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Research article

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Drug utilization pattern of anti-diabetic drugs among type 2 diabetes mellitus patients – a prospective study

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ABSTRACT

Introduction

Diabetes mellitus (DM) is emerging as major health problem. There has been worldwide increase in prevalence of DM, especially in developing countries. With this increased prevalence of diabetes, drug utilization study of antidiabetic drugs is very useful from health care viewpoint.

Aim

The aim of study was to investigate the drug utilization pattern in type-2 diabetic patients.

Methods

A prospective observational study was carried out in Palakkad Diabetic Centre, Palakkad, for 6 months. Patients with type-2 diabetes and on drug therapy with or without co morbidities and complications were included. Patients' socio-demographic and clinical data were noted in a pre-designed proforma. Data was analyzed by using SPSS version 16 and Excel 2007.

Result

Total 428 patient were enrolled with Mean± SD age 57.72± 10.8, were females are more prevalent (52%) and 77% had family history. Hypertension (26%) was most common co-morbid disease followed by dyslipidemia (21%). Totally 32% of patients were on Monotherapy and Metformin was commonly prescribed. In combination therapy, Glimpiride and Metformin (77%) were mostly consumed followed by Glibenclamide and Metformin (12%) there was no evidence of Polypharmacy.

Conclusion

Metformin was the most commonly used drug. The prescribing trend also appears to be moving towards combination therapy particularly two drug therapy. All insulin preparations were human insulin. . Incidence of diabetes has been found higher in female as compared to male and majority of the patients develop diabetes in the most productive years of their life .This study contributes to the growing body of literature on drug utilization research.

Keywords: Prevalence, Co morbidities, Drug utilization, Poly Pharmacy

INTRODUCTION

Drug utilization has been defined as the marketing, distribution, prescription, and use of drugs in a society, with emphasis on the resulting medical and social consequences. The principal aim of drug utilization studies (DUS) is to facilitate the rational use of drugs in population. DUS is an essential part of pharmacoepidemiology as it describes the extent, nature and determinants of drug exposure and it is used to identify treatment adherence problems. [1]

Diabetes represents a spectrum of metabolic disorders, which has become a major health challenge worldwide. By the year 2030, over 85 percent of the world's diabetic patients will be in developing countries. In India alone, the prevalence of diabetes is expected to increase from 31.7 million in 2000 to 79.4 million in 2030 [2]. Diabetes results from the failure of the pancreas to produce a sufficient amount of insulin. Hormone that regulates the body's use of glucose is insulin the pancreas produces a sufficient amount of insulin, but if the insulin is blocked from the body's cells and cannot be used. This causes patients to have abnormally high amounts of sugar in their urine and blood. Diagnosing a patient with diabetes is more complicated than measuring the glucose level of urine only one time. The diagnosis involves several hours of glucose-tolerance tests (GTT). These tests measure the rate in which sugar is removed from the bloodstream and after the test are complete, high glucose level indicates insufficient insulin and the patient is diagnosed with diabetes [3]. Drug utilization studies can provide useful insight into the prescribing patterns and patient medication taking behavior [4].

Since 1995, a dozen orally administered diabetes medications or combination of medications for the management of type-2 diabetes mellitus have been approved by FDA. They play a primary defense function against hyperglycemic events in comparison to insulin therapy. Traditionally in oral hypoglycemic agent therapy, sulphonyl ureases have always been the agents of first choice, while Biguanide and alpha-glucosidase inhibitors were unpopular. A good number of

diabetes patients suffer from cardiovascular disease such as hypertension, hyperlipidemia and ischemic heart disease [5]. The present project was designed to study pattern of antidiabetic drug use in outpatient.

METHODS

This prospective observational study was carried out over a period of 6 months from December 2016 to May 2017 in patients attending Palakkad Diabetic Centre. The present study protocol was approved by institutional ethics committee. Newly diagnosed and patient who are not willing to participate were excluded from the study. The data was collected from prescription, patient record book and patient interview. All necessary and relevant baseline information was collected on a standard patient data collection proforma, which contains demographic data, social history, diagnosis data, laboratory investigations, treatment chart. For drug utilization we have analyzed 428 of type2 diabetes patients.

STATISTICAL ANALYSIS

Data analysis was done by using SPSS16.0 Microsoft excel 2007

RESULTS

In the present study 428 patients were participated, 224 (52%) were females who were more when compared to males (48%). mean \pm SD age of the participant was 57.72 ± 10.8 most of the patient belong to age group of 51-60 (33%) followed by 61-70 (32%) (Table 1). Mean duration of diabetes was 6.5 ± 4.5 and it was recorded that 77% of participants had a strong family history. In this study nearly half (50%) had below matriculation education. Glycemic level were found to be high, FBS 144 ± 53.8 and PPBS 219.18 ± 86.080 . The data also shows that 2% (n=10) patients were smokers and 7% (n=28) being alcoholics.

Table 1 Distribution of Diabetic patients according to age (n = 428)

Age in years	No: of patients	PERCENTAGE (%)
20-30	4	1
31-40	22	5
41-50	80	18
51-60	140	33
61-70	136	32
71-80	46	11

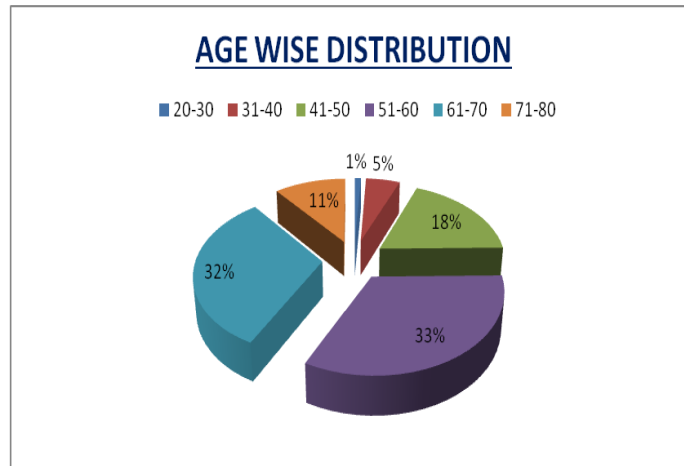


Figure 1 Distribution of diabetic patients according to age

(Table 2) The co morbid conditions found to be 26% (n=181) had hypertension, 21% (n=149) had dyslipidemia, 7% (46). The major complications

are retinopathy 22% (n=153) and 14% had neuropathy (n= 102.3).

Table 2 Distribution of co morbidities and complications

Co morbidities and complications	Number of patients (percentage)
Hypertension	181 (26%)
Dyslipideamia	149 (21%)
Thyroid	46 (7%)
Chronic kidney disease	15 (2%)
Cardio vascular disease	9 (1%)
Retinopathy	153 (22%)
Neuropathy	102 (14%)
Foot ulcer	24 (3%)
Skin diseases	29 (4%)

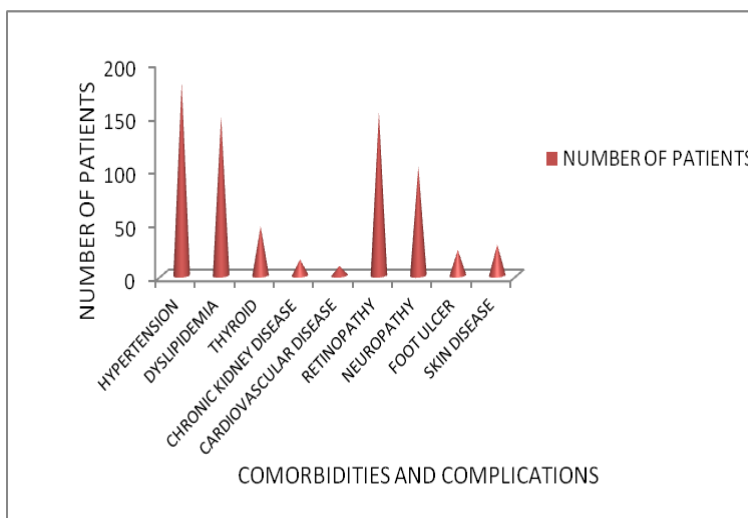


Figure 2 Distribution of co morbidities and complications

(Table 3) Among all the patients 32% (n=138) were treated with Monotherapy and 68% (n= 290) were on combination therapy.

Table: 3 Distribution based on drug therapy

Drug therapy	No: of patients	Percentage (%)
MONO THERAPEY	138	32
TWO DRUGCOMBINATION THERAPY	290	68

Table 4 shows that anti- diabetic drug utilization pattern among the study population. Antidiabetic agents prescribed were injectable agents (different types of insulin) and oral antidiabetic drugs of different groups; sulfonylureas, biguanides, thiazolidinediones, Dipeptidyl peptidase 4 (DPP-4) inhibitors. All prescribed insulin preparations were human insulin. Among drug combinations 64 % (n=229) of patients were received oral hypoglycemic while

36% (129) were received insulin preparations. The study reveals that in oral hypoglycemic Monotherapy metformin 27 % (was the most prescribed drug metformin was the most commonly prescribed drug. Among the combinations metformin and Glimepiride (77%) was most commonly prescribed followed by Metformin and Glibenclamide 12% (27) and Metformin and Gliclazide 11% (25) (Table 5).

Table 4 Drug utilization of Antidiabetic drugs- Monotherapy

ATC code	Drugs	Total number of drugs prescribed	Percentage (%)
A10AB	INSULIN	129	36
A10BA02	METFORMIN	98	27
A10BB12	GLIMEPIRIDE	58	17
A10BG03	PIOGLITAZONE	59	16
A10BH01	SITAGLIPTIN	14	4

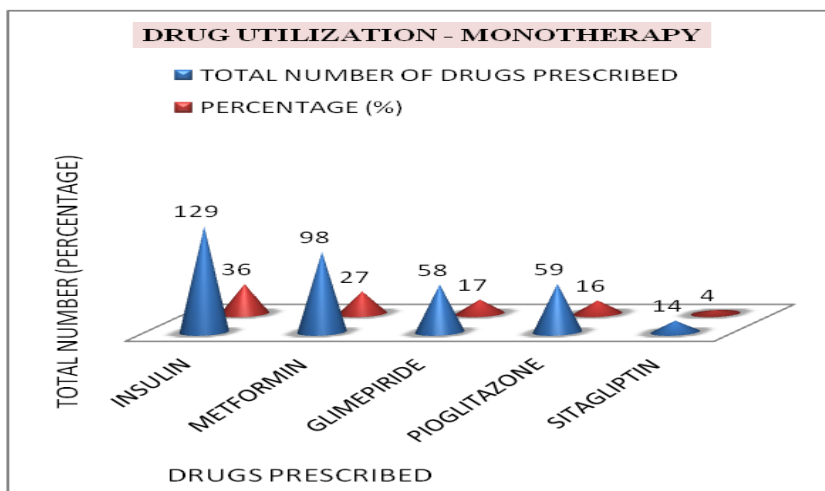


Figure 3 DRUG UTILIZATION MONO-THERAPY

Table 4 Drug utilization of oral hypoglycemics- combination therapy

Drugs	Total number of drugs prescribed	Percentage (%)
METFORMIN+GLIMEPIRIDE	179	77
METFORMIN+GLIBENCLAMIDE	27	12
METFORMIN+GLICLAZIDE	25	11

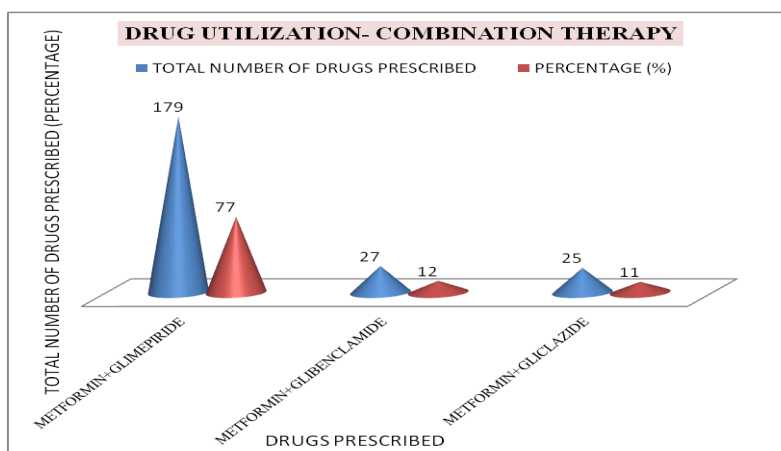


Figure 4 DRUG UTILIZATION- COMBINATION THERAPIES

DISCUSSION

A drug utilization study is considered to be one of the most effective methods to assess and evaluate the prescribing attitude of physician and help to promote rational use of drugs. Type 2 DM is a non-autoimmune, complex, heterogeneous and polygenic metabolic syndrome where the body fails to produce enough insulin, characterized by abnormal glucose homeostasis. The burden of diabetes is to a large extent the consequence of macro vascular (coronary artery disease, peripheral vascular disease, and atherosclerosis) and micro vascular (retinopathy, neuropathy, and

nephropathy) complications of the disease ^[1]. The life-style modifications and dietary changes and the pharmacological treatment an integral component in the management of diabetes [7].

In our study, the prevalence of diabetes mellitus is more in females (52%) than males (48%). The middle aged group people(40-60yrs) are more prevalence to the diabetes mellitus similar results were obtained in study the of drug utilization pattern and effectiveness analysis in diabetes mellitus conducted by Premalatha Das[6].

Duration of diabetes has a significant role in its management. Patients who have diabetes for <5 years could usually be managed with single drug therapy while combination therapy is required in patients having diabetes for more than this period. In the present study, most of the patients (48.9%) had a diabetic history of <5 years, a finding consistent with that of other studies [7, 8].

Co-morbidity has been shown to intensify health care utilization and to increase medical care costs for patients with diabetes. The associated Co morbid conditions seen with diabetes mellitus are hypertension, dyslipaemia, neuropathy, nephropathy and retinopathy. About 20-60% of diabetic patients are associated with hypertension as a co morbid condition [9]. Our study also was in agreement with published standards where hypertension being the most common condition 26 % (n=181) followed by dyslipaemia 21% (n=149) [10]. The history suggested that a strong family background was noticed in the study 77% (n=329).

The management of Type 2 diabetes can be complicated by hypoglycemia, which can seriously limit the pursuit of glycemic control. Here, too, metformin has advantages over insulin and some types of insulin secretagogues; by decreasing excess hepatic gluconeogenesis without raising insulin levels, it rarely leads to significant hypoglycemia when used as a monotherapy. Metformin is widely considered an ideal first-line agent for the treatment of Type 2 diabetes. As like the Nigerian study, Metformin being most commonly used drug for all Type II DM. In uncontrolled cases, sulphonylureas or Insulin was added as the combination therapy as per ADA guidelines and WHO where Metformin seems to first line drug followed [11]. In this study, combination of biguanides and sulphonylureas was found to be most effective, and this was consistent with a studies conducted in Kathmandu, Nepal and Mangalore, India [12, 13]. The combination therapy (68%) is more in use in the current study area setting and is more preferred in order to control the FBS of the patients, a common finding observed with early study of V. Sivasankari et.al [1] on drug utilization pattern of anti-diabetic drugs and Khushali et.al [14] on evaluation of anti-diabetic prescriptions which also suggests that combination of biguanides and sulphonylureas were most frequently used combination and are most

effective. Our study states that 2-drug combination is more in use. In 2-drug combination Metformin+Glimeperide (77%) was most commonly prescribed than other combinations like Metformin+Glibenclamide (12%), Metformin+Gliclazide (11%) a common finding identified with early study of Bela Patel et.al [15] on patterns of anti-diabetic drugs use but which is in contrast with a study conducted by V.Sivasankari on drug utilization pattern of anti-diabetic drugs states that glibenclamide+metformin was most commonly prescribed drug.

In contrast to sivasankari MD et al our study also shows that combination of biguanides and sulphonylureas was found to be most effective, and this was consistent with a studies conducted in Kathmandu, Nepal and Mangalore, India. Poly pharmacy was commonly reported in a studies conducted in developing countries whereas average number of drugs used per prescription in our study was 1.7 ± 0.52 which is consistent with the study conducted in Nepal and Chennai [16,17]. Polypharmacy has been reported as one of the causes of adverse drug reactions [18]. Polypharmacy and ADR were less in our study indicating minimal and rational prescribing practices. This showed that rational approach reduced the complications and improved the glycemic control. In our study 70% of them were literate hence the compliance was also good.

CONCLUSION

Metformin was the most commonly used drug. The prescribing trend also appears to be moving towards combination therapy particularly two drug therapy. All insulin preparations were human insulin. Hypertension was most common associated co morbidity in diabetic patients. Incidence of diabetes has been found higher in female as compared to male and majority of the patients develop diabetes in the most productive years of their life .This study contributes to the growing body of literature on drug utilization research.

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