Scholars Journal of Applied Medical Sciences (SJAMS)
Abbreviated Key Title: Sch. J. App. Med. Sci.
©Scholars Academic and Scientific Publisher
A Unit of Scholars Academic and Scientific Society, India
www.saspublishers.com

ISSN 2320-6691 (Online)
ISSN 2347-954X (Print)

Pharmacology

Demographical Evaluation of Type 2 Diabetes Mellitus and Effect of Prescribed Anti Diabetic Drugs on Maintaining Optimal Glycemic Levels in Diabetic Patients: An Observational Study

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Original Research Article

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Article History
Received: 18.12.2018
Accepted: 27.12.2018
Published: 30.12.2018

DOI:
10.36347/sjams.2018.v06i12.045

Abstract: The aim of the study was to evaluate Type 2 Diabetes Mellitus patients demographically and Effect of Prescribed Anti Diabetic Drugs in maintaining optimal glycemic levels in diabetic patients attending Medicine outpatient in the department of medicine at a tertiary care teaching hospital in Western Rajasthan. This was a prospective, non intervention and observational study, conducted over a period of 1 year with association of the Department of Pharmacology and the Department of Medicine, Dr. S. N. Medical College, Jodhpur Information of patients collected included age, sex, diagnosis, duration of medicine, habit of blood glucose monitoring, Fasting Blood Glucose level and Post-Prandial Blood glucose level was noted in case record form and analyzed. Out of 250 patients, 193 (77.2%) were male and 57 (22.8%) were female. Male to female ratio was 3.38:1. A maximum number of patients were between the age of 60-69 years (62.4%). The majority of patients having Fasting Blood Glucose level between >130 mg/dl (51.2%) after taking antidiabetic treatment while the majority of patients had Post-Prandial Blood glucose level between 181-250 mg/dl (61.6%) after taking antidiabetic treatment. The majority of anti diabetic patients taking antidiabetic medicine for 6-10 years (37.6%). The rising prevalence of diabetes is driven by a combination of factors like rapid urbanization, sedentary lifestyles, unhealthy diets, and increasing life expectancy. The majority of patients having poor glycemic control. Most common reason behind this is lack of awareness, poor socioeconomic status and lack of education.

Keywords: Type 2 Diabetes Mellitus, Fasting Blood Glucose level, Post-Prandial Blood Sugar.

INTRODUCTION

The ancient Indian physician gave the term madhumeha (honey urine) to diabetes mellitus because it has attracted ants [1, 2] and they mentioned that lean diabetes is difficult to treat. The term *"Mellitus"* (Latin, 'sweet like honey') was coined by the British Surgeon-General John Rollo in 1798, to distinguish this diabetes from other diabetes (*insipidus*) in which the urine was tasteless [3]. Diabetes Mellitus (DM) refers to a group of common metabolic disorders characterized by hyperglycemia [4]. Factors associated with hyperglycemia are a defect in insulin secretion, insulin action, decreased glucose utilization and increased glucose production [5]. In 1997, the American Diabetes Association (ADA) defined diabetes as; "A group of metabolic disorders characterized by hyperglycemia resulting from defects in insulin secretion, insulin action or both. "

DM may present with a characterized symptom such as thirst, polyuria, polydipsia, weight loss, sometimes polyphagia, blurred vision, impairment of growth, susceptibility for infections and its most severe form, with ketoacidosis or non-ketoacidosis hyperosmolarity, which in the absence of effective treatment lead to stupor, coma, and death. Often symptoms are not severe or may even be absent. In Type 1 Diabetes Mellitus symptoms usually develop much more slowly and may be subtle or absent in Type 2 Diabetes Mellitus (T2DM) [6].

Diagnosis criteria for diabetes have changed considerably over the past three decades. The criteria only help us to decide if a person has diabetes or not; they do not help us to decide the type of diabetes he or she has. The definitions were given by the American Diabetes Association (ADA) and World Health

Organization (WHO) is the currently accepted criteria for the diagnosis of diabetes.

Prediabetic or patients with impaired glucose tolerance (IGT) individual are usually asymptomatic but they are at higher risk of developing cardiovascular disease than the general population. They also have a risk of progressing to diabetes and must be followed up at regular intervals.

Table-1: Blood glucose diagnostic criteria for Diabetes [7-10]

Measure	American Diabetes Association		World Health Organization	
	Diabetes	Prediabetes	Diabetes	Impaired Glucose Regulation
Fasting plasma glucose	≥126 mg/dl	100–125 mg/dl (IFG)	≥126 mg/dl	100–125 mg/dl (IFG)
2-Hr plasma glucose (during an OGTT with a loading dose of 75 g)	≥200 mg/dl	140–199 mg/dl (IFG)	≥200 mg/dl	140–199 mg/dl (IFG)

Table-2: Glycated hemoglobin (dcct %) Criteria for Diabetes and Prediabetic

Measure	American Diabetes Association		World Health Organization
	Diabetes	Prediabetes	Diabetes
Glycated hemoglobin	≥6.5%	5.7–6.4%	≥6.5%

Self-monitoring of blood glucose and HbA1C are integral components of the standards of care in diabetes. These are necessary to assess the effectiveness of a treatment plan and provide guidance in selecting appropriate medications and dosage/s[11].

MATERIALS AND METHODS

This study was a prospective, noninterventional and observational study. It was conducted in association with the Department of Medicine in Mathura Das Mathur (M.D.M.) Hospital, Jodhpur (Tertiary Care Teaching Hospital). This study included 250 outpatients with Type 2 Diabetes Mellitus. The candidate has not advised any new drug by the investigator during the study period. All participants in the study were clearly explained the purpose and nature of study in their language. All patients were included after receiving informed consents. All data of patients were kept confidential.

INSTITUTIONAL ETHICAL APPROVAL

After approval from the Institutional Ethics Committee (IEC) of Dr. S. N. Medical College Jodhpur. Permission sought through proper channel from the head of the medicine department before beginning the study. This entire study was conducted at Mathura Das Mathur Hospital Jodhpur Rajasthan.

STUDY DESIGN

A prospective, noninterventional and observational study.

CONDUCT OF STUDY

Every Wednesday we visited diabetic OPD and collected all information pertaining to every patient, such as the name, age, gender, address, relevant medical history, past history, family history etc complete information was obtained either direct conversation with patients or from prescribed OPD slips, then mentioned using Case Record Form.

Inclusion Criteria

- Known case of Type 2 diabetes mellitus with and without complications
- Patients aged more than 20 yrs.
- Patients were included in this study only after receiving written informed consent.
- Outpatient only

Exclusion Criteria

- Pregnant ladies
- Gestational diabetes patients
- Type 1 diabetes pateints
- Patient not willing to participate
- Bedridden patients.

After recording the obtained information in the Case Record Form the data were subjected to further analysis. Data collection was analyzed further as Number of patients, gender wise distribution of study patients, patients were divided into age group as for the analysis of the occurrence of T2DM, Fasting blood glucose level, Postprandial blood glucose level, frequency of blood glucose monitoring and treatment duration of diabetic medicine.

OBSERVATIONS AND RESULTS

The demographic profile of patients

Number of patients

A total of 250 patients who fulfilled the inclusion criteria were taken for study at Mathura Das Mathur Hospital Jodhpur, attached group of Hospitals of Dr. S. N. Medical College, Jodhpur (Rajasthan).

Gender wise distribution of study patients

Table-3: Gender wise distribution of study patients

Sex	Number of patients	Percentage
Male	193	77.2
Female	57	22.8
Total	250	100

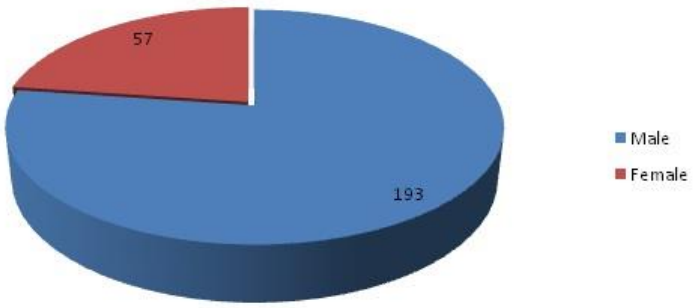

Fig-1: Gender wise distribution of study patients

Out of 250 patients, 193 (77.2%) were male and 57 (22.8%) were female. Male to female ratio was 3.38:1.(table 3, figure 1)

Age wise distribution of study patients

The major contribution of patients was between the age of 60-69 years (62.4%), followed by 70 years or above (24.4%), 50-59 years (9.6%), 40-49 years (3.2%) respectively. Least Number of patients contributed below the age of 39 years (0.4%) (Table 4).

Table 4: Age wise distribution of study patients

Age (years)	Number of patients	Percentage
≤39	1	0.4
40-49	8	3.2
50-59	24	9.6
60-69	156	62.4
≥70	61	24.4
Total	250	100

Age and Gender wise distribution of study patients

Table-5: Age and Gender wise distribution of study patients

Age (in years)	Male		Female		Total
	N	%	N	%	
≤39	1	0.52	0	0	1 (0.4%)
40-49	4	2.07	4	7.02	8 (3.2%)
50-59	20	10.36	4	7.02	24 (9.6%)
60-69	119	61.66	37	64.91	156 (62.4%)
≥70	49	25.39	12	21.05	61 (24.4%)
Total	193	77.2	57	22.8	250

The major contribution of patients was between the age of 60-69 years (Male=61.66% and Female = 64.91%), followed by age group 70 year or more than 70 years (Male = 25.39% and Female =21.05%), age group 50-59 years (Male =10.36% and Female =7.02%), age group 40-49 years (Male =2.07% and Female =7.02%) respectively. Least Number of patients contributed below the age of 39 years (0.4%), only one male patient was recorded (Table 5, figure 2).

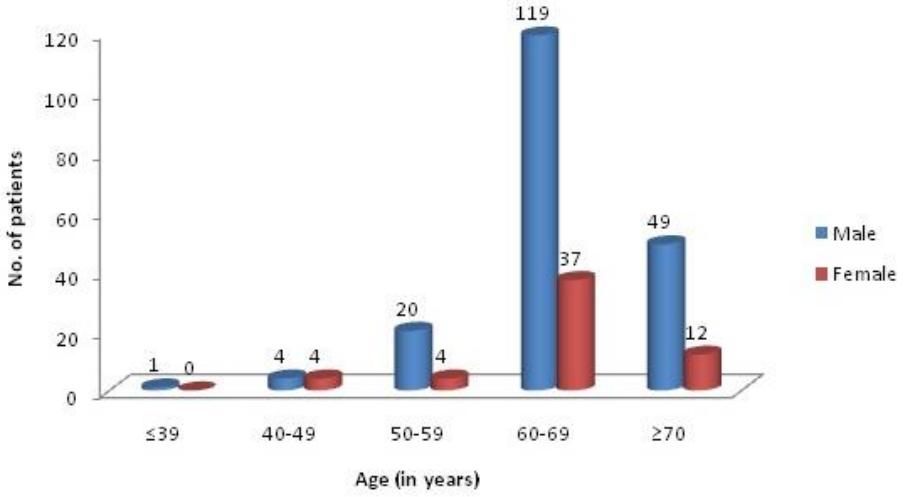

Fig-2: Age and Gender wise distribution of study patients

Fasting Blood Sugar (FBS) distribution wise of study patients

Among male patients, maximum number belongs to FBS group ≤130 mg/dl (51.29%) followed by 131-150 mg/dl (25.38%) and minimum from group ≥181mg/dl (9.33%) . Among females, maximum number of patients belong to FBS group ≤130 mg/dl (40.35%) followed by 131-150mg/dl (26.31%), FBS group ≥181 mg/dl (21.05%) and minimum in FBS group is 151-180 mg/dl (12.28%) were recorded. The majority of patients belong to FBS group ≤130 mg/dl (48.8%) (Table 6).

Table-6: Fasting Blood Sugar (FBS) wise distribution of study patients

FBS(mg/dl)	Male		Female		Total
	N	%	N	%	
≤130	99	51.29	23	40.35	122 (48.8%)
131-150	49	25.38	15	26.31	64 (25.6%)
151-180	27	13.99	7	12.28	34 (13.6%)
≥181	18	9.33	12	21.05	30 (12%)
Total	193	77.2	57	22.80	250

Post-Prandial Blood Sugar (PPBS) wise distribution of study patients

Among male patients, maximum number belong to PPBS group 181-250 mg/dl (61.66%) followed by PPBS group ≥251 mg/dl (20.21%), PPBS group 141-180 mg/dl (12.95%) and minimum in group ≤140 mg/dl (5.18%). Among females, a maximum number of patient belongs to PPBS group 181-250 mg/dl (61.40%) followed by PPBS group ≥251 mg/dl (28.07%), PPBS group 141-180 mg/dl (8.77%) and minimum with PPBS group is ≤140 mg/dl (1.75%) were recorded. The majority of patients contributed from PPBS group 181-250 mg/dl (61.6%) (Table 7).

Table 7: Post-Prandial Blood Sugar (PPBS) wise distribution of study patients

PPBS	Male		Female		Total
	N	%	N	%	
≤140	10	5.18	1	1.75	11 (4.4%)
141-180	25	12.95	5	8.77	30 (12%)
181-250	119	61.66	35	61.40	154 (61.6%)
≥251	39	20.21	16	28.07	55 (22%)
Total	193	77.2	57	22.8	250

The frequency of blood glucose monitoring (Days) distribution of study patients

Among male patients, the maximum number belongs to Frequency of blood glucose monitoring group 16-30 days (77.62%) followed by 8-15 days(17.62%), ≤7days (3.63%) and minimum in the group>30 days (1.04%). Among females, a maximum number of patient belongs to Frequency of blood glucose monitoring group 16-30 days (85.96%) followed by ≤7 days (7.02%), 8-15 days (5.26%), and minimum with Frequency of blood glucose monitoring group of >30 days (1.75%). The majority of patient belongs to Frequency of blood glucose monitoring 16-30 day (79.6%)(table 7).

Table-7: Frequency of blood glucose monitoring (Days) distribution of study patients

Frequency of blood glucose monitoring (Days)	Male		Female		Total
	N	%	N	%	
≤7	7	3.63	4	7.02	11 (4.4%)
8-15	34	17.62	3	5.26	37 (14.8%)
16-30	150	77.72	49	85.96	199 (79.6%)
>30	2	1.04	1	1.75	3 (1.2%)
Total	193	77.2	57	22.8	250

Distribution according to the duration of antidiabetic therapy for study patients

Among male patients, the maximum number belongs to the duration of Diabetic medicine group ≤5 years and 6-10 years (each 32.64%) followed by 11-20 years (27.98%) and minimum in the group >20 years (6.74%).(table 8)

Table-8: Distribution according to the duration of antidiabetic therapy for study patients

Duration of medicine (years)	Male		Female		Total
	N	%	N	%	
≤5	63	32.64	11	19.30	74 (29.6%)
6-10	63	32.64	31	54.39	94 (37.6%)
11-20	54	27.98	13	22.81	67 (26.8%)
>20	13	6.74	2	3.51	15 (6%)
Total;	193	77.2	57	22.8	250

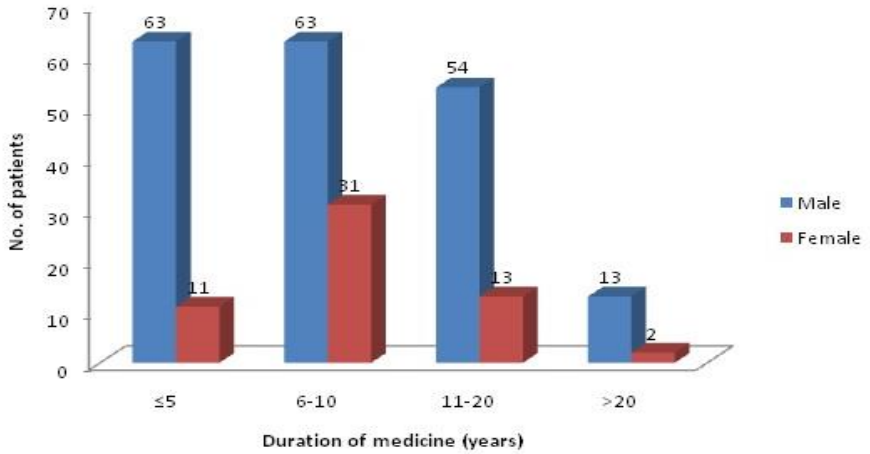

Fig-3: Distribution according to the duration of antidiabetic therapy for study patients

Among females, a maximum number of patient belongs to the duration of Diabetic therapy group 6-10 years (54.39%) followed by 11-20 years (22.81%), in ≤5 years (19.30%), and minimum with duration of Diabetic therapy group of >20 years (3.51%) respectively. The majority of patient belongs to the duration of Diabetic medicine group of 6-10 years (37.6%)(Table 8, figure 3).

DISCUSSION

Diabetes mellitus Type 2 (T2DM) is a progressive group of metabolic disorders causing both localize and systemic consequences. In addition to significant healthcare costs, DM type 2 causes a significant reduction in health-related quality of life. Effective management of DM type2 has been shown to reduce the rate of exacerbations, hospitalizations, mortality and to improve health-related quality of life.

In the present study, the prescription of total 250 patients was analyzed. The majority of the patients were of the male sex which was as high as (77.2%). The females accounted for (22.8%) and Male to Female ratio was 3.38:1. It is not in accordance with the study of Nordström A *et al*. where the prevalence of type 2 diabetes was recorded higher in older men than in older women & male to female ratio was 1.6:1[12] while Hilawe EH *et al*. recorded in their study that overall prevalence of diabetes mellitus did not significantly differ by gender [13].

In the present study maximum patients belong to more than 60 years age group (86.8%). According to World Health Organization India report (2018), an estimated 8.7% prevalence of diabetic population in the age group of 20 and 70 years. The rising prevalence of diabetes is driven by a combination of factors like rapid

urbanization, sedentary lifestyles, unhealthy diets, and increasing life expectancy.

Optimal glycemic control is achieved when FBG is 70–130 mg/dL, 2 h postprandial <180 mg/dL, and bedtime glucose is 90–150 mg/Dl. In the present study, the majority of the patient had FBS less 130 mg/dl (48.8%) and 51.2% of patients had FBS more than 130 mg/dl after taking antidiabetic drugs. Whereas the majority of the patient had PPBS between 181-250 mg/dl (61.6%) after taking antidiabetic drugs. Which is accordance several studies where more then 50% of diabetic patients found with poor glycemic control [14,15]. Similarly, Agarwal AA *et al.* in their study they found that about 41% of patients on anti-diabetic drugs had controlled optimal glycemic levels, while 59% had inadequate/uncontrolled glycemic levels [16]. This show poor glycemic control after treatment and main reason behind this is the lack of follow up, poor dietary control, lack of awareness, poor patients compliance, poor socioeconomic status, ignorance, illiteracy but most importantly advancing age (most patients were above 60 years of age) and long-standing diabetes with other co-morbid conditions like hypertension.

Currently used anti-diabetic drugs are very effective, however, because of the lack of patient compliance, clinical inertia, insulin resistance, lack of exercise and lack of dietary control leads to unsatisfactory control of hyperglycemia. In India, limited studies have focused on diabetes care and provide insight into the current profile of patients and their management. More than 50% of people with diabetes have poor glycemic control, uncontrolled hypertension, and dyslipidemia, and a large percentage have diabetic vascular complications [17].

In the present study, the majority of T2DM patients Frequency of blood glucose monitoring or self-blood glucose monitoring (SBGM) were very poor. Majority of the patient (79.6%) monitored their blood glucose between 16-30 days which indirectly lead to poor glycemic control. Most common reason behind this is lack of awareness, poor socioeconomic status and lack of education. According to the study of Chaudhury A *et al*. Self-monitoring of blood glucose is necessary in patients with diabetes who are on an intense insulin regimen. It monitors and prevents hyperglycemia and a possible side effect of hypoglycemia. Blood glucose level is usually checked prior to meals, prior to exercise, prior to driving, and at bedtime [18]. Similarly, Malanda UL *et al*. concluded in their study that evidence for potentially beneficial SMBG-induced effects on glycemic control, hypoglycemic periods, and potential harms in type 2 diabetic patients who were treated with oral hypoglycemic agents justify the use of SMBG. Moreover, the use of SMBG is associated with huge costs [19]. While on the base of their evidence Young LA *et al*. concluded that, routine daily SMBG in patients with an oral hypoglycemic agent, reasonably well-controlled type 2 diabetes is probably a low-value activity on a population level. However, patients with less–well-controlled type 2 diabetes, or those who are using the information in a targeted fashion to gain behavioral insight or to make treatment decisions, maybe had modest benefit in terms of overall glycemic control [20].

In our study maximum patients taking antidiabetic medicine were belong to duration ≤5 years and 6-10 years (each 32.64%) and least number of patients taking antidiabetic medicine were belong to duration of >20 years years which show that most common diagnosis of T2DM occur in between 55-60 years of age and this is in accordance to other studies which show that T2DM were common in age of around 60 years.

As Diabetes mellitus is reaching potentially epidemic proportions in India. The level of morbidity and mortality due to diabetes and its potential complications are enormous and pose significant healthcare burdens on both families and society. Worryingly, diabetes is now being shown to be associated with a spectrum of complications. In India, the steady migration of people from rural to urban areas, the economic boom, and a corresponding change in lifestyle are all affecting the level of diabetes. A large number of diabetes patients were in the age group of 40 -60 years. Resulting in the development of diabetic related complications in most productive years of life, as compared to western studies were mean age is around 60 years. In a chronic disease like diabetes, day to day management and adjustment of treatment, SBGM, constant follow up for successful management and extra treatment added or withdrawn in the face of complications is a must.

Limitation of study

Glycated hemoglobin was not recorded because of the high cost of investigation so long-term control of blood glucose was not analyzed and data of the study was very small so for final conclusion need another study with a large amount of data.

ACKNOWLEDGMENTS

The authors express their thanks to the Dr Anusuya Gehlot mam, senior professor Department of Pharmacology, Dr Shyam Mathur sir, professor Department of Medicine, Dr. S. N. Medical College, Jodhpur and staff of the Department of Medicine, Mathura Das Mathur Hospital, Jodhpur Affiliated with Dr, S. N. Medical College, Jodhpur (Rajasthan) for their assistance in conducting the study.

Conflict of Interest

The authors declare that no conflict of interest, financial or otherwise, exists.

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