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TO STUDY VARIOUS FACTORS AFFECTING GLYCEMIC CONTROL AND DRUG PRESCRIPTION PATTERN AMONG DIABETIC PATIENTS - A PROSPECTIVE CROSS-SECTIONAL OBSERVATIONAL STUDY

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ABSTRACT

Objective: To determine the status of glycemic control and study various factors associated with glycemic control, drug prescription pattern of anti-diabetic drugs, and medication adherence of patients by using the Morisky scale- A Prospective Cross-Sectional Observational single-center study. **Method:** 301 samples were included in the study and noted in the case report form. Factors affecting glycemic control, drug prescribing pattern, and medication adherence were analyzed. **Result:** The maximum number of patients (29.6%) affected by diabetes under the study, between the age group of 61-70 years. 44.9% of patients were highly adherent. maximum patients(80.7%) were having stress.(71.0%) patients were not engaged regularly with exercise. duration of diabetes in study was (36.2%) in between 1-5 years. (97.0%) patients were of type 2 diabetes. The prescription pattern showed that metformin was most prescribed drug (37.9%), glimepiride (14.6%) followed by combination therapy (21.9%). **Conclusion:** The present study highlights that most important factors influencing poor glycemic control in that population were age, stress, exercise, and duration of diabetes.

KEYWORDS: Diabetes, glycemic control, prescription pattern.

INTRODUCTION

Diabetes mellitus is a metabolic disorder that may be caused by multiple etiologies and characterized by chronic hyperglycemia due to defects in insulin secretion, insulin action, or both.[1] There are five types of diabetes mellitus: type1 diabetes, type 2 diabetes, gestational diabetes, LADA, and MODY. LADA is latent autoimmune disease generally occur in adult. It is slowly progressed autoimmune disease. MODY is a maturity-onset of diabetes of the young, it is a hereditary form of the disease caused due to Autosomal mutation of gene.[2] Type 1 DM accounts for about 5-10 % of all cases of DM whereas T2DM is accounted for 85-90%.[3] The prevalence of T2DM is 2.4% in rural and 11.6% in an urban population in Indians.[4] 62.0 million prevalent cases of diabetes mellitus is estimated in India.[4] "India is the diabetic capital of the world".[5] In India alone, the prevalence of diabetes expected to increase from 31.7 million in 2000 to 79.4 million in 2030. In Maharashtra, 9.2 million people affected by DM.[4] Factors responsible for poor glycemic control are family history, exercise, medication adherence, duration of sleep, duration of diabetes, age, obesity, socio-economic status, high intake of sugar, and stress.[6] Diagnostic criteria for diabetes: When the fasting plasma glucose is ≥ 126 mg/dl or Random blood glucose level is ≥ 200mg/dl. Oral glucose tolerance test (OGTT) using 75 g of anhydrous glucose with FBG ≥126 mg/dl and/or 2-hr plasma glucose ≥ 200 mg/dl. According to American Diabetes Association (ADA), Good glycemic control is fasting blood glucose level is 70-130 mg/dl, whereas poor glycemic control is FBS is <70 mg /dl and > 130 mg /dl.[7]

Good glycemic control is the best way for the control and prevention of diabetic complications as well as to improve the quality of life of the patients.[6] The prescription pattern on antidiabetic drugs provides useful information about current prescribing evaluations, and it will help to achieve rational drug therapy, optimal glycemic control and decrease health care cost for patients and society in a large scale.[8]

MATERIALS AND METHODS

Study site: The study was conducted at Government Medical College and Hospital, Aurangabad, Maharashtra, a tertiary care centre during the period of October 2018 to March 2019.

Study design: A prospective cross-sectional observational study.

Study population

Study population: Patients admitted in general medicine ward, Department of Medicine, Government Medical College and Hospital, Aurangabad.

Inclusion Criteria: All patients age of 18 -80 years who were known cases of diabetes admitted in general medicine wards; given consent for the study.

Exclusion Criteria: Patient not given consent. Any pregnant woman at the time of enrollment.

Sample Size: 301.

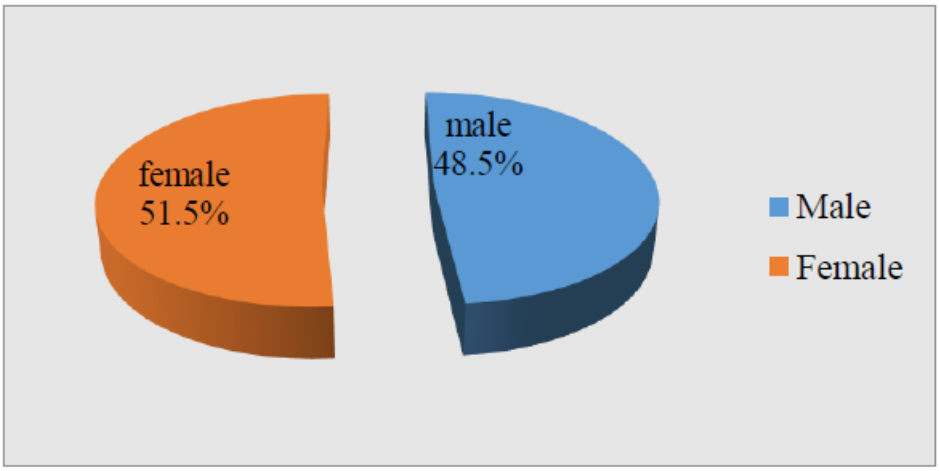
Study procedure: The data was collected using a specially designed case report form and information regarding demography of the patients, medication history, duration of diabetes, family history of the patient, diagnosis, laboratory investigations, medicines prescribed and factors such as addiction habits, exercise, stress, occupation, socioeconomic status, medication adherence, and daily notes were recorded to analyze drug prescribing pattern were collected.

Detail study procedure: The study initiated after getting approval from the Institutional Ethics Committee of Government Medical College and Hospital, Aurangabad (NO: Pharma/IEC- GMCA/403/2018, Dated: 16/10/2018). The study procedure was explained to the diabetic patients that given consent were enrolled 4in the study. Socioeconomic status assessed using kuppuswamy modified socioeconomic scale 2018 and patients' medication adherence assessed using the Morisky scale was collected.

RESULTS

Gender

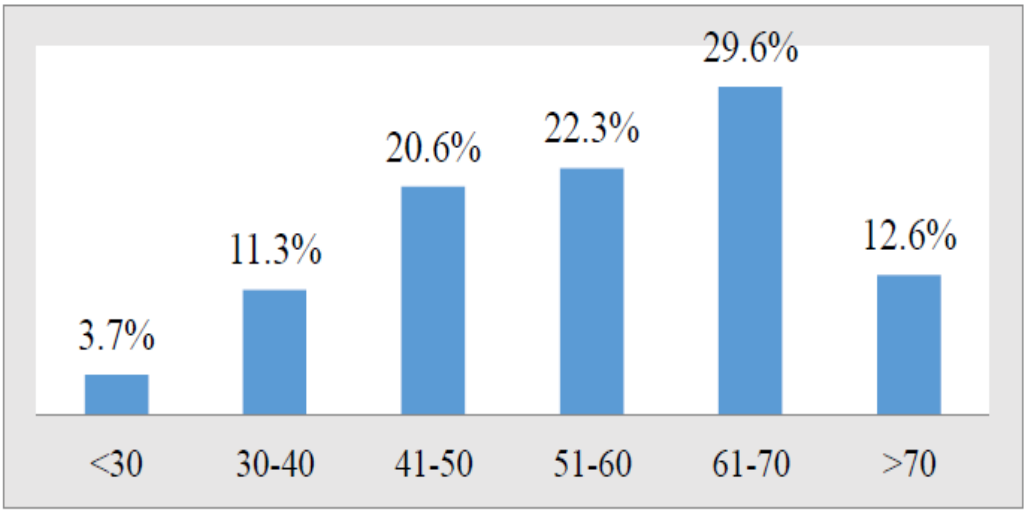
According to gender distribution among study participants, 48.5 % of the population was found males and 51.5 % of females.



Graph 1: Gender wise distribution of patients.

Age

The maximum patients enrolled in the study were between 18-80 age groups. It means a maximum number of the older population is affected by diabetes under the study, between the age group of 61-70 years and followed 51-60.



Graph 2: Age-wise distribution of patients marital status.

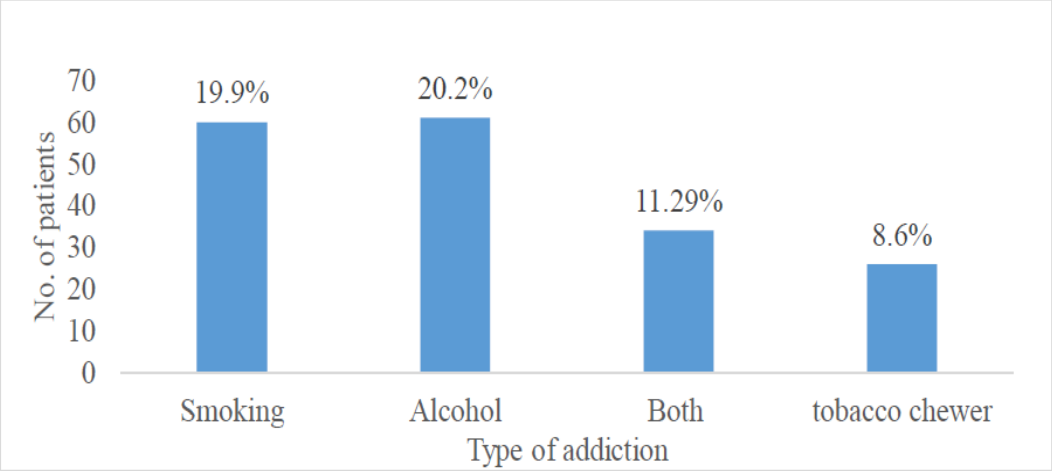
Marital status shows the distribution of patients 91.7% were married, 2.0 % were unmarried and 6.3% was a widow.

Table 1: Marital status.

Marital status	%
Married	91.7
Unmarried	2.0
Widower	6.3

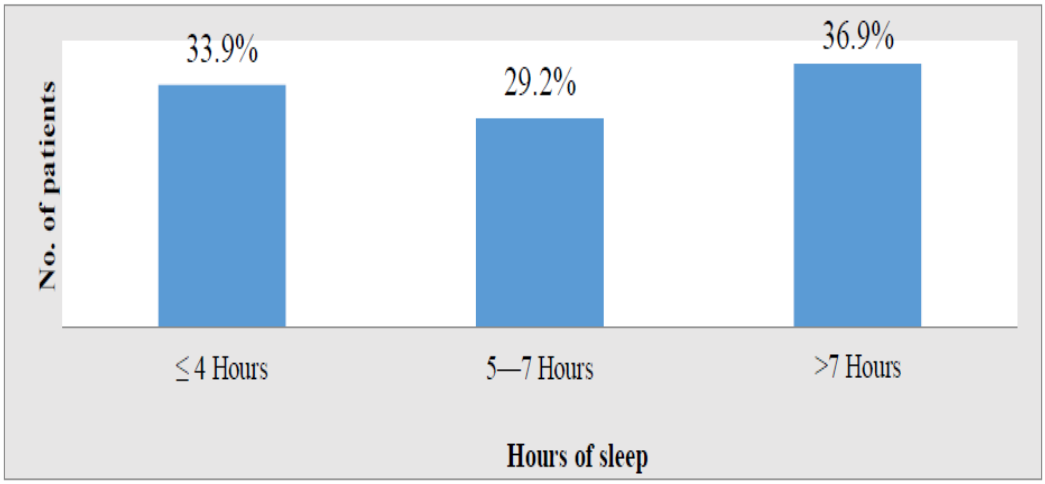
Type of addiction

Out of 301 patients, 19.9% of patients were smokers, 20.2% were alcoholics and 8.6% patients were tobacco chewer and 11.29 patients were both alcoholic and smokers while remaining patients were not having any social history.



Graph 3: Distribution of patients according to the type of addiction duration of sleep.

In our study 33.9% of patients were having a duration of sleep of ≤4 hours, 29.2% patients were having a duration of sleep between 5-7 hours, and remaining 36.9% patients were having a duration of sleep >7 hours.



Graph 4: Distribution of patients according to duration of sleep.

Family history of diabetes

Out of 301 patients in our study, 40.2% of patients were having a family history and 59.8 % of patients were not having a family history.

Table 2: Family history.

Family history	%
YES	40.2
NO	59.8

Body mass index

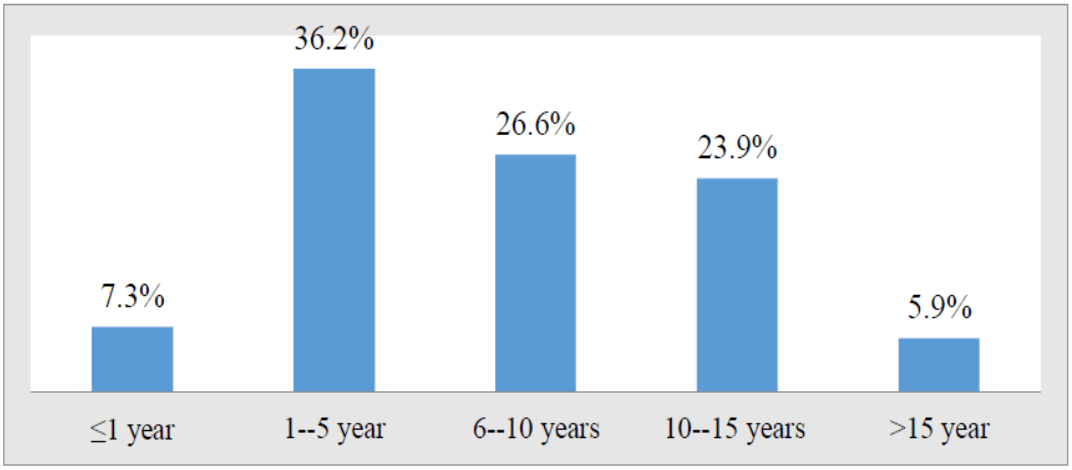
In This study 42.9 % of patients were overweight, 18.6 were obese and 31.9% were normal and 6.6 % were having underweight BMI.

Table 3: Body mass index

	Class	%
Body mass index	Underweight	6.6
	Normal	31.9
	Obese	18.6
	Overweight	42.9

Duration of DM

The duration of DM in our study was found to be 36.2% in between 1-5 years, 26.6% in between6-10 years, 23.9% in between 10-15 years, 7.3% in less than 1 year and 5.9% in greater than 15 years.



Graph 5: Distribution of patients according to duration of DM Type of diabetes.

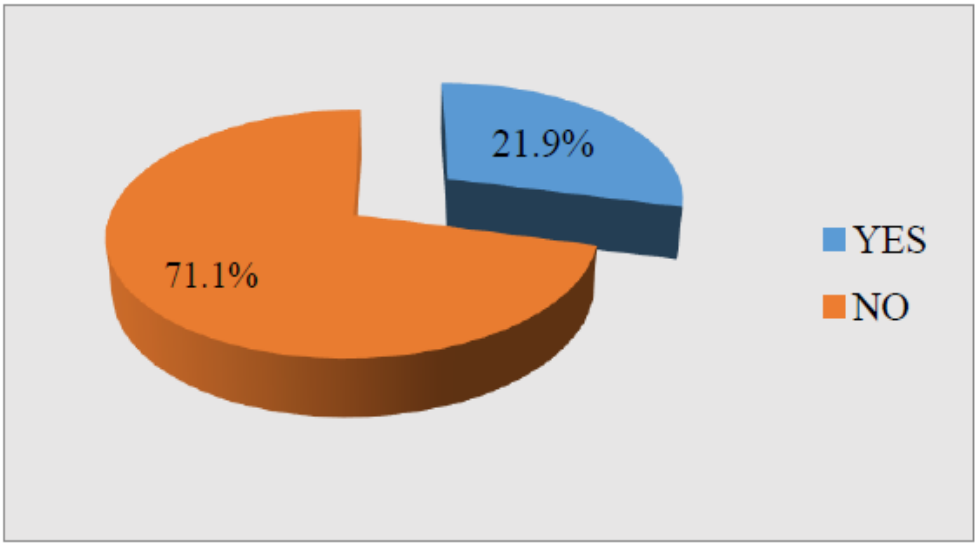
Type 2 DM was widely observed in this study that is 97.3% and 2.7% were having Type1 DM.

Table 4: Type of diabetes.

Type of Diabetic	%
Type I DM	2.7
Type II DM	97.3

Distribution of patients according to exercise

71.1 % of patients were not engaged regularly with their exercise whereas 28.9% of patients do regular exercise.



Graph 6: Distribution of patients according to exercise Distribution of patients according to occupation.

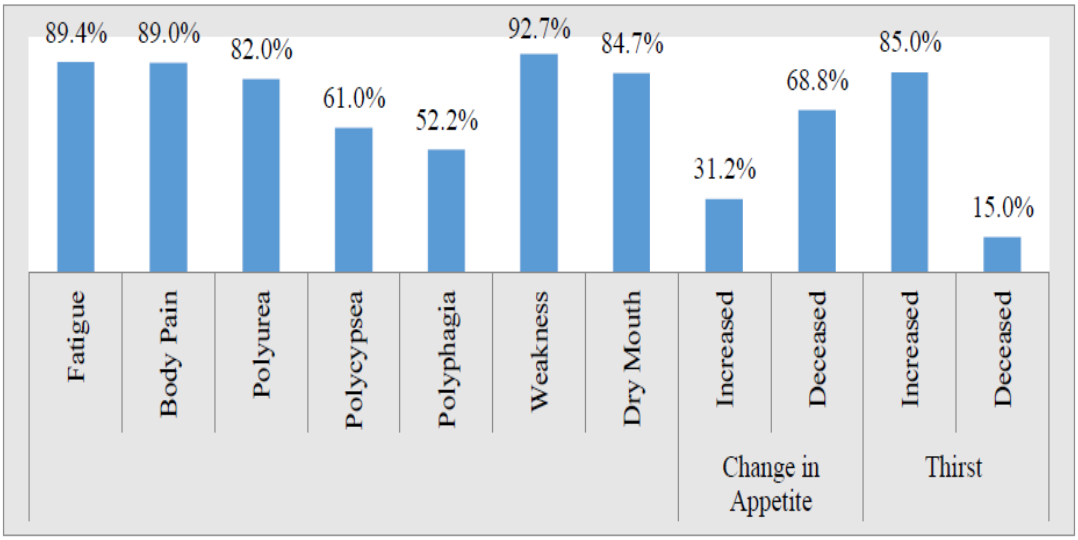
Among 301 patients, 5.6% of patients were govt. servants, 10.96 % were skilled workers, 22.25% were farmers, 35.21% were housewives, 23.25% were night workers and 2.6% were students.

Table 5: Distribution of patients according to occupation.

Type of occupation	%
Government servant	5.6
Skilled workers	10.96
Farmers	22.25
Housewives	35.21
Night Workers	23.25
Students	2.6

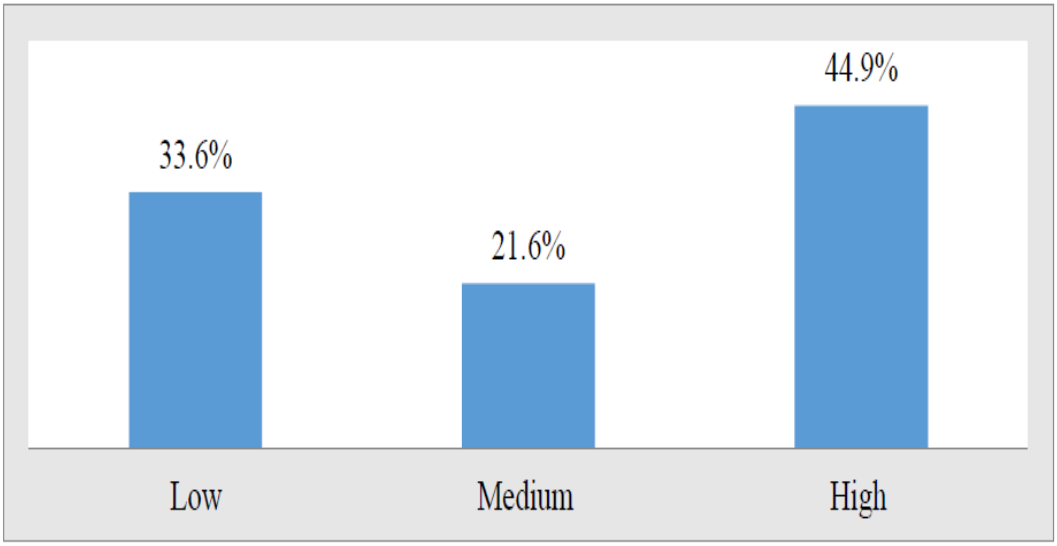
Distribution of patients according to symptoms

In this study, 89.4% of patients were having fatigue, 89% were having body pain, 82% were having polyurea, 61% were having polydipsia, 52.2% were having polyphagia, 92.7% were having a weakness, and 84.7% were having a dry mouth. In 31.2% of patients, appetite was increased and in 68.8% patient's appetite was decreased. In 85% of patients, thirst is increased and in 15% of patients, it is decreased.



Graph 7: Distribution of patients according to symptoms Medication adherence (Morisky scale).

Among 301 patients, 44.9% of patients were considered highly adherent (adherence score 4) to their medications respectively. 21.6% of patients were considered in medium class (adherence score 2-3) and 44.9% of patients were in the lower class (adherence score 0-1).



Graph 8: Distribution of patients according to the medication adherence.

Distribution of patients according to diet

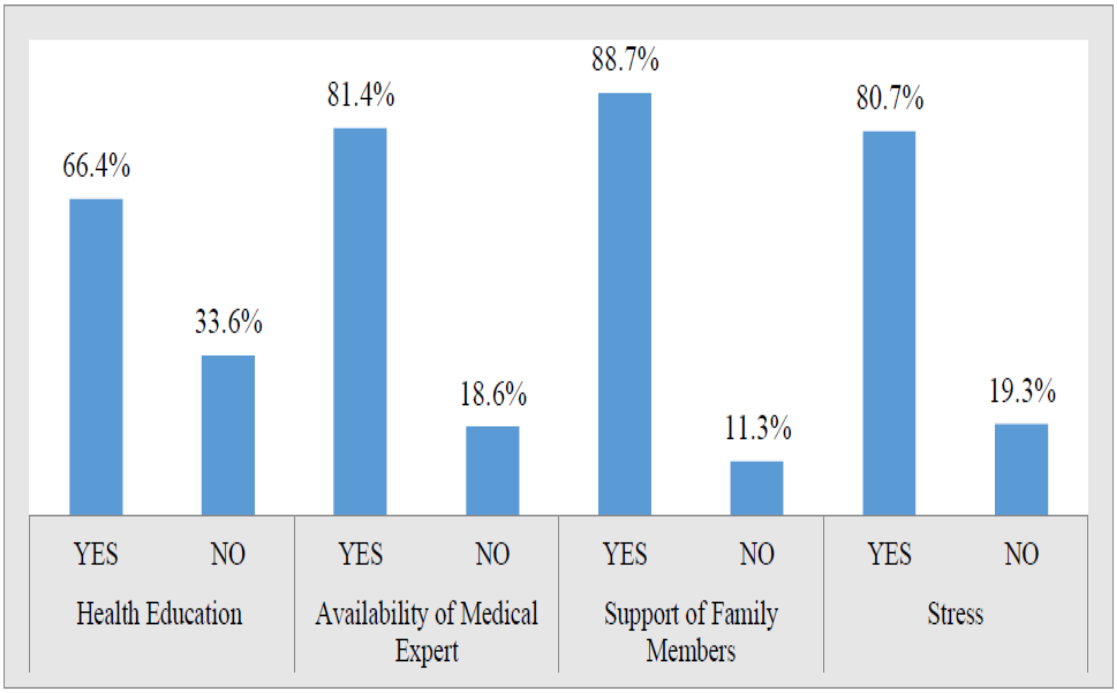
Out of 301 patients, 39.5% of patients were taking a sugary diet and 60.5% of patients were not taking a sugary diet. And 59.5% of patients follow diet and 40.5% of patients have not followed the diet.

Table 6: Distribution of patients according to diet.

Diet		%
Sugary diet	YES	39.5
	NO	60.5
Follow diet	YES	59.5
	NO	40.5

Reasons: Distribution of patients according to knowledge about the disease, Availability of medical expert

Out of 301 patients, 66.4% of patients were having knowledge about the disease.81.4% patients were having the availability of medical experts near to residence.88.7% patients were having the support of family members.80.7% patients were having stress, which is the major risk factor for diabetes.



Graph 9: Distribution of patients according to knowledge about disease, availability of medical Expert, support of family members and stress.

Socioeconomic status

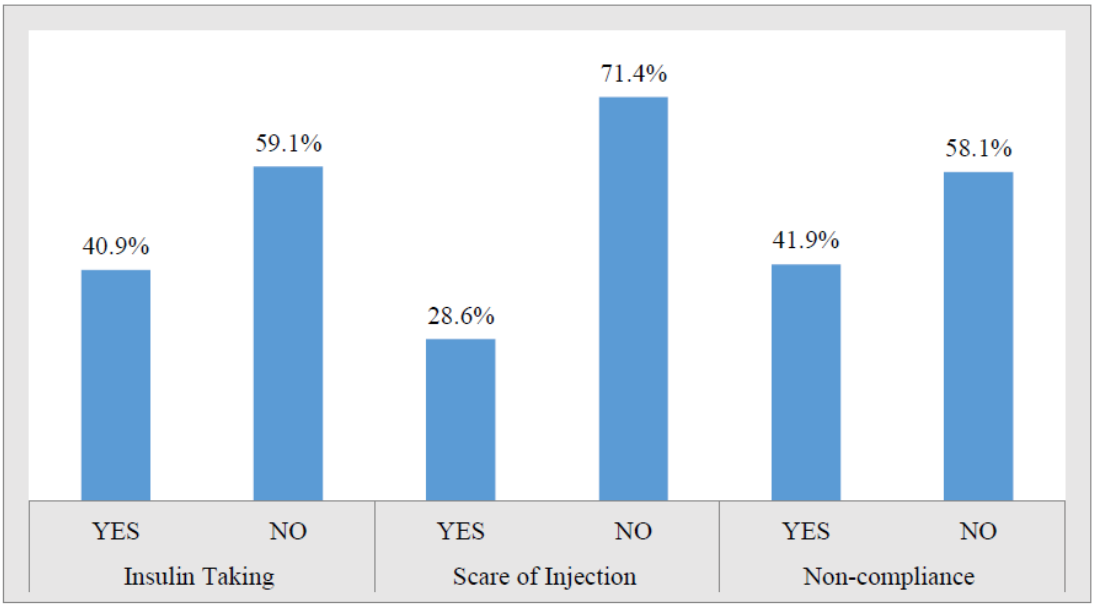
Among total patients, 43.9% of patients belong to an upper lower class, 24.9% of patients belong to the lower class, 17.9% of patients belong to the lower middle class, 12.0% of patients belong to the upper-middle class and 1.3% patients belongs to upper socioeconomic class.

Table 7*:* Socioeconomic status

Economic Status	%
Upper	1.3
Upper Middle	12.0
Lower Middle	17.9
Upper Lower	43.9
Lower	24.9

Reasons for not taking insulin

40.9% of patients among 301 were taking insulin.28.6% patients found that they were having the scare of injection whereas 126 patients were non-compliant.



Graph 10: Reasons for not taking insulin.

Distribution of patients according to anti-diabetic Medication

The medications taken by the patients include OHA, insulin, and combination therapy.58.1 % of patients were taking OHA, 12.6% of patients were taking insulin and 29.2% of patients were taking OHA+ insulin. In the case of OHA, metformin was the most frequently prescribed drug in patients, combination therapy (metformin+ glimepiride) was given to 21.9% patients, tab glimepiride was given to 14.6% patients, tab gliclazide was given to 4.7% patients, tab glipizide was given to1.3% patients, and tab voglibose was given to 7% patients.

In the case of insulin, short-acting insulin, (INJ. CI), was given to 23.6% patients, long-acting insulin i.e. human mixture was given to 15.6% patients and injection act rapid was given to 2.7% patients.

Table 8: Distribution of patients according to anti-diabetic medication.

		%
Medication	Oral	58.1
	Insulin	12.6
	Oral + Insulin	29.2
Type of anti-diabetic medication	Tab. Metformin	37.9
	Tab. Glimepiride	14.6
	Tab. Gliclazide	4.7
	Tab. Glimepiride+ Metformin	21.9
	Tab. Glipizide	1.3
	Tab. Voglibose	7.0
	Inj.CI	23.6
	Inj. Human Mixtard	15.6
	Inj. Act Rapid	2.7

Association between fasting blood sugar levels with risk factors

A Chi-square test was used to determine the association between glycemic control and other risk factors like Exercise, stress, follow the diet, health education/ awareness about the disease and medication adherence. There was a significant association found between stress, health education/ awareness about the disease, medication adherence, and FBS. The association of exercise and follow a diet with FBS was found non-significant.

Table 9: Association between fasting blood sugar levels with risk factors.

Risk factors		**Fasting blood sugar levels**		**Chi-square value**	**p-value**
		Good [n=62]	**Poor [n=239]**		
Exercise	Yes	16	38	3.45	P=0.010 NS
	No	13	201		
Stress	Yes	24	219	2.34	P=0.034 S
	No	38	20		
Follow diet	Yes	41	138	1.43	P=0.231 NS
	No	21	101		
Health education	Yes	51	149	8.73	P=0.003 S
	No	11	90		
Morisky scale	Low	35	66	10.1	P=0.006 S
	Medium	14	51		
	High	13	122		

Table 10: Comparison of the mean of FBS, RBS, and PPBS with the status of medication adherence.

		Mean	SD	95% CI		F-value	P-value
				Lower Bound	Upper Bound		
Fasting blood sugar levels	Low	190.15	72.092	175.92	204.38	3.51	P=0.031 S
	Medium	197.71	74.936	179.14	216.28		
	High	173.40	57.527	163.61	183.19		
Random blood sugar levels	Low	254.15	71.236	240.09	268.21	2.65	P=0.043 S
	Medium	232.58	60.777	217.52	247.64		
	High	236.16	70.893	224.09	248.22		
Post-meal blood sugar levels	Low	331.01	82.658	314.69	347.33	2.97	P=0.037 S
	Medium	331.01	82.658	314.69	347.33		
	High	305.84	84.115	291.53	320.16		

* Good glycemic Control is Fasting blood glucose level is 70-130 mg/dl,

* Poor glycemic control is FBS is <70 mg /dl and > 130 mg /dl.

Mean of FBS compared with the status of medication adherence, the result was significant and F=3.51, the mean of RBS compared with the status of medication adherence, the result was significant and F=2.65, p = 0.043. The mean of post-meal blood sugar level compared with the status of medication adherence, the result was significant and F=2.97, p=0.037.

Model: For Multiple regression fasting blood sugar levels as a dependent variable and BMI, Duration of sleep, Diabetic since, Exercise, Diet & Stress are the independent variables.

Model		Understandized coefficients		T	Sig.
		B	Std. error		
1	Constant	183.017	28.841	6.346	0.000
	BMI	0.286	0.888	0.323	0.747
	Duration of sleep	0.106	1.689	0.063	0.950
	Diabetic since	0.564	0.734	0.769	0.043
	Exercise	19.179	8.920	2.150	0.032
	Diet	-11.941	8.153	-1.465	0.014
	Stress	-11.478	9.831	-1.168	0.044

Model summary

Mode	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	361[a]	.026	.006	66.975

a. Predictors: (Constant), Stress, Duration of Sleep, Diet, Diabetic Since, BMI, Exercise

b. Dependent Variable: Blood Sugar Levels

Model – I: Multiple regression was carried out to investigate whether BMI, Duration of sleep, Diabetic since, Exercise, Diet & Stress would significantly predict the fasting blood sugar Levels of patients. The result of regression indicated that Model I explained 36% of the variance and that model was a significant predictor of fasting blood sugar levels of patients. F= 2.54 & P = 0.032 while Diabetic since, Exercise, Diet & Stress was contributed significantly to the model on the contrary BMI & Duration of sleep was insignificant.

DISCUSSION

The present study showed that the glycemic control was unsatisfactory. Poor glycemic control has been similarly shown in other studies in Malaysia and other countries.[6]

In this study older population was affected by diabetes, older age increases the risk of poor glycemic control but some other study stated that achieving glycemic control was not associated with sex and age of the patient.[9,10,6]

60 patients were smoker and 61 patients found to be alcoholics in this study. The who were smokers and alcoholics had a high blood sugar level and a study which is conducted in a developed country showed that there was a great impact of smoking and alcoholism on poor glycemic control.[6]

33.9 of patients were having duration of sleep less than 4 hr and 36.9% patient having duration of sleep more than 7 hr. The study conducted in Saudi Arabia showed that the duration of sleep affects the glycemic control of the patient. They found that, patients who took less sleep are at risk of poor glycemic control.40.2% patients having a family history and 59.8% of patients were not having a family history of diabetes. There is no association seen between family history and glycemic control.[10,6]

The study conducted in the developed country revealed that a maximum number of patients had a family history of diabetes who's glycemic control was unsatisfactory.[9,11]

42.9% of patients were overweight, they had an influenced on glycemic control. Many other studies stated that obesity is the most important factor which is responsible for uncontrolled diabetes mellitus.[12]

This study showed that most of the patients had diabetes mellitus since 5-year .other study revealed that the duration of diabetes mellitus was significantly associated with glycemic

control. A Study conducted in Hongkong showed that the duration of diabetes is responsible for poor glycemic control.[9,6,13]

This study showed that housewives and night workers were more prone to develop diabetes mellitus. Mainly night workers were not able to achieve good glycemic control because of lesser sleep.[9]

Patients with low medication adherence could not achieve glycemic control. Many studies showed that, patients who's medication adherence was high, were able to achieve good glycemic control.[14,15,6]

The upper-lower and Lower socioeconomic classes were associated with poor glycemic control. In contrast, due to the higher literacy rate in a developed country, there were better glycemic control was found.[14,5,16]

Many patients did not take insulin continuously because some people had a scare of injection, some people didn't know how to take it, and therefore BSL was not maintained.[17]

In this study, the metformin was the most frequently prescribed oral hypoglycemic agent. By using monotherapy we were not able to achieve blood sugar level. Another study showed that more than 2 years is required to maintain BSL by using monotherapy. The insulin and OHA combination was helpful to achieve glycemic control.[18,17,9]

Glycemic control is not satisfactory when the patient was having stress. In our study people who follow the diet, their glycemic control was poor. But other studies reveal that patients who follow the diet, their glycemic control was good. Maximum patients are those patients who did not engage with regular exercise and had poor glycemic control. In Another study showed that there is no impact of exercise on glycemic control.[6,14]

CONCLUSION

The present study highlights that the most important factors influencing poor glycemic control in that population were age, stress, exercise, and duration of diabetes. Low medication adherence also influences glycemic control. Metformin was the most frequently prescribed drug in diabetes followed by glimepiride and combination therapy in tertiary care hospital. From this study, we can say that to achieve good glycemic control, intensification of current treatment as well as planning multiple drug intervention with lifestyle modification is

necessary. There is a need for prospective longitudinal research using large scale samples to explore the barriers for controlling diabetes among tertiary care hospital.

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Conflict of interest: None.

Ethical approval: The study was approved by the Institutional Ethics Committee.

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