ORIGINAL

Drug use evaluation of oral hypoglycemics in diabetic patients in a tertiary care hospital, India

Evaluación del uso de fármacos de hipoglucemiantes orales en pacientes diabéticos en un hospital de atención terciaria, India

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Abstract

Objective: To evaluate drug use of oral hypoglycemic in hospitalized diabetic patients in a tertiary care hospital.

Methodology: A retrospective study of 6 months duration was undertaken during 2017-2018. A total number of 110 patients case sheets were utilized for study from diabetics patients, department of Sapthagiri Institute of Medical Sciences & Research Centre (SIMSRC). Patients were included in study with any age with diagnosis of diabetes mellitus. Randomization was done by selecting alternative case sheets. The data's were collected in proforma, which includes name, age, gender, diagnosis, number of drugs prescribed, with dose and routes of drug administration and also condition of patient on discharge were recorded. blood transfusion and nutritional preparations were not included in the study. Source of data was collected from patient's case sheets obtained from record section. Ethical clearance was taken from institutional ethical committee. Drugs data on the utilization of oral hypoglycemics and patient's data were computed using MS Excel and statistical analysis was done by using SPSS (Statistical package for the social sciences).

Results: Out of 110 patients enrolled in the study from inpatient department, Majority of patients 34.5% belonged to age group of 51-60 years. the number of Female patients were high by 10.9%. 55.4% patients were females and 44.5% patients were males. In Diabetes mellitus patients the most common co-morbid conditions are Hypertension (47.4%), Ischemic Heart Disease (11.4%), Coronary Artery Disease (8%), Unstable Angina (6.8%), Asthma (4%), Chronic Kidney Disease (4%), Anemia (3.4%), Myocardial Infarction (3.4%), Liver Dysfunction (2.2%), Congestive Cardiac Failure (1.7%), COPD (1.7%), ESRD (1.1%) and hyperlipidemia, Infection (1.1%). Among these 15 co-morbid conditions Hypertension and Ischemic Heart Disease are comparatively high. Out of 110 prescriptions, the total number of drugs prescribed were 816. Number of appropriate prescriptions were 95.4% and Number of inappropriate prescriptions were 4.5%. Anti-diabetics were the commonest class of drugs prescribed accounting for 20.7% of the total drugs. Glimepiride + metformin was used most widely 54.2% as a combination therapy. Out of 173 Oral Hypoglycemic prescribed 69.9% were given as Twice a day, followed by 21.9% were given as Three times a day and Once daily in 5.2%.

Conclusion: This study gives an overview of the Evaluation Of Oral Hypoglycemics in the study area. The study showed that patients between the ages of 51 and 60 years were admitted more frequently than other age groups. The most common illness for which patients were hospitalized involves Type 2 DM, Hypertension, Ischemic Heart Disease, Coronary Artery Disease and Unstable Angina. In Diabetes mellitus patients the most common co-morbid condition is Hypertension. In this study Anti-diabetics were the commonest class of drugs prescribe. In monotherapy, Biguanides (Metformin) utilization was high and in combination therapy, Glimepiride + metformin was used most widely. The most frequency of treatment observed were given twice a day.

Keywords: Oral hypoglycemics, Diabetes mellitus, Metformin, Biguanides, Glimepiride, Hypertension, Evaluation.

Resumen

Objetivo: Evaluar el uso de fármacos hipoglucemiantes orales en pacientes diabéticos hospitalizados en un hospital de tercer nivel.

Metodología: Se realizó un estudio retrospectivo de 6 meses de duración durante 2017-2018. Un número total de 110 pacientes hojas de casos hojas se utilizaron para el estudio de los pacientes diabéticos, del departamento de Sapthagiri Institute of Medical Sciences & Research Centre (SIMSRC). Se incluyeron en el estudio pacientes de cualquier edad con diagnóstico de diabetes mellitus. La aleatorización se hizo seleccionando hojas de casos alternativos . Los datos se recogieron en un formulario que incluía el nombre, la edad, el sexo, el diagnóstico, el número de medicamentos prescritos, la dosis y las vías de administración de los mismos, así como el estado de salud de los pacientes. de los medicamentos, con la dosis y las vías de administración de los mismos, así como el estado del paciente al ser dado de alta. no se incluyeron en el estudio. La fuente de datos se recogió de las hojas de los casos de los pacientes obtenidas en la sección de registros. La autorización ética fue de ética del comité ético institucional. Los datos sobre la utilización de hipoglucemiantes orales y los datos de los pacientes se calcularon con MS Excel y el análisis estadístico se realizó con el SPSS (Statistical package for the social sciences).

Resultados: De los 110 pacientes inscritos en el estudio en el departamento de hospitalización, la mayoría de los pacientes, el 34,5%, pertenecían al grupo de edad de 51-60 años. El número de pacientes femeninos era elevado, un 10,9%. El 55,4% de los pacientes eran mujeres y el 44,5% eran hombres. En los pacientes con diabetes mellitus, las afecciones comórbidas más comunes son la hipertensión (47,4%), la cardiopatía isquémica (11,4%), la arteriopatía coronaria (8%) y la enfermedad inestable. coronaria (8%), angina inestable (6,8%), asma (4%), enfermedad renal crónica (4%), anemia (3,4%), infarto de miocardio (3,4%), disfunción hepática (2,2%). (2,2%), insuficiencia cardíaca congestiva (1,7%), EPOC (1,7%), enfermedad renal terminal (1,1%) e hiperlipidemia, infección (1,1%). Entre estas 15 condiciones de comorbilidad, la hipertensión y la cardiopatía isquémica son comparativamente altas. De las 110 prescripciones, el número total de medicamentos recetados fue de 816. El número de prescripciones apropiadas fue del 95,4% y el número de prescripciones inapropiadas fue del 4,5%. Los antidiabéticos fueron la clase de fármacos más recetados, con un 20,7% del total de fármacos. La glimepirida y la metformina fueron los más utilizados El 54,2% se utilizó como terapia combinada. De los 173 hipoglucemiantes orales prescritos, el 69,9% se administró dos veces al día, seguido del 21,9% se administraron tres veces al día y el 5,2% una vez al día.

Conclusión: Este estudio ofrece una visión general de la evaluación de los hipoglucemiantes orales en el área de estudio. El estudio mostró que los pacientes entre 51 y 60 años fueron ingresados con mayor frecuencia que otros grupos de edad. La enfermedad más común por la que los pacientes fueron hospitalizados son la DM tipo 2, la hipertensión, la cardiopatía isquémica, la arteriopatía coronaria y la angina inestable. En los pacientes con mellitus la enfermedad comórbida más común es la hipertensión. En este estudio, los antidiabéticos fueron la clase de fármacos más prescritos. En monoterapia, la utilización de Biguanidas (Metformina) fue alta y en terapia combinada, Glimepirida + metformina fue la más utilizada. ampliamente. La mayor frecuencia de tratamiento observada se administró dos veces al día..

Palabras clave: Hipoglucemiantes orales, diabetes mellitus, metformina, biguanidas, glimepirida, hipertensión, evaluación.

Introduction

Diabetes mellitus (DM) is one of the oldest diseases known to man, which was the first reported in Egyptian literature about 3000 years ago[1]. The name diabetes was first given by the Greek Physician Aretaeus (30-90CE). Avicenna, is the famous Arabian physician who first described the complications and progression of the disease[2]. People living with type 2 DM are more vulnerable to various forms of both short and long-term complications, which often lead to their premature death. The world health organization (WHO) defines diabetes mellitus as "A metabolic disorder of multiple etiology characterized by chronic hyperglycemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in the insulin secretion, insulin action, or both."[3,4] India has the largest population of diabetes in the world. The international diabetes federation (IDF) estimates the number of people with diabetes in India will reach 80million by the year 2025.[5] The world health organization (WHO) has projected that the global prevalence of type-2 diabetes mellitus will more than double from 5 million in 1995 to 300 million by 2025. Between 1995 and 2025, there will be a 35% increase in worldwide prevalence of diabetes mellitus, from 4 to 5.4%.[6]

Diabetes prevalence is continuously growing all over the world. Type 2 diabetes constitute about 85% to 95% of the diabetic population in the developed countries and even higher in the developing countries. In 2003, 194 million people having age between 20 to 79 years are diabetic and a quarter of them belong to developing countries. There is a rapid increase in the prevalence of diabetes in Asian countries.[7] Various classes of anti-diabetic drugs including insulin and oral hypoglycemic agents (OHA) are currently used in the treatment of diabetes, which acts by different mechanisms to reduce the blood glucose levels to maintain optimal glycemic control.[8] There are several classes of oral drugs used to control blood glucose levels, including: Sulfonylureas, such as glipizide and glimepiride, are considered hypoglycemic agents because they stimulate the release of insulin from beta cells in the pancreas, thus reducing blood glucose levels.[9] Glipizide 2.5 to 10mg PO before breakfast and evening meal, start with low dose.45 glimepiride 1 to 2 mg orally once a day.[10]

Diabetes mellitus requires ongoing medical care as well as patient and family education both to prevent acute illness and to reduce the risk of long term complications. Evaluation of drug use has become an integral part of the pharmacotherapy. Participation in drug utilization study programmes can directly improve the quality of patients' care, by preventing the use of unnecessary or irrational drug therapy and by preventing adverse drug reactions[11]. Drug utilization studies provide physicians with feedback on their performance and assist the design of educational programmes that may improve prescribing and drug use performance[12]. Considering the fact that, India carries a huge diabetic population which is swelling further, medicine utilization studies might be one of the strategies to rationalize the medicine use in diabetics and to manage disease better in the community. Hence a medicine utilization study of oral hypoglycemic was carried out at the Medicine Outpatient Department (OPD) in tertiary care hospital. There were two aims of the study to assess the prescribing pattern of oral hypoglycemic drugs by using ADA guideline, and to correlate association of diabetes with demographic details of patients.

Materials and methods

This study was conducted for a period of 6 months, the study included 110 patients from IP department of Sapthagiri Institute of Medical Science, a tertiary care hospital in Bangalore.

The purpose and other details of the study were discussed with the patients. An oral consent was taken from all the participating patients, prior inclusion in the study. diabetes mellitus patients, irrespective of age and sex, who were prescribed at least one oral hypoglycemic were included in the present study. Diagnosed diabetic patients who do not receive pharmacological therapy, unable to reply verbal questions as well as mentally retarded and unconscious patients were excluded from the study. This is a retrospective and prospective observational study. The patients who satisfied the inclusion criteria was enrolled into the study with the help of patient consent form. The clinical pharmacist reviewed the patient case notes, medication chart, laboratory data and other relevant data. A structured data collection form was used to record all the necessary data including patient demographic details, patient medication history, co morbid conditions and reason for admission, medication details and lab investigation. The pattern of drug dosing was also recorded.

Result and discussion

This study was carried out with an aim to assess the Oral Hypoglycemics used in hospitalized patients of tertiary care hospital in Sapthagiri Institute of Medical Science And Research Centre, Bangalore. The duration of study was six months.

The patient were divided in six age group such as 30-40, 41-50, 51-60, 61-70, 71-80 and >80.

The majority of patients, 34 % were on age group 51-60 years, this may be due to fact that age is a risk factor for developing diabetes mellitus supported by Mandana Moradi et.al.[13] (**Table I**)

Table I: Age Distribution Of Patients Observed (n=110).

Age distribution (in years)	Total No. of patients	IN percentage
30-40	11	10%
41-50	13	11.80%
51-60	38	34.50%
61-70	25	22.70%
71-80	17	15.40%
>80	6	5.40%

Out of 110 patients, 49 (44.5%) patients were males and 61 (55.4%) patients were females. the number of female patients were high by 10.9%.The study shows that female patients are more than male patients, however in earlier study female predominance were seen which is in agreement with our result supported by Syed Muhammad Ashar et.al.[14] The reason for having diabetes more in fmales than in males could be because of lifestyle.

In Diabetes mellitus patients the most common co-morbid conditions are Hypertension, Ischemic Heart Disease, Coronary Artery Disease, Unstable Angina, Asthma, Chronic Kidney Disease, Anemia, Myocardial Infarction, Liver Dysfunction, Congestive Cardiac Failure, COPD, ESRD and hyperlipidemia, Infection. Among these 15 co-morbid conditions Hypertension and Ischemic Heart Disease are comparatively high (**Table II**).

Table II: Co-Morbid Conditions Of Patients (n=175).

Co-morbid conditions	No. of Patients	In Percentage
Hypertension	83	47.40%
IHD	20	11.40%
CAD	14	8%
Unstable angina	12	6.80%
Asthma	7	4%
CKD	7	4%
Anemia	6	3.40%
MI	6	3.40%
Liver dysfunction	4	2.20%
CCF	3	1.70%
Acute kidney injury	3	1.70%
COPD	3	1.70%
Infection	3	1.70%
ESRD	2	1.10%
Hyperlipidemia	2	1.10%

The total number of drugs prescribed were 816. Average number of drugs per prescription were 7.41. The risk of drug interaction may increase with increase innumber of drugs per prescription which ultimately lead to prescribing errors and in hazardous to the health of patient. Anti-diabetic drugs were the most common drugs prescribed which accounts for 169 (20.7%) of total drugs (**Table III**).

Table III: Number Of Medications Prescribed In Study Population.

Total no of prescriptions	110
Total no of drugs prescribed	816
Average no of drugs per prescription	7.41
No. of appropriate prescriptions	105 (95.4%)
No. of inappropriate prescriptions	5 (4.5%)

In the present study 47.4% patient reported hypertension along with diabetes mellitus, these results were supported by Dashputra AV at el .[15] this study indicates that hypertension is the commonest co-morbidity seen with diabetes mellitus. Anti-platelet were the second commonest drug prescribed which accounts for 69 (9.3%) antibiotics 53 (6.4%), Analgesic 45 (5.2%), Diuretics 37 (4.5%), Hypolipidemic 35 (4.2%), Anti-angina 31 (3.7%), Respiratory agent 14 (1.7%), Calcium channel blocker 12 (1.4%), Benzodiazepines 8 (0.9%), Antihistamine 8 (0.9%), Antihypertensive drugs 8 (0.9%), and others (PPIs, IV fluids, Corticosteroids, Antacid, Anti-emetic, Antifungal, Vitamins) 328 (40.1%) were prescribed (**Table IV**).

Table IV: Distribution Of Different Types Drugs Prescribed (n=816).

Drugs prescribed	Total No. of drugs	In Percentage
Anti-diabetic	169	20.70%
Anti-platelet	69	9.30%
Antibiotics	53	6.40%
Analgesic	45	5.20%
Diuretics	37	4.50%
Hypolipidemic	35	4.20%
Anti-angina	31	3.70%
Respiratory agent	14	1.70%
Calcium channel blocker	12	1.40%
Benzodiazepines	8	0.90%
Antihistamine	8	0.90%
Antihypertensive drugs	7	0.80%
Others*	328	40.10%

* PPIs, IV fluids, Corticosteroids, Antacid, Anti-emetic, Antifungal, Vitamins

Anti-diabetic drugs commonly prescribed as monotherapy were metformin (49.2%), Glimepiride (25.36%), Sitagliptin (15.21%), Glyburide (10.1%) and as combination therapy Glimepiride/metformin (54.2%), Glimepiride/metformin/voglibose (25.7%), Sitagliptin/metformin(20%). Biguanides (metformin) (49.2%) utilization was high as monotherapy in prescription, this may be due to its high advantages of no weight gain these results were supported by Ramachandran G at el [16]. In combination therapy Glimepiride/metformin combination was most widely used (54.2%) (**Table V**).

Table V: Evaluation Of Single Prescribed Oral Hypoglycemics (n=138).

Monotherapy	Number Of Prescription	In Percentage
Metformin	68	49.20%
Glimepiride	35	25.36%
Sitagliptin	21	15.21%
Glyburide	14	10.10%
Total	138	100.00%

Anti-platelet were the second commonest drug prescribed which accounts for 69 (9.3%) antibiotics 53 (6.4%), Analgesic 45 (5.2%), Diuretics 37 (4.5%), Hypolipidemic 35 (4.2%), Anti-angina 31 (3.7%), Respiratory agent 14 (1.7%), Calcium channel blocker 12 (1.4%), Benzodiazepines 8 (0.9%), Antihistamine 8 (0.9%), Antihypertensive drugs 8 (0.9%), and others (PPIs,

IV fluids, Corticosteroids, Antacid, Anti-emetic, Antifungal, Vitamins) 328 (40.1%) were prescribed (**Table VI**).

Table VI: Evaluation Of Combination Therapy Of Oral Hypoglycemics (n=35).

Combination therapy	N° of Prescription	In Percentage
Glimepiride/metformin	19	54.20%
Glimepiride/metformin/voglibose	9	25.70%
Sitagliptin/metformin	7	20%
Total	35	100

Out of 173 Oral Hypoglycemic prescribed 69.9% were given as Twice a day, followed by 21.9% were given as Three times a day and Once daily in 5.2%. This is based on the choice and course of drugs for the therapy (**Table VII**).

Table VII: Distribution of frequency of treatment observed (n=173).

Frequency of treatment	Number of patients prescribed with antibiotics	IN percentage
Once Daily	9	5.20%
Twice a day	121	69.90%
Three times a day	38	21.90%
Four a a day	5	2.80%

Conclusion

This observational study of evaluation of oral Hypoglycemics shows metformin was the most commonly prescribed anti-diabetic drug in Monotherapy followed by Glimepiride. Among Fixed drug combination therapy Glimepiride/metformin was the most commonly prescribed antidiabetic drug. The study showed that Majority of patients belonged to age group of 51-60 years. 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. In this study, males were found to be more affected by type 2 diabetes mellitus than females. Most of the patients were prescribed two Oral Hypoglycemic. Average number of drugs per prescription was found to be 7.1. The most commonly drugs prescribed apart from antidiabetic were Anti-platelet drugs followed by Analgesics. It was observed that most prescribed Oral Hypoglycemic was Metformin, Glimepiride and Sitagliptin.

Interests conflict

The researchers declare that they have no conflict of interest.

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