A PROSPECTIVE STUDY ON PRESCRIBING PATTERN IN TYPE 2 DIABETES MELLITUS PATIENTS IN A TERTIARY CARE HOSPITAL

(Dr) Urooj Ahmedi[1]*, Dr Shaheda Siddiqui[2], (Dr) Shafia Baseera[3], Dr Pramod Ratnam[4]

[1,2,3]Dept of Pharmacy Practice, Deccan School of Pharmacy, Hyderabad.
[4]Dept of General Medicine, Deccan College of Medical Sciences, Owaisi Hospital and Research Center.

*Corresponding Author: Dr. Urooj Ahmedi

Dept of Pharmacy Practice, Deccan School of Pharmacy, Hyderabad.

ABSTRACT

The study involves screening the prescription trends in type 2 diabetes mellitus patients with comorbid complications imposed with diabetes. However study was undertaken in the Owaisi Hospital and Research Center, to evaluate prevalence rate of type II diabetes mellitus in males and females & actual appropriateness which deserve clinical attention and choice of prescribing pattern promoting rational use of medications. The study was Simple Prospective observational study which was carried out for a period of two months.150 cases were collected in the study which determines number of OADDS therapy administered for type II DM patients ruling out generic or essential drug prescribing and also patients were counselled regarding the medications and diet to be followed to manage DM. The results were analysed. Maximum number of patients were in the age group of above 60 years (40.66%) and among 150 cases, males constituted 61 (40.66%) and females 89 (59.33%). Out of 150 patients 137 patients (91.33%) patients were found suffering with co morbid concurrent illness hypertension followed by other complications associated like CAD, CKD, Hypothyroid, Asthma, Rheumatoid Arthritis and other comorbidities. Essentially assessment of therapy and management of disease with combination therapies of insulin and different oral anti-diabetic drugs were prescribed for proper glycemic control. As well clinical attention on patient counselling by clinical pharmacist indicates clinical effectiveness of therapy influenced by prescribed agent selection and therapy changes as well patient's adherence with drug regimens.

KEYWORDS: Prescribing pattern, Patient counselling, Generic use, Comorbidity.

INTRODUCTION

Drug utilization study, is a process which is used to assess the choice of drug therapy and patient drug use in a given health care environment, Drug utilization studies seek to monitor, evaluate and implement remedies in the prescribing practice with the aim of making the medical care rational and effective. A study of prescription pattern is to determine rational drug therapy. Prescribing Guidelines in review of prescription patterns (according to W. H. O.) provide attempts to analyze treatment options in type 2 D. M. patients with comorbid concurrent illness. However Type 2 diabetes is more often and significantly estimates were 90% of all diabetes cases worldwide. It occurs most frequently in adults even observed increasingly in adolescents. WHO has estimated that, 31.7 million individuals on average affected by diabetes in India.

The goal of management in people with diabetes is to provide.

- Relief from diabetic symptoms and improve quality of life.
- Prevention of acute complications, Prevention of infections. The compliance of people with diabetes management covers treatment as well educating programs include.
- A positive attitude
- Appropriate self-care skills.
- In depth information about diabetes its complications and treatment.
- Appropriate resources of self-care.
- Self-monitoring skills.

Patient care indicators

Essentially studies on patient.
Average consultation time for each individual.
Average dispensing time estimating proportion of drugs actually dispensed to the illness of patient.
Percentage of drugs adequately labeled to patients knowledge of correct dosage.

Most uncommon causes of diabetes (1% to 2% of cases) include endocrine disorders like (acromegaly, Cushing's disease), gestational diabetes mellitus (GDM), effects of exocrine pancreas (e.g., pancreatitis) and drug regimens

(e.g., glucocorticoids, pentamidine, niacin. Type II D. M., called non-insulin dependent diabetes, is the common form of diabetes, affecting 90% to 95% of population which are chiefly associated with insulin resistance syndrome. Gaining insight into physician's pattern in order to identify prescribing problem ensures proper measures in improving quality of prescription and patient care. Therefore, the present study is to understand the prescription pattern.

Role of oral hypoglycemic Agents and insulin in therapy

Considering the importance of the safety in diabetic patient emphasis present study use of OHAs still dominate the prescribing pattern, but there was a trend toward the use of insulin preparations in treating Type 2 diabetes mellitus. Insulin is two chain polypeptide having 51 amino acids. The peptide hormones directly involved in responding to control blood glucose level and located in the islets of Langerhans in pancreas; insulin secretion regulated by β-cells and glucagon by α2-cells. The 51 AA in two chains connected by 2 disulphide bridges, a single gene product cleaved into two chins during post translational modifications. Therapeutic half-life (t1/2:5-10 minutes degraded by glutathione insulin Tran's dehydrogenase (insulinase) which cleaves disulphide links.

Insulin acts by binding to specific receptors. Insulin receptor is a glycoprotein made up of two α and two β subunits. Insulin receptors are present on almost all cells in body. Insulin binds to these receptors on surface of the target cells. Phosphorylation and de- phosphorylation reactions which stimulate or inhibit the enzyme involved in metabolic actions of insulin. These bindings stimulate tyrosine kinase activity in the β subunit.

Factors regulating insulin

Pancreatic beta cells integrate signals from several metabolites and hormones to control the secretion of insulin. In general, glucose triggers insulin secretion while other factors can amplify or inhibit the amount of insulin secreted in response to glucose. Factors which increase insulin secretion include the incretin hormones Glucose-dependent insulinotropic polypeptide (GIP and glucagon-like peptide-1 (GLP-1), acetylcholine, and fatty acids. Factors which inhibit insulin secretion include adrenaline and noradrenaline.

Increased blood glucose levels from dietary carbohydrate play a dominant role in insulin release from the beta cells of the pancreas. Glucose catabolism in the beta cell is the transducer that links increased glucose levels to insulin release.

Diabetic complications

Long-term complications of diabetes develop gradually. The longer a person have diabetes — and the less controlled the blood sugar — the higher the risk of complications. Eventually, diabetes complications may be disabling or even life-threatening. Possible complications include:

- **Cardiovascular disease.** Diabetes dramatically increases the risk of various cardiovascular problems, including coronary artery disease with chest pain (angina), heart attack, stroke and narrowing of arteries (atherosclerosis).
- **Nerve damage (neuropathy).** Excess sugar can injure the walls of the tiny blood vessels (capillaries) that nourish the nerves, especially in the legs.
- **Kidney damage (nephropathy).** The kidneys contain millions of tiny blood vessel clusters (glomeruli) that filter waste from your blood. Diabetes can damage this delicate filtering system.
- **Eye damage (retinopathy).** Diabetes can damage the blood vessels of the retina (diabetic retinopathy), potentially leading to blindness.
- **Foot damage.** Nerve damage in the feet or poor blood flow to the feet increases the risk of various foot complications.
- **Skin conditions.**
- **Hearing impairment.**
- **Alzheimer's disease.** Type 2 diabetes may increase the risk of Alzheimer's disease.

METHODS
Study area and data collection process

This prospective observational study was carried at Department of General Medicine, in the Owaisi Hospital and Research Center. In this study, 150 cases were collected in which describing the selection therapy and drugs were administered for type II diabetes mellitus. The patients were involved in the study based on inclusion and exclusion criteria. In this study, the type of OAADS mostly administered to patients whether single or in combination triple therapy was evaluated ascertaining gender, age of the patient, type of OADDS and co morbid concurrent illness with relevancy were studied and the results were analysed.

Inclusion criteria
Type 2 diabetes (male & female patients)
Age>18years
Both In Patients and Out Patients were included.

Hospitalized for complications like macro vascular (coronary artery disease, HTN, peripheral vascular disease). History of heart failure, myocardial infarction, coronary revascularization (coronary artery bypass graft surgery), or stroke in the last 6 months.

Exclusion criteria
1) Patients age below 18 years 2) Gestational diabetic patient population 3) Juvenile D.M patients.

Study parameters
a. Percentage of drugs prescribed by generic name.
b. Percentage of prescriptions with OADDS

prescribed.
c. Estimation of prescriptions with injectable preparations.
d. Combination therapy, fixed dose combinations.
e. Co morbidities along with life style, diet and occupation percentages omong patients.

Data collecting method
The study was conducted on the basis of patient perspective and is a sort of prevalence based study.

The medical history consisting of inpatient medical records are reviewed for specific period of time.

Data recorded as patient demographic characteristics, clinical status duration of disease, type of complication.

Data analysis process
The data includes demographic variables, date and name of medication, dosage forms, doses and frequency. Descriptive statistics like frequency and other parameters were computed to determine the overall prevalence. The procedure completed with consent of authorities of the concerned institutions and confidentiality of the prescriptions was maintained strictly. The specific types of data necessary to measure the prescribing pattern were recorded for each patient encountered.

Plan of work
☐ Collection and review of literature pertaining to the project.
☐ Preparing study protocol including study design, design of proforma.
☐ Enrolment of patients according to the inclusion and exclusion criteria.
☐ Collection of patient details.
☐ Interpretation of data.
☐ Analyzing the data.
☐ Submission of report.

RESULTS
In this study 200 cases involving O. H. As administration were included.

Table 1 Gives demographic characteristics of patients to whom O. H. As were administered based on age and gender. Maximum number of patients were in the age group of 60 years above (40.66%) and among 150 cases, males constituted 61 (40.66%) and females 89 (59.33%).
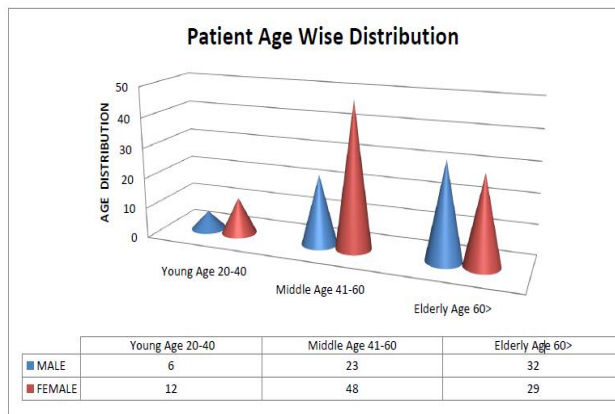

Fig. 1: Patient Age Wise Distribution.

	Young Age 20-40	Middle Age 41-60	Elderly Age 60>
■ MALE	6	23	32
■ FEMALE	12	48	29

Percentage of age wise distribution
The study enumerates demographic distribution of number of patient's male, female in percentage according to age wise.
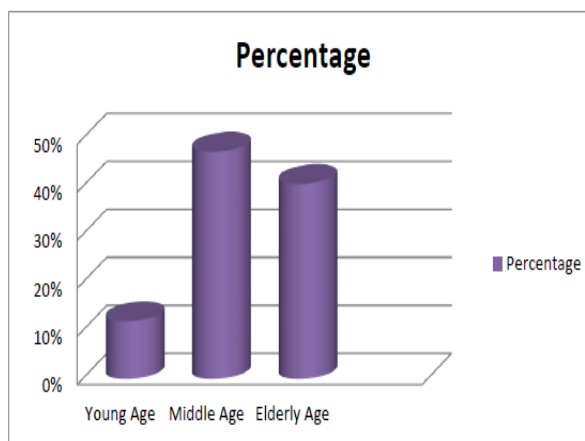

Fig 2: Percentage age wise distribution Sex wise distribution.

Implicative of gender wise distribution estimates to proper interpretation of study demographics.
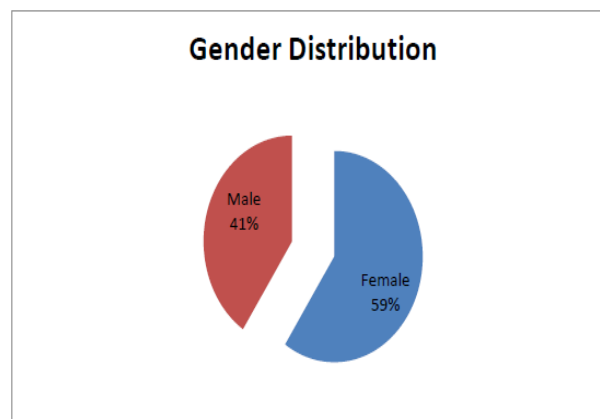

Fig.3: Gender wise distribution Comorbid illness distribution.

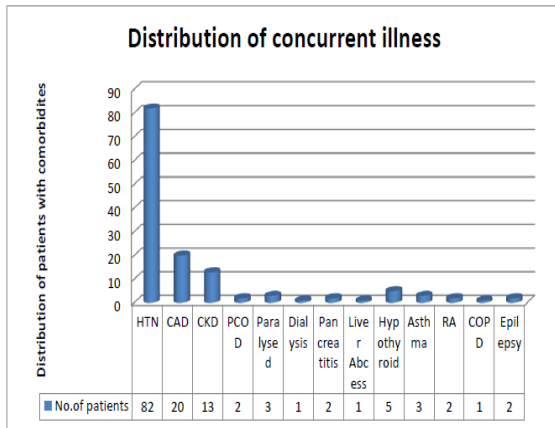The study emphasis the exact count of patients with respective comorbid illness along with diabetes.

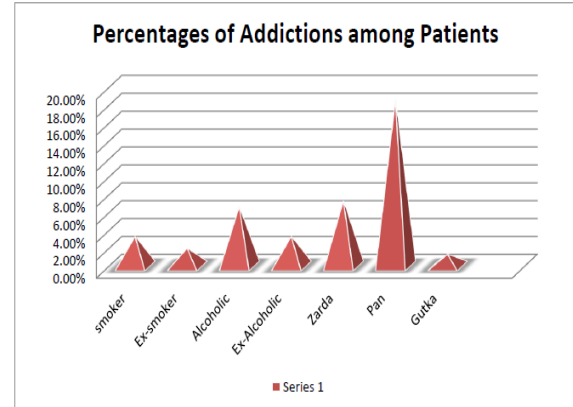**Fig.4: Comorbid illness distribution.**

Percentage of distribution

Fig. 5: Percentage of comorbid illness distribution.

Out of 150 patients 82 patients (54.66%) patients were found to be suffering with co morbid concurrent illness hypertension followed by complications associated like CAD 20(13.3%), CKD 13(8.66%), Asthma 3(2%), Hypothyroid 5(3.33%), Epilepsy, Rheumatoid Arthritis, Pancreatitis and PCOD were 2 each (1.33%), whereas Liver abscess, COPD patients were 1 each(0.66%), 3 patients was paralysed(2%).

No. of addictions in patients

Fig.6: No. of addictions in patients.

Percentage of addictions among patients

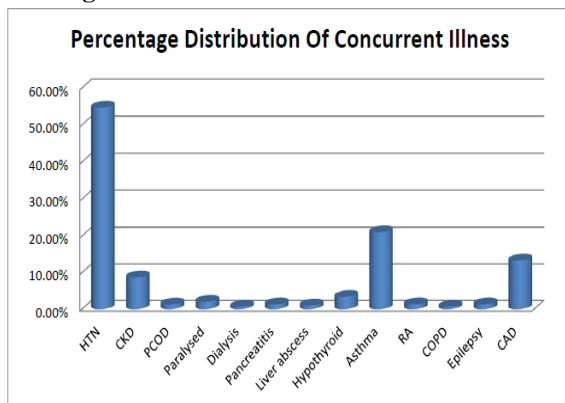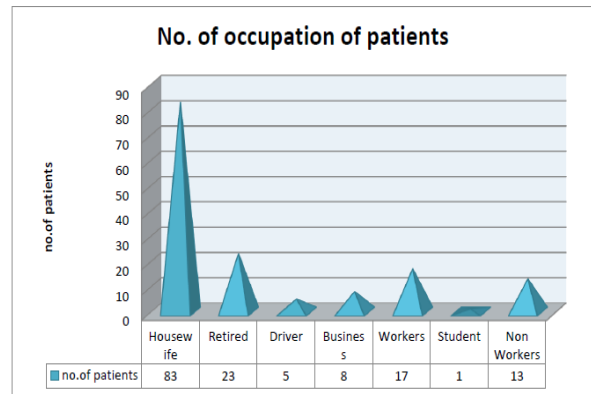**Fig.7: Percentage of addictions among patients.**

In figure 7, addictions among patients are enlisted in their respective percentage i.e., 28 (18.6%) PAN chewers, 11(7.33%) were eating ZARDA, alcoholic 10(6.66%), ex-alcoholic 5(3.33%), Smoker 5(3.33%), ex-smoker 3 (2%) and Gutka chewer were about 2(1.33%).
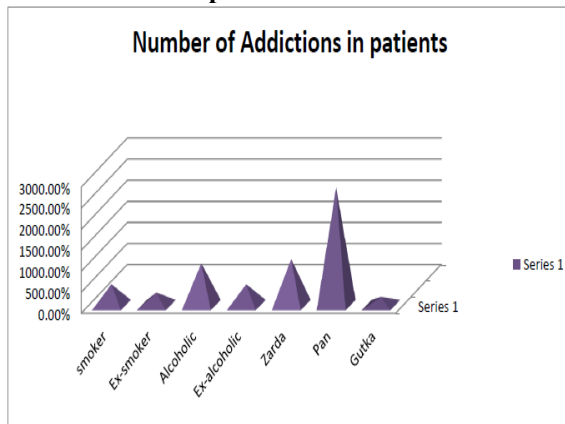

Fig. 8: No. of occupation of patients.
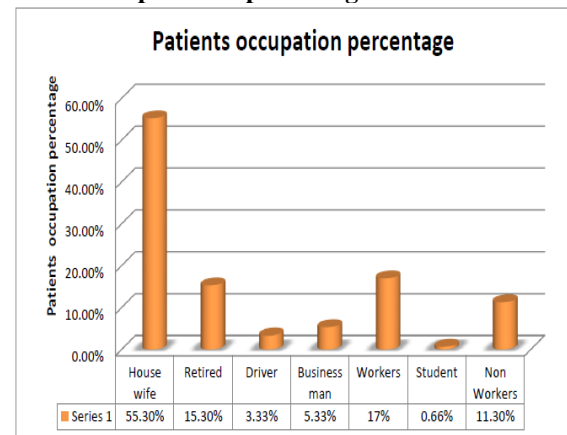
Patients occupation in percentage

Fig. 9: Patients occupation.

Among the total no. of patients, there were Housewives 55.30%, Retired persons 15.30%, Driver 3.33%, Business man 5.33%, Workers 17%, Student 0.66% and Non-Workers 11.30%.
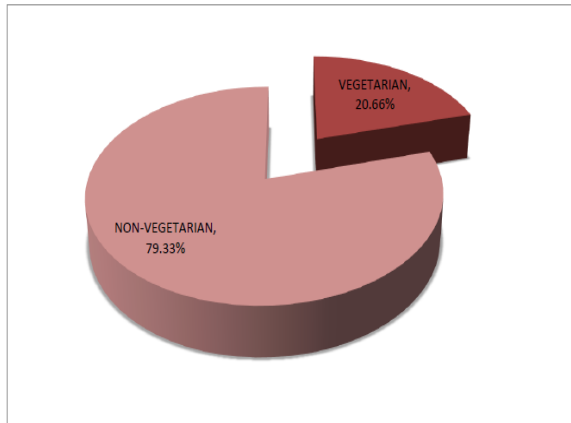
DIET

Fig. 10: Non-Vegetarians were 119(79.33%) and vegetarians were 31(20.66%).

Life Style

Fig. 11: Life style of the patients.

The above chart showed that out of 150 patients 35 (23.33%), were living sedentary life style and 115(76.66%) were active in their daily life.
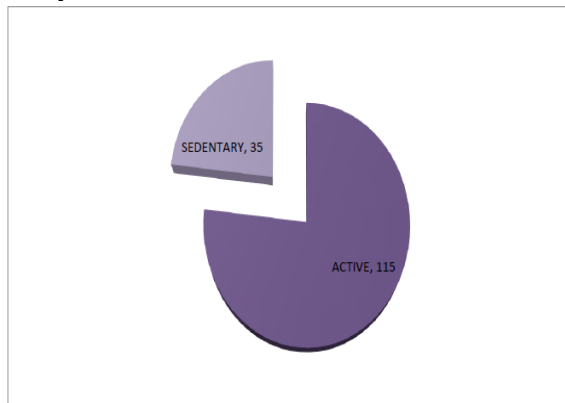
Table 1: Pattern of prescribing details in diabetic patients.

Details of prescription	Number
Total no. of prescriptions analyzed.	**150**
No. of drugs prescribed by generic name out of total no. of drugs prescribed.	**0**
No. of injections out of total no. of drugs prescribed.	**43(28.66%)**

Total number of prescriptionz analysed were 150, No. of drugs prescribed by generic name out of total no. of drugs prescribed were 0 and No. of injections out of total no. of drugs prescribed were 43(28.66%).

Table 2: Anti-diabetic prescription pattern.

S.NO	Drugs	Total number of prescriptions	Percentage
	O.H.As used	Monotherapy	%
1.	Biguanides(Metformin)	11	7.3%
2.	Sulfonylureas(Gliclazide)	3	7.3%
3.	Sulfonylureas(Glimepiride)	5	3.33%
4.	Sulfonylureas(Glipizide)	2	1.33%
5.	Sulfonylureas(Glibenclamide)	1	0.66%
6.	Insulin	34	22.6%

S.NO	Drugs	Total number of prescriptions	Percentage
	O.H.As used	Dual Therapy	%
1.	Metformin+Glimepiride	46	30.6%
2.	Metformin+Glipizide	4	2.66%
3.	Metformin+Gliclazide	3	2%
4.	Metformin+Insulin	5	3.33%

5.	Metformin+Glibenclamide	3	2%
6.	Metformin+Sitagliptin	3	2%
7.	Metformin+Vildagliptin	1	0.66%
8.	Tenegliptin+Insulin	1	0.66%
9.	Glimepiride+Vildagliptin	1	0.66%

S.NO	Drugs	Total number of prescriptions	Percentage
	O.H.As used	Triple Therapy	%
1.	Metformin+Glimepiride+Voglibose	6	4%
2.	Metformin+Sitagliptin+Insuline	2	1.33%
3.	Metformin+Glimepiride+Tenegliptin	5	3.33%
4.	Metformin+Glibenclamide+Pioglitazone	3	2%
5.	Metformin+Gliclazide+Pioglitazone	1	0.66%
6.	Metformin+Insulin+Voglibose	1	0.66%
7.	Metformin+Insulin+Acarbose	1	0.66%
8.	Acarbose+Glimepiride+Metformin	1	0.66%
9.	Metformin+Glimepiride+Insulin	5	3.33%
10.	Linagliptin+Glaclazide+Insulin	1	0.66%

S.NO	Drugs	Total number of prescriptions	Percentage
	O.H.As used	Quadruple Therapy	%
1.	Metformin+Glimepiride+ Voglibose+Sitagliptin	1	0.66%

Table 3: Fixed Dose Combinations.

S.NO	Drugs	Total number of prescriptions	Percentage
	O.H.As used	Fixed Dose Combination	%
1.	Metformin+Glimepiride+Voglibose	6	4%
2.	Metformin+Sitagliptin	3	2%
3.	Metformin+Glimepiride	46	30.6%
4.	Metformin+Glipizide	4	2.66%
5.	Metformin+Gliclazide	3	2%
6.	Metformin+Glibenclamide+Pioglitazone	2	1.33%
7.	Metformin+Vildagliptin	1	0.66%
8.	Metformin+Gliclazide+Pioglitazone	1	0.66%

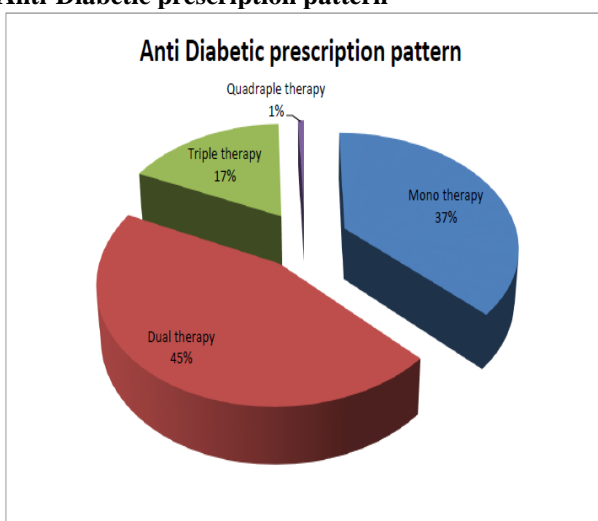**Anti-Diabetic prescription pattern**

Fig.12: Anti-Diabetic prescription pattern.

The percentage of patients on anti-diabetic monotherapy (56,37.33%), dual-therapy (67,44.66%), triple therapy (24,17.33%) and quadruple therapy (1,0.66%) fig.12.

The study reveals that human insulin preparation is the most prescribed 34 patients (22.6%) as in monotherapy followed by Metformin 11(7.3%), Glimepiride 5(3.33%), Gliclazide 3(2%), Glipizide 2(1.33%) and Glibenclamide 1(0.66%).

Among the dual combination 46 patients received Glimipride + Metformin combination (30.6%) followed by Metformin+Insulin 5(3.33%), Metformin+Glipizide 4(2.66%), Metformin+Gliclazide, Metformin+Sitagliptinand Metformin+Glibenclamide 3,(2%), Metformin+Vildagliptin, Tenegliptin+Insulin and Glimepiride+Vildagliptin 1(0.66).

Respectively triple therapy combination of O.H.As were analyzed as such Metformin+Glimepiride+Voglibose 6(4%), Metformin+Glimepiride+Tenegliptin and Metformin+Glimepiride+Insulin5(3.33%), Metformin+Glibenclamide+Pioglitazone 3(2%), Metformin+Glimepiride+Tenegliptin 2(1.33%) and rest of the combinations follows the sequence with frequency 1 and percentage 0.66% and they are Metformin+Gliclazide+Pioglitazone,

Metformin+Insulin+Voglibose, Metformin+Insulin+Acarbose, Acarbose+Glimepiride+Metformin and Linagliptin+Glaclazide+Insulin.

Only one prescription was found to have a quadraple combination of therapy i.e., Metformin+Glimepiride+Voglibose+Sitagliptin 1(0.66%).

DISCUSSION
The present study indicates administration of OADDs along with comorbid illness drugs treating in the general medicine ward of hospital. Demographic characteristics showed that out of 150 patients The results were analysed, maximum number of patients were in the age group of above 60 years (40.66%) and among 150 cases, males constituted 61 (40.66%) and females 89 (59.33%). Out of 150 patients 137 patients (91.33%) patients were found suffering with co morbid concurrent illness hypertension followed by other complications associated like CAD, CKD, Hypothyroid, Asthma, Rheumatoid Arthritis and other comorbidities.

There was high prevalence in elderly age group due to life style habits, obese, physical inactivity, smoking; alcoholism (males) unmasks blood sugar to rise.

However the pattern of anti-diabetic drug utilization most common therapy in which the oral anti diabetic drugs prescribed were mono therapy Metformin 11(7.3%), Glimepiride 5(3.33%), Gliclazide 3(2%), Glipizide 2(1.33%) and Glibenclamide 1(0.66%) and as injection Insulin was prescribed. Among the dual combination 46 patients received Glimipride + Metformin combination (30.6%) followed by Metformin+Insulin 5(3.33%), Metformin+Glipizide4(2.66%), Metformin+Gliclazide, Metformin+Sitagliptin and Metformin+Glibenclamide3,(2%), Metformin+Vildagliptin, Tenegliptin+Insulin and Glimepiride+Vildagliptin 1(0.66).

Respectively triple therapy combination of O.H.As were analyzed as such Metformin+Glimepiride+Voglibose 6(4%) was mostly opted as triple therapy followed by, Metformin+Glimepiride+Tenegliptin and Metformin+Glimepiride+Insulin5(3.33%), Metformin+Glibenclamide+Pioglitazone 3(2%), Metformin+Glimepiride+Tenegliptin 2(1.33%) and rest of the combinations follows the sequence with frequency 1 and percentage 0.66% and they are Metformin+Gliclazide+Pioglitazone, Metformin+Insulin+Voglibose, Metformin+Insulin+Acarbose, Acarbose+Glimepiride+Metformin and Linagliptin+Glaclazide+Insulin.

Only one prescription was found to have a quadraple combination of therapy i.e., Metformin+Glimepiride+Voglibose+Sitagliptin 1(0.66%), whereas a study conducted by Pavan Gara et al in Bengaluru shows different results of monotherapy, dual therapy and triple therapy and there wasn't any quadruple therapy.

When cases were screened thoroughly, it was found that numbers of cases of Monotherapy cases were (56,37.33%) and combination therapy cases were mono+dual+triple+quadraple(92,61.33%). This shows that prescription suggested for administration was more preferred to be combination therapy. Among the use of combination therapy drugs in number in dual therapy (67,44.66%)was the highest one then, triple therapy (24,17.33%) and quadruple therapy(1,0.66%).

In this study, Out of 150 patients 82 patients (54.66%) patients were found to be suffering with co morbid concurrent illness hypertension followed by complications associated like CAD 20(13.3%),CKD 13(8.66%), Asthma 3(2%), Hypothyroid 5(3.33%), Epilepsy, Rheumatoid Arthritis, Pancreatitis and PCOD were 2 each (1.33%), whereas Liver abscess, COPD patients were 1 each(0.66%), 3 patients was paralysed(2%), which was more than in the study reported in Nepal (hypertension accounted for 70.62% of total complication) as wel as the results for HTN were lower in the study conducted by **Pavan Gara et al in** Bengaluru shows 66.27% of HTN among other complications related with DM. No. of injections out of total no. of drugs prescribed were 43(28.66%) and all the drugs prescribed by their brand names, where as 90.35% of drugs were by their brand names which is lower and 2.33% were prescribed by generic names which is higher in the study conducted by Manjusha S et al in department of medicine, Bharati hospital, Poona.

Prospective drug utilization study is one of the most effective methods to assess and evaluate the prescribing pattern and help to promote rational use of drugs .in patients with type II DM treatment may be initiated with monotherapy and early intervention with a combination of oral anti-diabetic agents. In our study insulin as a monotherapy secured highest utilization percentage 53(26.5%) among all anti-diabetic drugs. Numerous studies show that a combination of insulin and sulfonylureas is more effective than insulin alone in treatment of type II DM patients. In few patients failure of OAADs allowed to switch over insulin preparations. Combination of sulfonylureas and metformin were widely used, as in all combinations.

Finally, the establishment of conventional therapies for management of type II DM for adequate metabolic control should be optimized with intense prescribing modes in accordance to therapy in establishment of therapeutic guidelines; a constant monitoring of diabetic condition of a patient reduces the threat and improves quality of life. It is important to note that drugs should be prescribed in their generic names. Although there are both advantages and disadvantages of generic prescribing, there is more to gain by this practice,

especially in a teaching hospital which has a dual responsibility of providing patient service as well improving quality of life.

CONCLUSION

The study has shown that majority of patients with type-II DM were managed by insulin Monotherapy [34 patients (22.6%)] as well the current prescribing trends of oral anti- diabetic drugs do achieve adequate optimal glycemic control. However combination therapies of insulin with different oral anti-diabetic drugs were prescribed for proper glycemic control in severe glycemic levels.

Diabetic clinics should be strongly encouraged for optimal glycemic control with mono or dual therapy in order to prevent early emergence of complications that tend to increased morbidity and mortality in these patients. The epidemic rise of diabetic prevalence was gradually high in current years. It need conventional therapies and intense management of type-II DM for adequate metabolic control of blood glucose level should be achieved in prescribing appropriate therapy and newer agents like DPP-IV inhibitors for the management of DM.

The results of present study highlights the need for comprehensive management of diabetic patients including life style changes, dietary changes can control hyperglycemia, cardiovascular prevention, treatment of complications and comorbidity. Clinical effectiveness of therapy is influenced by prescriber agent selection and therapy, as well patients' adherence with prescribed drug regimens.

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