

A PROSPECTIVE, OBSERVATIONAL STUDY TO UNDERSTAND THE DRUG USAGE COMPOSITION OF ANTI-DIABETIC MEDICATIONS IN A RURAL CENTRE IN KERALA

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ABSTRACT

BACKGROUND

With exponentially higher number of patients being diagnosed with diabetes in India, it has gained an epidemic status here.^{1,2} Globally, the prevalence of diabetes in 2030 is expected to be almost double that in 2000 with the major contribution being from India, nearly 79.4 million.^{3,4} The potential burden that diabetes may impose upon India is highly disturbing. It is important to study the factors currently affecting diabetes in India that are making this potential health burden so extreme and to bring about changes. Drug usage studies help to identify the treatment adherence problems and improve proper drug usage.

Aim- The aim of this study was to evaluate the usage pattern of anti-diabetic drugs in Type II DM patients in a rural population in Kerala.

MATERIALS AND METHODS

A prospective observational study was carried out at a tertiary care teaching hospital for a period of 9 months. 1113 patients were screened from which 69 Type II DM patients were included and a structured questionnaire was used to collect data and analysis was done. Patients aged 20 to 80 yrs. who were already following life style modification and diet advice were included in the study.

RESULTS

The prevalence was about 6.19% and 68.11% of them were 40-60 years of age. Metformin was the most commonly prescribed drug and 21.74% of patients were on monotherapy. Glimepiride and Metformin (33.33%) was the mostly used oral combination followed by Glibenclamide and Metformin (8.69%). Inj. Human Mix insulin with Metformin was used in 27.53%. 15.94% of patients were on statins. The most common comorbid condition was hypertension (21.73%) followed by dyslipidaemia (8.6%).

CONCLUSION

Both oral hypoglycaemic drugs and insulin were used for proper control of diabetes. Metformin was the most commonly used drug. Statins and low dose ACE inhibitors were used to minimize the complications of DM.

KEYWORDS

Drug Usage, Type 2 Diabetes Mellitus, Anti-Diabetic Drugs, Kerala.

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BACKGROUND

Drug utilisation studies include the study of the use of drugs in a society and also their marketing, distribution and prescription, with emphasis being laid on the resulting medical and social consequences.¹ Drug utilization studies help to identify the adherence to standard guidelines and extent of drug use and to evaluate the rational drug usage. It helps to facilitate the rational use of drugs in population and to identify treatment adherence problems.

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Diabetes is a growing challenge for India in the health care sector, but the awareness seems to be low. India presently has more than 60 million people with diabetes and this is likely to increase to over 100 million by 2030.^{5,6} In adult population, the prevalence of diabetes is around 10% in rural and 20% in urban areas.⁷

Intense blood glucose control helps to significantly reduce microvascular complications and many different classes of ant diabetic drugs are used to attain a good glycemic control.^{8,9,10,11}

Though we have a better understanding of the pathophysiology of diabetes and have developed many new drugs, still the overall diabetic control seems inadequate; probably due to clinical inertia of the treating physician, lack of patient compliance, or improper life style modification.^{12,13,14,15,16,17,18,19} In majority of patients the control of diabetes and associated factors like hypertension and lipids seems inadequate resulting in more number of complications.^{20,21}

Urbanization, western diet and sedentary life style has led to an increased incidence of diabetes in rural areas of India.²² Not many studies have focussed on drug usage pattern in rural parts of South India. Hence, we planned this study to evaluate the drug usage pattern among diabetic patients in a rural population of Kerala, South India.

MATERIALS AND METHODS

This prospective observational study was carried out for a period of 9 months from January to September 2014 at WIMS Wayanad. A total of 1113 patients were screened, from which 69 cases of DM aged between 20 to 80 yrs. who were under treatment and following life style modification and diet advice were included in the study. Majority of the patients belonged to low and middle socioeconomic groups. Patients not willing for informed consent, those with diabetic complications and serious medical conditions requiring subsequent hospital admissions, prediabetic status, Gestational Diabetes were excluded from the study. A structured questionnaire was explained in the local language (Malayalam). Demographic data, detailed medical history, medications for diabetes mellitus, medications for co morbid diseases, lifestyle, dietary pattern, exercise routine 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 compiled for evaluation.

Statistical Analysis

The appropriateness of the collected data was analysed, and interpretation was made. Statistical analysis was done by SPSS software.

Statistical methods used were Simple frequencies and percentages.

RESULTS

Of the total 1113 patients screened, 69 type 2 DM patients were selected according to the study protocol. There were 47 (68.11%) males and 22 (31.88%) females in the study. Most patients belong to the age group of 40-60 years (68.47%) followed by 60-80 (17.39%) years. There was a strong family history of DM in 44.9% (n=31) patients. The socioeconomic status of the patients calculated from the monthly income showed that 53 (76.81%) patients were in low socioeconomic status. In the study group 7 (10.1%) of patients were smokers and 12 (17.3%) were alcoholics.

Age in Years	No. of Patients	Percentage
20-60	10	(14.49%)
40-60	47	(68.11%)
60-80	12	(17.39%)
Total	69	100%

Table 1. Distribution of The Diabetic Patients According to Age (n=69)

Comorbidities were found in 27 (39.13%) participants. Hypertension was the most common comorbid condition found in 15 (21.73%), followed by dyslipidaemia 6 (8.6%) and hyperuricemia 4 (5.79%).

Drugs Prescribed	Number	Percentage (%)
Metformin	15	21.74%
Glimepiride + Metformin	23	33.33%
Glimepiride + Metformin + Pio	2	2.89%
Glibenclamide + Metformin	06	8.69%
Glibenclamide + Metformin + Pio	01	1.44%
Glipizide+ Metformin	02	02.89%
Human Mix insulin+ Metformin	19	27.53%
Gliptins (Sitagliptin)	1	1.44%
Total	69	100%

Table 2. The Anti-Diabetic Drug Usage Pattern

Table 2 showed that 15 (21.74%) of patients were on monotherapy and 54 (78.26%) were on combination therapy.

Drug	Number	Percentage
Telmisartan	6	40%
Enalapril	2	13.33%
Ramipril	1	6.66%
Amlodipine	5	33.33%
Cilnidipine	1	6.66%
Total	15	100%

Table 3. The Antihypertensive Medicines Used

The study documented that Metformin was the most commonly prescribed drug. Among the drug combinations 50 (72.46%) received oral hypoglycaemic drugs while 19 (27.53%) received Insulin preparation (inj. Human Mix Insulin) with Metformin. In oral hypoglycaemic drugs, the most commonly used combination was Glimepiride and Metformin (33.33%) followed by Glibenclamide with Metformin (8.69%). Statins were co-administered in 11 (15.94%) of patients.

DISCUSSION

In this study, we have attempted to describe the current prescribing pattern and trend of anti-diabetic drug therapy in a tertiary care hospital in rural Kerala. Such studies bring out the prescribing attitude of physicians and help to promote rational drug use. Micro and macrovascular complications contribute largely to the burden of diabetes. Sanjay Kumar et al had reported a prevalence of 5.99% in rural areas²³ which was similar to ours (6.19%).

In developed countries the prevalence of Diabetes is more above 65 years. However, a study conducted in our neighbouring country 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.

Hypertension, dyslipidaemia, neuropathy, nephropathy and retinopathy are the usual comorbidities. Around 20-60% of diabetics had hypertension as a co morbidity.²⁴ In our study too hypertension was the most common comorbid condition seen in 15 (21.73%) followed by dyslipidaemia in 6 (8.6%) participants.²⁵

A positive family history was noticed in 42.02% (n=29). Hence screening of first-degree relatives at regular intervals is strongly recommended to diagnose diabetes at the early stage. Metformin was the most commonly prescribed drug for all Type 2 DM in accordance with standard guidelines. Sulfonylureas or Insulin was used as add on therapy in many patients.^{26,27}

Poly pharmacy was a common problem in studies from developing countries; however, the average number of drugs per prescription in this study was 2.18 which was similar to some other studies.^{28,29} Adverse effects were reported by 3.26% in the rural population.

Both polypharmacy and adverse drug reactions were less in our study probably due to rational prescriptions.^{29,30} The centre being a teaching institute could have positively influenced the prescribing practices. This showed that rational approach reduced the complications and improved the glycaemic control. The recent guidelines recommend that statin therapy should be added to all diabetic patients regardless of their baseline lipid status along with ACE inhibitors to prevent complications.³¹

CONCLUSION

The present study showed the drug usage pattern of anti-diabetic drugs among type 2 DM patients in a rural area in Kerala. With increasing prevalence of the disease, this study provides an insight to create awareness about the drug usage among rural population. OADs are still the predominantly prescribed drugs, but there was a shift towards the use of insulin in the management of Type 2 diabetes mellitus. Intensification of current drug treatment as well as planning multiple drug interventions with lifestyle modification is necessary. Metformin is the most commonly used drug and among the sulfonylureas Glimepiride is the most commonly used. Gliptin usage is very low probably because of the cost. To maintain prescribing standards, every physician should update himself with the latest recommendations and follow the guidelines recommended by various standard international organisations.

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