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### RESEARCH ARTICLE

## DRUG UTILIZATION EVALUATION IN DIABETIC PATIENTS IN A TERTIARY CARE TEACHING HOSPITAL: A PROSPECTIVE OBSERVATIONAL STUDY

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### ABSTRACT

Drug utilization is defined as the study of usage of drugs in the community or race. The drug utilization evaluation studies (DUES) aims to analyse the rationality of drugs usage and also describes the nature and drug exposure, and may also help to identify non-adherence problems. In a developing country India, Diabetes mellitus is a clinical issue in population. The type II diabetes mellitus has more prevalence among Indian individuals. The objectives of the study were to evaluate the Prescription pattern, assessment of Drug Interactions and To evaluate the occurrence of Diabetes with other comorbidities. A prospective observational study was conducted in Basaveswara Medical College Hospital and Research Centre, Chitradurga. The study was conducted for a period of six months from December-2012 to May-2013. Out of 201 patients, 101 patients were males and 100 patients were females and large numbers of diabetic patients were between the age group of 51-60 year. In case of prescription pattern, more number of patients prescribed with Monotherapy (68.15%), among the monotherapy, Insulin was largely prescribed (76.64%). Among the combination therapy Glimiperide with Metformin was largely prescribed. Total 154 prescriptions found with Drug Interactions. Out of all DI's, Moderate drug interactions are more (42.78%), followed by Minor (19.4%) and Major Drug Interactions (14.42%). The present study concluded sulfonylureas was the most commonly prescribed oral hypoglycaemic drug in this hospital followed by combination with biguanides (i.e. Glimiperide with metformin)..Among insulin therapy, human actrapid (regular) was most commonly prescribed drug.

**Key words:** Drug utilization, Hyperglycaemia, Drug Interactions, Prescribing pattern

### INTRODUCTION

Drug utilization is defined as the study of usage of drugs in the community or race. The drug utilization evaluation studies (DUES) aims to analyse the rationality of drugs usage and also describes the nature and drug exposure, and may also help to identify non-adherence problems. In a developing country India, Diabetes mellitus is a clinical issue in population. The type II diabetes mellitus has more prevalence among Indian individuals.

Diabetes Mellitus complications are likely to reduce the quality of life of patient and owned as national public health issue<sup>3</sup>. Type II diabetes population have higher risk of death from CVD when compared to non-diabetes population. Type II diabetes population of majority is under the general practitioners and efficiently able to control hyperglycemias. Specialists are credited for the failure of achievement of glycaemic control. Specialists like cardiologists, endocrinologists, ophthalmologists play prominent role. In critical care both Type-I and Type-II Diabetes management is done by Insulin therapy

and educating patients. Self management is known aspect in Diabetic population. Prevalence in India is increasing day by day and the awareness in the increase population is rare. These two are the main factors which are really affecting the Indian public health and quality of life. Complications that affect the quality of life are diabetic nephropathy, diabetic retinopathy and diabetic neuropathy occurring due to poor glycaemic control. By creating awareness improves cost effectiveness and benefits the diabetic patient quality of life. Requirement of rationalized therapy, proper monitoring and proper patient counselling that helps patients in attaining glycaemic control. Adherence to diet, drugs, exercise, monitoring of blood glucose, care of foot are the self care activities. Proper assessment of patient clinical condition and knowledge of self management on diabetes enacts proper interventions to be effective in glycaemic control in various studies.<sup>6</sup> Invigorate assessment of glycaemic control in diabetics patients likely avoids different complications of eye, Heart, kidney, etc.

**Factors that contributes to DM:**

Highly increased glucose level (hyperglycaemia) is referred as Diabetes. Type II diabetes patients can also have hypertension, chronic high levels of insulin and hyperlipidaemia. These factors contribute to the long-term complications of diabetes includes the following:

**Impact on memory:** Studies have shown diabetes to increased risk factor of memory loss, early Alzheimer's disease and also cognitive deficits.

**Diabetic neuropathy:** Peripheral neuropathy always causes pain otherwise numbness in the limbs, and autonomic neuropathy, which causes gastro-paresis and contributes to decreased sexual instinct and incontinence.

**Eye diseases:** Diabetes is a mostly cause of visual impairment and blindness including diabetic retinopathy, glaucoma and cataracts.

**Atherosclerosis, Diabetic angiopathy, Heart conditions and Stroke:** These cardiovascular disorders are leading cause of diabetic patient death, in which self management of diabetes becomes difficult.

**Diabetic nephropathy:** Chief cause of end-stage of renal disease is diabetes. The requirement of dialysis or kidney transplantation makes patient condition critical.

**Wounds and Infections:** Diabetic patient wounds are of poor healing and leads to cause of non-traumatic foot and leg amputations. Diabetes population can be prone to infections such as periodontal disease, thrush, urinary tract infections and yeast infections.

**Musculo-skeletal disorders:** Conditions from gout to osteoporosis and restless legs syndrome to myofascial pain syndrome ranges more commonly in diabetic patients<sup>7</sup>.

There are several guidelines existing for diabetes management by maintaining proper diet. The guidelines are proposed to provide evidence-based nutritional recommendations by healthcare professionals for the people who are at risk of, and those living with complications. Appropriate food choices are proven to reduce the risk of Type II diabetes and diabetes-associated tissue damage obtains optimal glycaemic control and increases the quality of life. Specified diet is an important put forth for diabetic patient in the effective management of diabetes and helps to maintain optimal glycaemic control and reduces the risk of long-term tissue damage. The Diabetes UK 2011 explores to the extent that all members of the multidisciplinary team can deliver and implement evidence-based nutritional advices. All advices should be based upon scientific evidence-based and taking an account of personal and cultural preferences, beliefs, lifestyle; and the advices should be provided for an individual in lucid language either by orally or as a leaflet or both preferably by patient.

Notably, these guidelines are to be:

- Support self-management to reduce the complications of Type II diabetes and the comorbidities associated
- To improve quality of life

- To meet the needs of all individuals, including those with co-morbidities; e.g. coeliac disease and cystic fibrosis<sup>8</sup>.

**Cancer:** Diabetes increases the risk of malignant tumours in the pancreas, colon, liver and several other organs.

**OBJECTIVES****General objective:**

- ❖ To evaluate the Drug utilization in diabetic patients in a tertiary care teaching hospital.

**Specific objectives:**

- ❖ Determine demographic and clinical characteristics of inpatients
- ❖ To evaluate the Prescription pattern of Anti Diabetic drugs
- ❖ To assess the severity of Drug Interactions
- ❖ To evaluate the occurrence of Diabetes with other comorbidities

**METHODOLOGY****Study site:**

The study was conducted in Basaveswara Medical College Hospital & Research Centre, Chitradurga. It is 650 bedded multi-speciality tertiary care teaching hospital. It consists of various departments like General Medicine, OBG, Paediatrics, Orthopaedics, Surgery, Psychiatry, ENT, Dermatology, Casualty and Pharmacy. Approximately 200-250 patients are being treated in general medicine department per month. The patients who visit this hospital are usually from in and around district of Chitradurga.

**Study design:**

The study was a prospective observational study, which assessed the drug utilization in diabetic patients.

**Study duration:**

The study was conducted for a period of six months from December 2012 to May 2013.

**Study criteria:****➤ Inclusion Criteria:**

1. Newly diagnosed and known cases of Diabetes Mellitus with comorbidities who were receiving anti-hyperglycemics and patients who were hospitalized included.
2. Inpatients of either sex or patients aged 18 years and above were included.

**➤ Exclusion Criteria:**

1. Patients with gestational diabetes were excluded from the study.
2. Out patients are also excluded from our study

**Source of data:**

The patient demographical data, clinical data, therapeutic data and various other relevant and necessary data collected from:

- Medical records of inpatients

- Personal interview of patients to determine the chief complaint, history of the present illness, past medical and medication history.
- Patient's prescriptions
- Interviews of patient care takers

#### Study procedure:

All the patients who admitted to the General Medicine department were reviewed daily to identify the patients diagnosed with Diabetes or with other co morbidities. The patients who met the study criteria were enrolled in the study. Ethical clearance from Institutional Ethical Committee, by Basaveswara Medical College Hospital & Research Centre, Chitradurga was obtained prior to the study. A suitable data collection form designed (Annexure-III) to collect all the relevant and necessary data. The demographic details of the patient such as name, age, sex, IP number; clinical data such as diagnosis, clinical condition; therapeutic data such as name of the drug, dose, route, frequency, duration of therapy and other relevant details were collected by reviewing the case notes, treatment charts, lab data reports and by interviewing the patients and patient care takers. A personal visit was made to all the patients who were included in the study to collect any further information. Their medications were crosschecked with the treatment chart.

All the patients were monitored from the day of admission to the day of discharge. During the treatment

with anti- diabetic drugs the enrolled patients were evaluated clinically every day to assess the clinical outcome. The patients were also monitored for possible Drug Interactions during the course of treatment with Anti- Diabetic drugs.

#### Data analysis:

All the data was analysed in order to assess the drug utilization in diabetic patients, to evaluate the prescription pattern, drug interactions and other illness associated with Diabetes. Analysis is also based on evaluating the potential drug interactions. The data was analysed and the percentage value was calculated for the use of different class of oral anti-diabetics in medicine unit.

#### RESULTS:

A total of 201 patients aged 18 years and above admitted to the hospital who were known case of DM and newly detected diabetic patients were enrolled in the study.

#### Demographic details:

Out of 201 patients, males were 101(50.25%) and females were 100(49.75%). From the analysed data we found that, the large number of diabetic patients were at the age group of 51–60 years (26.86%), followed by 61–70 years (25.37%), 41–50 years (18.90%), 71–80 years (17.41%), 31–40 years (5.97%) and above 80 years (1.99%).

**Table 1: Distribution of the diabetic patients according to Age (n=201)**

Age group(Years)	No of patients	Percentage
21 – 30	7	3.48%
31 – 40	12	5.97%
41 – 50	38	18.90%
51 – 60	54	26.86%
61 – 70	51	25.37%
71 – 80	35	17.41%
81 and above	4	1.99%
Total	201	100%

#### Co Morbidities in Diabetic patients:

Out of 201 patients, 152 patients (75.62%) were identified with co morbidities and 49 patients (24.37%) were without co morbidities. From the data, Out of 152 co morbid associated patients 92 were encountered with

cardiovascular diseases (60.52%), followed by 37 patients were experienced with infectious diseases (24.34%), 12 patients were experienced with respiratory diseases (7.89%) and 11 patients with Renal failure (7.23%).

**Table 3: Details of Co morbidities in Diabetic patients (n=152)**

Co morbidities	No of patients	Percentage
Cardiovascular diseases	92	60.52%
Infectious diseases	37	24.34%
Respiratory diseases	12	7.89%
Renal failure	11	7.23%
Total	152	100%

**Prescription pattern of Anti Diabetic drugs:**

Study revealed that out of 201 patients, 137 patients were on Monotherapy (68.15%) followed by 47 patients were

on Two drug combination therapy (23.38%), 14 patients were on Three drug combination therapy (6.96%) and 3 patients were on Four drug combination therapy (1.49%).

**Table 4: Mono therapy and Combination therapy of Anti Diabetic drugs (n=201)**

Drug therapy	No of patients	Percentage
Mono therapy	137	68.15%
Two drug combination therapy	47	23.38%
Three drug combination therapy	14	6.96%
Four drug combination therapy	3	1.49%
Total	201	100%

**Assessment of Drug Interactions:**

Among 201 prescriptions, 154 prescriptions were found with drug interactions. Out of those, Major(Highly clinically significant. Avoid combinations; the risk of the interaction outweighs the benefit) drug interactions in 14.42% prescriptions, Moderate (Moderately clinically

significant. Usually avoid combinations; use it only under special circumstances).drug interactions in 43.28% prescriptions and Minor(Minimally clinically significant. Minimize risk; assess risk and consider an alternative drug, take steps to circumvent the interaction risk and/or institute a monitoring plan) drug interactions in 18.9% prescriptions respectively.

**Table 4: Distribution of diabetic patients according to severity of Drug Interactions (n=201)**

Severity of Drug Interaction	No of patients	Percentage
Major	29	14.42%
Moderate	87	43.28%
Minor	38	18.9%
No Interactions	47	23.38%

**DISCUSSION**

Drug utilization study is known to be one of the most effective methods to assess and evaluate the physicians prescribing nature and their by to promote rational use of drugs<sup>1</sup>. This is a cross sectional study conducted on subjects having diabetes, who visits doctor in tertiary care hospital, essentially focusing on drug utilization among diabetes patients.

The necessity of management of diabetes by drugs is to lessen the morbidity, mortality and to improve the patient's life quality. Patient's demographic details are considered while taking measures for adequate control of plasma glucose including co-morbid conditions. After newly diagnosed; especially when the initial A1C is less than 8%, any available anti-hyperglycaemic drugs are capable of controlling hyperglycaemia. Oral agents can be used as additives for therapeutic effects, especially at lower doses. Individualization is often necessary as initial choices make patients clinical situations vary widely. So the drug choice for management should be based on some considerations, which are mentioned in the following:

- Contraindications
- Synergy of mechanisms of action
- Therapeutic response
- Side effects likely to occur
- Hypoglycaemia
- Oedema
- Weight gain
- Cost effectiveness

- Convenience and adherence

In the clinical situations, the best initial choice is a sulfonylurea, as they are effective as any other. Special directions are to be given for administration of drug, storage, side effects and management of side effects. Pharmacotherapy only by one drug cannot control blood glucose level when highly elevated, will have to employ another drug to gain the adequate response. For example, the combination of sulfonylureas with metformin, has maximum potency to lower the blood glucose levels and favours these agents include low cost. However, there is an in vigorous rationale for using this combination before titrating to full dosage of the first agent and the therapeutic effects are not proportional. Metformin side effects increase progressively like gastrointestinal discomfort for patients at 2,000 mg/day. For example, adding 2-4 mg of glimepiride or 5-10 mg extended-release glipizide once daily to 500-1000 mg metformin with supper reduces blood glucose level without risk of gastrointestinal distress. Insulin is given when oral therapy response is inadequate. Based on individualization of patients clinical situation the approach of insulin in the management of diabetes has to be considered along with oral agents or insulin alone as per the drug therapeutic response on patient.

**CONCLUSION**

The present study concluded sulfonylureas was the most commonly prescribed oral hypoglycaemic drug in this hospital followed by combination with biguanides (i.e.

Glimepiride with metformin). Among insulin therapy, human actrapid (regular) was most commonly prescribed drug. drug interactions are checked by Medscape

interaction checker in that most of the interactions are moderate type and 90% cases are co-morbid condition.

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