



**PROFILE AND PRESCRIBING PATTERN OF ANTI DIABETIC
DRUGS IN PATIENTS WITH DIABETES MELLITUS IN A TERTIARY
CARE TEACHING HOSPITAL AT DAKSHIN KANNADA DISTRICT,
KARNATAKA**

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ABSTRACT

Diabetes mellitus can virtually affect every system of the human body leading to micro vascular and macro vascular complications. Patients with diabetes mellitus are at higher risk of polypharmacy and more vulnerable to irrational prescription. The study aimed to evaluate profile and prescribing pattern of anti-diabetic agents in patients with diabetes mellitus in a tertiary care teaching hospital at dakshin kannada district, Mangalore, Karnataka, A prospective, cross-sectional study

was carried out in the out-patient clinic of general medicine department for three months from January 2015-march 2015. All the patients with diabetes mellitus who visited the out-patient department during the study period were interviewed and their prescriptions were reviewed by the researchers, based on the study objectives. The details were entered in the data form and later were analyzed by using descriptive statistics. A total of 137 patients with

60 males (43.79%) and 77 females (56.20%) were enrolled into the study. The mean (\pm standard deviation) age and duration of diabetes was 56.79 ± 9.81 and 8.03 ± 7.38 years respectively. Among these, 56 (40.87%) were in the age group 51-60 years, 91(66.42%) had a history of Diabetes mellitus of 1-10 years, 82 (59.85%) had no family history of diabetes and 108 (78.83%) had at least one concurrent illness. Hypertension (44.82%) was most common co-morbid illness. Metformin (37.85%) was the most common prescribed anti-diabetic drug followed by insulin (36.42%). Metformin with glimepride (70.17%) was the most prescribed combination. Biguanides and insulin were the most commonly prescribed anti diabetic drugs. As patients with diabetes mellitus are associated with multiple co-morbidities, poly pharmacy is unavoidable. The study also witnessed a shifting trend towards the use of insulin preparations and combination therapy in the management of diabetes mellitus.

KEYWORDS: Diabetes mellitus, Prescription pattern, Anti-diabetic agents, Dakshin Kannada.

INTRODUCTION

Diabetes mellitus is the most common endocrine disorder recognized as the major public health problems and main threats to human health that is affecting the population of both developed and non-developing countries.^[1] According to World Health Organization (who), it is estimated that more than 346 million people worldwide have diabetes mellitus and this number is more likely to be doubled by 2030 until or unless preventive steps have been taken.^[2] Diabetes mellitus is defined as a chronic metabolic disease characterized by hyperglycaemia due to absolute (Type 1 DM) or relative (Type 2 DM) deficiency of insulin hormone or both. Uncontrolled blood sugar or hyperglycemia over a long period of time is associated with macro vascular & micro vascular complications, diabetic foot ulcer and recurrent infections leading to increased morbidity and mortality and adverse effect the quality of life of the patient.^[3] The chronic complications and associated cardiovascular conditions such as hypertension, ischemic heart disease and dyslipidemia in patients with diabetes mellitus makes it more difficult to avoid multiple drug use. Such patients are prescribed with Polypharmacy for long term therapy and sometimes to irrational prescriptions. Several studies on anti- diabetic drugs published in different healthcare setting from various parts of the world can facilitate rational drug use in patients with diabetes mellitus. More over irrational prescribing will provide an insight to occurrence of drug

related problems and non-adherence to the prescribed medications and also will increase the drug cost and healthcare costs.^[4] A study from the United States of America (USA) reported that about 1.3 million adults with diabetes mellitus did not take their medications as prescribed because of cost as a result more than half reported with health problems^[5]. Carrying out a prescribing pattern study can provide valuable information to the researchers, policy makers, Pharmacy & therapeutic committee (PTC) and health care professional's members to determine the drug use pattern. Therefore, the present study was carried out to establish current prescribing pattern of anti-diabetic drugs in outpatient general medicine department of a university teaching hospital in dakshin Kannada district, Karnataka, India. The main objectives of the study includes

- 1) To study the demographic details of out -patients with diabetes mellitus.
- 2) To study the pattern of prescribing anti-diabetic drugs in out- patients with diabetes mellitus.

MATERIALS AND METHODS

The study was carried out at a tertiary care teaching hospital centrally located at dakshin Kannada district, Karnataka. The institutional Ethical Committee approval was obtained prior to the study. It was a prospective observational study carried out for a period of three months from January 2015 to March 2015. Patients with diabetes mellitus of all age group who visited the out-patient general medicine department were included in the study after obtaining written informed consent. Patients with gestational diabetes mellitus, and patients with diabetes mellitus who are on diet control and not prescribed with any anti-diabetic medications were excluded from the study. The patient data including the socio demographic details and other relevant clinical data including the prescription detail were collected and documented in the suitably designed data collection form designed as per the need of the study. The socio demographic details included were age, gender, mother tongue, marital status, family history of diabetes mellitus and educational qualification. Clinical data includes duration of diabetes and co-morbidities and complications associated with diabetes mellitus and anti diabetic medications. The drugs written on the prescription were assessed on the basis of drugs used as anti-diabetic agents and brand names were decoded to generic names using standard CIMS (Current Index of Medical Specialities) India and Internet. The collected data were later analysed by using the SPSS statistical software version 20 and Microsoft excel 2007 for various above mentioned parameters including most common anti diabetic drugs and therapeutic category of anti -diabetic drugs. Descriptive statistics for

continuous variables were expressed as means and standard deviation (SD). Categorical variables were described as frequencies with percentages for the total sample.

RESULTS

A total of 137 patients were enrolled in to the study. Of the total study populations, male were 60 (43.79) and female were 77 (56.20). Among these patients, the greatest number were in the age group 51-60 years [56 (40.87)], followed by 61-70 years [36 (26.27)], 41-50 years [24 (17.51)], 71-80 years [12 (8.75)], 31-40 years [9 (6.56)]. There were no patients included in our study aged less than or equal to 30 years and aged more than or equal to 81 years of age. The mean \pm SD age of the patients was 56.79 ± 9.81 years. Considering the mother tongue among the study populations, almost equal number of Malayalam (49.63%) and Kannada (50.36%) language patients were included in the study. Comparing the educational status of the study populations, most of the patients had primary school level of education [68 (49.63)] followed by illiterate [30 (21.89)] and secondary school level of education [15 (10.94)]. There were six patients (4.37%) with diabetes mellitus who had graduation and above level of education in our study populations. In the case of marital status, majority of the patients [135 (98.54)] were married and 2 (1.45) patients with diabetes mellitus were unmarried. Among the study population, most of the patients [82 (59.85)] had no family history of diabetes mellitus were as 55 patients (40.14) had a family history of diabetes mellitus. Considering the duration of diabetes among the study populations, 14 patients (10.21%) had a diabetic history of less than one year, followed by 1-10 years in 91 patients (66.42), 11-20 years in 24 patients (17.51), 21-30 years in 5 patients (3.64) and greater than or equal to 31 years in three patients (2.18). The average mean \pm SD duration of diabetes mellitus was found to be 8.03 ± 7.38 years. Among the total 137 study populations, 29 patients (21.16) had no co-morbidities followed by 61 patients (44.52) with one co-morbidity, 32 patients (23.35) had two co-morbidities, 11 patients (8.02) had three co-morbidities and 3 patients (2.18) had 4 co-morbidities. There was one patient (0.72) who has presented with five co-morbidities. The details regarding the socio demographic characteristics of the study population with diabetes mellitus is shown in the following table no 1.

Table 1: Socio demographic characteristics of study populations (N= 137)

Sl no	Characteristics	Value (%)
1	Gender	
	Male	60 (43.79)
	Female	77 (56.20)
2	Age (years)	
	≤ 30	Nil
	31-40	9 (6.56)
	41-50	24 (17.51)
	51-60	56 (40.87)
	61-70	36 (26.27)
	71-80	12 (8.75)
≥ 81	Nil	
3	Mother Tongue	
	Kannada	69 (50.36)
	Malayalam	68 (49.63)
4	Educational status	
	Illiterate	30 (21.89)
	Primary school	68 (49.63)
	Secondary school	15 (10.94)
	Graduate & above	6 (4.37)
5	Marital Status	
	Married	135 (98.54)
	Unmarried	2 (1.45)
	Widow	Nil
	Divorced	Nil
6	Family history	
	Yes	55 (40.14)
	No	82 (59.85)
7	Duration of Diabetes Mellitus	
	< 1	14 (10.21)
	1-10	91 (66.42)
	11-20	24 (17.51)
	21-30	5 (3.64)
	≥ 31	3(2.18)
8	No. of Co-morbidities	
	0	29 (21.16)
	1	61 (44.52)
	2	32 (23.35)
	3	11 (8.02)
	4	3 (2.18)
	5	1 (0.72)

Considering the concurrent illness among the study populations, 108 patients (78.83) had at least one coexisting illness during the study period. A total of 174 illnesses were identified in these 108 patients. Hypertension was the most frequent comorbid condition (44.82) observed

in the study. The details regarding the coexisting illness of the study patients is shown in the table no 2.

Table 2: Prevalence of concurrent illness (N=174)

Sl no	Co-morbidity	Frequency (%)
1	Hypertension	78 (44.82)
2	Dyslipidaemia	19 (10.91)
3	Renal failure	7 (4.02)
4	Heart failure	5 (2.87)
5	Stroke	3 (1.72)
6	Acute coronary syndrome	24 (13.79)
7	Thyroid	7 (4.02)
8	Asthma	5 (2.87)
9	COPD	13 (7.47)
10	Psychiatric Illness	4 (2.29)
11	Rheumatoid arthritis	2 (1.14)
12	Tuberculosis	3 (1.72)
13	Liver disease	3 (1.72)
14	Atrial fibrillation	1 (0.57)

COPD- Chronic Obstructive Pulmonary disease

Among the total 137 patients with diabetes mellitus, 22 patients (16.05) were received only insulin followed by 30 patients (21.89) with single OHA, 49 patients (35.76) with two OHAs and 7 patients (5.10) with three or more OHAs. There were 29 patients (21.16) receiving both insulin and oral hypoglycaemic agents during the study period. The details about the anti-diabetic medications treatment approach has been shown in the following table no 3.

Table 3: Details about treatment approach of Anti-diabetic medications

Sl No	Therapy	Number of patients (%)	
1	Only Insulin	22 (16.05)	Monotherapy (37.94%)
2	Single OHA	30 (21.89)	
3	Two OHA	49 (35.76)	Combination therapy (62.02%)
4	Three or more OHA	7 (5.10)	
5	Insulin + OHA	29 (21.16)	

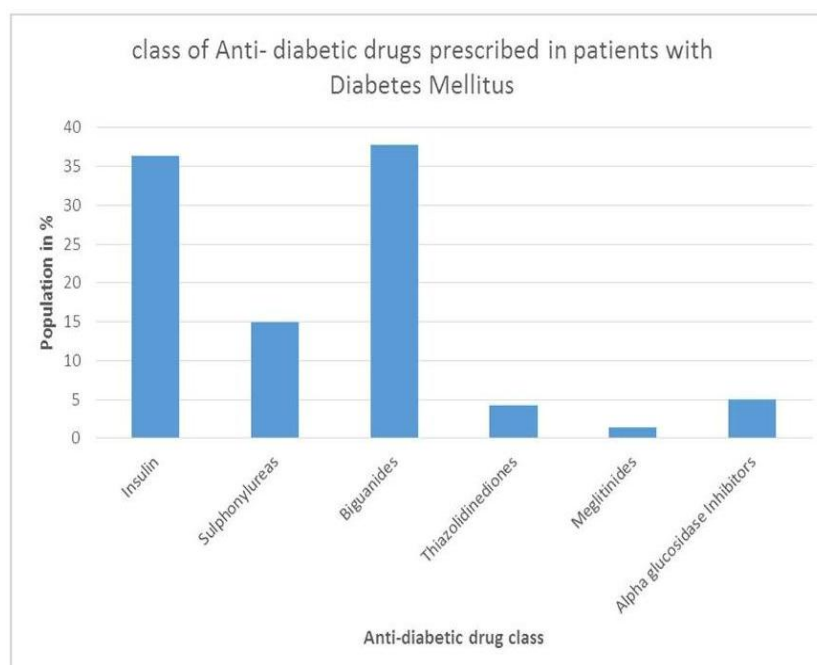
OHA – Oral hypoglycaemic agent

Among the various anti-diabetics prescribed, biguanides were the most common class of drugs accounting for 53 (37.85) of the total anti-diabetics followed by insulin 51 (36.42), Sulphonylureas 21 (15.0), alpha glycosidase inhibitors 7 (5.0), thiazolidinedione's 6(4.28), and Meglitinides 2 (1.42). The details regarding the prescribing pattern of anti-diabetic drugs is shown in the table no 4 and their graphical representation is shown in the figure no1.

Table 4: Prescribing pattern of Anti-diabetic drugs

Sl no	Drug class	Name of the drug	Frequency (%)
1	Insulin	Insulin	51 (36.42)
2	Sulphonylureas	Glimepride	9 (6.42)
		Glibenclamide	7 (5.0)
		Glipizide	4 (2.85)
		Gliclazide	1 (0.71)
		Total	21 (15.0)
3	Biguanides	Metformin	53 (37.85)
4	Thiazolidinedione's	Pioglitazone	6 (4.28)
5	Meglitinides	Repaglinide	2 (1.42)
6	Alpha glycosidase Inhibitors	Voglibose	7 (5.0)

N= 140

**Figure 1: Percentage of class of Anti-diabetic drugs prescribed in patients with Diabetes Mellitus**

Considering the combination of anti-diabetic drugs prescribed in our study populations, most of the patients were prescribed with metformin and glimepiride combination (70.17) followed by metformin and Glibenclamide combinations (15.78). There were one patient who received triple drug combination consisting of metformin, Glipizide and pioglitazone. The details of different anti-diabetic drugs combinations is shown in the following table no 5.

Table 5: Distribution of Anti – diabetic drug combinations

Sl no	Combination (s)	Frequency (%)
1	Metformin + Glibenclamide	9 (15.78)
2	Metformin + Glimepiride	40 (70.17)
3	Metformin + Glipizide	3 (5.26)
4	Metformin + Gliclazide	1 (1.75)
5	Metformin + Pioglitazone	1 (1.75)
6	Metformin + Sitagliptin	2 (3.50)
7	Metformin + Glipizide + Pioglitazone	1 (1.75)

N= 57

DISCUSSION

Diabetes mellitus is a chronic lifelong metabolic disturbance affecting a large group of population in the developing countries including India. Diabetes mellitus needs lifelong management including pharmacological and non-pharmacological therapy to control the blood glucose level and micro and macro vascular complications. Although lifestyle modifications, diet and exercise plays a vital role in diabetes management, drugs become unavoidable in majority of the patients during the later part of their life. In the early stages of pharmacological management, either insulin or single oral agents can be used to control the glucose level, but in later stages combination therapy may be needed for better glycaemic control. Hence, the present study was carried out to evaluate the prescription pattern of anti-diabetic drugs in out-patients with diabetes mellitus in a tertiary care teaching hospital.

A total of 137 patients with diabetes mellitus case sheets were evaluated during the study period. In the case of gender distribution, the current study showed a female dominance over male populations (female 56.20% versus male 43.79%). Similar results were obtained in other studies.^[6, 7, 8] However, the results are in contrast to studies conducted in India and other countries which showed male predominance over female populations in their reports.^{[9, 10, 11].}

Majority of the patients were in the age group of 51-60 years (40.87) which is in concordance with the earlier published studies^[12, 13]. Another study carried out in India showed majority of the patients with diabetes mellitus belongs to age group greater than 60 years of age.^[14] The mean age of the patients in the current study was 56.79 years (age range: 33-79 years), a finding similar to that obtained in studies conducted in Nepal and Ahmedabad, which have reported the mean age of patients as 56.9 and 56.8 years respectively^[15, 17]. Duration of diabetes mellitus plays an important role in its management with patients who have diabetes of less than 1-5 years could usually be managed with single oral hypoglycaemic agent or

insulin. Whereas patients with more 5-10 years duration of diabetes may require combination of oral hypoglycaemic agents or insulin with oral hypoglycaemic agents for its management. In the present study, nearly two-thirds of the patients had a history of Diabetes mellitus for less than 10 years. This observation was in contrast to the observation made by various authors in their study.^[13, 15, 16] The mean duration of diabetes observed was 8.03 ± 7.38 years which is comparable with the study results from various authors which showed the mean duration of diabetes as 8.3 ± 9.4 years and 7.92 ± 0.37 years respectively. Out of the 137 patients, 55 patients (40.14%) had a family history of diabetes which is comparable with the study by various different authors.^[16, 17] Patients with uncontrolled blood glucose are at higher risk of developing complications. Cardiovascular diseases is the most common co-morbidity that possess a major threat in patients with diabetes mellitus. In the present study, co-morbid condition was seen in 108 patients (78.83%). Hypertension (44.82%) was the most common co-morbid condition, followed by acute coronary syndrome (13.79%) and dyslipidaemia (10.91%). Our findings are similar to the studies from India and other countries which reported a similar observation with regards to the co-morbidity in patients with diabetes mellitus, however the prevalence of hypertension has ranged from 31-70% (8, 18). Considering the treatment approach towards anti-diabetic medications, the present study showed 37.94% of the patients were on monotherapy [either receiving only insulin (16.05%) or single OHA (21.89%)] and 62.02% of patients were on combination therapy [receiving Two or more OHAs or insulin with OHA]. As the diabetes mellitus disease progresses, functional decline in beta cells is usually apparent and the conventional management with single drug therapy often fails and need for combination therapy becomes unavoidable and will be an integral part of the disease management. So there will be an increase in prescribing pattern of combination drugs for better glycaemic control and symptomatic control to prevent the progression of diabetic complications. Our study findings were consistent with the study conducted in rural areas of Tamil Nadu, monotherapy and two drug combinations therapies were prescribed in 21.7% and 78.3% patient's respectively.^[19] Among the anti-diabetic drugs, metformin belonging to biguanides category made the bulk and accounted for 37.85% of the total drugs, followed by Insulin (36.42%) and Sulphonylureas (15.0%). The results are in line with study findings carried out by various authors across India which showed metformin was the most common drug category prescribed in their study followed by Sulphonylureas.^[9,13,16,17,18] The choice of anti-diabetic drug depends on the type of patients, their concurrent illness, cost factors as well as the availability of drugs. Metformin has the advantage of weight neutral when compared with other anti-diabetic agents such as

Sulphonylureas, thiazolidinedione's, Meglitinides and alpha glycosidase inhibitors and insulin which makes it as the drug of choice for obese patients. Furthermore, the aggressive pharmacotherapy of diabetes mellitus can be complicated by hypoglycaemia which can seriously limit the pursuit of glycaemic control. Metformin acts by decreasing excess hepatic gluconeogenesis without raising insulin levels considered safer drug in terms of hypoglycaemia, a much added advantage over insulin and some types of insulin secretagogues when used as a monotherapy. In addition, the favourable profile on several cardiovascular risk factors and the low cost of metformin makes affordable and cheap by the patients in economically developing countries like India. As a result, metformin stands at the top and preferred as an ideal first line agent for the treatment in patients with diabetes mellitus. Insulin preparations is the second most commonly used anti-diabetic drugs in our study. This observation may be because of the fact that glycaemic control is not adequately achieved by the use of oral hypoglycaemic agents and can be controlled more effectively with the addition of insulin. Prescription of Voglibose (alpha glycosidase inhibitor) was noted in 5% of patients. Voglibose acts by delaying the absorption of carbohydrates from the intestine and thereby it reduces the post prandial hyperglycaemia without significant increase in insulin levels. Several studies showed that a combination of Sulphonylureas with metformin has been most widely used. In the present study prescriptions of combination of Sulphonylureas and metformin were identified in (94.64%) cases with majority (70.17%) of the patients receiving metformin + glimepiride combination therapy followed by metformin + Glibenclamide (15.78%). Our results are in concordance with the observation of some other studies.^[13,15,20,21] Among the glitazone and Meglitinides category the only drug prescribed was found to be pioglitazone and Repaglinide.

CONCLUSION

The present study concluded that metformin is the most commonly prescribed anti-diabetic drug followed by insulin preparations and Sulphonylureas in the management of diabetes mellitus. Metformin with glimepiride is most widely used oral hypoglycaemic agent combination therapy in the present study. Although it may be concluded that the drug use in the management of diabetes mellitus is quite rational but the more frequent use of insulin in our study probably may be because of the long duration of diabetes mellitus, associated co-morbid conditions and high glycaemic status of the study subjects necessitates earlier prompt control of hyperglycaemia specially in the setting of glucotoxicity and pancreatic exhaustion.

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CONFLICT OF INTERESTS: None

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