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PRESCRIBING PATTERN OF ANTI DIABETIC DRUGS AMONG TYPE 2 DIABETES MELLITUS PATIENTS IN NORTH KERALA TERTIARY CARE TEACHING HOSPITAL

Nikitha B.*, Anoop Kumar, Rajeev P. Thomas, Smitha P, Anil Babu A. and Anju T. S.

Department of Pharmacy Practice, National College of Pharmacy, Kozhikode 673 602, Kerala.

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***Corresponding Author**
Nikitha B.
Department of Pharmacy Practice, National College of Pharmacy, Kozhikode 673 602, Kerala.

ABSTRACT

Background: Type 2 Diabetes mellitus is characterized by insulin resistance and progressive β cell failure. To achieve good metabolic control in diabetes and keep long term, a combination of changes in life style and pharmacological treatment are necessary. At present oral and injectable formulations are available, which act by different mechanisms to reduce the blood glucose. The majority of people with diabetes on anti‑diabetic drug therapy. Objective: to determine the prescribing pattern of antidiabetic drug in type 2 Diabetes mellitus. **Methods:** The prospective observational study was conducted as per protocol approved by IEC. Patient diagnosed with type 2 DM with co-morbidities were selected. Glycemic control was assessed by recording their HbA1c. Descriptive analyses were performed using statistical package for the social science version 20. **Results:** Based on the study criteria 199 patients were evaluated in the study, including 54.9% male and 45.7% female. Most of the patients were in an age group of 56 to 65 years. The level of HbA1c was found to be higher in 129 patients. A total of 199 prescription were analyzed OHAs were the most common class of drugs prescribed in the study. Sulphonyl urea was used in majority of the population. Glimepiride(11.5%), metformin(9.4%), glybenclamide(1.5%), repaglinide (0.5%), and the least prescribed drug was voglibose.

KEYWORDS: Prescription pattern, T2DM, OHA, HbA1c.

INTRODUCTION

Diabetes mellitus is a group of metabolic disorders characterized by hyperglycemia. It is associated with abnormalities in carbohydrate, fat and protein metabolism and results in chronic complications including micro vascular, macro vascular and neuropathic disorders.[1] DM is a highly prevalent, chronic epidemic in India. In 2000 India topped the world with the highest number of people with diabetes. Some genetic factors coupled with environmental influences such as obesity associated with rising living standards, steady urban migration and life style changes are the common etiologies of diabetes in India.[2]

The two broad categories of DM are designated as type 1 and type 2. In T2DM genetic factors, β cell defect, and peripheral site defects have been implicated in pathophysiology.[3] T2DM accounts for 90-95% of those with DM, characterized by insulin resistance and a relative lack of insulin secretion, with progressively lower insulin secretion over time.[4,5] Most patients with T2DM were obese and may have an increased percentage of body fat distributed predominantly in the abdominal region, which itself causes insulin resistance. Hypertension, dyslipidemia, and elevated PAI-1 are common in these individuals. Due to this insulin resistance syndrome (metabolic syndrome) T2DM patients are at increased risk of developing macrovascular complications.[6]

Prescribing Pattern of Type 2 Diabetes Mellitus

The development of new classes of anti-diabetic medications to supplement the older therapies, such as lifestyle-directed interventions, insulin, sulphonylureas, and biguanides has increased the number of treatment options available for T2DM. Whether used alone or in combination with other blood glucose-lowering interventions, the increased number of choice available to practitioners and patients has heightened uncertainty regarding the most appropriate means of treating this widespread disease.

Various classes of anti-diabetic drugs including insulin and oral hypoglycemic agents (OHA) are currently used in the treatment of diabetes, which acts by different mechanisms to reduce the blood-glucose levels to maintain optimal glycemic control.

Diabetic treatment aims to keep the level of blood glucose within the normal level as safely possible. T2DM is initially treated through changes to lifestyle (healthier diet and increased exercise), followed by oral anti-diabetic drug. Insulin therapy also considers which delay the onset of complications in T2DM[7]. The goal of treatment is to ensure glycemic control. Early

detection and treatment with metformin in combination with lifestyle modifications helps to achieving good glycemic control. Combination therapy and early intervention with insulin would be good for patients with severe symptoms[8]. As per ICMR guidelines the T2DM treatment should be individualized.

MATERIALS AND METHODS

This single centered prospective observational study was conducted as per the protocol approved by the institutional Ethics committee. This study was conducted in the general medicine department of KMCT medical college hospital at Kozhikode in North Kerala. Total duration of the study was 9 months. The study consists of 199 patients who diagnosed with T2DM in outpatient and inpatient units of general medicine department and who met the inclusion criteria. Patients who were diagnosed to have T2DM and age greater than 30 were included in this study.

In order to record necessary data from the sources mentioned above, a separate data collection form was designed based on the data required for the study, it included: demography of the patient, duration of diabetes, medication history of the patient, diagnosis, date of visit, languages known, complaints on admission, laboratory findings, discharge medications etc.

The data regarding demographic and socioeconomic factors, clinical details such as duration of illness, modality of treatment and presence of other comorbidities or complications due to DM were collected by interviewing the patient and from patient medical records. Laboratory data were collected. Glycemic control was assessed by recording their HbA1c which is reported to be a reliable indicator of blood glucose level for the last 3 months prior to testing. HbA1c level was categorized as a level less that 7% as good glycolic control, >7 poor glycemic control. Descriptive analyses were performed using Statistical Package for the Social Sciences Version 20.

RESULTS AND DISCUSSION

A total of 199 T2DM patients evaluated including 54.9% male and 45.7% female were evaluated. Most of the patients aged between 56 and 65. Social habits of the study population were evaluated from which 13.6% were use alcohol, 12.1% use tobacco and 33.7% were smokers. 11.6% were illiterate and majority of the population 92.5% were non vegetarians. (Table 1).

Table. 1.

Variable	Total patient N (%)
Gender	
Male	108(54.3)
Female	91(45.7)
Age	
30 – 45	18(9)
46-55	61(30.7)
56-65	81(40.7)
>66	39(19.6)
Marital status	
Married	197(99)
Unmarried	2(1)
BMI	
Normal	109(54.8)
Over weight	73(36.7)
Obese	17(8.5)
Occupational status	
Employed	108(54.3)
Unemployed	91(45.7)

The level of HbA1c was found to be higher in 129 patients. Total of 120 patients had hypertension. 91 patients from the total population had dyslipidemia. 75 patients had CAD. From the total population 17 patients were suffering from different stages of CKD. 24 patients had nephropathy, 91 had pheripheral neuropathy and 13 patients had retinopathy. (Table 2).

Clinical characteristics of diabetic patients.

Table. 2.

Variable	Total patients N(%)
Duration of diabetes (year)	
<1	18(9)
1-5	60(30.2)
6-10	68(34.2)
11-15	36(18.1)
>15	17(8.5)
HbA1c	
≤ 7	70(35.2)
>7	129(64.8)
Family history of T2DM	
Yes	86(43.2)
No	113(56.8)
Types of complication	
Hypertension	120(60.3)
Dyslipidemia	91(45.7)
CAD	75(37.7)

CKD	17(8.5)
Nephropathy	24(12.2)
Peripheral neuropathy	91((45.7)
Retinopathy	13(6.6)

A total of 199 prescriptions were analyzed, OHA's were the most common class of anti-diabetic drugs prescribed in this study. In monotherapy sulfonylureas was the most commonly used OHA followed by biguanides in this study population. 11.5% patients treated with glimepiride and 9.04% treated with metformin. glibenclamide(sulfonyl ureas) prescribed for 1.5% patients, repaglinide(meglitinides) 0.5% and the least prescribed drug was voglibose(α-glucosidase inhibitors)1%. Insulin therapy was prescribed to 41 patients of which mixture of long acting insulin and fast acting insulin was prescribed to 30 patients, followed by fast acting for 11 patients. 11(5.52%) patients were prescribed with a combination of insulin 6(3.01%) treated with insulin and metformin, From the total 62(31.10%) patients were prescribed with metformin and glimepiride, followed by metformin and glibenclamide combination. A combination of glimepiride and voglibose were prescribed for 1 patient. A combination of insulin+metformin+glimepiride were prescribed for 1 patient, Insulin+ metformin+glimepiride used for16 (8.8%)patients. (Table 3).

Details of Different Anti-Diabetic Drugs (Add) Used in the Study Populaion.

Table. 3.

Type of therapy	**Drugs**	**N**	**%**
Monotherapy	Insulin	41	20.05%
	Metformin	18	9.04%
	Glibenclamide	3	1.50%
	Glimepiride	23	11.50%
	Voglibose	1	0.50%
	Repaglinide	3	1.50%
Combination therapy	Combination of insulin	11	5.50%
	Insulin+Metformin	7	3.51%
	Insulin+Glibenclamide	3	1.50%
	Insulin+Repaglinide	1	0.50%
	Metformin+ Glibenclamide	7	3.50%
	Metformin+Glimepiride	62	31.10%
	Glimepride+Voglibose	1	0.50%
	Insulin+Metfomin+Glimepiride	16	8.80%
	Metformin+Glimepiride+Voglibose	1	0.50%
	Insulin+Metformin+Glibenclamide	1	0.50%
Total		**199**	**100%**

We found total 81 patients were treated with monotherapy from this population 41 (20.05%) patients were using insulin.

In monotherapy sulphonylureas were prescribed the most followed by biguanides. Sulphonyl ureas are widely used in the management of type 2 diabetes mellitus, in this study we found that glimipiride, the third generation sulphonyl urea was given majority of the patients. Several studies reported the most commonly used OHA was metformin in monotherapy but in our study we found glimipiride used in majority of patients with monotherapy. Glimipiride has a longer duration of action (upto 24 hours) when compared to metformin. Dual therapy analysis exhibits a pattern were sulphonylureas + biguanides were the most preferred combination for the treatment of type 2 diabetes mellitus. Other studies supported that the combination of metformin and glimipiride was superior to monotherapy with metformin or sulphonyl urea alone.[9,10] Former studies suggested metformin and glimipiride combination was superior to metformin and glybenclamide combination[11]. Among the various combinations of sulphonylureas and biguanides, the most preferred drugs in this population were glimipiride and metformin. Long acting insulin followed by fast acting insulin were most preferred insulin therapy pattern in this present study. 8.8% of patients were used glimipiride, metformin and insulin and the same reported by earlier studies.[12,13] Addition of glimipiride to insulin metformin combination is effective in lowering HbA1c level. This study has some limitations, it was a single centered study and this prospective observational study analyzing only the single visit and does not provide any information regarding changing pattern in prescription.

CONCLUSION

Among all the anti-diabetic drugs, in monotherapy insulin was highly preferred over OHA. glimipiride accounted for the most commonly prescribed oral hypoglycemic agent followed by metformin. In this population combination of metformin and glimipiride was prescribed to majority of patients. Not only rational prescribing pattern also patient compliance and life style modification are important to control diabetes mellitus. Identifying T2DM early will further improve the quality of life of diabetes patients and also reduce overall treatment costs.

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