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THERAPEUTIC EFFICACY AND DRUG RELATED PROBLEMS IN PATIENTS WITH TYPE TWO DIABETES MELLITUS WITH HYPERTENSION IN AN OUTPATIENT CLINICAL PRACTICE

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ABSTRACT

Objectives: *To study the therapeutic efficacy and drug related problems in patients with type two diabetes mellitus & hypertension in out-patient clinical practice.*

Methods*: A prospective observational study was conducted for a period of eight months. Out-patients who are above 18 years of age of either sex with type 2 diabetes & hypertension and who receives at least one anti-diabetic drug and anti-hypertensive drug of general medicine department were reviewed. The drug related problems were classified into different categories; untreated indication, sub therapeutic dosage, over dosage, failure to receive drug, adverse drug reaction, improper drug selection, drug-drug interaction, drug use without indication and others. Results were expressed as frequency or percentage.*

Results*: A total of 98 drug related problems were identified in 87 patients. The most common drug related problem identified in our study was potential drug-drug interactions (23.3%); out of this 8 major drug interactions, 20 moderate interactions and 7 minor interactions were identified. The therapeutic efficacy of anti-diabetic drugs were 25% and anti-hypertensive drug were 15%.*

Conclusion*:Drug related problems were frequently observed in type 2 diabetes with hypertension patients. Early detection of types and pattern of DRP can improve the treatment and reduce the number of DRPs in T2DM patients with hypertension.*

Keywords: *Drug related problems, Type two diabetes mellitus, and hypertension.*

INTRODUCTION

"The term efficacy is used by a pharmacologist to know the consequences of agonist versus antagonist binding to receptors of endogenous mediators, beyond this confusion pharmacologist deserve biochemical & physiological effects in terms of dose response relationship. Clinical efficacy is defined as the effect in a randomized controlled trial with clinical end points". The efficacy mainly depends on the use to which the information is provided. For example aspirin effectiveness in reducing arterial thrombosis is approximately 25%-30% risk reduction across a large range of age and underlying risk [1]. The drugs used in the management of diabetes are very essential, but due to lack of patient compliance, insulin resistance, therapeutic inertia and sedentary life style, it leads to poor control of high glucose level. Not many study have done on care of diabetes mellitus and mainly looks into the present profile of patients and their management. About 50% of people with diabetes mellitus have very low glycemic and hypertension control and large group have diabetic complications [2].

"A DRP is an undesirable patient experience that involves drug therapy & that actually or potentially interferes with desired patient outcomes."

- A medical condition that need a drug therapy but the patient is not prescribed with the drug for that particular indication
- A medical condition for which the wrong drug is being given.
- A medical condition for which low dose of the correct drug is being prescribed.
- A medical condition for which large dose of correct drug is being taken.
- A medical condition resulting from an adverse drug reaction.
- A medical condition resulting from a drug-drug interaction.
- A medical condition for which the prescribed drug is not received.
- A drug is prescribed for which there is no medical condition.

The main purpose of this eight drug related problem categories is to provide sequence in a pharmaceutical care of patients. Thus the eight categories should be accepted as a representation of clinical reality [3].

"Diabetes mellitus is defined as a group of chronic metabolic disorder that are characterized by high glycaemic level and are associated with long term microvascular, macrovascular, and neuropathic complications." Controlling the glycemic level remains the main Purpose in treating diabetes and its complications. Among the diabetes type 2 diabetes mellitus is commonly seen in 90% to 95% of all diagnosed patients. The increase and wide spread of diabetes mellitus is due to three types: life style, race, and age. Physical inactivity along with larger intake of food containing high fats and larger size has resulted in increasing number of persons being overweight. The diabetes mellitus incidence is greater with age about 2% of individuals 20 to 39 years of age to 20.9% of people older than 60 years of age. As the population becomes old, the incidence of diabetes mellitus is expected to be huge.

The JNC7 report describes four stages of blood pressure classification and provides guidance on non-pharmacologic and pharmacologic approaches to managing patients with hypertension. The four stages of blood pressure classification include normal, prehypertension, stage 1 hypertension and stage 2 hypertension. These stages are defined as such to indicate a level of risk and thus the need for varying intensities of intervention with drug therapy.

The current study is intended to analyse the therapeutic efficacy and drug related problems in out-patients of type two diabetes and hypertension that are caused during the pharmacological management of disease.

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MATERIALS AND METHODS

The study conducted involved subjects from outpatient department of general medicine at a multispecialty hospital in dakshina Kannada. This was a prospective observational study and was conducted over a period of eight months. Ethical commite approval for the study was obtained before initiating the study. The study criteria included patients above 18 years age of either sex with type two diabetes and hypertension and who receives at least one anti-diabetic and anti-hypertensive drug. The criteria excluded patients who are identified as pregnancy induced hyperglycemia and hypertension and who are not willing to participate.

During the study period data was collected from out-patients of general medicine department with type 2 diabetes mellitus with hypertension who are taking medicines were observed. Those patients who met the study criteria was enrolled in this study. After obtaining informed consent, sociodemographic data along with details of anti-diabetic therapy and anti-hypertensive therapy was recorded. In addition, fasting and postprandial blood glucose was measured. Through study of patient case notes and follow up was done after three months during the study period to check the therapeutic efficacy. The identified DRPs were documented in DRP form. The drug related problems were categorised based on Helper and strand classification.

The data were analysed by descriptive statistics using Statistical Package of Social Sciences (SPSS) software version 16.0.

RESULTS AND DISCUSSION

Demographic status of study population:

Of the 150 patients with type 2 diabetes & hypertension who participated in the study, the distribution of disease with respect to gender was 106 (70.7%) male and 44 (29.3%) female. The prevalence of the disease among different age group was observed. The frequency of occurrence was 3 (2%) in age group of 20-29 years, 6 (4%) in age group of 30-39 years, 18 (12%) in age group of 40-49 years, 41(27.33%) in age group of 50-59 years, 51(34%) in age group of 60-69 years, 20 (13.33%) in age group of 70-79 years, 11(7.33%) in age group of 80-89 years. The mean age of total patients were 22±87.

Table No. 1: Incidence of comorbidity associated with type 2 diabetes and hypertension

Comorbidities	Frequency	Percentage
Cardiovascular disease	41	27.3
Respiratory tract infection	25	16.7
Renal impairment	21	14
Dyslipidaemia	13	6.7
Liver impairment	7	4.7
Osteoarthritis	5	3.3
Gastro intestinal disease	4	2.6
Benign prostate hyperplasia	4	2.7

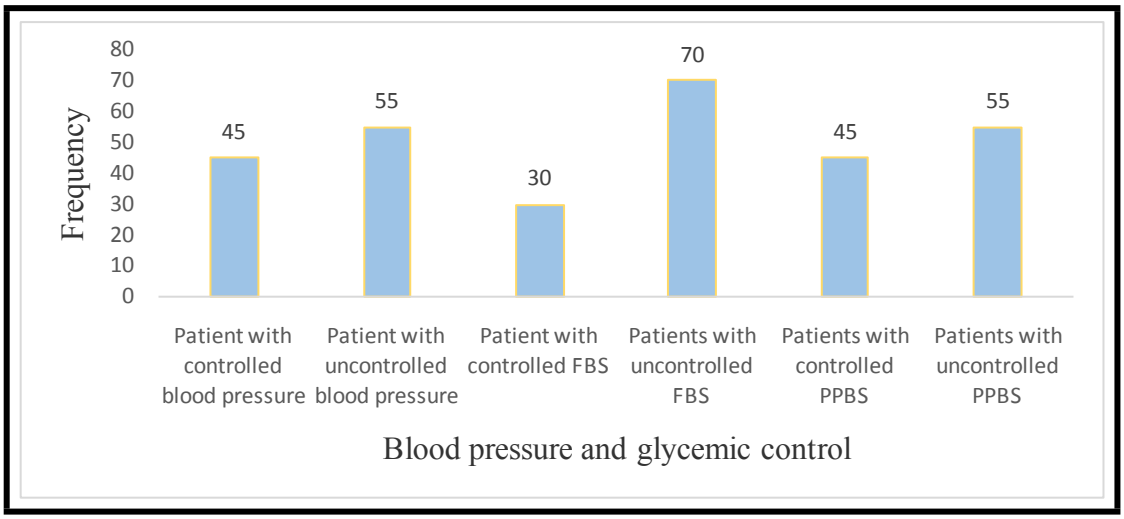

Fig. 1: Patients blood pressure control and glycemic control

Drug Related Problems:

Among 150 patients 98 drug related problem were identified in 87 patients. The most common drug related problems identified was potential Drug-Drug interaction were 35 (23.3%), untreated indication was the next major drug related problem, it was 32 (21.3%), there were 14 (9.3%) Others, 8 (5.3%) failure to receive drugs, and 7 (4.7%) adverse drug reaction, 2 (1.3%) drug use without indication. Under the "untreated indication" category most of the patients were not treated for hypertension at the first consultation as they were given time for change in their life style modification and after three months if the hypertension is same then the medication was prescribed. Under the "others" category the problem encountered was the insufficient awareness of disease and health, most of the patients had a lack of knowledge about T2DM and hypertension. Also they were unaware about the disease complications and management of the disease. Under the "failure to receive drug" category non-compliance with anti-diabetic drug and anti-hypertensive drug were common. Under the "drug use without indication" Proton pump inhibitors were the commonly prescribed drugs.

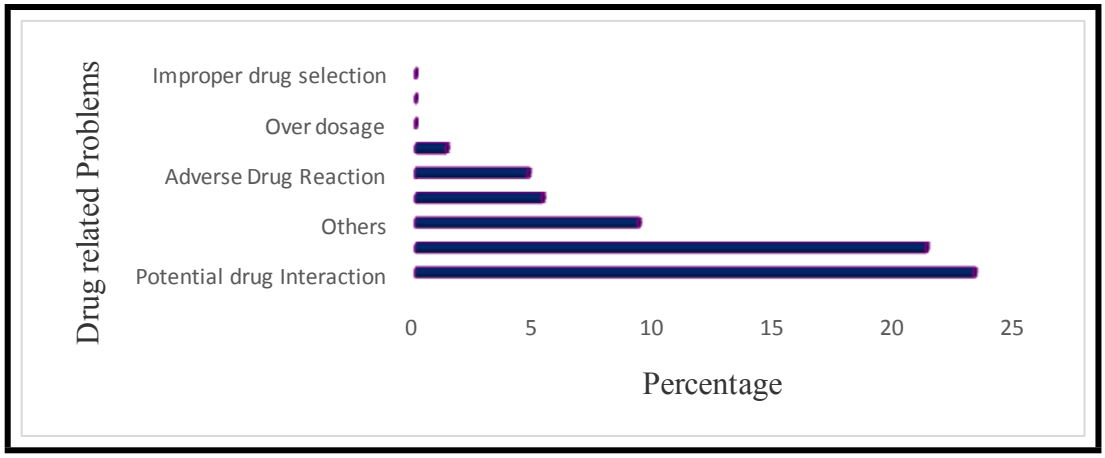

Fig. 2. Drug related Problems

Table No. 2: Adverse Drug Reaction:

Class of drug	Drug	ADR
Anti- diabetes	Gliclazide	Gastritis
Anti-diabetes	Insulin	Hypoglycemia
Lipid lowering drugs	Atorvastatin	Skin rash
Steroids	Methyl prednisolone	Swelling
Antacid	Ranitidine	Hypersensitivity
Anti-hypertensive	Amlodipine	Pedal edema
Antibiotics	Amoxicillin	Diarrhoea
Antibiotics	Linezolid	Difficulty in breathing

Table No. 3: Potential Drug-Drug Interactions

Potential Drug-drug interaction severity	Frequency (n=35)	percentage
Major	8	22
Moderate	20	57
Minor	7	20

DISCUSSION

In this study the male (70.7%) patients were more when compare to female (29.3%) patients. Which is similar to the study done by zaman H [6, 14]. et.al. In their study male patients were 51.5% and female patients were 48.5%. In this study the majority of drug related problem were seen in the age group of 60-69 (34%) years which is in contrast with the study done by Kumar AY.[14] et.al. where the age group was between 41-60 years (52.8%).

In this study 87 patients were identified with 98 drug related problems. When correlated with a similar study with sample size almost equal and they also used helper and strand classification system, the total number of DRPs were 261 which is larger than this study. A similar Helper and strand method was used, the differencein the studydone by Kumar A [14]. et.al may be due to the use of different methods to identify the drug related problems. For example in their method there was passive and reactive interventions, where as in our study there is no intervention.

A total of 35 drug-drug interactions were found in 87 patients among them 8 major drug- drug interaction was found and remaining 27 interactions were moderate. It was noticed that these interactions were not taken seriously as the drug therapy out weighed more benefit to the patients as the cure is found to be crucial. The most commonly recorded potential drug interaction in this study were aspirin and clopidogrel. Other reported potential drug interaction were ciprofloxacin and metformin, amitriptyline and moxifloxacin which is similar to the study done by Roozendaal V W.[7] et.al and these interactions are in contrast with the study done by Zaman H [6]. et.al where the drug interaction identified was NSAIDS and ACE inhibitors which is mostly based on the literature and evidence.

Among 98 drug related problems 21.3% were accounted to be untreated indications. There were patients missing therapy for clear indication, this was especially in the case of hypertension. Most of the patients in their first consultation they were not prescribed with the drug, the patients were suggested to have a diet plan and exercise and after three months if the hypertension is same they were prescribed with the drug. The study identified few cases where patients were not prescribed with lipid lowering drug. Which is similar to the study done by Roozendaal V W [7]. et.al.

1In 5.3% of cases most of the patients didn't have any knowledge about the disease that they are suffering from especially diabetes and hypertension and drug therapy. This lead to poor glycemic control and blood pressure control, it was similar to the study done by Zama H [6]. et.al

Among the 98 drug related problems it was noticed that there were 7 cases failed to receive the drugs and some patient forgets to take the medicines. It was due to unavailability of the drugs based on their brand names and forgetfulness. It was also noticed that majority of the patients were in the age group of 60-69 years i.e. geriatric patients.

There were 7 adverse drug reaction in this study. In antibiotics, linezolid induced breathing difficulty and amoxicillin induced diarrohea were identified. Other reactions include amlodipine induced pedal edema, ranitidine induced hypersensitivity reactions. These reports were contrast with the study results of zaman H [6]. et. al & Roozendal V.W.[7]et.al were both the study experienced hypoglycaemia by the use of oral hypoglycemic agent and insulin.

In this study 1.3% of DRPs category accounted for drug use without indication. Most of the patients were prescribed with pantoprazole which was not required. Which was in contrast to the study done by Kumar A .Y et.al[14]et.al. Were the drug use without indication was 18%.

Therapeutic Efficacy:

In patients who are taking anti-hypertensive drug about 15% of patients had their blood pressure control and 19% of patients had uncontrolled blood pressure. About 25% patients prescribed with the drugs to treat diabetes had controlled glucose level while 41% had uncontrolled glucose level. The other studies done by Agarwal A.A [2]. et.al and Roozendal V W [7]. et.al shows that 41% of patients had controlled diabetes and 59% of patients had inadequate glycemic levels and in other study a high proportion of

patients had poor glycemic control and blood pressure control was suboptimal.

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