An analytical study of the prevalence and prescribed pattern vascular complication for type II diabetic patient in Indian tertiary care hospitals

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ABSTRACT

Diabetes mellitus (DM) is a common metabolic disorder. It is associated with complications which will affect the quality of life. Failure to control elevated blood sugar or inadequate treatment of diabetes could cause many complications. A prospective observational study is used to assess the prevalence of diabetic vascular complications in 105 types of II diabetic patients. A date was collected regarding patient’s demographic and clinical characteristics. Based on our study criteria, males were more when compared to females in getting vascular complications & also. Complications were more prominent in the age group of 50-65 years. Of all microvascular complications, Nephropathy was major, whereas, in macro-vascular complications, CAD was prominent. Poor glycemic control and a long length of ailment appear to be the most significant danger factors for these complexities. Doctors assume a significant function to endorse hostile to diabetic meds and Pharmacist plays a sharp task to assess the medicine design so as to accomplish fruitful treatment. The currently anti-diabetic drugs are effective, but a lot of factors such as patient adherence, education related to diabetes, lifestyle modification, cost and type of medication have an association with glycemic control. The commonly prescribed anti-diabetic drug was Insulin. Metformin was the most preferred drug both as monotherapy and combination therapy. Although polypharmacy was observed, drug utilization pattern can be rational owing to a higher prevalence of complications. Minimization of the occurrence of complications should be courage by early diagnosis, intensive blood glucose control and rational drug selections.

INTRODUCTION

Diabetes Mellitus (DM) is a common metabolic disorder & is defined as “A metabolic disorder of multiple etiology characterized by chronic hyperglycemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in the insulin secretion, insulin action, or both” (WHO), which requires life-long medical care and ongoing patient self-management and support to prevent acute complications and to reduce the risk of mor-
High glucose is the sign of diabetes that expands the danger of complexities. Inability to control raised glucose or deficient treatment of diabetes could cause numerous inconveniences (World Health Organization, 1999). Generally, the injurious effects of diabetes are separated into macro-vascular complications (coronary artery disease, peripheral arterial disease, and stroke) and microvascular complications (diabetic nephropathy, neuropathy, and retinopathy). (Fowler, 2008)

These complications related to DM pose a significant health care burden and affects the overall quality of life. (Mohan et al., 2013) Effective management of DM requires stringent and sustained glycemic control to lower the risk of macro & micro-vascular complications. In 2015, in excess of 415 million grown-ups have DM internationally, and this number is assessed to increment to 642 million by 2040. India is one of the focal points of the worldwide DM plague and has the second-most elevated number of individuals with the infection on the planet ~69 million people as of 2015. (Litwak et al., 2013) The micro-vascular and macro-vascular complications of DM account for most of the morbidity and mortality associated with the disease.

Studies were done in Chennai (2000-2008) revealed that the prevalence of diabetic retinopathy (DR) was 17.6%, micro-albuminuria was 26.9%, neuropathy was 26.1%, coronary artery disease (CAD) was 21.4% and peripheral vascular disease (PVD) was 6.3%. (IDF Diabetes Atlas, 2015) Poor glycemic control and a long duration of illness seem to be the most important risk factors for these complications. Also, these long term complications develop gradually as the age advances making the elderly more prone. According to the International Diabetes Federation, Four out of every five people with diabetes now live in developing countries, with most affected men and women of working age. Diabetes and its risk factors increase the risk of myocardial infarction by 3-6 times. Similarly, it increases the risk of heart failure by 2-3 times, risk of amputation 45 times, blindness 10-25 times and Kidney failure 15-20 times.

(Rema et al., 2005) The currently anti-diabetic drugs are effective, but a lot of factors such as patient adherence, education related to diabetes, lifestyle modification, and cost and type of medication have an association with glycemic control. (Unnikrishnan et al., 2007; Pradeepa et al., 2008) Medication costs, regimen complexity, and irrational prescribing are the challenges for patient compliance and therapy adherence that consequences will lead to poor glycemic control and increase the morbidity and mortality. Study on anti-diabetic prescribing patterns provides useful insights into the current prescribing evaluation, and it eventually leads to achieving rational drug therapy, optimal glycemic control and reduces the health-care cost for patients and society in a large scale.

MATERIALS AND METHODS

Study type
This was the Multi-Centre, prospective observational study. All the patients who meet inclusion criteria were taken as the study population.

Study site
This study was carried out in Manipal tertiary care Hospital, Vijayawada.

Study Population and Inclusion and Exclusion Criteria
The study population of this study was all diabetic patients had complete medical records. The patients who met the inclusion criteria were enrolled in the study. The inclusion and exclusion criteria were as follows.

Sample Size
The study population is of 105 patients.

Study duration
From July 1st to November 1st 2019

Data Collection
Data collection form was developed to collect the data, which includes demographic details and medication list.

Data Entry and Analysis
We choose paired t-test, Co-relation and regression, and anova test. These all statistical procedures analyzed by Statistical program for the Social and sciences (SPSS-26version)

RESULTS AND DISCUSSION
Based on the study criteria, 105 cases were selected and taken for the study. Of the total patient majority were male (58.09 N: 61) in comparison to female (41.90 N: 44) and 49 (46.6%) were belonged to the age group 50-65 years and 45 (42.8%) were in the age group >65. According to the body mass index (BMI), 10 (9.5%) of the patient has normal weight followed by 41 (39.04%) were overweight and 54 (51.4%) patients were obese. Of the 105 patients, 16(15.23%) were suffering from diabetes for <5 years followed by 52(49.5%) and 37(35.2%)
had type 2 diabetes mellitus for 5-10 years and >10 years respectively. The glycosylated haemoglobin (HbA1c) level was mostly observed in the study population was between 7.1 – 8.5. Among comorbidities hypertension, 59 (56.19%) is most prevalent among cardiovascular complication (Mohan et al., 2001).

**Age**

The Mean value for age is 62.16, and Standard Deviation (SD) is 12.193, and Standard Error Mean (SEM) is 1.561, i.e., (Mean ± SD) = (62.16 ± 12.193). T value for age is 39.819, and 95% CI is 59.04 lower, 65.29 upper Figure 1.

**RBS & HbA1c**

RBS: Mean value is 230.82, Standard Deviation (SD) is 114.536, and Standard Error Mean (SEM) is 14.787. Hba1c- mean value is 7.08, Standard Deviation (SD) is 16.72, and Standard Error Mean (SEM) is 0.216. RBS & HbA1c Correlation value is 0.263, Sig. is 0.042. RBS, Hba1c mean is 223.737; Standard Deviation (SD) is 114.107; 95% Confidence Interval (CI) is 194.260 lower; 253.214 upper.

**Figure 1: This graph represents the relation between the Age and BMI of the patients**

**Table 1: Age-wise distribution of Diabetic Vascular Complications**

<table>
<thead>
<tr>
<th>Complication</th>
<th>35-50yrs</th>
<th>50-65yrs</th>
<th>&gt;65yrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microvascular</td>
<td>4</td>
<td>22</td>
<td>23</td>
</tr>
<tr>
<td>Macrovascular</td>
<td>2</td>
<td>26</td>
<td>23</td>
</tr>
<tr>
<td>None</td>
<td>1</td>
<td>6</td>
<td>6</td>
</tr>
</tbody>
</table>

Table 1, shows that, age-wise distribution of diabetic vascular complications. From that table, Age group>65 years were having more microvascular complications, whereas the age group 50-65 years were having more macro-vascular complications.

**Figure 2: Gender wise distribution of Micro & Macrovascular Complications**

Figure 2, shows gender-wise diabetic vascular complications. Out of 52 Micro-vascular complications, 32 were male, 20 were female patients. Whereas from 52 Macro-vascular complications, 29 were male, 23 were female patients. This shows that males were very prone to having Diabetic vascular.

**Figure 3: Overall distribution of microvascular complications**

Figure 3, shows the overall distribution of microvascular complications. Of all 52 micro-vascular complications, Nephropathy (n=25, 48.07%) complication was major followed by Neuropathy (n=14, 26.9%), Retinopathy (n=8, 15.3%), Nephropathy & Neuropathy (n=3, 5.76%), Nephropathy & Retinopathy (n=1, 1.9%), and Nephropathy, Neuropathy & Retinopathy (n=1, 1.9%). (Premalatha et al., 2000; Unnikrishnan et al., 2016)

**Table 2: Overall distribution of macrovascular complications**

Table 2, shows the overall distribution of macrovascular complications. Of all 52 macro-vascular complications CAD (n=30, 57.6%) were major, followed by Stroke (n=8, 15.38%), PVD (n= 8, 15.3%), CAD, PVD (n=3, 5.76%), and CAD, Stroke (n=3, 5.76%). (Dulal and Karki, 2009; Juarez et al., 2006)

Figure 4, shows different therapies used by type II diabetic patients in our study. Of all these therapies,
Table 2: Macro-vascular complications include Stroke, CAD, and Peripheral vascular disease

<table>
<thead>
<tr>
<th>Macro-vascular Complications</th>
<th>Total</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAD</td>
<td>30</td>
<td>57.69</td>
</tr>
<tr>
<td>PVD</td>
<td>8</td>
<td>15.3</td>
</tr>
<tr>
<td>CAD, PVD</td>
<td>3</td>
<td>5.76</td>
</tr>
<tr>
<td>CAD, Stroke</td>
<td>3</td>
<td>5.76</td>
</tr>
</tbody>
</table>

Figure 4: Mono, Dual & Triple therapies of Diabetic drugs used

Table 3: Type of Hypoglycemic Agents Prescribed (n=105)

<table>
<thead>
<tr>
<th>Types of Hypoglycemic agents</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin</td>
<td>54(51.4)</td>
</tr>
<tr>
<td>Sulphonyl ureas</td>
<td>31(29.5)</td>
</tr>
<tr>
<td>Biguanides</td>
<td>78(74.2)</td>
</tr>
<tr>
<td>Sitagliptin</td>
<td>7(6.6)</td>
</tr>
<tr>
<td>Teneligliptin</td>
<td>5(4.7)</td>
</tr>
</tbody>
</table>

Table 4: Overall Utilization Pattern of Drugs (n=438)

<table>
<thead>
<tr>
<th>Drugs</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-Diabetic</td>
<td>175(39.9)</td>
</tr>
<tr>
<td>Anti-Hypertensive</td>
<td>77(17.5)</td>
</tr>
<tr>
<td>Anti-Platelets</td>
<td>59(13.4)</td>
</tr>
<tr>
<td>Statins</td>
<td>32(7.3)</td>
</tr>
<tr>
<td>Analgesics</td>
<td>25(5.7)</td>
</tr>
<tr>
<td>GI drugs</td>
<td>75(17.1)</td>
</tr>
<tr>
<td>Vitamins &amp; Minerals</td>
<td>17(3.8)</td>
</tr>
<tr>
<td>Others</td>
<td>21(4.79)</td>
</tr>
<tr>
<td>Levothyroxine</td>
<td>17(3.8)</td>
</tr>
</tbody>
</table>

Figure 5, shows the combinational usage of drugs prescribed for type II diabetic patients. Of all them, Glimepiride + Metformin (n=46, 43.8%) was mostly commonly prescribed, followed by Gliclazide + Metformin (n=15, 14.28); Glipizide + Metformin (n=10, 9.52); Sitagliptin + Metformin (n=6, 5.7); Teneligliptin + Metformin (n=4, 3.8); Glimepiride + Metformin + Voglibose (n=3, 2.8). (Rhee et al., 2005)

CONCLUSIONS

As per the findings of the study, type II DM was more prominent among male gender and was highly prevalent on age group over 50 years of age. At least one chronic complication was found in 65 (61.9%) of the study population. The reasons for a higher prevalence of complications might be the longer duration of diabetes, poor glycemic control, as observed in the study. The observed diabetic complications were as follows viz. retinopathy (n=8, 15.3%), nephropathy (n=25, 48.07%), neuropathy (n=14, 26.9%), CAD (n=30, 57.6%), Stroke (n=8, 15.38%), PVD (n=8, 15.3%). The overall utilization pattern of drugs were as follows viz. anti-diabetics (n=175, 40%), anti-hypertensive (n=77, 17.57%), anti-platelets (n=59, 13.4%), lipid-lowering agents (n=32, 7.3%).

Among anti-diabetic drugs, metformin (n=37, 35.2%) was the most preferred agent both as
monotherapy and combination therapy. Although polypharmacy was observed, drug utilization pattern can be rational owing to a higher prevalence of complications. Minimization of the occurrence of complications should be encouraged by early diagnosis, intensive blood glucose control and rational drug selections.

Conflict of Interest
The authors declare that they have no conflict of interest for this study.

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