

Poor-Glycaemic-Control Prevalence and Determinants among Type 2 Diabetes Mellitus Patients Attending a Primary Health Care Setting in Central Kerala

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ABSTRACT

BACKGROUND

The prevalence of type 2 diabetes mellitus (T2DM) is increasing quickly all over the world. In spite of effective treatment guidelines for type 2 diabetes, in majority of the people, the disease is poorly controlled with existing therapies. Glycaemic control is considered as the most important step for prevention of organ damage and other complications of diabetes. A study on the prevalence and determinants of poor glycaemic control can assist in understanding the expanse of this problems and the ways to address it. We wanted to study the prevalence and determinants of poor glycaemic control among adult patients with type II diabetes mellitus attending a primary health care setting.

METHODS

The cross-sectional study was conducted in the outpatient department of NCD clinic in a Primary health centre of Kerala for a period of six months. Two hundred and fifty individuals diagnosed with Type II DM for a year were recruited as study participants. The study participants were interviewed using a semi-structured questionnaire. Adherence to medication was assessed using The Morisky Medication Adherence Scale. Anthropometric measurements and blood pressures were recorded. HbA1c and RBS was measured using semi quantitative technique. Any patient with an HbA1c of more than 7 was defined as having poor glycaemic control.

RESULTS

64.4 % of the participants had poor glycaemic control. Poor adherence to medication, fewer visits to doctor, lack of diet modification, frequent junk food consumption, higher body mass index and lack of exercise were found to be significantly associated with poor glycaemic control.

CONCLUSIONS

A focused approach targeting these modifiable risk factors, especially in primary care setting, has the potential to bring about better glycaemic control which can prevent and minimize the occurrence of diabetes complications.

KEYWORDS

Poor Glycaemic Control, Uncontrolled Diabetes, Diabetes Mellitus, HbA1c, Diabetes Complications

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BACKGROUND

The global diabetes prevalence in 2019 is estimated to be 9.3 % (463 million people), increasing to 10.2 % (578 million) by 2030 and 10.9 % (700 million) by 2045.¹ In India the prevalence of diabetes has been reported to be between 10.2 % and 36 % in various population-based surveys.^{2,3,4,5} Kerala is the diabetes capital of India with a prevalence of diabetes as high as 20 %.^{6,7} In spite of clear cut treatment guidelines for type 2 diabetes, disease is poorly controlled in a majority of people with existing therapies. Glycaemic control is considered as the most important step for prevention of organ damage and other complications of diabetes. The glycosylated haemoglobin, or HbA1c is considered as the best indicator for measuring blood glucose values over a period of time. It is the clinical marker for predicting complications, particularly microvascular complications.^{8,9,10} HbA1c is measured mainly because it comprises of glycosylated haemoglobin which is least affected by recent fluctuations in blood glucose. In previous literature, glycated haemoglobin (A1c) levels > 7 % were found to be associated with an increased risk of both macrovascular and microvascular complications, irrespective of the treatment taken.^{11,12,13} Even in newly diagnosed type 2 diabetic patients who had poor glycaemic control, frequency of micro vascular complications is much higher as compared to those who had average glycaemic control.¹⁴

In many epidemiological analyses, it can be seen that a variety of factors such as sociodemographic, anthropometric and metabolic profiles have an impact on the glycaemic control of diabetes mellitus.^{15,16} The research on these factors are scarce in primary care settings. In a country like India with a growing diabetic population with majority of them approaching primary care setting for long term treatment it is vital to have an understanding on the factors that influence glycaemic control in the setting of primary care. Considering the importance of glycaemic control on the outcome of diabetes and its complications, it is imperative to know the percentage of patients with poor glycaemic control among those who were diagnosed with Type II diabetes mellitus. A study on the prevalence and determinants of poor glycaemic control can assist in understanding the expanse of this problems and the ways to address it.

METHODS

A facility based cross sectional study was conducted at outpatient department of NCD clinic in a primary health centre, KMCH, Ettumanoor of Kerala, for a period of six months. Two hundred and fifty individuals diagnosed with Type II DM for a year were recruited as study participants.

This sample size was calculated using the formula

$$n = Z^2 \times P \times (1-P) / d^2$$

where Z value was 1.96 for 95 % CI (Confidence Intervals), $p = 63\%$ ¹⁷ and absolute precision of 6 % was taken. Minimum sample size was calculated and found to be 249.

Patients who were suffering from type 1 diabetes, critically ill people and pregnant females were excluded from this study. The patients who came to the OPD (Out Patient Department) were first informed about the study objectives and the willing patients were requested to sign a consent form. Confidentiality of the data was maintained at all stages of the study. After getting informed consent the patients were interviewed with a semi structured interview schedule which included questions on socio-demographic factors, life style factors, drug therapy and self-care. Anthropometric measurements like height, weight, waist circumference and waist hip ratio were recorded by using a weighing machine of sensitivity 500 grams and measuring tape of sensitivity of 0.5 cm, with the help of trained health workers. Body Mass Index (BMI) was calculated after taking the patient's weight in kilograms, divided by height in meters squared (Kg / m^2). BMI was classified as underweight if BMI was < 18.5 Kg / m^2 , normal if BMI was 18.5 – 24.9 Kg / m^2 , overweight if BMI was 25 – 29.9 Kg / m^2 , and obese if BMI was $\geq 30 \text{ Kg} / \text{m}^2$. Blood pressure was measured following the standard technique by the medical officer.

Blood was collected from the ante cubital vein in K3 EDTA (Ethylene-diamine-tetra-acetic acid) vacutainers. Random blood sugar value and HbA1c was measured using semi quantitative technique. Any patient with a HbA1c of more than 7 was defined as having poor glycaemic control.¹⁸

Adherence to medication was assessed using The Morisky Medication Adherence Scale (Morisky 8-Item Medication Adherence Questionnaire).¹⁹ Adherence to medication was assessed using the MMAS-8. The scale has a total of eight questions. First seven items having a dichotomous answer (yes / no) that indicates adherent or non-adherent behaviour. For the eighth question, a patient can choose an answer on a 5-point Likert scale, expressing how often a patient forgets to take his medications. Patients who scored > 8 was considered to have good adherence, between scores of 6 and 8 medium adherence, and those who scored ≤ 6 points were considered as having low adherence.

Operational Definitions

1. Junk Food: National Institute of Nutrition (NIN) has defined junk food as food that contains little or no protein, vitamin or minerals but is rich in salt, fat and energy.²⁰
2. Adequate Exercise or Physical Activity: For adults aged 65 years and above at least 150 minutes of moderate-intensity physical activity throughout the week, or at least 75 minutes of vigorous-intensity physical activity throughout the week, or an equivalent combination of moderate- and vigorous-intensity activity as per world health organization.²¹
3. Overweight / Obesity: As per WHO criteria overweight is a body mass index greater than or equal to 25; and obesity is body mass index greater than or equal to 30.²²

Ethics

The ethical clearance was obtained from the Institutional Ethics Committee (vide Letter No.- IRB No: 98/ 2019 dated 18/11/2019)

Statistics

The data was properly coded and entered in MS EXCEL & analysed using SPSS 16.0 version software. The prevalence of poor glycaemic control was expressed as percentage and its confidence intervals. For assessing the association between poor glycaemic control and qualitative factors, chi square test was used. The p-value < 0.05 was considered as significant. For calculating the odds ratio univariate analysis (Chi square test) and regression was used and its 95 % confidence interval was found out.

RESULTS

Demographic Variables	Number of Subjects	Percent
Age group		
< 40 years	14	5.6
40 - 50 years	22	8.8
50 - 60 years	124	49.6
60 - 70 years	67	26.8
≥70 years	23	9.2
Educational status		
Illiterate	7	2.8
Primary school	35	14
Middle school	52	20.8
High school	106	42.4
Post high school	42	16.8
Graduate or above	8	3.2
Occupational status		
Unemployed / Home Maker / Retired	154	61.6
Unskilled worker	36	14.4
Semi-skilled worker	14	5.6
Skilled worker	21	8.4
Clerk, shop, farm	19	7.6
Semi Professional and above	6	2.4
Religion		
Hindu	139	55.6
Christian	86	34.4
Muslim	25	10
Income (monthly)		
Below 5000	124	49.6
5000 – 10000	92	36.8
10000 and above	34	13.6

Table 1. Socio-Demographic Variables of the Study Participants (n = 250)

Among the 250 study participants 124 (49.6 %) belonged to the age group of 50 - 60 years. 106 (42.4 %) had high school education and majority 154 (61.6 %) were not working (home makers, unemployed or retired) at the time of study (Table 1). Only 89 (35.6 %) of the study participants had good glycaemic control (HbA1c < 7), the rest of the study participants 161 (64.4 %) had poor glycaemic control. Among them 61 (24.4 %) had HbA1c between 7 to 8, while 58 (23.2 %) had HbA1c values between 8 - 9. 42 (16.8 %) had HbA1c value more than 9 (Table 2).

The percentage of people with poor glycaemic control was more among those who had a positive family history of diabetes mellitus. However, this was not found to be statistically significant (p value = 0.17). The glycaemic control was seen to be different with different diet modification pattern. Those who were following diabetic diet had better glycaemic control, and the percentage of patients with poor glycaemic control was more in those with partial diet modification, and the proportion was even higher in those who did not have any modifications in their diet (p value = 0.01, OR = 3.46). The frequency of consumption of junk food also has a significant association with glycaemic control (p value = 0.021, OR = 2.27). Those who had junk food rarely had better glycaemic control when compared with those who had junk food weekly or more frequently. Those who exercised less than the recommended 150 minutes per week were seen to have poor glycaemic control when compared to those who exercised as per the recommendation (p value = 0.02, OR = 2.03). Similar to this observation, those who were obese or over weight (WHO guidelines) was found to be having poor glycaemic control as compared to those who were having normal body mass index (p value = 0.004, OR = 2.29) (Table 3).

As per the Morisky medication adherence scale, in the study, poor medication adherence was found to be significantly associated with poor glycaemic control (p value = 0.01, OR = 8.27).

Association of Factors With Poor Glycaemic Control	% of Patients with Poor Glycaemic Control in the Group (n)		P	OR (CI)	Remarks
Family H / O of DM	Present	70.8 (137)	0.17	1.82 (1.08 - 3.08)	Not significant
	No family history of DM	57.1 (113)			
Diet modification for DM	No diet modification	82.9 (96)	0.01*	3.46 (2.01 - 5.96)	Significant Partially and no modification combined
	Partially	73.1 (119)			
	Completely	46.9 (35)			
Junk food consumption	Thrice weekly or more	80.8 (26)	0.021*	2.27 (1.25 - 4.13)	Significant Thrice weekly or more and Weekly combined
	Weekly	74.1 (54)			
	Rarely	58.6 (170)			
Exercise	< 150 minutes or no exercise	67.8 (199)	0.02*	2.03 (1.09 - 3.79)	Significant
	150 minutes / week (51)	51 (51)			
Visit to doctor	> 3 months or irregular	91.9 (104)	0.01*	11.29 (4.92 - 25.9)	Significant
	At least once in 3 months	50 (146)			
Body mass Index	Overweight / Obese	69.6 (184)	0.004*	2.29 (1.29 - 4.06)	Significant
	Normal (66)	50 (184)			
Treatment type	Insulin / Insulin + other drugs	73 (101)	0.01*	2.41 (1.41 - 4.11)	Significant * 1 st 2 rows and last 2 rows combined
	Sulfonylureas + Biguanides + other drugs	79.2 (24)			
	Sulfonylureas + Biguanides	63.5 (85)			
	Diet / Biguanides	35 (41)			
Adherence to medication	Good	37.8 (37)	0.01*	8.27 (4.6 - 14.87)	Significant*Good and medium combined
	Medium	35 (60)			
	Low	82.4 (153)			

Table 3. Association of Factors with Poor Glycaemic Control (n = 250)

p value < 0.05 taken as significant** only row % shown

HbA1c	Number	Percentage
< 7 (Controlled DM)	89	35.6
7 - 8 (Un Controlled DM)	61	24.4
8 - 9 (Un Controlled DM)	58	23.2
> 9 (Un Controlled DM)	42	16.8

Table 2. HbA1c Values of the Study Participants (n = 250)

Those who visited doctors more often, at least once in 3 months, had better glycaemic control as compared to those who had less frequent visits (p value = 0.01, OR = 11.29) (Table 3).

DISCUSSION

Diabetes affects the lives of people in divergent ways. The premature morbidity, mortality, reduced life expectancy, financial and psychosocial effects of diabetes weigh heavy in the global burden of diseases. The study was done to find out the prevalence and determinants of poor glycaemic control among patients with Type II diabetes mellitus.

In the study, 161 (64.4 %) had poor glycaemic control while 89 (35.6 %) of the study participants had good glycaemic control (HbA1c < 7), than the rest of the study participants. Among those with poor glycaemic control, 61 (24.4 %) had HbA1c between 7 to 8, while 58 (23.2 %) had HbA1c values between 8 - 9. 42 (16.8 %) had HbA1c value more than 9. The findings are similar to the results obtained in the study done in South India where 63 % of the study participants had HbA1c $\geq$ 7 %.¹⁶ A study done in Saudi Arabia had revealed the percentage of patients with poor glycaemic control as 67.7 %.²³ In the Gulf countries, poor glycaemic control ranges from approximately 89 % to 59 %.²⁴ If we look at the European countries, approximately three-fourth of European out-patients with Type 2DM had poor glycaemic control.²⁵ When compared to other regions Canada has better results with HbA1c $\leq$ 7.0 % met approximately by 50 % of type 2 DM patients.²⁶

As per the current study even though the percentage of patients with poor glycaemic control was more among those with a positive family history of diabetes mellitus, it was not found to be statistically significant (p value = 0.17). Similar results were observed in a study conducted by Mohammad Haghghatpanah et al, in Manipal, India.¹⁶ However, a study conducted in Jiangsu Province, China has found a statistically significant association between family history of diabetes and poor glycaemic control.²⁷

Dietary modification has got utmost importance in maintaining good glycaemic control in patients with diabetes mellitus. Those who followed diabetic diet had better glycaemic control (value = 0.01). A parallel finding to this dietary modification is that, patients who had less frequent intake of junk foods had better glycaemic control (p value = 0.01). A number of studies has explored the association between dietary modifications and glycaemic control and have found significant associations between dietary patterns and glycaemic value.^{28,29}

World health organization in its global recommendation of physical activity for adults, recommends that adults aged 18 – 64 should at least have 150 minutes of moderate-intensity aerobic physical activity throughout the week. In

the study the glycaemic control of the patients who followed this recommendation was compared with those who did not follow this. A statistically significant finding of better glycaemic control was observed in those who followed these recommendations (p value = 0.02). A multi centric study conducted in over 18000 patients in Austria and Germany has shown a similar association.³⁰ It is interesting to note that even in healthy volunteers' low physical activity can impair glycaemic control.^{31,32}

It is well known that body mass index has a strong relationship with insulin resistance. The mechanisms of this relationship are widely studied.^{15,33} In this study those who were obese, or overweight were found to be having poor glycaemic control as compared to those who were having normal body mass index (p value = 0.004). An electronic data base record study conducted in US has found similar results, i.e., in patients who were overweight or obese they were found to have statistically significant increase in their HbA1c values.³⁴ However, a study conducted by Razieh Anari et al, did not observe a difference in glycaemic values among obese and non-obese study participants.³⁵

In this study medication adherence was found to be significantly associated with poor glycaemic control (p value = 0.01). A study conducted among 358 Japanese study participants with diabetes observed an association between poor medication adherence and poor glycaemic control.³⁶ A study conducted using electronic health records in 228,846 diabetes patients treated by oral anti-glycaemic medication using a different scale to assess adherence has also similar results.³¹

Clinical attendance also had an influence on the glycaemic value of the patients. Those who visited doctors more often, at least once in 3 months, had better glycaemic control as compared to those who had less frequent visits (p value = 0.01). Greater rates of missed appointments was also seen to be associated with significantly poorer glycaemic control in a study conducted in Israel among patients with type II diabetes mellitus.³⁷

CONCLUSIONS

A good proportion of patients with type II diabetes mellitus had poor glycaemic control. Poor adherence to medication, fewer visits to doctor, lack of diet modification, frequent junk food consumption, higher body mass index and lack of exercise were found to be significantly associated with poor glycaemic control. Modifying these risk factors through a focused approach, especially in primary care setting, has the potential to bring about better glycaemic control which can prevent and minimize the occurrence of diabetes complications.

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