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Research Article

Pattern of antidiabetic drugs use in type-2 diabetic patients in a medicine outpatient clinic of a tertiary care teaching hospital

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ABSTRACT

Background: Diabetes mellitus (DM) is an important public health problem in developing countries. Drug utilisation study of antidiabetic agents is of paramount importance to promote rational drug use in diabetics and make available valuable information for the healthcare team. The aim of study was to investigate the drug utilization pattern in type-2 diabetic patients.
Methods: A prospective, cross-sectional study was carried out in medicine outpatient clinic of tertiary care hospital, Ahmedabad for eight weeks. Patients with type-2 diabetes and on drug therapy for at least one month were included. Patients' socio-demographic and clinical data were noted in a pre-designed proforma. Data was analysed by using SPSS version 20 and Excel 2007.
Results: Total 114 patients were enrolled with mean (± standard deviation) age and duration of diabetes of 56.8 ± 10.5 and 8.3 ± 9.4 years respectively. Male: Female ratio was 0.72:1. Mean fasting and postprandial blood glucose levels were 147.5 ± 73.1 and 215.6 ± 97.3 mg/dl respectively. Most common symptom was weakness/fatigue (77.2%). Hypertension (70.2%) was most common co-morbid illness. Mean number of drugs prescribed were 7.8 ± 2.5. Total numbers of patients receiving more than five drugs were 89.5%. Most commonly used drug group was biguanides (87.7%) followed by sulphonylureas (68.4%).
Conclusion: Metformin (biguanide) was the most utilized (87.7%) antidiabetic drug for type-2 diabetes. This study revealed that the pattern of antidiabetic prescription was rational and largely compliant with NICE (National Institute for Health and Clinical Excellence) guidelines.

Keywords: Diabetes, Blood glucose, Anti-diabetic drugs, Metformin

INTRODUCTION

Diabetes mellitus (DM) is an important public health problem in developing countries. Several anti-diabetic drug utilization studies have been published in the healthcare setting from various parts of world can facilitate rational drug use in patients with diabetes. Drug utilization studies provide useful insights into the current prescribing practices and also identify irrational prescribing. The consequences of irrational prescribing include non-adherence to medications, which can result in complications due to uncontrolled blood glucose levels and also escalate drug costs and health care costs. Drug utilization studies results can suggest modifications in the current prescribing practices to the prescribers, policy makers and drug and therapeutic committees to encourage rational use of drugs.

As per World Health Organization (WHO), around 31.7 million individuals in India were affected by diabetes during the year 2000 which may further rise to 79.4 million by the year 2030.[1] Diabetes mellitus (DM) is the chronic disorder emerging as major health problem which increases the rate of morbidity and mortality.[2] Poor management of this disorder leads to several complications.[3] Management of type-2 DM requires both pharmacological and non-pharmacological interventions.[4]

According to Intercontinental Marketing Service (IMS) data, the leading groups of drugs utilized worldwide are cardiovascular drugs which are usually co-prescribed along with anti diabetic drugs as result of co-existence of cardiovascular diseases and diabetes.[5] The prevalence of type 2 diabetes mellitus is major among Indian individuals.[6]

Diabetes is a common and very prevalent disease affecting the citizens of both developed and developing countries and is the most common endocrine disorder globally.[7] Concurrent illness such as hypertension in diabetics makes it more difficult to avoid multiple drug use; hence diabetics are more prone to polypharmacy and sometimes to irrational prescriptions.[8] Drug utilisation study of antidiabetic agents is of paramount importance to promote rational drug use in diabetics and make available valuable information for the healthcare team.[9] This study is therefore aimed at determining the pattern of drug prescription among type-2 diabetic patients so as to evaluate the degree of physicians' compliance to current evidence and clinical guidelines and analyse the prescription according to WHO core drug prescribing indicators.

METHODS

The study was a cross-sectional study and started after approval from Institutional Review Board. Data was collected for eight weeks from medicine outpatient department. Sample size of 108 was determined by taking, standard deviation 0.57, alpha 0.05, critical difference 0.2 and power of the study 95%.[10]

Study population

All patients with 18 years and above diagnosed with type-2 diabetes attending the outpatient department of medicine of a tertiary care teaching hospital and on drug therapy for at least one month were included in the study after obtaining written informed consent. Newly diagnosed and patients not willing to participate were excluded. Socio demographic and relevant clinical data of participants was noted. The socio demographic details included were age, gender, occupational class, marital status, number of children and educational qualification. Clinical and biochemical data included number of symptoms, fasting and postprandial blood glucose level (FBG, PPBG), duration of diabetes, co-morbidities / complications, drugs prescribed and non-pharmacological measures followed by patients. Glycemic control was determined by latest FBG and PPBG levels. The glycated haemoglobin (HBA1c) test, usually preferred for the assessment of long-term glycaemia control, was not available to us.

Statistical analysis

Data was analysed using the SPSS statistical software version 20 and Microsoft Excel 2007. 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

Out of 140 patients invited to participate in the study, 114 consented for participation (response rate - 81.43%). Participants' mean age was 56.8 ± 10.5 years and 48 (42.1%) were male. Out of 114 patients, 40 (35.1%) patients had a family history of diabetes. Socio demographic characteristics of study participants are depicted in (Table 1).

Table 1: Socio demographic characteristics of study participants (N=114).

Parameter	Value
Age (years) (Mean ± SD) [Range]	56.8 ± 10.5 [35-78]
Gender n (%)	
Male	48 (42.1%)
Female	66 (57.9%)
Religion n (%)	
Hindu	58 (50.9%)
Muslim	56 (49.1%)
Marital status n (%)	
Married	84 (73.7%)
Single	8 (7%)
Widowed	22 (19.3%)
No. of children n (%) [Range]	[0-10]
0-3	56 (49.1%)
≥4	58 (50.9%)
Weight n (%)	
Normal/underweight	42 (36.8%)
Moderately obese	50 (43.9%)
Obese	22 (19.3%)
Educational status n (%)	
Uneducated	32 (28.1%)
Up to school level	64 (56.1%)
Graduate	10 (8.8%)
Postgraduate	8 (7%)
Occupational class n (%)	
White collar	8 (7%)
Self employed	8 (7%)
Blue collar	10 (8.8%)
Others (housewives, retired etc.)	88 (77.2%)
SD-Standard Deviation	

About 70% of participants had presented with at least three symptoms at the time of interview. Most common symptom was weakness / fatigue (77.2%). Hypertension (70.2%) was most common co-morbid illness followed by ischemic heart disease (31.6%). About 43.8% of patients were following non-pharmacological measures (reduced sugar intake, walking, exercise and yoga) in addition to pharmacotherapy. Clinical variables of the participants are shown in (Table 2).

Table 2: Clinical variables of the participants (N = 114).

Clinical variables	Frequency n (%)
Symptom counts [Range]	[0-11]
No symptom	4 (3.5)
1 symptom	16 (14)
2 symptoms	14 (12.3)
≥3 symptoms	80 (70.2)
Prevalence of symptoms	
Polyuria	54 (47.4)
Polydipsia	36 (31.6)
Polyphagia	20 (17.5)
Weight loss	60 (52.6)
Weakness, fatigue	88 (77.2)
Blurred vision	24 (21.1)
Tingling numbness	68 (59.6)
Co morbidities / Complications [Range]	[0-4]
Hypertension	80 (70.2)
Ischemic heart disease	36 (31.6)
Stroke	6 (5.3)
Diabetic retinopathy	2 (1.8)
Diabetic nephropathy	2 (1.8)
Duration of diabetes (years) (Mean ± SD) [Range]	8.3 ± 9.4 [0.08-36]
0-4.9	58 (50.9)
5-9.9	18 (15.8)
10-14.9	10 (8.8)
15-19.9	10 (8.8)
≥20	18 (15.8)
FBG (mg/dl) (Mean ± SD) [Range]	147.5 ± 73.1 [72-454]
PPBG (mg/dl)	215.6 ± 97.3 [86-485]
Number of drugs prescribed [Range]	7.58 ± 2.49 [1-12]
0-4	12 (10.5)
5-8	66 (57.9)
9-12	36 (31.6)
*Controlled diabetics n (%)	28 (24.6)
Uncontrolled diabetics	86 (75.4)
Non-pharmacological measures [Range]	[0-5]
Compliant	50 (43.8)
Non-compliant	64 (56.1)
SD-Standard Deviation	
FBG – Fasting Blood Glucose,	
PPBG – Post Prandial Blood Glucose	
*FBG >130 and / or PPBG >180 mg/dl[1] considered as uncontrolled.	

Most commonly prescribed drug group was biguanide (87.7%) followed by sulphonylureas (68.4%). Antiplatelet drugs (61.4%) formed the most commonly prescribed drug group for cardiovascular co-morbidities, followed by statins (56%). Table 3 shows prescribing pattern of drugs in this study population.

Table 3: Prescribing pattern in type 2 diabetic patients (N = 114).

Drug group	Frequency (%)
Anti-diabetic drugs	
Biguanides	100 (87.7)
Sulphonylureas	78 (68.4)
Insulin	26 (22.8)
α glucosidase inhibitors	24 (21.1)
Dipeptidyl peptidase 4 inhibitors	12 (10.5)
Thiazolidinediones	12 (10.5)
Cardiovascular drugs	
Antiplatelets	70 (61.4)
HMG CoA reductase inhibitors	64 (56)
AT1 antagonists	54 (47.4)
β blockers	28 (24.6)
Calcium channel blockers	28 (24.6)
Nitrates	28 (24.6)
Diuretics	24 (21.1)
ACE inhibitors	22 (19.3)
Others	
Multivitamins, Folic acid, Iron	30 (26.3)
Proton pump inhibitors	22 (19.3)
Pregabalin + Methylcobalamin	20 (17.5)
Calcium	10 (8.8)
H2 receptor blockers	8 (7.0)
Antiemetics	6 (5.3)
AT1 – Angiotensin 1	
ACE – Angiotensin Converting Enzyme	

Glimepiride + Metformin (50%) was most commonly prescribed combination followed by Metformin + Voglibose (7.02%). Table 4 shows distribution of antidiabetic combinations.

Table 4: Distribution of antidiabetic combinations (N=114).

Combination (s)	Frequency (%)
Glimepiride + Metformin	57 (50)
Metformin + Voglibose	8 (7.02)
Glimepiride + Metformin + Pioglitazone	8 (7.02)
Metformin + Vildagliptin	4 (3.51)
Glibenclamide + Metformin	2 (1.75)
Sitagliptin + Metformin	2 (1.75)
Metformin + Methylcobalamin	2 (1.75)

Drugs were prescribed as monotherapy in 81.58% patients. Two drug combinations were prescribed to 65.78% patients and three drug combinations were prescribed to 7.02% patients (Table 5). Biguanides - Metformin was prescribed as monotherapy in 40.35% patients, whereas prescribed as combination therapy in 72.8% patients. Table 6 summarizes distribution of classes of antidiabetic drugs prescribed in type-2 diabetic patients as monotherapy and combination therapy.

Table 5: Monotherapy and combination therapy of antidiabetic drugs prescribed in type-2 diabetic patients.

Drugs	Frequency (%)
Monotherapy	93 (81.58)
Two drug combination	75 (65.78)
Three drug combination	8 (7.02)

Table 6: Distribution of classes of antidiabetic drugs prescribed in type-2 diabetic patients as monotherapy and combination therapy.

Drug groups	Monotherapy n (%)	Combination therapy n (%)
Biguanides	46 (40.35)	83 (72.8)
Sulphonylureas	14 (12.28)	67 (58.77)
α glucosidase inhibitors	19 (16.67)	8 (7.02)
DDP4 inhibitors	6 (5.26)	6 (5.26)
Thiazolidinediones	8 (7.02)	8 (7.02)

Average number of drugs per prescription was 7.58 ± 2.49. Only 3.94% of drugs were prescribed by generic name. Percentage of drugs prescribed from WHO essential drugs list was 22.45%. Percentage of drugs prescribed from National List of Essential Medicines of India, 2011 were 45.49%. Table 7 describes WHO core drug prescribing indicators.

Table 7: WHO core drug prescribing indicators.

Indicators	Value
Average number of drugs per prescription	7.58 ± 2.49
Percentage of drugs prescribed by generic name	3.94%
Percentage of encounters with an antibiotic prescribed	0.81%
Percentage of encounters with an injection prescribed	3.70%
Percentage of drugs prescribed from essential drugs list	22.45%

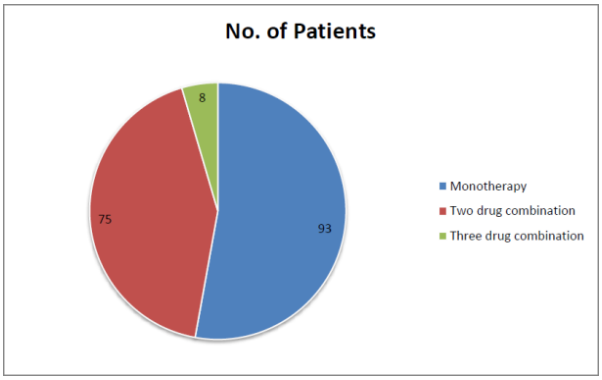

Figure 1: Monotherapy and combination therapy of antidiabetic drugs prescribed in type-2 diabetic patients.

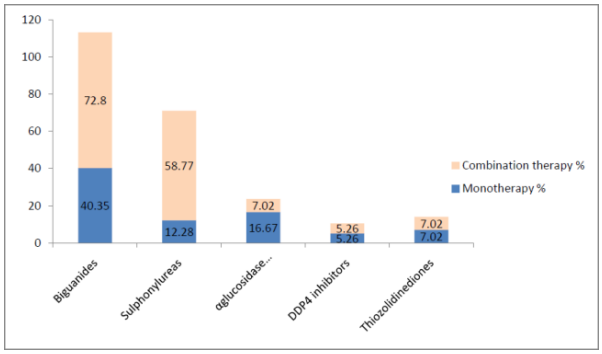

Figure 2: Distribution of classes of antidiabetic drugs prescribed in type-2 diabetic patients as monotherapy and combination therapy.

About 76.32% of prescriptions were according to NICE (National Institute of Health and Clinical Excellence) guideline of May 2009.

DISCUSSION

Diabetes mellitus is a major public-health problem worldwide. Its prevalence is rising in many parts of the developing world, and India is no exception to this. It will become diabetes capital of the world in near future. Individuals with Type 2 DM are considered on high priority as they are potential candidates for rapid evaluation to prevent and halt the progression of complications.[11]

The mean ± SD age of patients in this study was 56.8 ± 10.5 years, a finding similar to that obtained from studies in India and other countries.[5,12,13] A high proportion of diabetic patients in this study were represented by females similar to the study from UAE[12] and in contrast with other report from India.[11,13,14] In the present study, slight preponderance of females was noticed similar to Sutharson L et al, 2003.[15] In contrast, some other studies indicated male predominance in their reports.[16-19]

The mean duration of diabetes mellitus observed was 8.3 ± 9.4 years which is comparable with the study from Spain showed the mean duration of diabetes as 11.8±8.0 years.[20] This observation was in contrast to the observation made by Upadhaya et al[8] and Lisha Jenny et al.[12] Out of 114 patients, 40 patients (35.1%) had a family history of diabetes which is comparable with the study of Lisha Jenny[12] and R Ramesh.[14] In this study, hypertension (70.2%) was the commonest co-morbidity observed. Different studies[9,12,14,19] also reported similar observation with regard to the co-morbidity in patients with diabetes.

The average number of drugs per prescription was 7.58 ± 2.49 which is high compared to the study from UAE.[12] The average number of drugs prescribed to this outpatient diabetic population was high mainly because of co-morbid illnesses of patients enrolled in the study, who would require more medications for their additional illnesses. The high average number of drugs prescribed to patients with diabetes is not surprising. It is recognized that patients with diabetes mellitus are generally prescribed more drugs than other patients.[21] The trend in this study showed that previous studies had positively influenced the diagnostic skills and the prescribing habits of doctors, though there is still need for improvement.

Metformin alone and Metformin combination was the commonly prescribed anti-diabetic drug observed in the present study, in line with findings of Upadhyay et al, 2007,[8] Johnson et al, 2006,[18] Yurgin N et al, 2007;[19] Sultana G et al, 2010;[22] and in contrast to R Ramesh et al, 2011;[14] Chiang CW et al, 2006;[23] Al Khaja KA et al, 2001;[24] where in Sulfonylureas were the commonly prescribed anti-diabetic drug. Metformin was the most utilized anti-diabetic drugs utilization in the zone. This result contrasts the reports of some studies done in Indian[25] and Hong Kong[26] which reported that Glibenclamide was the most commonly prescribed anti-diabetic drug. Sudha et al, 2008[16] reported that in their study metformin was the most prescribed drug. Among the second generation sulfonylureas, glimepiride was the most commonly prescribed along with metformin which is in accordance with study from India.[4]

Metformin + glimepiride was most commonly prescribed combination for diabetes which is in contrast to the study from Nigeria[9] in which Metformin + glibenclamide was most common combination for diabetes. Metformin + sitagliptin was the most common combination observed by Lisha Jeeny et al study[12], while in Al Khaja KA et al, 2001 study[24], metformin+sulfonylurea was the most common combination. Metformin is considered to be safer and cost effective drug over others in terms of hypoglycemia could be the probable reason for this finding.

The fact that metformin was the most prescribed drug complies with its endorsement as the preferred antidiabetic agent by current clinical guidelines, for example, Canadian Diabetes Association, 2008[27]; International Diabetes Federation, 2005;[28] National Institute of Health and Clinical Excellence, 2010[29] and Nathan et al, 2006.[30] The proportion of diabetic patients found to have co-morbid hypertension is high which is not surprising since it reflects what obtains globally.

The most commonly co-prescribed medications along with antidiabetic drugs were antiplatelets followed by hypolipidemic agents (statins) which is in contrast with the study from Nigeria[9] in which antihypertensives were most commonly coprescribed medications. The high antihypertensive prescriptions reflect the high rate of co-morbidity of hypertension and diabetes.[31]

The percentage of generics and drug use from essential drug list are very low. This further emphasizes the need to reduce the cost of medications to patients through increased prescription of drugs in their generic names and reduction in number of drugs per prescription to foster patients' compliance and rational drug prescription without a fall in treatment standards towards attaining optimal diabetic control. Prescribing by generic name allows flexibility of stocking and dispensing various brands of a particular drug that are cheaper than and as effective as proprietary brands. This is the basis of essential drugs list use. Some prescription by the proprietary names may have resulted from the good relationships existing between the physicians and the pharmaceutical sales representatives that market the drugs to the hospital.[5]

A low percentage of injection utilisation from this study is observed because we had taken only type-2 diabetes patients which are mainly on oral hypoglycaemic agents only. The most commonly prescribed injection was insulin which is only given in type-2 diabetes if hyperglycemia not controlled by diet and exercise or when these are not practicable, when oral hypoglycemics are not tolerated, temporarily to tide over special conditions or any complication of diabetes.

Limitations of the study include the small sample size which restricts the generalization of the findings. In conclusion, a wide spectrum of anti diabetic drugs was prescribed among the subjects, with metformin combination being the most commonly prescribed anti-diabetic medications.

CONCLUSION

Metformin (biguanide) was the most utilized (87.7%) antidiabetic drug for type-2 diabetes. Glimepiride + Metformin combination was the most commonly prescribed antidiabetic combination. This study revealed that the pattern of antidiabetic prescription was rational and largely compliant with NICE (National Institute for Health and Clinical Excellence) guidelines.

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