proper diet, physical activity, sleep and medication schedule. These differences of opinion were statistically significant ( $p < 0.00001$ ). There were more patients who reported stress and anxiety and this difference was statistically significant. Deterioration of glycaemic control and lipid profile

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was highly significant ( $p < 0.00001$ ). Mean body weight was increased by 6.67% at the end of the study and the difference was statistically significant.

**Conclusion:** In patients with diabetes, pandemic-related restrictions had a profound impact on the glycaemic control, metabolic status, adherence to medication and quality of life. This highlights the need for a multidisciplinary approach in managing patients with diabetes, focusing on various issues, including prevalence of poor diet control, physical inactivity and psychological stress, via various awareness and counselling programs, preferably through online mode.

**Keywords:** COVID-19 pandemic, type 2 diabetes, glycaemic control, lifestyle, physical activity, anxiety, sleep, lockdown, restrictions.

## INTRODUCTION

Many medical and social challenges have been noticed after the outbreak of the novel coronavirus disease 2019 (COVID-19) pandemic. Various nationwide lockdowns were implemented by many countries to halt the spread of disease. These lockdowns have caused millions of peoples to remain confined inside their homes for months (1). People of India had also faced months of lockdown affecting their lifestyle with all recommended precautions such as social distancing and social isolation (2).

On the other hand, type 2 diabetes mellitus continues to be a potential epidemic in India (3). It is a chronic metabolic disorder, mainly characterised by hyperglycaemia, which generally leads to pathogenesis of many microvascular and macrovascular disorders such as atherosclerosis, coronary artery disease, stroke and chronic kidney disease (4). Lifestyle changes, including nutritional intervention and proper physical activity, are important aspects for the management of diabetes mellitus (5).

As reported from many countries, the nationwide lockdowns have led to sudden limitation to physical activities, movement, and access to many food items, limiting the food choices. These circumstances have caused deprivation of social, mental and emotional well-being. Loss of employment have led to anxiety, stress and poor sleep, which all adversely affected the quality of life (6). However, there is insufficient documentation of the effect of these disturbances on glycaemic control in diabetic patients. Some earlier studies hypothesized the adverse effect of

lockdown on the glycaemic status of patients with type 2 diabetes mellitus (7). Other non-communicable diseases such as hypertension, dyslipidaemia, ischemic heart disease, obesity, etc, which often co-exist in patients with type 2 diabetes mellitus, are also likely to be adversely affected by the sudden limitations to lifestyle and access to routine visits to their consultant doctors.

Limitation of access to routine healthcare services and breach in regular consultation, along with disruption in eating pattern and increased dependency on processed food items is also documented to have an adverse impact on glycaemic control in type 2 diabetes mellitus patients (8). However, some other authors had a contrary opinion in this regard and did not expect that these changes in people's lifestyle could have such an alarming effect on the glycaemic status of patients with diabetes (9). A similar study based on online and telephonic surveillance found that lifestyle disturbances did not have any profound impact on the glycaemic status of diabetic patients (10).

In the above-mentioned studies, alteration in eating pattern, physical activities and limited access to regular consultation and medications were reported to adversely affect blood glucose and other metabolic parameters. Apart from these, fear and anxiety were also found to be higher in patients with diabetes than the general population because of the higher fatality rate due to SARS-CoV-2 (11). These psychological disturbances and stress disrupt the hormonal homeostasis and can lead to hyperglycaemia. Stress may have a stronger effect on the level of post-prandial blood glucose than that of fasting blood glucose because there is less sympathetic activity with sleep (12).

A contradicting result was reported in another survey, where the authors noticed a post-lockdown improvement in body weight and blood glucose level (13). So, there is still not enough evidence of real-world data to comment on the effect of disruption caused by lockdown on patients with type 2 diabetes mellitus.

The long-term consequences of social lockdown may become blurred in our vision. But the short-term effect of alteration in physical activities, eating pattern and psychological disturbances can provide us valuable feedback.

So, the present study was planned to explore the effect of lockdown or self-imposed restrictions due to pandemic on the glycaemic control in patients with diabetes mellitus and the possible determinants, including diet, sleep, physical activity and adherence to treatment. □

## MATERIALS AND METHODS

This was an observational and analytical study conducted in the Outpatient Department of Endocrinology and Department of Pharmacology of Indira Gandhi Institute of Medical Sciences (IGIMS), Patna, India, after approval by the Institutional Ethics Committee (IEC) of IGIMS, Patna (vide Letter No.-171/IEC/IGIMS/2021 dated 25/06/2021). Informed consent was taken from each study participant. The study duration was of three months from July 2021 to September 2021.

### Inclusion criteria

Patients with diabetes who attended our endocrine outpatient department and had a good glycaemic control (14) in the past, without any chronic complications, and willing to participate in the study were included. Their selection was based on previous follow-up clinical records. The following inclusion criteria for enrolment into the study were used:

- adult patients previously diagnosed with type 2 diabetes mellitus on treatment;
- patients who were willing to participate in the study;
- patients on oral anti-diabetic drug.

### Exclusion criteria

- Type 1 diabetes mellitus
- Type 2 diabetes patients with moderate to severe complications of diabetes or any other coexisting disease

- Patients with established microvascular or macrovascular complication of diabetes
- Pregnancy
- Non-willingness to participate in the study
- Patients who had been SARS-CoV-2 positive or had SARS-CoV-2 infection
- Patients with incomplete records and inaccessible data who had comorbidities such as liver disease, renal failure, active infection, cancer.

Based on the inclusion and exclusion criteria, 103 patients were selected from the outpatient Department of Endocrinology. Comparative analysis of various parameters, including glycaemic status, metabolic parameters and treatment adherence, was done.

Data collection was divided into two parts:

1. *Retrospective pre-lockdown data* – Patients' clinical records and interviews (offline, online or by telephone) were searched to collect relevant data such as random blood sugar (RBS), glycated hemoglobin (HbA<sub>1c</sub>), weight, hypoglycemic episodes, lipid profile from prescriptions, inpatient department files and laboratory reports.
2. *Data during prospective lockdown/when self-imposed restrictions were placed to refrain from getting infected* – A questionnaire focused on lifestyle, glycemic control, metabolic parameters and treatment adherence was used. Patients' laboratory reports were also collected.

The questionnaire was developed according to similar research reported in the literature (15, 16). Assessment of face and content validity was done by a panel of five experts and the content validity index (CVI) for the questionnaire was 0.8. Intraclass correlation coefficient (ICC) was used to assess the reliability of the questionnaire and the ICC value was found to be 0.89 (17).

### Statistical analysis

Descriptive analysis was done to interpret the results by using Microsoft excel. Qualitative data was expressed in proportion and percentages and quantitative data as mean and standard deviation (SD). The difference in proportion was analysed by using the chi-square test and the significance level for tests was 95% ( $P < 0.05$ ). We used one way (analysis of variance) ANOVA for the inter-phase comparison of quantitative data and re-

**Questionnaire**

Name (optional): \_\_\_\_\_ Age/Sex: \_\_\_\_\_  
 Mobile no.: \_\_\_\_\_ Family income: \_\_\_\_\_

Tick only one option from following questions:

1. What is your diet type?  
 a) Vegetarian \_\_\_\_\_ b) Non-vegetarian \_\_\_\_\_
2. What was the effect of COVID-19 lockdown/restrictions on your **adherence to diet pattern as suggested by your doctor/physician**?  
 a) Increased/Improved \_\_\_\_\_ b) Decreased/Disturbed \_\_\_\_\_ c) No effect \_\_\_\_\_
3. What was the effect of COVID-19 lockdown/restrictions on your **physical activity**?  
 a) Increased/Improved \_\_\_\_\_ b) Decreased/Disturbed \_\_\_\_\_ c) No effect \_\_\_\_\_
4. What was the effect of COVID-19 lockdown/restrictions on your **sleep**?  
 a) Increased/Improved \_\_\_\_\_ b) Decreased/Disturbed \_\_\_\_\_ c) No effect \_\_\_\_\_
5. What was the effect of COVID-19 lockdown/restrictions on your **schedule of proper medication as told by doctor**?  
 a) Increased/Improved \_\_\_\_\_ b) Decreased/Disturbed \_\_\_\_\_ c) No effect \_\_\_\_\_
6. What was the effect of COVID-19 lockdown/restrictions on your **visit to doctor or your check-up (like blood test)**?  
 a) Increased/Improved \_\_\_\_\_ b) Decreased/Disturbed \_\_\_\_\_ c) No effect \_\_\_\_\_
7. Has COVID-19 lockdown/restrictions increased **financial stress (problem of less money)** of your family?  
 a) Yes \_\_\_\_\_ b) No \_\_\_\_\_
8. Were you stressed and anxious about spread of COVID-19?  
 a) Yes \_\_\_\_\_ b) No \_\_\_\_\_
9. Were you stressed due to loss of your interactions from your closed ones?  
 a) Yes \_\_\_\_\_ b) No \_\_\_\_\_
10. Were you anxious about the news of your closed ones being affected with COVID-19?  
 a) Yes \_\_\_\_\_ b) No \_\_\_\_\_
11. Were you stressed or afraid of missing your visit to your doctor and not getting essential medicines?  
 a) Yes \_\_\_\_\_ b) No \_\_\_\_\_
12. Was your blood sugar  $\leq 70$  mg/dL (as checked by glucometer)? If yes, then how many times?  
 a) 1 \_\_\_\_\_ b) 2 \_\_\_\_\_ c) 3 or more \_\_\_\_\_

peated measure one way ANOVA for comparison of parameters in the same phase. □

### RESULTS

During the three months of study from July 2021 to September 2021, 103 patients who fulfilled the inclusion criteria were selected to participate in the present study. Their pre-lockdown relevant data was collected from prescrip-

tions, clinical records, laboratory reports and of-line or online or telephonic interviews. Data during prospective lockdown included laboratory reports and response to questionnaire which primarily focussed on questions related to lifestyle changes, alteration in glycaemic control, changes in metabolic parameters and treatment adherence. Analysis of questionnaire responses as well as demographic and baseline characteristics showed that patients' age was  $50.11 \pm 3.03$

Lifestyle parameter	No. of patients with response (a) i.e., increased/improved (%)	No. of patients with response (b) i.e., decreased/disturbed (%)	No. of patients with response (c) i.e., same as before (%)	P value (chi-square)
Adherence to diet as suggested by doctor/dietitian	6 (5.83)	67 (65.05)	30 (29.13)	P value < 0.00001
Physical activity	9 (8.74)	79 (76.70)	15 (14.56)	
Sleep	27 (26.21)	29 (28.16)	47 (45.63)	
Adherence to prescribed medication schedule	5 (4.85)	17 (16.50)	81 (78.76)	
Adherence to scheduled consultation and investigation	1 (0.97)	83 (80.58)	19 (18.45)	

**TABLE 1.** Lifestyle changes during lockdown (n=103) as assessed by responses to questions from 2 to 6

No.=Number

Psychosocial changes	Yes (%)	No (%)	P value (chi-square)
Financial stress	60 (58.25)	43 (41.75)	P value < 0.00001
Stress and anxiety of SARS-CoV-2*	87 (84.47)	16 (15.53)	
Stress due to disturbance in social interaction	71 (68.93)	32 (31.07)	
Anxiety of loved ones affected with SARS-CoV-2*	21 (20.39)	82 (79.61)	
Anxiety of missing necessary consultation and medicines	79 (76.70)	24 (23.30)	

**TABLE 2.** Psychosocial changes during lockdown (n=103)

SARS-CoV-2\* = severe acute respiratory syndrome coronavirus 2

Parameters	Pre-lockdown period	Lockdown period			P value (ANOVA)
		First follow-up (one month)	Second follow-up (two months)	Third follow-up (three months)	
RBS (mean ± SD) in mg/dL	168.21 ± 15.13	178.19 ± 14.52	192.09 ± 13.85	209.01 ± 11.85	<0.00001
HbA <sub>1c</sub> (mean ± SD) in %	6.72 ± 0.24	7.22 ± 0.15	7.71 ± 0.34	7.98 ± 0.41	<0.00001
Weight (mean ± SD) in kg	65.22 ± 9.61	67.33 ± 8.74	68.11 ± 9.13	69.57 ± 10.31	0.0107
<b>Hypoglycaemia</b>					<b>P value Chi-square test</b>
No. of patients with 0 episodes	90	71	66	68	Chi-square: 19.130 P value: 0.0241
No. of patients with one episode	10	22	23	21	
No. of patients with two episodes	2	7	9	8	
No. of patients with 3-5 episodes	1	3	5	6	

**TABLE 3.** Comparison of diabetes related clinical parameters between the pre-lockdown and lockdown period (n=103)

SD=standard deviation; RBS=random blood sugar; HbA<sub>1c</sub>=glycated haemoglobin

(mean ± SD). Most of them belonged to the age group of 40-60 years. Out of all patients, 55 were males and 48 females. There were 89 non-vegetarians, a significantly higher number than that of vegetarians (only 14 of all patients). Regarding the socioeconomic status, the majority of patients (67) belonged to the middle class and had an income between rupees 5-10 lakhs/year as per Indian currency, followed by 25 patients with a lower socioeconomic status and an annual income < rupees five lakhs and 11 patients with an upper socioeconomic status and an annual income > 15 lakh rupees as per Indian currency.

Lifestyle changes were assessed by responses given to questions from 2 to 6 in the question-

naire. These questions elicited the effect of SARS-CoV-2 pandemic induced lockdown on changes in dietary pattern, physical activity, sleep, adherence to prescribed medication, and scheduled consultations and investigations. Responses to these questions were (a) increased/improved, (b) decreased/disturbed, and (c) no effect/same as before. The number of patients with either of responses were summed up to understand the effect of lockdown/self-imposed restrictions due to pandemic on lifestyle parameters.

Analysis of responses showed that adherence to diet as well as scheduled consultations and investigations were disturbed, physical activity was decreased, but there was no sleep disturbance in

Parameters	Pre-lockdown period	Lockdown period			P value (ANOVA)
		First follow-up (one month)	Second follow-up (two months)	Third follow-up (three months)	
Total cholesterol	168.96 ± 21.32	168.49 ± 18.77	171.03 ± 20.83	171.16 ± 23.16	0.7222
Triglycerides	138.62 ± 13.42	143.53 ± 10.13	145.21 ± 11.41	147.67 ± 14.37	<0.00001
Low density lipoprotein	97.87 ± 15.32	99.63 ± 13.27	102.13 ± 14.37	103.31 ± 15.67	0.0364
High density lipoprotein	43.37 ± 3.32	40.15 ± 3.47	39.86 ± 4.18	38.32 ± 4.62	<0.00001
Very low-density lipoprotein	27.72 ± 2.68	28.71 ± 2.03	29.04 ± 2.28	29.53 ± 2.87	<0.00001

TABLE 4. Comparison of lipid profile data between pre-lockdown and lockdown period (n=103)

most participants during the SARS-CoV-2 pandemic. Observations were summarised in Table 1.

Psychosocial changes during lockdown were evaluated on the basis of patients’ responses to questions from 7 to 11 (Table 2).

Clinical parameters related to diabetes, including random blood sugar, glycated haemoglobin, weight and incidence of hypoglycaemia, collected from clinical records and laboratory reports, were compared between the pre-lockdown and lockdown period.

When lipid profile data were explored, there was a significant increase in triglyceride, low density lipoprotein (LDL) and very low-density lipoprotein (VLDL) levels and a significant decrease in high density lipoprotein (HDL) values during lockdown as compared to the pre-lockdown period (Table 4). □

### DISCUSSION

To the best of our knowledge, this was probably the first study from Eastern India at the time of our research that has investigated the effect of lockdown and restrictions imposed during the SARS-CoV-2 pandemic on lifestyle, psychosocial aspects and metabolic parameters of patients with diabetes.

Most participants to our study were aged between 40 and 60 years, similarly to a global statistical report which documented that the majority of patients with diabetes are over 60 years old in developed countries, but belong to the working age group (40-60 years) in developing countries

(18). People of the latter age group generally have a more sedentary lifestyle than younger age groups. Rise in urban culture in developing countries results in more sedentary lifestyle, which is a major contributor to increasing the prevalence of diabetes (16). There is an urgent need to decrease the effects of urbanization on people’s lifestyle. The results of programs focused on people’s lifestyle are satisfactory (20, 21).

In our study, the number of male patients was greater than that of female patients, which is similar to worldwide trends in older age groups (22). According to the Centres for Disease Control and Prevention (CDC), men are more likely to receive a diagnosis of diabetes than women.

Most patients in our study belonged to the middle class (65.05%), followed by lower class (24.27%) and upper class (10.68%).

The majority of patients reported that the lockdown or restrictions imposed due to SARS-CoV-2 had affected their lifestyle adversely. Adherence to scheduled consultations and/or investigations were affected in the first place, followed by physical activity. These differences in opinions were statistically significant (p <0.00001). Earlier studies also reported the disturbance of availability and accessibility to medicines among patients who lived far away from town (7, 8), but our study population was from the capital city; thus, only 17 participants reported some disturbance in their prescribed medication schedule, which was not due to unavailability of medicines but to increased workload and economic concerns. Disturbance in sleep was only reported by

28.16% of patients, while 65.05% of all participants agreed that they had difficulty in following the diet schedule as suggested by their doctor or dietitian. Similar results were reported by earlier studies (6, 23), while findings of other studies were not in accordance with ours.

More than half of patients agreed that the lockdown/restrictions due to SARS-CoV-2 had added to their stress and anxiety. Stress and anxiety due to loss of employment and in arranging livelihood was major concern for private jobholders. Also, 84.47% of participants agreed that they were anxious about the greater trend mortality and morbidity in patients with diabetes due to SARS-CoV-2. Disturbance in social interactions also added to patients' distress. Twenty one participants also experienced pain and anxiety because their closed ones were suffering from SARS-CoV-2 infection. These differences in opinion were also statistically significant ( $p < 0.00001$ ).

A previous study found that about 87% of people with type 2 diabetes mellitus had psychological stress and anxiety and 27% experienced insomnia during pandemic lockdown and restriction period (8, 24), although another study (10) reported that 40% of participants were concerned about SARS-CoV-2 and most of them (73%) were very optimistic that the situation would improve in the future. Watching entertaining shows on television, doing chores around the house and spending enough time with their family members may help many patients to deal with stress and anxiety. However, there was a pattern of unhealthy eating habits in those with increased stress and insomnia. Anxiety about the mortality caused by SARS-CoV-2 had a considerable effect on sleep quality and quantity. Awareness and education of vulnerable people regarding necessary skills and activities to deal with the situation, especially women, need time in maintaining mental cohesion during upcoming waves of SARS-CoV-2. Lifestyle changes and depression were identified as potential causes of disruption of glycaemic control in a recent study from Central India (25).

There was a significant deterioration of glycaemic control during the lockdown and restriction period, which was evident from mean RBS and HbA<sub>1c</sub> data. Similar results were reported by some earlier studies too (8, 26). The negative impact on lifestyle and psychological condition, as documented in our study, was probably the obvious reason for this. The impact of disturbance in ad-

herence to healthy dietary pattern and physical activity was also reflected in the lipid profile. Thus, there was a significant decrease in HDL levels and an increase in LDL, triglyceride and VLDL levels. Disturbances in dietary and medication adherence had also led to an increased number of hypoglycaemic episodes.

The considerable increase in HbA<sub>1c</sub>, observed in those with an "unhealthy eating pattern" and low physical activity, highlights the need of maintaining a healthy lifestyle. Major concerns were reported in many previous research articles too (7, 8, 24, 27). Significant concern about sedentary lifestyle and "unhealthy eating pattern" is particularly prominent in the elderly. It was also frequently seen in those who missed their drugs during restriction periods. These findings highlighted the poor awareness among people, which we found to be an important field for future intervention. There was a 6.67% increase in patients' mean body weight at the end of the study, which was both statistically and clinically significant. Adequate maintenance of body weight is defined as less than 3% increase from baseline body weight and more than 5% increase in body weight is considered clinically significant (28).

According to a similar study from North India, there was a significant decrease of egg consumption and an increased water intake among men during lockdown, while women reported that there was no alteration in their physical activity levels even during lockdown as compared to the pre-COVID times. Also, medication adherence and glycaemic control were found to be improved during the lockdown period as compared to pre-lockdown times (29).

In a similar study from Central India, worsening of hyperglycaemia was significantly observed in the majority of patients and addition of medications was required for control of blood glucose levels. Psychological stress was reported to be the most common factor for worsening of hyperglycaemia followed by change in diet and exercise (26). In contrast to our study, a similar study from South India found that the overall physical activity and adherence to prescribed diet remained unchanged in more than 80% of participants (24).

As we used specific exclusion criteria, patients whose factors could exert an effect on lifestyle and glycaemic control were already excluded from the study, which helped us eliminate many confounders. There were very few studies that

had compared metabolic parameters before and after lockdown.

Our study has some limitations too. Face to face offline interaction was kept to a minimum due to preventive measures. Our study participants were from urban area, which was less affected in terms of access to consultations and medication. Also, because of restrictions there were times when we had to rely on telephonic retrieval of information, so sometimes calls went unanswered. Due to the limited duration of our study, long term effects on metabolic parameters and glycaemic status could not be known. ▣

### CONCLUSION

**O**ur study revealed a negative impact of lockdown or restriction periods due to SARS-CoV-2 pandemic on overall glycaemic control. Disturbance of lipid profile and clinically significant increase in body weight was also found. Our survey has also confirmed a disturbance in proper dietary adherence, physical activity and

sleep as well as an overall increase in stress and anxiety. Thus, our results support the strong association between these factors and poor glycaemic control. This highlights the need for a multidisciplinary approach to managing patients with diabetes, focusing on various issues, including prevalence of poor diet control, physical inactivity and psychological stress, via various awareness and counselling programs, so that we are better equipped in handling these issues in case of upcoming waves of SARS-CoV-2 pandemic. ▣

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