A PROSPECTIVE STUDY FOR DEMOGRAPHICAL EVALUATION OF TYPE 2 DIABETES, SELF-MONITORING OF BLOOD GLUCOSE AND EFFECT OF PRESCRIBED ANTI-DIABETIC DRUGS ON MAINTAINING OPTIMAL GLYCEMIC LEVELS IN DIABETIC PATIENTS IN WESTERN RAJASTHAN

Akhtar Ali, Rajkumar Rathore, Anusuya Gehlot, Shyam Mathur, Mohd Nadeem

ABSTRACT

Aim: Aim of this study is to evaluate T2DM demographically including age and sex, awareness for self monitoring of blood glucose (SMBG) and as well as to find out the effects of prescribed anti-diabetic drugs on maintaining optimal blood glucose level in diabetic patients.

Methodology: This was a prospective, non interventional observational study, conducted at Department of Pharmacology in association with Department of Medicine, Dr. S. N. Medical College, Jodhpur. Information of patients collected included age, sex, diagnosis, duration of medicine, frequency of blood glucose monitoring, Fasting Blood Glucose level and Post-Prandial Blood glucose level were noted in case record form and analyzed.

Results: Total 250 patients, 193 (77.2%) male and 57 (22.8%) female were included in the study. Male to female ratio was 3.38:1. 30.8% of T2DM patients were recorded with age of ≤60 years and 69.2% of T2DM patients recorded with age more than 60 years, whereas 50% of patients had poor glycemic control.

Conclusion: Demographic features of patients with type 2 diabetes treated in primary care are associated with optimal glycemic control. This study strongly highlights the domination of OHA 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.

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. 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. 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 diabetes3. Middle and low economic countries are having 79% of the global burden of DM as a result of population growth, aging and sedentary lifestyles3. Currently, India is having second position in respect of 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 world3.

Worldwide, DM is regarded as one of the most complex chronic disease. 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 knowledge4,5.

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 patients6,7,8,9.

In India, limited studies have focused on diabetes care and provide insight into the current profile of patients and their management. Therefore, this study was carried out to find the 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) which is the largest hospital in Western Rajasthan. This study included 250 outpatients with Type 2 Diabetes Mellitus. Patients were not advised any new drug(s), by the investigator during the study period. All patients were included after receiving informed consent as well as clearly explained the purpose and nature of study in their language. All data of patients were kept confidential.
We visited the diabetic OPD every Wednesday and collected all informations 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 women, 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

The demographic profile of patients

A total of 250 patients who fulfilled the inclusion criteria were included in the study at Mathura Das Mathur Hospital, Attached group of Hospitals of Dr. S. N. Medical College, Jodhpur a largest hospital in Western Rajasthan.

Gender wise distribution of study patients

<table>
<thead>
<tr>
<th>Sex</th>
<th>Number of patients</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>193</td>
<td>77.2</td>
</tr>
<tr>
<td>Female</td>
<td>57</td>
<td>22.8</td>
</tr>
<tr>
<td>Total</td>
<td>250</td>
<td>100</td>
</tr>
</tbody>
</table>

Table 1: Gender wise distribution of study patients

Figure 1: Gender wise distribution of study patients.

Incidence of T2DM is more in male compare to the female. Out of 250 patients, 193 (77.2%) were male and 57 (22.8%) were female. Male to female ratio was 3.38:1 which is quite high, shown in table 1 and figure 1.
The major group of patients was between the age of 61-70 years (56.8%), followed by 71 years or above (12.4%) and least number of patients were in the age group 60 years and below the age of 60 years (30.8%) as shown in table 2 and figure 2. This is also indicating that majority of T2DM patients were more than 60 years of old.

In the age group less than 60 years, fasting Blood Glucose was ≤130 mg/dl in 29 patients and was ≥131 mg/dl in 48 patients. While Fasting Blood Glucose was ≤130 mg/dl in 93 patients ≥61 years and was ≥130 mg/dl in 80 patients as mentioned in table 3 and figure 3. Overall 48.8% of patients had Fasting Blood Glucose ≤130 dg/dl and 51.2% had fasting blood glucose ≥130 mg/dl.

Significantly more controlled optimal FBS levels were found in age more than 60 years diabetic patients compared to less than 60 years old diabetic patients.

### Table 2: Age and Gender wise distribution of study patients

<table>
<thead>
<tr>
<th>Age (Years)</th>
<th>Male</th>
<th>Female</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>%</td>
<td>N</td>
<td>%</td>
</tr>
<tr>
<td>=60</td>
<td>60</td>
<td>31.09%</td>
<td>17</td>
</tr>
<tr>
<td>61-70</td>
<td>106</td>
<td>54.02%</td>
<td>36</td>
</tr>
<tr>
<td>≥71</td>
<td>27</td>
<td>13.99%</td>
<td>4</td>
</tr>
<tr>
<td>Total</td>
<td>193</td>
<td>77.2%</td>
<td>57</td>
</tr>
</tbody>
</table>

### Table 3: Fasting Blood Sugar (FBS) wise distribution of study patients

<table>
<thead>
<tr>
<th>Age (Years)</th>
<th>130 mg/dl</th>
<th>131 mg/dl</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>Percentage</td>
<td>Number</td>
</tr>
<tr>
<td>=60 years</td>
<td>29</td>
<td>37.57%</td>
</tr>
<tr>
<td>≥61 years</td>
<td>93</td>
<td>53.76%</td>
</tr>
<tr>
<td>Total</td>
<td>122</td>
<td>48.8%</td>
</tr>
</tbody>
</table>

### Figure 2: Age wise distribution of study patients.

Maximum number of T2DM patients had age between 61-70 years.

### Figure 3: Distribution of study patients based on their Fasting Blood Sugar (FBS)
Among the patients age less than 60 years, Post-Prandial Blood Sugar was ≤180 mg/dl in 11 patients and ≥180 mg/dl in 66 patients. Post-Prandial Blood Sugar was ≤180 mg/dl in 30 patients who were ≥61 years and 143 patients in the study group had fasting blood glucose levels ≥181 mg/dl (table 4 and figure 4). Overall 16.4% patients had Post-Prandial Blood Sugar ≤180 mg/dl and 83.6 % had post-prandial blood sugar ≥181 mg/dl Post-Prandial indicating poor Post-Prandial Blood Sugar control, which is shown in table 4 and figure 4.

Table 4: Post-Prandial Blood Sugar (PPBS) wise distribution of study patients

<table>
<thead>
<tr>
<th>Age (Years)</th>
<th>≤180 mg/dl</th>
<th>≥180 mg/dl</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;60 years</td>
<td>11</td>
<td>66</td>
<td>77</td>
</tr>
<tr>
<td>≥61 years</td>
<td>30</td>
<td>143</td>
<td>173</td>
</tr>
<tr>
<td>Total</td>
<td>41</td>
<td>200</td>
<td>241</td>
</tr>
</tbody>
</table>

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.

Maximum number of patients were from the group 16-30 days (79.6%) frequency of blood glucose monitoring, followed by 8-15 days (14.8%), ≤7 days (4.4%) and minimum in the group >30 days (1.2%). Majority of patients belonged to frequency of blood glucose monitoring 16-30 day (79.6%) shown in table 5 and figure 5. There was no significant difference in frequency of blood glucose monitoring in ≥61 years and ≤60 years age groups, respectively. Frequency of blood glucose monitoring was quite low in patients shown in table 5 and figure 5. Patients who were doing glucose monitoring in 15 days or less than 15 days were also having a low self monitoring of blood glucose.

Table 5: Frequency of blood glucose monitoring (Days) distribution of study patients

<table>
<thead>
<tr>
<th>Frequency of blood glucose monitoring (Days)</th>
<th>Age (Years)</th>
<th>Frequency</th>
<th>N</th>
<th>Percentage</th>
<th>N</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤7 days</td>
<td>≤60 years</td>
<td>2</td>
<td>2.5%</td>
<td>3</td>
<td>5.2%</td>
<td>11(44.4%)</td>
</tr>
<tr>
<td>8-15 days</td>
<td>≤60 years</td>
<td>11</td>
<td>14.3%</td>
<td>26</td>
<td>15.0%</td>
<td>37(14.8%)</td>
</tr>
<tr>
<td>16-30 days</td>
<td>≤60 years</td>
<td>63</td>
<td>81.6%</td>
<td>136</td>
<td>78.6%</td>
<td>199(79.6%)</td>
</tr>
<tr>
<td>&gt;30 days</td>
<td>≥61 years</td>
<td>1</td>
<td>1.3%</td>
<td>2</td>
<td>1.6%</td>
<td>3(1.2%)</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>77</td>
<td>30.8%</td>
<td>173</td>
<td>69.2%</td>
<td>250</td>
</tr>
</tbody>
</table>

Frequency of blood glucose monitoring (Days) distribution of study patients.

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.

Maximum patients monitoring their blood glucose levels were in the group 16 to 30 days.
DISCUSSION
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. Our aim in this study was to evaluate T2DM demographically like age and sex wise, awareness for self-blood glucose monitoring (SBGM) and as well as to find out the effect of prescribed anti-diabetic drugs on maintaining optimal blood glucose level 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 who reported that 42.2% diabetic patients had age 60 years or above 60 years. Observations in our study were quite similar to the study conducted by Mathur et al.10 who reported 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 was less than 20% of and was performed in a range from 3 days to 15 days. This less frequency of blood glucose monitoring and may be because of high-cost of SMBG, lack of awareness and poor health education. This results in 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 HbA1c level of 0.4% (P < 0.0001) compared with less frequent monitoring. Because of the study design of current study, we could not find out the causal association between SMBG and glycemic control; it is possible 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 HbA1c levels.

In current study majority of the patients were receiving oral hypoglycemic agents (OHAs) which did not need strict SMBG. 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/s16. SMBG allows patients to assess their 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-up17.

Self-monitoring of blood glucose is essential in patients with diabetes who are on an 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 regimen18.

In the present study, 37.67% diabetic patients were ≤60 years old and had FBS ≤130 mg/ dl. 53.76% diabetic patients were ≥61 years old and had FBS ≤130 mg/ dl. Overall 51.2% patients had FBS ≥131 mg/ dl. 69.2% of patients had Post-Prandial Blood Sugar ≥181 mg/ dl and there was no significant difference in age more than 60 years or age less than 60 years. This indicates that more than 50% of patients had not achieved optimal glycemic control and this was similar to several other studies19,20, 21 et al where more than 50% of diabetic patients were having poor glycemic control. This poor glycemic control is not justifiable and can occur due to various reasons like increase insulin resistance with age, the lack of awareness to SMBG, poor health education, poor dietary control, lack of follow up, high cost of medicine and as well as 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-management22. Guidelines implementation is meeting many barriers, such as lack of follow-up, lack of awareness and lack of awareness of novel recommendations among physicians23.

CONCLUSION

Demographic features of patients with type 2 diabetes treated in primary care are associated with glycemic control. Physicians should take into consideration patient 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**

HbA1c level was not performed because of the high cost of investigation 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, so for final conclusion further studies are warranted, with a large amount of data.

**ACKNOWLEDGMENTS**

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**CONFLICT OF INTEREST**

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

**REFERENCES**