TO STUDY THE EFFECT OF PANDEMIC RESTRICTION ON QUALITY OF LIFE AND MEDICATION ADHERENCE OF TYPE 2 DIABETES PATIENTS

Deekshitha L[1], Chandana K S[1], Bindu B N[1], Ashmita Modak[1], Parthasarathy G[2*]

Department of Pharmacy Practice, The Oxford college of Pharmacy, Bengaluru, India.

ABSTRACT

Objectives: To study the effect of covid 19 pandemic restrictions on quality of life and medication adherence in diabetic patients.

Methods: A prospective cross-sectional study was conducted in The Oxford Medical College and Research Centre with 124 patients diagnosed with a-history of Type 2 diabetes(Type 2 DM). Consent was taken, and information was collected through a data entry form between May 2022 and October 2022. These subjects were interviewed using WHOQOL BREF and MORISKY MEDIATION ADHERENCE SCALE -8(MMAS-8) used to measure the effect of pandemic restriction in detail on quality of life and medication adherence. A follow-up was done after 2 weeks to measure the improvement in medication adherence.

Result: A total of 124 Type 2 DM patients were included in this study. 33.05% of patients rated poor quality of life (QOL), and 71.75% were dissatisfied with their health during the pandemic period. Medication adherence during pandemic was low with mean score of (5.12±1.86) evaluated with MMAS-8

Conclusion: The study suggests that the pandemic restrictions have widely impacted the QOL, physical activity, lifestyle and adherence. From the study we conclude that there are significant changes in Quality of life and medication adherence of diabetic patient during pre-pandemic and pandemic period.

KEY WORDS: Type II DM, Quality of life, WHOQOL BREF, MORISKY MEDICATION ADHERENCE SCALE 8.

INTRODUCTION

Covid-19 is a viral infectious disease caused by the SARS-COV-2 virus [1]. The strain was first identified in WUHAN, CHINA on 31st December 2019 and has spread to entire world. Although many measures were taken to control the spread of disease, the viral transmission rate was extremely high, with the WHO declaring Covid-19 a pandemic. In order to control and as a preventive measure against the Covid-19 pandemic in India on the evening of 24th march 2020 the government of India ordered a Nationwide lockdown for 21 days. Then later the lockdown was extended up to 31 may 2020 followed by unlock. The lockdown restricted people from stepping out of their homes. All the transport services were suspended. General restriction like physical distancing, restricted to stay at homes, work from home, online classes were implemented, parks and gyms were shutdown. Due to this restriction the life style of many diabetes patients was changed drastically some good changes and some bad changes were seen. Diabetes mellitus (DM) is a metabolic disorder involving inappropriately elevated blood glucose levels called hyperglycemia resulting from a defect in either insulin secretion, insulin action or both [2]. The chronic hyperglycemia of diabetes is associated with specific long-term microvascular complications and macrovascular complication[2]. Due to the restriction most of physical activity was reduced due to lack of movement, healthcare services access was limited because focus was more on management and control of covid and psychological stress these are negative outcome whereas as positive outcomes being limited access to junk food. Deprived sleep due to binge watching and unhealthy habits many other factors showed changes in glycemic index of patients. [3-5] The Medication non adherence is common among diabetes and it is one of the leading public health challenges and restricted access to healthcare facilities the prevalence of medication non adherence became much more common. Poor adherence leads to poor glycemic controls, increased rate of complication leading to increased morbidity and mortality, during lockdown period. when sedentary lifestyles, poor dietary habits and sleep deprivation prevailed which are potentially modifiable risk factors for poor glycemic index control, due to financial crisis like loss of work, many people discontinued the use of medication and poor dietary and eating habits.[4]All this factors affect the QOL and medication adherence of the diabetes patients hence this study assesses the Quality of Life in diabetic patients during pre-pandemic and pandemic period using WHOQOL BREF questionnaires and assess the Medication adherence of diabetic patients during Pandemic period using MMAS-8 which is a tool used to investigate medication adherence of individual patient and compare the scores pre counseling and post counseling.

METHODOLOGY

Study type

A prospective cross-sectional study on effect on medication adherence and quality of life in type 2 diabetic patients during pandemic period in tertiary care hospital.

Study location

The clinical study was conducted on the inpatients and outpatients admitted in the General Medicine department of The Oxford Medical College hospital and Research Centre, Attibele, Bangalore.

Duration of clinical study

This study was conducted for minimum 6 months of duration from MAY 2022 to OCTOBER 2022.

Study sources

- Patient case records
- WHOQOL BREF QUESTIONNAIRES (To assess the quality of life before and during the pandemic period)
- MORISKY 8 MEDICATION ADHERENCE SCALE

- Patient interview

Sampling calculation and Sampling method

Based on the prevalence [6] rate of diabetes the sample size was calculated using cochran's formula[7] for a cross sectional design.[8] A calculated sample size of 124 patients were included in the study through Simple random sampling technique.

Inclusion criteria

- Informed consent form
- >18 years age
- Both male and female patients
- Patients with Type 2 DM with cardiovascular comorbidities

Exclusion criteria

- Pregnant and lactating women
- Patients with Type 1 diabetes

Ethical approval

This study was initially approved by the Institutional Ethics Committee of The Oxford Medical College Hospital and Research Centre, Attibele, Bangalore. (Reference number: IEC/TOMCHRC/202/2022-23)

WHOQOL BREF QUESTIONNAIRE:

It is a survey instrument to assess Quality of life of Diabetes patients.[9-11] It was developed by WHO and published in 1995.. The WHOQOL BREF is a self-administered questionnaire comprising 26 questions. Responses to questions are on a 1- 5 Likert scale where 1 represents "disagree" or "not at all" and 5 represents "completely agree" or "extremely".[12-15]It consists of four domains: Physical health (7 items), psychological health (6 items), Social relationships (3 items) and Environmental health (8 items); Each individual item of the WHOQOL BREF is scored from 1 to 5 on a response scale, which is stipulated as a five-point ordinal scale. The scores are then transformed linearly to 0 – 100 scale. The scores obtained from patients' interview are calculated using a WHOQOL BREF online calculator.[16-18]

MORISKY MEDICATION ADHERENCE SCALE-8: It is a validate assessment tool used to measure medication adherence in a variety of patient populations. Question 1 through 7 have categorical responses (yes/no). Item 8 has five points Likert scale. each "No" is coded "0 "and each "yes" is coded "1 ". For question 8, if participant select A, it codes "0", if participant select B to E, it codes "1".[19-22]

The total MMAS – 8 scores from 0 – 8. The adherence level is considered LOW if the MMAS score ranges between 3-8, MEDIUM if in the range of 1 to 2 and HIGH if equal to 0.[23]

RESULTS

A total of 124 subjects were included in the study. In which 63%(78) were male and 37%(46) were female. The maximum numbers of patients were in the age group 40-69 years (50.80%) which may be due to lifestyle changes and dietary habit changes. The occupational data shows that majority of the patient were daily labour (24%), housewife (22%), self-employed (20%), unemployed (14.5%), and least number of patients was found to be farmer (13%) and IT employee (6%). 72% of patients had decreased their physical activity in pandemic period compared to pre pandemic period. More than half of the patients (60%) were overweight based on BMI. Only 11% had good control of HbA1C where ¾ of the patients had poor control of HbA1C similar percentage is related to GRBS where only ¼ of patients has normal GRBS level as shown in TABLE 1

Table 1: Distribution of diabetic patients according to their socio-demographic details

| Characteristics (n = 124)	n	%
Gender		
Male	78	63%
Female	46	37%
Age in years		
30-39	13	10.4%
40-49	32	25.80%
50-59	29	23.38%
60-69	31	25%
70-79	14	11.29%
Occupation		
Daily labour	30	24%
Farmer	16	13%
Housewife	28	22%
Unemployed	18	14.5%
It employee	7	6%
Self employed	25	20%
Physical activity in Pandemic		
Increased	5	4.03%
Decreased	90	72.58%
No Change	29	23.38%
Body mass index		
Under weight	1	1%
Over weight	75	60%
Normal	38	31%
Obese	10	8%
Under weight	1	1%
GRBS (mg/dl)		
<140 mg/dL	2	1.61%
140-200	16	12.90%
>200	106	85.48%
HbA1C (%)		
5.7-6.5	5	4%
6.5-7.0	9	7%
7.0-8.0	28	23%
8.0-10	55	44%
>10	27	22%

Through WHOQOL BREF questionnaires it was found that the average mean score for Q1 was **3.85** (SD 0.585) during Pre-Pandemic period and **2.75** (SD 0.782) in Pandemic period and average mean score for Q2 was **3.76** (SD 0.603) during Pre-Pandemic period and **2.60** (SD 0.806) in Pandemic period. This shows that Overall Quality of life was good in Pre Pandemic Period and poor in Pandemic period

The average mean score of the physical health domain in pre pandemic period is 66.96 (SD 12.78) and 42.75(SD 15.05) in pandemic period, the average mean score of the psychological health domain in pre pandemic period is 67.66(SD 13.40) and 46.83(SD 14.01) in pandemic period, the average mean score of the social relationship domain in pre pandemic period is 69.14(SD 10.16) and 62.98(SD 12.49) in pandemic period and the average mean score of the environmental health domain in pre pandemic period is 66.73(SD 10.69) and 47.38(SD 9.80) in pandemic period as shown in table 2 and figure1. The p value obtained based on the statistical analysis using wilcoxon test is 0.0001 revealing that QOL of the diabetic patient

Table 2 : Distribution of Mean and Standard deviation scores of diabetic patients Based on WHOQOL BREF questionnaire

| Domains	Pre pandemic period	Pandemic period
	Mean ± SD	**Mean ± SD**
Q1. How would you rate your QoL?	3.85 ± 0.585	2.75 ± 0.782
Q2. How satisfied are you with your health?	3.76 ± 0.603	2.06 ± 0.94
Physical health	66.96 ± 12.78	42.75 ± 15.05
Psychological health	67.66 ± 13.40	46.83 ±14.01
Social relationships	69.14 ± 10.16	62.58 ±12.49
Environmental health	66.73 ± 10.69	47.38± 9.80
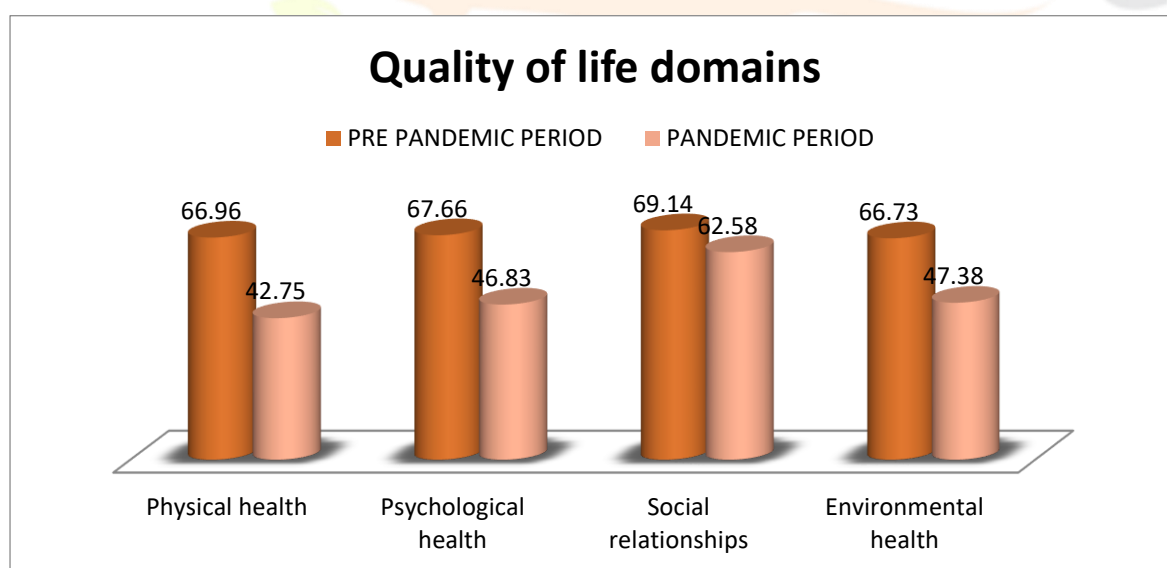
Fig 1: Graph showing Quality of life of 4 domains in pre and pandemic period

 Out of the total 124 patients, **(n=80, 64.5%), (n=36, 29.03%) and (n=8, 6.45%)** were low, medium and high adherent groups respectively during pandemic period i.e., Pre-Counselling medication adherence scores. Out of total 124 patients, **(n=17, 13.70%), (n=48, 38.70%) and (n=59, 47.58%)** were low, medium and high adherent scores of the groups respectively after 2 weeks of counseling as shown in table 3 and figure 2. low adherent to medications in pandemic period may due to financial crisis, lockdown restrictions, low access to healthcare, reduced follow up visits but after proper counseling about the importance of medication adherence there was an improvement seen in the patients where more than half of the patients were highly adherent to medications may be due to effect of counselling, decreased burden of finance as covid 19 was almost in control, decreased lockdown restrictions, increased access to health care services[24-27]statistical analysis using

wilcoxon sign rank test was performed obtaining the P value of 0.0004 which revealed that the medication adherence was improved post counseling

Table 3: Distribution of mean and standard deviation scores of medication adherence in pre and post counseling

Adherence	Pre counselling Medication adherence	Post counselling Medication adherence
High Adherence (0)	8 (6.45%)	59 (47.58%)
Medium Adherence (1-2)	36 (29.03%)	48 (38.70%)
Low Adherence ≥ 3	80 (64.5%)	17 (13.70%)
Mean ± SD	5.12 ± 1.86	2.06 ± 0.94
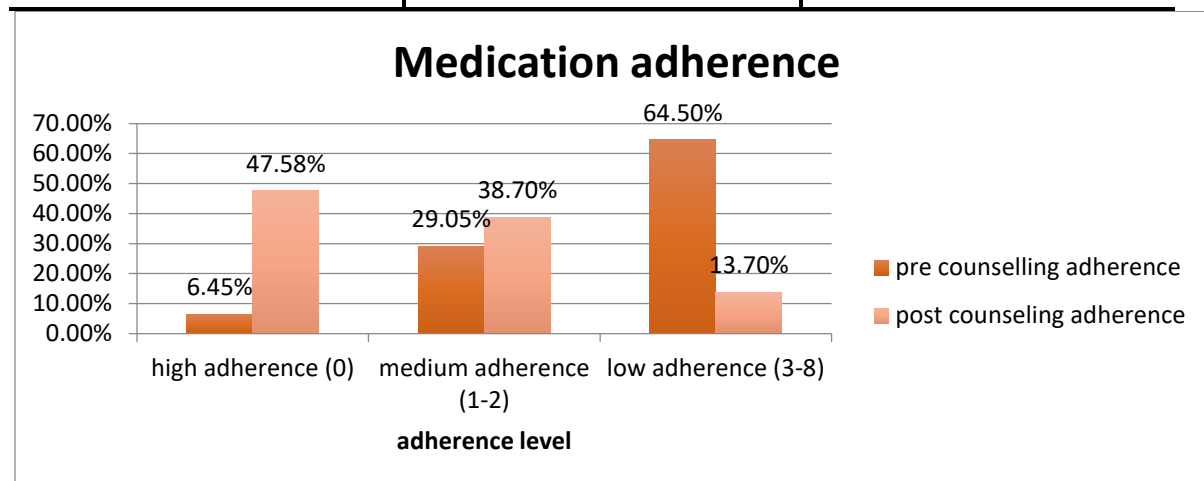
Fig 2: Graph showing Medication adherence in Pre and Post counseling

DISCUSSION

This study was performed to evaluate the effect of pandemic restriction on QOL AND MA of diabetic patients. The study expresses the result in 4 domains and their changes observed during pre-pandemic and pandemic period. The mentioned four domains are physical health, psychological health, social relationship and environmental health. And even the lifestyle and dietary pattern is also assessed in this study.

In this study out of 124 patients it was found that 78 were male and 56 were female participants, it is due to increased fat deposition around the abdomen and increased waist size among male than female. The age wise distribution showed that the maximum number of patients enrolled were of age group 40-69 years (50.80%) which may be due to lifestyle changes and dietary habit changes.

It was also observed that out of 124 patients, **72.58%** of patient's physical activity was decreased significantly, **23%** of patient's physical activity decreased and only **4%** of patient's physical activity increased during Pandemic period against pre pandemic period. It may be due to the restrictions allotted, social distancing, physical mobility reduction. The patients were classified based on BMI and the study shows that the majority of the patients enrolled i.e., 60% (75) of patients has increased body mass index who falls under the category overweight and 8% were obese this is due to reduced physical activity and changed lifestyles as 60% of patients were overweight hence the Random blood glucose was measured in which 85.48% of patients had RBS more than 200mg/dL hence the HbA1c levels were measured and patients were classified based on HbA1c level which revealed that only 11% of the patients had excellent control of HbA1c level where as 89% of patients had poor control of HbA1c levels which is due to change in dietary intake like reduced intake of pulses, fibre rich food and increased consumption of carbohydrates food like rice, starch rich food, change in physical activity due to restriction in mobility and closure of parks and gym and reduced medication

adherence due to financial crisis[28]. Also, the study revealed that 89% of patients had increased HbA1c levels. The results were found similar with the study conducted by **Joseph et al [29], 2020**

The patients were classified based on QOL Among 124 patients, **2.4%** patients had an Overall poor QoL, **79.02%** patients had an Overall good QoL during Pre pandemic period whereas **33.05%** patients had an overall poor QoL, **14.5%** patients had Overall good QoL during Pandemic period. From the 4 domains of QoL Physical health, Psychological health and Environmental health scores were decreased in Pandemic period compared to Pre pandemic period and social relationships scores in the Pandemic Period were almost similar to Pre Pandemic Period.The decrease in Physical health domain score is due to restriction in mobility, closures of gyms, parks etc., work from home, reduced health care services. Decrease in Psychological health scores is due stress and fear of Covid 19 crisis and news related to Pandemic deaths which is spread all around. Decrease in Environmental health domain scores is due to decreased financial resources, decreased transport facility, decreased opportunities for acquiring new information and skills.

Medication adherence plays a very important role in the diabetic patients to maintain normal glucose levels in the body[30-31]. our study revealed that 64.5% patient were low adherent may be due to financial crisis, reduced access to health care and decreased follow up visits. Counseling was given to the patients about the importance of adherence to diabetic medicines and given awareness for the complications leading to non adherence. After 2 weeks of counseling patients were reviewed for their adherence where only 4% patients were low adherent. The increase in adherence is may be due to effect of counseling, decreased burden of finance as we counseled regarding Jan aushadhi where generic medicines are given in affordable cost or may be covid 19 was almost in control which made people to carry out their daily works and earn their income, decreased lockdown restrictions, increased access to health care services.

Overall, the study revealed that there were significant changes in the quality of life of diabetic patients in the pandemic period due to pandemic restrictions. The statistical analysis was performed using SPSS v20 Wilcoxon signed rank test was performed to test the hypothesis at the significant level (>0.05), as the result that P value was found to be 0.0004 hence stating that there were changes in quality of life.

CONCLUSION

The study suggest that the pandemic restrictions has widely impacted the quality of life due to restriction that was imposed. Also due to restriction there were restrictions in lack of mobility, closed parks and gyms, and imposition of work from home which all contribute to reduced physical activity, due to availability of limited resources and financial condition the dietary changes such as reduced fiber intake and increased carbohydrates was observed, sleep changes was observed due to binge watching of tv and stress and fear of pandemic , changes in adherence and behavior of taking medication was observed due to financial crisis[32-36]. The study revealed that there were changes in QOL and medication adherence during pre-pandemic and pandemic period. The QOL and medication adherence was found to be decreased in pandemic period.

This study will help in improving the quality of life and medication adherence of patients through patient counselling. The study also prepares the diabetic patients to tackle the disease management in whatever pandemic situation or any inconvenience that may occur. The study provides information regarding how to manage and maintain the medication adherence even during the financial crisis. This study will also help the health care professional to analyze and help the patient to manage the disease condition.

ACKNOWLEDGEMENT

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