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A PROSPECTIVE STUDY TO EVALUATE SELF-MONITORING OF BLOOD GLUCOSE AND MAINTAINING OPTIMAL GLYCEMIC CONTROL IN TYPE 2 DIABETIC PATIENTS AT TERTIARY CARE CENTER IN WESTERN RAJASTHAN

Pharmacology

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ABSTRACT

Aim: Aim of this study to evaluate T2DM patients for awareness of self-monitoring of blood glucose (SMBG) and maintaining optimal blood glucose control in type 2 diabetic patients.

Methodology: This was a prospective, non-interventional, observational study, conducted at Department of Pharmacology in association with the Department of Medicine, Dr. S. N. Medical College, Jodhpur. Information pertaining to the patients collected directly from patients or from OPD slip which were noted in case record form and further analyzed.

Results: Out of total 250 patients, 77 patients (30.8%) were recorded with age ≤60 years and 173 patients (69.2%) had age more than 60 years. 48.8% of patients had Fasting Blood Glucose ≤130 dg/dl whereas ≥181 mg/dl Post-Prandial Blood Sugar in 83.6% of patients. 199 patients(79.6%) were monitoring their blood glucose between 16 to 30 days.

Conclusion: Demographic features of patients with type 2 diabetes treated in primary care are associated with optimal glycemic control. The study strongly highlights the domination of oral hypoglycemic agents but documents shifting trend towards insulin in the treatment of Type 2 diabetes and the need for periodic blood-glucose monitoring in patients receiving anti-diabetic drug treatment to identify inadequately controlled glycemic levels, so that drug therapy can be modyfied and multiple drug interventions can be planned in order to obtain an optimal glycemic level.

KEYWORDS

Type 2 DM, FBS, PPBS, SMBG

INTRODUCTION

Diabetes mellitus (DM) is a metabolic disorder that adversely affects the normal physiological ability to produce or utilize insulin[1]. It is characterized by hyperglycemia. Elevated blood sugar level is found in diabetes that can cause severe short-term and long-term consequences ranging from brain injury to heart disease and amputations[2]. So, diabetes mellitus is one of the heterogeneous carbohydrate metabolism disorders where defects occur in insulin utilization and secretion.

DM has dreadful complications and can significantly compromise the quality of life. In 2017 according to International Diabetes Federation Atlas 424.9 million people suffer from DM and the number is expected to rise further to 628.6 million by 2045.3 Healthcare expenditures for people with diabetes are assumed to be on average two-fold higher than people without diabetes[3]. Middle and low economic countries are having 79% of the global burden of DM as a result of population growth, aging, and sedentary lifestyles[3]. Currently, India is having the second position with respect to the most number of diabetes patients after China. By 2045 it is expected that India will have 134.3 million diabetes patients, the most in world[3].

Worldwide, DM is regarded as one of the most complex chronic diseases. T2DM is the 7th leading cause of morbidity and mortality in the USA. Diabetic patients require life-long personal care to decrease the chance of developing long-term complications. The chronic nature of the disease, which is burdened with many complications, and the high costs of treatment contribute to rising demand for high-quality diabetes care. In diabetes care should be involved the construed to have the degree to which medical services, in relation to individual buyers and to the entire population, increase the likelihood of obtaining desired outcomes of treatment and are consistent with current knowledge[4,5].

The course and level of metabolic control of type 2 diabetes are affected by many factors related to lifestyle, physical activity, diet control and as well as the quality of medical care. The place of residence of the patient also matters as it determines the availability of health care, education, therapy, specialist advice, and the degree of patient adherence to medical recommendations. Striving for the highest quality of patient care, as well as multidirectional action to improve the health and living conditions of people with diabetes, is of great importance, especially in the context of a number of reports based on a multi-centre clinical trials, which confirm the importance of good metabolic control in preventing complications and improving the quality of life of patients[6,7,8,9].

In India, limited studies have focused on diabetes care which provide insight into the current profile of patients and their management. Therefore, this study was carried out to find the awareness for SMBG among patients and efficacy of prescribed anti-diabetic drugs in maintaining adequate glycemic control in diabetic patients attending a tertiary care teaching hospital in Western Rajasthan.

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) the largest hospital in Western Rajasthan. This study included 250 outpatients with Type 2 Diabetes Mellitus. Patient has not been advised any new drug(s), by the investigator during the study period. To all the patients, purpose and nature of study clearly explained in their language and included after receiving informed consent. All data of patients were kept confidential. We have visited the diabetic OPD on every Wednesday 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 and then mentioned in Case Record Form.

Known cases of Type 2 Diabetes Mellitus with and without complications, patients aged more than 20 years and only outpatients were included in this study. Pregnant females, Gestational diabetes patients, Type 1 Diabetic patients, patient not willing to participate and bedridden patients were excluded from this study.

After recording the obtained information in the Case Record Form the data were subjected to further analysis. Data collection was analyzed further as a number of patients, gender-wise distribution of study patients, patients were divided into age group for the occurrence of

type 2 diabetes mellitus, fasting blood glucose level, post-prandial blood glucose level and frequency of blood glucose monitoring.

RESULTS

A total of 250 patients who fulfilled the inclusion criteria were taken for study at Mathura Das Mathur Hospital, Attached group of Hospitals of Dr. S. N. Medical College, Jodhpur the largest hospital in Western Rajasthan. Out of 250 patients, 193 (77.2%) were male and 57 (22.8%) were female, shown in **table 1 and figure 1**. Male to female ratio was 3.38:1 which was quite high.

Table 1: Age and Gender wise distribution of study patients

Age (Years)	Male		Female		Total
	N	%	N	%	
≤60	60	31.09%	17	29.82%	77 (30.8%)
61-70	106	54.92%	36	63.16%	142(56.8%)
≥71	27	13.99%	4	7.02%	31(12.4%)
Total	193	77.2%	57	22.8%	250

The major contribution of patients was between the age of 61-70 years (56.8%), followed by 60 years and below the age of 60 years (30.8%) and Least Number of patients contributed by 71 years or above (12.4%) shown in **table 1 and figure 1** and it is indicating that the majority of T2DM patients were more than 60 years old .

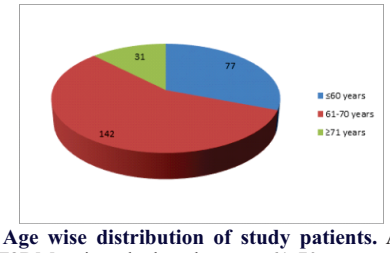

Figure 1: Age wise distribution of study patients. A maximum number of T2DM patients had age between 61-70 years.

Table 2: Fasting Blood Sugar (FBS) wise distribution

Age (Years)	Fasting Blood Glucose				Total
	≤130 mg/ dl		≥131 mg/ dl		
	Number	Percentage	Number	Percentage	
≤60 years	29	37.67%	48	62.33%	77 (30.8%)
≥61years	93	53.76%	80	46.24%	173(69.2%)
Total	122	48.8%	128	51.2%	250

Among the age less than 60 years and 60 years patients, Fasting Blood Glucose ≤130 mg/ dl in 29 patients and ≥131 mg/ dl in 48 patients. While Fasting Blood Glucose ≤130 mg/dl in ≥61years were in 93 patients and ≥130 mg/ dl Fasting Blood Glucose in 80 patients, which is mentioned in **table 2 and figure 2**. Overall 48.8% of patients had Fasting Blood Glucose ≤130 dg/dl and ≥131 mg/ dl Fasting Blood Glucose in 51.2%.

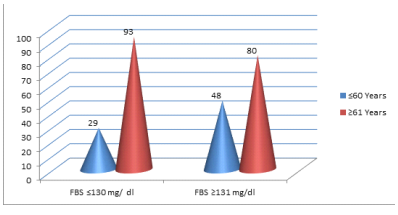

Figure 2: Fasting Blood Sugar (FBS) wise distributi on. Signific antly more controlled optimal FBS level found in age more than 60 years of diabetic patients compared to the age of less than 60 years old diabetic patients.

Table 3: Post-Prandial Blood Sugar (PPBS) wise distribution

Age (Years)	Post-Prandial Blood Sugar (PPBS)				Total
	≤180 mg/ dl		≥181 mg/ dl		
	Number	Percentage	Number	Percentage	
≤60 years	11	14.29%	66	85.71%	77 (30.8%)
≥61years	30	17.34%	143	82.66%	173(69.2%)
Total	41	16.4%	209	83.6%	250

Among the age less than 60 years and 60 years patients, Post-Prandial Blood Sugar ≤180 mg/ dl in 11 patients and ≥181 mg/ dl in 66 patients. While Post-Prandial Blood Sugar ≤180 mg/dl in ≥61years were in 30 patients and ≥181 mg/ dl Post-Prandial Blood Glucose in 143 patients, which is mentioned in **table 3 and figure 3**. Overall 16.4% patients had Post-Prandial Blood Sugar ≤180 mg/dl and ≥181 mg/dl Post-Prandial Blood Sugar found in 83.6% patients and it was showing that poor Post-Prandial Blood Sugar control, which is shown in **table 3 and figure 3.**

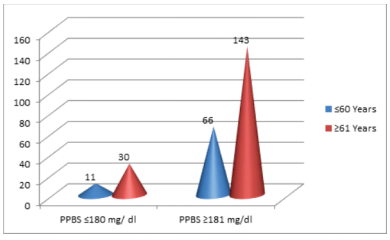

Figure 3: Post-Prandial Blood Sugar (PPBS) wise distribution. No significant difference was found in age less than 60 years and age more than 60 years for controlling optimal Post-Prandial Blood Sugar level.

Among all patients, the maximum number of patients were monitoring their blood glucose between 16 to 30 days (79.6% patients), followed by 8-15 days(14.8%), ≤7days (4.4%) and least number of patients monitored their blood glucose in more than 30 days (1.2% pateints) respectively, shown in **table 4**. Patients those were doing glucose monitoring in 15 days or less than 15 days were doing their self-monitoring of blood glucose which indicates that SMBG found only in 19.2% patients and it was very low. Whereas SMBG found more in ≥61 Years old patients (20.22%) compare to ≤60 Years old patients (16.9%).

Table 4: Frequency of blood glucose monitoring (Days)

Frequency of blood glucose monitoring (Days)	Age (Years)				Total
	≤60 Years		≥61 Years		
	N	Percentage	N	Percentage	
≤7 days	2	2.6%	9	5.20%	11(4.4%)
8-15 days	11	14.3%	26	15.02%	37(14.8%)
16-30 days	63	81.8%	136	78.62%	199(79.6%)
>30 days	1	1.3%	2	1.16%	3(1.2%)
Total	77	30.8%	173	69.2%	250

DISCUSSION

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. Our aim of this study was to evaluate T2DM patients for awareness of self-monitoring blood glucose (SMBG) and as well as to find out the effect of prescribed anti-diabetic drugs on maintaining optimal blood glycemic control in diabetic patients.

In the current study 77.2% of diabetic patients were male and 22.8% diabetic patients were female. Male to female ratio was 3.38:1 which was not accordance to Mathur et al[10] and Nordstrum et al[11] they found in their study that sex ratio in T2DM is 1:1 and 1.6:1, respectively.

In the present study incidence of T2DM patients with age ≤60 years was 30.8% while the incidence of patients with age more than 60 years was 69.2%, which was not similar to the study of Muhammad et al[12] in their study they found 42.2% diabetic patients had age 60 years or above 60 years. But our study was quite similar to the study of Mathur et al [10]in their study they found that 65.2% of patients were more than 60 years old. This incidence is justifiable because T2DM is an old age disease and routine diagnosis of T2DM remain quite late as patients remain asymptomatic for a long time.

In the current study, SMBG found less than 20% of patients and which range from 3 days to 15 days. This less frequency of blood glucose monitoring may be because of high-cost SMBG, lack of awareness and poor health education, which may result into poor optimal glycemic control in T2DM patients. Franciosi et al[13] investigated the frequency of SMBG and its association with metabolic control and quality of life by use of a questionnaire. No association was found between a higher frequency of SMBG and better glycemic control in patients with type 2

diabetes who are not using insulin. However, SMBG frequency of at least one time a day was significantly related to higher levels of distress, worries, and depressive symptoms. Distress and worries were also significantly related to SMBG frequency of at least one time per week. Karter et al[14] used a cohort design (n = 17,601) to assess the association between SMBG and glycemic control. They found that monitoring at the recommended frequency (at least daily) was associated with a better HbA_{1c} level of 0.4% ($P < 0.0001$) compared with less frequent monitoring. Because of the study design, it cannot be determined if the association between SMBG and glycemic control was causal since we cannot exclude the possibility that more motivated subjects choose to initiate SMBG. Soumerai et al.[15] evaluated a policy providing free blood glucose monitors, and they found that initiating SMBG was associated with a significant reduction in HbA_{1c} levels.

In the current study maximum patients were taking oral hypoglycemic agents (OHAs) so strict SMBG was not needed. Self-monitoring of blood glucose and HbA1C are integral components of the standards of care in diabetes. They are designed to assess the effectiveness of a treatment plan and provide guidance in selecting appropriate medications and dosage/s[16]. SMBG allows the patient to assess his own response to medication, minimize the risk of hypoglycemia, and determine whether they are achieving glycemic control. Optimal glycemic control is achieved when FPG is 70–130 mg/dl, 2 h postprandial <180 mg/dl, and bedtime glucose is 90–150 mg/dl. However, testing six to eight times daily may burden patients and may result in non-compliance. Therefore, it is recommended to ensure that patients are properly instructed and are given regular evaluation and follow-up[17]. Self-monitoring of blood glucose is essential in patients with diabetes who are on intense insulin regimen (three to four injections of basal and prandial or insulin pump). 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. The evidence is insufficient to prescribe SMBG for patients not receiving an intensive insulin regimen[18].

In present study37.67% diabetic patients those were ≤60 years old had FBS ≤130 mg/ dl while 53.76% diabetic patients those were ≥61years old had FBS ≤130 mg/ dl. Overall 51.2% patients had ≥131 mg/ dl. Whereas 69.2% of patients had Post-Prandial Blood Sugar ≥181 mg/ dl and not much significant difference in age more than 60years or age less than 60 years. Which indicate more than 50% of patients not achieved optimal glycemic control and this was similar to the several other studies[19,20] and Agarwal[21] et al where more than 50% of diabetic patients found with poor glycemic control. This poor glycemic control justifiable and can occur due to various reason like increase insulin resistance with age, lack of physical activities, the lake of awareness to SMBG, poor health education, poor dietary control, lack of follow up, the high cost of medicine and as well as the poor socioeconomic status of patients.

Diabetes control has a chance to improve due to standardized guidelines implementation in many countries. Many of these recommendations scope on holistic patient care delivered by general practitioners, dietitians, nurses, lifestyle consultants, social workers, psychologists and also including patients' self-management[22]. Guidelines implementation is meeting many barriers, such as lack of follow-up, lack of awareness and lack of awareness of novel recommendations among physicians [23].

CONCLUSION

Demographic features of patients with type 2 diabetes treated in primary care are associated with glycemic control. Physicians should take into consideration patients demographic characteristics, especially being a younger man, when planning treatment of type 2 diabetes. The study strongly highlights the domination of OHAs but documents shifting trend towards insulin in the treatment of Type 2 diabetes and the need for periodic blood-glucose monitoring in patients receiving anti-diabetic drug treatment to identify inadequately controlled glycemic levels, so that drug therapy can be intensified and multiple drug interventions can be planned in order to obtain an optimal glycemic level. It also highlights the need for lifestyle modification measures along with anti-diabetic drug treatment for achieving better glycemic control in Type 2 diabetes.

LIMITATION OF STUDY

HbA_{1c} level was not recorded because study of the population was poor and cost of the investigation was high so, long-term control of blood glucose was not analyzed. In our study rural population was not included and data of the study was very small and duration of the study was short, so for final conclusion, further studies are warranted, with a large amount of data and longer duration.

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Conflict of Interest

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

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