



DRUG UTILIZATION PATTERN OF ANTI-DIABETIC DRUGS IN A RURAL AREA OF TAMILNADU, SOUTH INDIA – A PROSPECTIVE, OBSERVATIONAL STUDY

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ABSTRACT

Diabetes mellitus is in alarming rise from 40 million to 70 million people by 2025 in India. Drug utilization studies help to identify the treatment of adherence problems and improve proper drug usage. Aims and Objectives:-To evaluate the drug utilization pattern of anti-diabetic drugs in Type II DM patients in a rural population. Methodology: A prospective observational study was carried out at Seeragapadi village, Salem for a period of 6 months. Out of 1456 patients screened, 92 Type II DM patients were included and a structured questionnaire was used to collect data and analysis done. Results:-The prevalence was about 6.3% and 68.47% of them were in 40 to 60 years of age. Hypertension was the most common co morbid condition (19.6%) followed by hypercholesterolemia (3.3%). Totally 21.74% of patients were on monotherapy and Metformin was commonly prescribed. In combination therapy, Glibenclamide and Metformin (35.86%) were mostly consumed followed by Glimepiride and Metformin (9.78%) and inj. Human Mixtard with Metformin (27.17%). Statins were co-administered in 5.5% of patients and there was no evidence of Polypharmacy. Conclusion:-Type II DM was treated effectively with both Insulin and Oral hypoglycemic drugs. Glimepiride can be substituted for Glibenclamide due to better pharmacokinetic and pharmacodynamic properties. Statins and low dose ACE inhibitors can be added according to recent ADA guidelines to minimize the complications of DM.

Keywords: Drug utilization, Type II Diabetes mellitus, anti-diabetic drugs, prescribing pattern



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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 consequences¹. 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. Diabetes has emerged as a major healthcare problem in India. According to Diabetes Atlas (ADA) published by the International Diabetes Federation (IDF), there is an alarming rise in disease progression from 40 million in 2007 to 70 million by 2025 in India and every fifth person with diabetes will be an Indian^{2,3}. A projected to rise from 171 million in 2000 to 366 million in 2030 is noted worldwide. The urban population in developing countries is projected to double between 2000 and 2030⁴. Nowadays the incidence is increasing in rural parts of India due to urbanization, obesity, unsatisfactory diet, sedentary life style, etc⁵. Since the literature review on drug utilization pattern in rural parts of India yielded a very few data, we planned to carry out a study to evaluate the drug utilization pattern among diabetic patients in a rural population of Tamilnadu, South India.

MATERIALS AND METHODS

This prospective observational household study was carried out for a period of 6 months from April to September 2012 at Seeragapadi village, Salem. This village is situated 1 km away from the Vinayaka Mission's Kirupananda Variyar Medical College with a population of around 3000. The major occupation being agriculture and weaving. A total of 1456 patients were screened, out of which 92 being a known case of DM under treatment of both genders and aged between 18 to 80 yrs were included in the study.

Majority of the patients received treatment from Government sectors with few of them rely on private hospitals. Patients with prediabetic status, diabetic complications and serious medical conditions requiring subsequent hospital admissions were excluded from the study. Door to door visits were made by the investigators with the help of health workers. A structured questionnaire was explained in the vernacular language. Demographic data, detailed medical history, medications for diabetes mellitus, concomitant medications for co morbid diseases, questions regarding lifestyle, dietary pattern, and exercise programme with laboratory investigations were recorded in the study proforma. Compliance, adverse effects and change in drug therapy were noted during the subsequent visits done at monthly intervals. These data were entered for evaluation. Confidentiality and anonymity of the patient's information will be maintained during and after the study. Prior permission from the Institutional Ethical Committee of Vinayaka Mission's Kirupananda Variyar Medical College, Salem along with written informed consent from all the participants were obtained.

STATISTICAL ANALYSIS

Data analysis and interpretation: The collected data were analyzed for their appropriateness and suitability and interpretation was made. Statistical analysis was done by SPSS (Version 11.2) software. Statistical methods used were Simple frequencies and percentages.

RESULTS

A total of 1456 patients were screened, out of this 92 being a case of type II DM were selected according to the study protocol. Totally 62 (67.4%) males and 30 (32.6%) females were participated. Most patients belong to the age group of 40-60 years (68.47%) followed by 60-80 (17.39%) years. It

was recorded that 44.6% (n=41) patients had a strong family background of diabetes and 8.7% died due to its complications. The socioeconomic status of the patients was calculated from the monthly income with 71 (77.1%) patients were in low socioeconomic

status. In the study group 9.8% (n=9) of patients were smokers with 13% (n=12) being alcoholics. Among the study population 69.57% (n=64) were literate and 30.43% illiterate (n=28). Table -1 provides the distribution of type II DM patients.

Table 1
Distribution of the diabetic patients according to age (n=92)

Age in years	No of patients (percentage)
20-40	13(14.13%)
40-60	63 (68.47%)
60-80	16 (17.39%)
Total	92

The Co morbid conditions were found to be in 28.2% (n=26) with most common being hypertension 19.6% (n= 18), followed by hypercholesteremia 3.3% (n=3), stroke 1.1% (n=1), and frequent infections 1.1% (n=1). Table-2 shows the anti- diabetic drug utilization pattern among the study population.

Table 2
The utilization pattern of anti-diabetic drug therapy

ATC CODE	DRUGS PRESCRIBED	NUMBER	PERCENTAGE (%)
A10BB01	Metformin	20	21.74%
A10BB01	Glibenclamide+ Metformin	33	35.86%
A10BB12	Glimepiride+ Metformin	09	09.78%
A10BB07	Glipizide+ Metformin	05	05.50%
A10BD02	Human Mixtard+ Metformin	25	27.17%
Total		92	100%

Table 3 showed 21.74% (n=20) of patients were on monotherapy and 78.26% (n=72) on combination therapy.

Table 3
Monotherapy and Combination therapy of anti-diabetic drugs

Drug therapy	No of patients	Percentage (%)
Monotherapy	20	21.74%
Two drug Combination	72	78.26%

The study revealed that Metformin was the most commonly prescribed drug. Among the drug combinations 51.14% (n=57) received oral hypoglycemic drugs while 27.17% (n=25) received Insulin preparation (inj. Human Mixtard) with Metformin. In oral hypoglycemic drugs, the most commonly used combination

being Glibenclamide and Metformin (35.87%) followed by Glimepiride with Metformin (9.78%) and Glipizide with Metformin (5.5%). Statins were co-administered in 5.5% (n=5) of patients. Our analysis confirmed that 41.30% (n=38) of the total study group underwent drug treatment with proper diet and regular exercise.

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 II 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. The prevalence of DM in the rural area was about 6.2% when compared to 3.2% as reported by Mohan et al.³. There are several studies from various parts of India which showed a rising trend in the prevalence of type II diabetes in the urban areas. A National Urban Survey in 2000 observed that the prevalence of diabetes in urban India in adults was 12.1 per cent per cent. This study illustrated that the impact of socio-economic transition which took place in past 15 years with an increase in prevalence of 6.4% from 2.4%⁶.

A study conducted in Nepal showed that the most frequently affected patients were in the middle productive age groups between 35-64 years and our study had the similar findings whereas in developed countries the prevalence appears to be more than 65 years^{7, 8, 9}. The Patient's ability is to carry out the diabetic care status along with the family members were compromised, thus adding the psychosocial problems to the individual and the

community. 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 condition¹⁰. Our study also was in agreement with published standards where hypertension being the most common condition 28.2% (n=26) followed by dyslipaemia 3.3% (n=3)¹¹. The history suggested that a strong family background was noticed in the study 44.6% (n=41). Hence these target population should be treated properly to prevent diabetic complications with their first degree relatives should be screened at regular intervals to diagnose diabetes at the early stage. As like the Nigerian study, Metformin being most commonly used drug for all Type II DM. In uncontrolled cases, sulfonylureas or Insulin was added as the combination therapy as per ADA guidelines and WHO where Metformin seems to firstline drug followed¹². 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^{13, 14}. Most of the Government hospitals preferred Glibenclamide as the 1st line Sulphonylureas of choice for the treatment of Type 2 diabetes mellitus. It can be replaced with Glimepiride since it can be administered as once daily preparation, effect at a low dose, additional anti-platelet activity, insulin sparing action,, predominant tissue specific effect on pancreatic K⁺ channel with limited interaction with cardiovascular K⁺ ATP channel, minimal adverse effects on cardiovascular system and lower incidence of hypoglycemia¹⁵. Hence the Government organizations and policy makers may consider Glimepiride in the place of

Glibenclamide as the first sulfonylureas of choice. A total of 41.30% patients were on diet and exercise along with pharmacotherapy. These populations should undergo a proper dietary counseling and exercise training programme to achieve better metabolic control. A structured program that should be emphasizes lifestyle changes that include moderate weight loss, regular physical activity with dietary strategies to achieve desired glycemic control. In few patients, failure of oral hypoglycemic allowed to switch over to Insulin preparations. Adverse effects were reported by 3.26 % in the rural population. Poly pharmacy was commonly reported in a studies conducted in developing countries whereas average number of drugs used per prescription in our study was 1.82 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. The recent ADA recommends that statin therapy should be added to all diabetic patients regardless of baseline lipid status along with ACE inhibitors which prevents macro vascular and micro vascular complications of diabetes mellitus ¹⁹. In cardiovascular risk patients,

Aspirin should be a primary preventive strategy to prevent the complications. This should be regularized in the rural areas with the underlying background knowledge and rationality in prescription. The recent ADA recommends that newly diagnosed type2 DM were initiated with Metformin with lifestyle changes (diet and exercise), early initiation of insulin therapy with or without other OHAs to bringdownHbA1c to <7% patients should be screened for micro vascular and macro vascular diseases at the time of diagnosis and treatment is started at initial stages and also by correcting dyslipaemia.

CONCLUSION

The present study showed the drug utilization pattern of anti-diabetic drugs among type II diabetic patients in a rural area, Tamilnadu with an increasing prevalence of the disease process thus providing an insight to create awareness about the drug treatment and diabetic complications among rural population. Among the sulfonylureas Glimepiride can be replaced for Glibenclamide because of its better pharmacokinetic and pharmacodynamic properties. To maintain the clinical standard of prescribing, a constant effort is mandatory by every physician to follow the guidelines recommended by various International bodies. Conflict of interest: Nil

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