

PATTERNS OF DRUG THERAPY AMONG DIABETIC HYPERTENSIVE PATIENTS WITH OTHER COMPLICATIONS

DR. ZAKIA HUSSAIN¹, DR. AMTUL SANA², SALAHUDDIN MOHAMMED*³, MOHAMMED ABDUL RAZZAQ⁴

College of Health Sciences, Department of Pharmacy, Mizan Tepi University, Mizan Teferi, Ethiopia, Malla Reddy College of Pharmacy, Dhulapally, Secunderabad. Deccan School of Pharmacy, Kanchanbagh, Hyderabad
Email: salahuddin_pharma48@yahoo.com

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ABSTRACT

Objectives: There are many variations in prescribing patterns of Diabetes mellitus with hypertension which requires lifelong treatment as enormously increased the burden of chronic diseases and needs much care while choosing drugs. In a tertiary care centre, prescribing pattern are powerful tools to ascertain the role of drugs in society. Hence, there is a need for appropriate, safe, effective and economical study to find out the patterns of drug therapy among diabetic hypertensive patients with other complications.

Methods: Retrospective, randomized and non-interventional study design was conducted from April 2012 to September 2012 at a 600 bedded multispecialty tertiary care teaching hospital in south India. The collected data are thoroughly analysed and prescriptions were checked for appropriateness. For easy sorting all data obtained were entered into Microsoft Excel 2000 and cross-checked for accuracy. The data collected were analysed to obtain averages, percentages and standard deviations. The data were grouped on the bases of age, gender, fasting blood glucose, blood pressure, co morbidities, various classes of drugs and analysed for significance.

Results: Patterns of drug therapy among Diabetic hypertensive patients with other complications was observed in 117 subjects, out of which males are more affected than females in the age group of 50-60 years. The most common drug administered for Diabetes was Metformin whereas for hypertension, Telmisartan was administered. There was a positive relationship between fasting blood glucose and systolic blood pressure.

Conclusion: Lacuna in the present prescribing pattern is underutilization of diuretics. Further studies from time to time are required in drug utilization pattern and standard treatment guidelines to be circulated among practicing physicians. Our study was done for a short period of time and the number of patients studied was low. Hence, similar studies covering large number of patients are needed to confirm our findings.

Keywords: Diabetes Mellitus, Hypertension, Drug Utilization, JNC VII, Treatment.

INTRODUCTION

Diabetes mellitus (DM) is group of common metabolic disorders that share the phenotype of hyperglycaemia which are caused by a complex interaction of genetics and environmental factors. In the United States, DM is the leading cause of end-stage renal disease (ESRD), traumatic lower extremity amputations, and adult blindness. It also predisposes to cardiovascular diseases. With an increasing incidence worldwide, DM will be a leading cause of morbidity and mortality for the foreseeable future. The treatment goal for DM is to prevent mortality and complications by normalizing blood glucose level. But blood glucose level might be increased despite of appropriate therapy in patients leading to diabetic complications, such as disturbances in fat metabolism, nerve damage, and eye disease [1-5].

The common causes of diabetic complication are poor control of diabetes either due to non-adherence, poor attitude towards the disease and its complications, unhealthy diet and insufficient physical activity and due to poor management by the health care professionals [6-8]. Despite this complications diabetes can predispose the individual for different infections [9-13]. The final outcome of diabetes is disability, and/or [9-13] indirect (costs of hospitalizations, loss of vision, lower extremity amputations, kidney failure, and cardiovascular events)[14,15].

Thus, prevention is cost effective than treatment and management of diabetic complications[16,17]. Though this is the case in many parts of the world especially in developed countries [8,16,18], to our knowledge comprehensive study is lacking in our country except on patterns of drug therapy and some on prevalence of complications[11]. Different studies in fact of different methodological quality [19] have documented the complications of diabetes in different setups including hospitals and community

[11,20,21] on attitude of patients [7,22-24] and adherence patterns[25-28]. These all can lead to death though one affects the other[6,9]. Diabetes and its complications are among common reasons for inpatient patient admissions accounting for about 4.4%[6] of total admissions leading to to about 3.4%[29] to 32.5% [9] total deaths. The prevalence of chronic complications varies from 52.0% to 74.2%[11, 12, 20, 30]. The common chronic complications were erectile dysfunction 64% [31], visual disturbance (33.8%[11]), Cardiovascular disorders (30.1%[30]) though hypertension alone was 68%[32], neuropathy (29.5%[11]), and nephropathy (15.7%[11]). Likewise acute complications had similar trend which ranges 30.5% among which DKA was 71% followed by hypoglycemia 19.4% but Hyperosmolar Hyper-glycemic State was insignificant[11]. The common risk factors for occurrence of complications were gender [7], long duration with diabetes[12], poor and inadequate glycemic control[21], negative attitude towards diabetes[21,22] poor treatment adherence [25] and poor knowledge about the disease and its management[21,22].

Negative attitude of patients towards diabetes managements such as dietary modifications, exercise, and insulin therapy are common and ultimately can lead to diabetic complications[33]. About 18% of patients perceive that balanced diet low in sugar/sweets is important for diabetes control while 52% thought that only sweets should be stopped [22]. Negative attitude can be developed due to various reasons one of which is lack of education [34]. Thus, better understanding of perceptions and attitudes among both patients and providers is needed to guide initiatives to improve the management of diabetes[19,27]. Though diabetes is fatal disease, of our knowledge there are no comprehensive studies conducted in the study area. Thus, this study is aimed in determining the prescription pattern in type-2 diabetes mellitus with coexisting hypertension, prevalence of diabetes related complications and related risk factors,

identifying the prescribing errors; and treatment adherence as per the JNC VII guidelines with its related barriers in the hospital.

MATERIALS AND METHODS

The intended work can be divided into the following steps.

Step 1: To collect randomly the prescriptions of patients diagnosed with diabetes.

Step 2: To separate the prescriptions prescribing Anti Diabetic Drugs and the ones without anti diabetic Drugs.

Step 3: To divide the prescriptions into various groups according to the following: Age and Sex of patient and diseases associated with DM.

Step 4: To statistically analyse the prescriptions on the following aspects:

- Demographic Characters of Patients.
- Showing incidence of DM according to sex.
- Showing incidence of DM according to different age groups.
- Analysis of Prescription in DM with respect to dosage forms.
- Analysis of prescription showing incidence with other diseases.
- Distribution of drugs in different categories based on ATC classification.
- Patterns of utilization of Major Pharmacological Drug classes.

Step 5: To analyses the frequency of diseases associated with DM statistically and the drugs according to their pharmacological categories.

Location

The study was conducted in the medical outpatient and inpatient wards of Malla reddy hospital, jeedimetla, in Andhra Pradesh state. It is a 600 bedded tertiary care teaching hospital located at Hyderabad, the hospital is a unique and well known for its services to people who came from various parts of city. The institution excels in diverse specialties like general medicine, general surgery, obstetrics, gynecology, paediatrics, orthopaedics, neurology, neurosurgery, radiology, cardiology, cardiothoracic surgery, pulmonology, gastroenterology, nephrology, ENT, dental surgery and department of physical rehabilitation. The hospital is well equipped with modern diagnostic facilities like 64 slice CT scan, 1.5 tesla MRI scan, ultrasound sonography, ECG, treadmill, echo colour Doppler etc. the hospital also have well equipped twelve hi-tech operation theatres, medicine intensive care unit, coronary care unit, catheterization laboratory performing diagnostic cardiac catheterisation, balloonvalvuloplasty, coronary stenting and haemodialysis.

Study design

It was a retrospective randomized non interventional study

Study period

Data was collected from April 2012 to September 2012 in between 9 am to 4 pm in the departments of general medicine, general surgery and ophthalmology.

Inclusion criteria:

All diabetic patients who have registered in the outpatient and inpatient departments.

Prescriptions of patients with at least one Antidiabetic drug

Exclusion criteria:

Paediatric patients and pregnant women.

Patients who were not willing to disclose their information

Data collection

A data collection format was designed to aid collection of data as shown in annexure I.

Case notes

Data on sex, age, groups of medicines prescribed, number of prescriptions and number of medicines occurring per prescription were obtained.

Data analysis

The collected data were thoroughly analyzed and prescriptions were checked for appropriateness. For easy sorting, all data obtained were entered into Microsoft Excel 2000 and cross-checked for accuracy. The data collected were analyzed to obtain averages, percentages and standard deviations.

Ethical issues

Permission was sought and obtained from the Malla Reddy hospital before commencement of study.

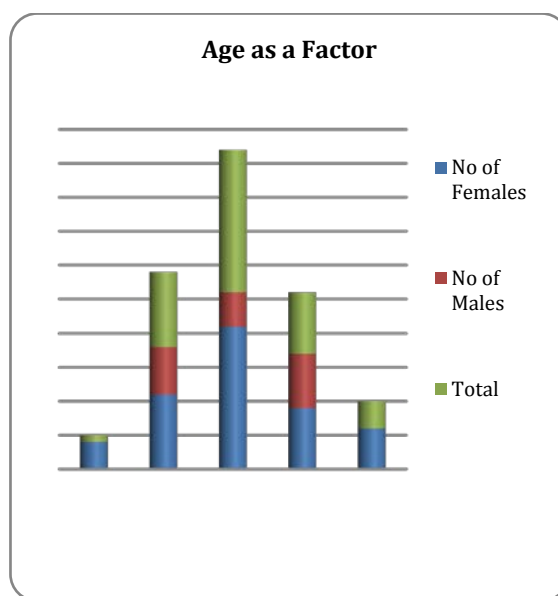


Fig. 1: Age as a factor

RESULTS AND DISCUSSION

Out of 117 diabetic patients, 43.6% were females (51) and 56.4% were males (66). Males were more sufferers than females. out of all the patients, 5 patients were in the age group 30-40 years (4.3%), 29 patients were in the age group 40-50 years (24.8%), 47 patients were in the age group 50-60 years (40.2%), 26 patients were in the age group of 60-70 years (22.2%) and 10 patients were in the age 70 years and above (8.6%). The more number of patients were in the age group 50-60 years may be because of sedentary life style and obesity. These demographic characteristics related to age and gender were shown in the figure number 1.

Table 1: Comparison of age, weight and mean fasting blood sugar levels among hypertensive and non-hypertensive diabetes mellitus patients

Characteristics	HDM	NHDM	P Value
Age (Years)	54.3 (10.6)	51.08(12.44)	0.358
Weight(Kg)	61.48 (9.84)	60.29(7.02)	0.17
Mean FPG (mmol/L)	162.2(54.98)	176.75(66.5)	0.316

When compared to hypertensive diabetes mellitus patients with non-hypertensive diabetes mellitus patients, latter were having higher mean fasting blood sugar levels (176.75 > 162.2). Mean age of hypertensive diabetes mellitus was 54.3 years slightly greater than that of non-hypertensive diabetes mellitus patients (51.08 years). The mean weight of hypertensive diabetes mellitus patients was 61.48kg and that of non-hypertensive diabetes mellitus patients was found to be 60.29kg. The data with standard deviations and significance values were shown in the table no. 1.

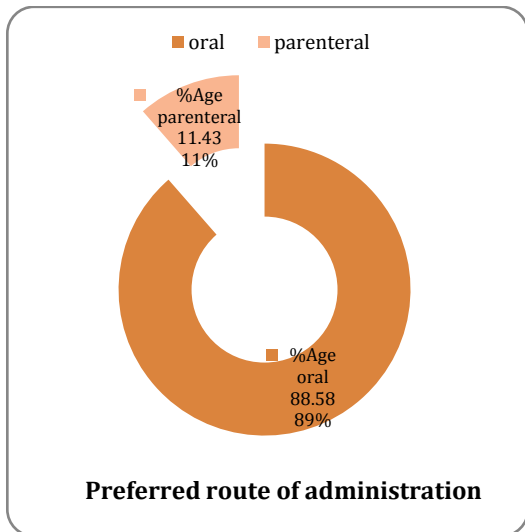


Fig. 2: Preferred route of administration of drugs in prescription

Oral route (88.58%) was most preferred than compared to parenteral route (11.43%) for diabetic patients. This may be due to ease of administration, availability of drugs. This data was shown in figure no. 2. The average number of medications per prescription was found to be 4.77.

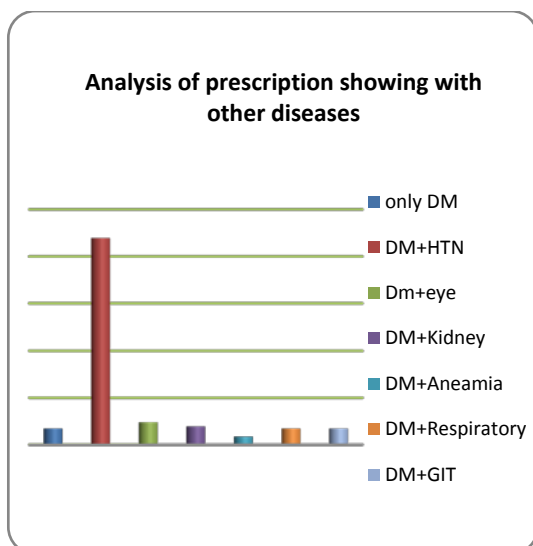


Fig. 3: Analysis of prescription showing with other diseases

While analysing the prescriptions showing incidence with other diseases it was clear that hypertension was the most prevalent disease (87.83%), which was associated with diabetes and followed by eye disorders like retinopathy, cataract (9.57%), kidney diseases

like nephropathy, chronic kidney disease (7.83%), respiratory diseases like asthma (6.96%), gastro intestinal tract disorders like cholelithiasis (6.96%), anaemia (3.48%). This was shown in the figure no.3.

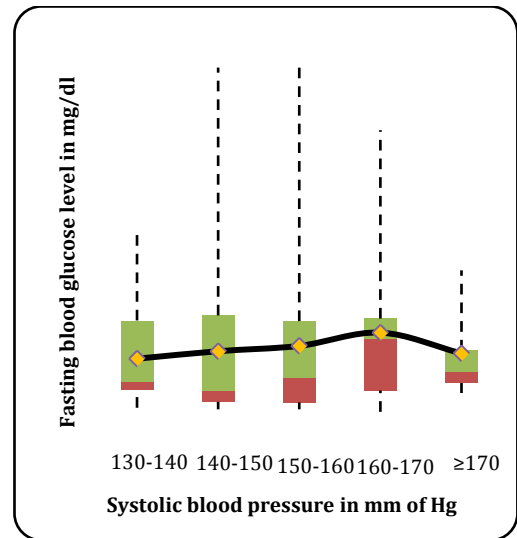


Fig. 4: Relationship between blood pressure and blood sugar

The systolic blood pressures of diabetic hypertensive patients were categorized into five groups i.e 130-140, 140-150, 150-160, 160-170 and 170 and above. The mean fasting blood sugars of the patients under each group were calculated and depicted in the figure no.4.

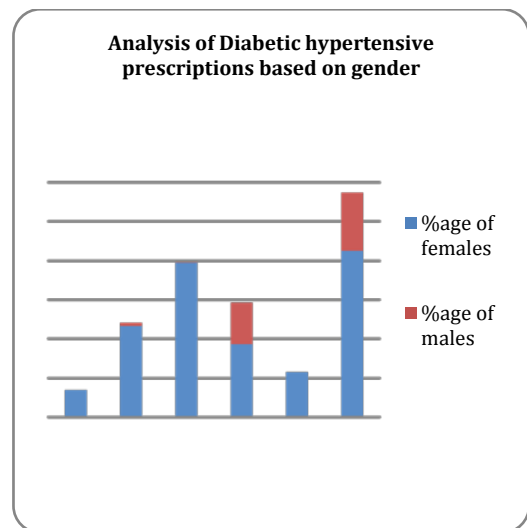


Fig. 5: Analysis of Diabetic hypertensive prescriptions based on gender

While analysing diabetic hypertensive patients prescriptions it was found to be patients with age 50-60 years were more in number (40 patients consisting of 39.54% females and 39.66% males), followed by patients with age 60-70 years (25 patients consisting of 18.61% females and 29.32% males). This was shown in the figure no. 5. 560 drugs were prescribed for 117 diabetic patients were categorised into 14 classes as per ATC classification as shown in annexure II. This was shown in the table no 2. The classes of drugs which were included in the various categories of ATC classification were analysed and tabulated. The main pharmacological drug classes involved with diabetes mellitus prescriptions were found to be A, C

and M. Most frequently were the drugs for GIT and metabolism (47.86%), followed by drugs for cardio vascular diseases (18.75%)

and drugs for musculo-skeletal system (8.93%). This data were shown in the table no. 3.

Table 2: Anatomical, Therapeutic and Chemical Classification of Drugs

A	Drug for GIT and Metabolism T.Metformin HCL T.PioglitazoneT.Ondansetron T.AtorvastatinT.PantaprazoleT.itopride T.RabeprazoleT.Glimepiride Vitamins Insulin injT.Glimepiride+metformin
B	Drugs for treatment of disorders of blood and blood sugar forming organs T.AsprinT.EnoxaparineT.Clopidogrel T.clopidogrel+AspirinInj.Heparin
C	Drugs for cardiovascular diseases T.MetoprololT.AmlodipineInj.furosemide T.NifedipineT.MetolazoneT.Prazosin T.CarvedilolT.isosorbidedinitrateT.Clonidine T.NebivololT.TelmisartanT.Enlpril T.Perindopril
D	Dermatological drugs
G	Drugs for urinary system and sex hormones
H	Hormones for systemic use except sex hormones
J	Anti-infections drug for systemic use Inj.Ceftriaxone Na Inj.Amikacin Inj. metronidazole
L	Antineoplastic and immunomodulating
M	Drugs for musculoskeletal system T.paracetamolT.Paracetamol+tramadolT.Hyoscine butyl Br T.Ibuprofen+paracetamolT.paracetamol+aceclofenac sodium T.Calcium citrate T.Dicycloverine HCL
N	Drugs for nervous system T.PregabalinT.AmitriptylineT.Alprazolam
P	Drugs for parasitic infections T.Amoxycillin+Clavulanic acid T.Piperacillin NA +tazobactam T.LevofloxacinT.CefiximeT.Azithromycin T.Artesunate+Mefloquine
R	Drugs for respiratory system T.Monteleukast+ LevocetizineT.Cetirizine HCL T.FlunerazineT.Doxofylline T.CyproheptadineHCL+ Tricholinecitrate+sorbital Na
S	Drugs for ears and nose
V	Various others

Table 3: Analysis of drugs based on ATC Classification

Drug class(based on ATC Classification)	Frequency	%
A Drug for GIT and Metabolism	268	47.86
B Drugs for treatment of disorders of blood and blood sugar forming organs	49	8.75
C Drugs for cardiovascular diseases	105	18.75
D Dermatological drugs	-	-
G Drugs for urinary system and sex hormones	-	-
H Hormones for systemic use except sex hormones	-	-
J Anti-infections drug for systemic use	27	4.83
L Antineoplastic and immunomodulating agents	-	-
M Drugs for musculoskeletal system	50	8.93
N Drugs for nervous system	10	1.79
P Drugs for parasitic infections	36	6.43
R Drugs for respiratory system	15	2.68
S Drugs for ears and nose	-	-
V Various others	-	-

Table 4: Analysis of anti hypertensive drug combinations

Combinations of anti-hypertensive drugs	Frequency
ARBS+Betablockers	2
CCBS +Beta blockers	2
ACE + Diuretics	0
ACE+CCBS	2
ACE+Beta blockers	2
CCBS+Diuretics	3
ARBS+Betablockers+ CCBS+Diuretics	3

By analysing anti hypertensive drugs based on systolic blood pressure, T. Telmisartan was prescribed to all categories of SBP more number of times. For the SBP category 150-160mm of Hg

Utilisation of antihypertensive drugs

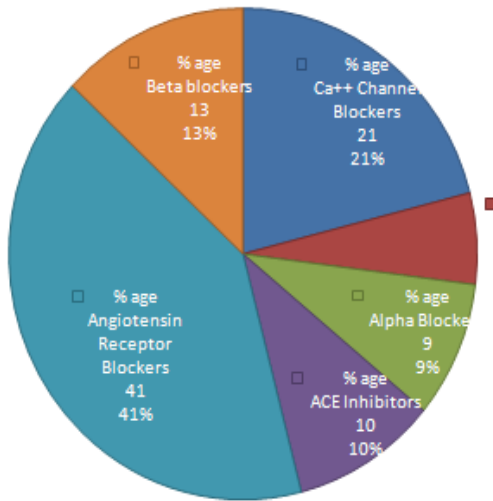


Fig. 6: Utilisation of antihypertensive drugs in diabetic hypertensive patients

Out of 100 drugs prescribed for diabetic hypertensive patients most commonly used category of drugs were angiotensin receptor blockers (41%), calcium channel blockers (21%) and beta blockers (13%). Most commonly prescribed drug was telmisartan. Diuretics, alpha blockers and ACE inhibitors were rarely prescribed. This data were shown in the figure no. 6.

T.Amlodipine was prescribed more number of times next to the T.telmisartan. T.Nebivolol and T.Enalapril were prescribed only for two patients. This data were shown in the Figure no. 7.

blockers + diuretics. This data were shown in the table no. 4. By analysing the anti-hypertensive drugs based on diastolic blood pressure (DBP), T.Telmisartan was prescribed for more number of times in the DBP level 100-110 mm of Hg than other drugs.

T. Nebivolol and T. Enalapril were prescribed only in the category DBP 90-100 mm of Hg. This data were shown in the Figure no. 8.

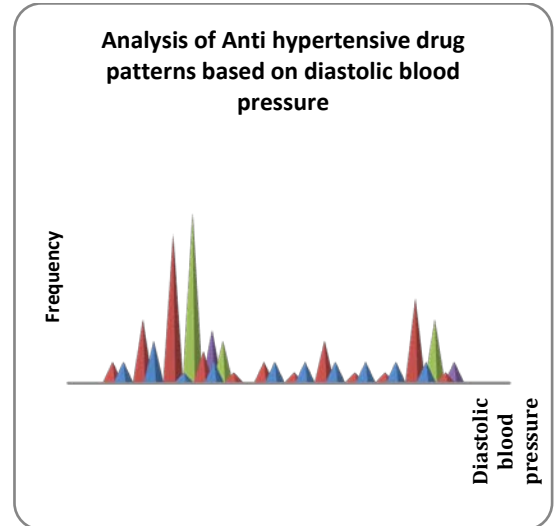


Fig. 8: Analysis of Anti hypertensive drug patterns based on diastolic blood pressure.

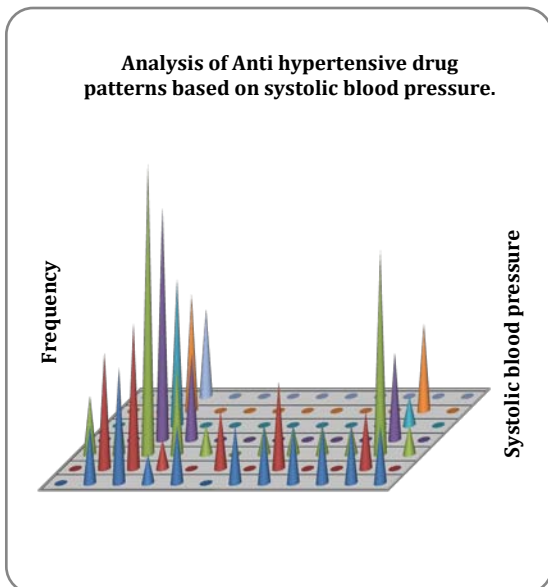


Fig. 7: Analysis of Anti hypertensive drug patterns based on systolic blood pressure.

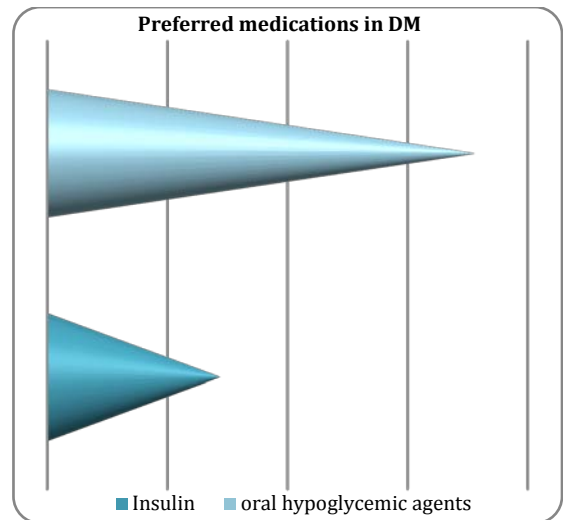


Fig. 9: Preferred medications in DM (N=111 drugs)

Out of the combinations drugs used for treatment of hypertension, 2 patients received angiotensin receptor blocker and beta blockers, 2 patients received calcium channel blockers and beta blockers, 2 patients received ACE inhibitors and calcium channel blockers, 2 patients received ACE inhibitors and beta blockers, 3 patients received calcium channel blockers and diuretics, 3 patients received angiotensin receptor blocker + beta blockers + calcium channel

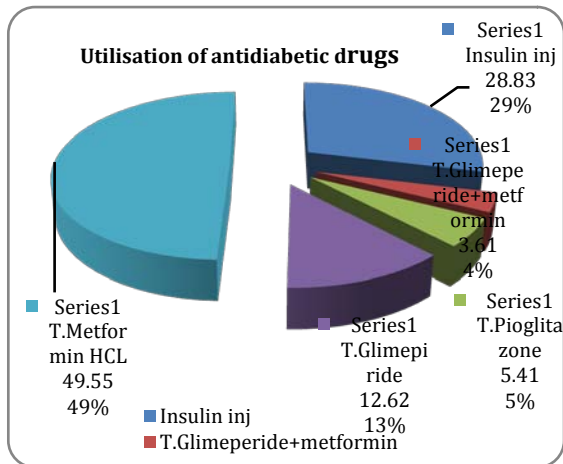


Fig. 10: Utilisation of anti-diabetic drugs in diabetic patients (N=111)

The anti-diabetic drugs prescribed for the patients include T. glimepiride + metformin, T. Pioglitazone, T. Metformin, T. Glimepiride, Inj. Insulin. Out of this most commonly prescribed drug was T. Metformin HCL (49%). The data were shown in the Fig. 10.

Out of 111 anti-diabetic drugs, 79 were oral anti diabetic agents (71.18%) and parenteral insulin injection constituted 32(28.83%). And the data were tabulated and depicted in the figure no.9. By analysing the Anti diabetic drugs based on Fasting blood glucose levels, T. Metformin was prescribed for more times in the category 120-130mg/dl than other drugs. T. Pioglitazone was prescribed only

two categories i.e 140-150 and 220-230 mg/dl for only two times. T. Glimepiride and metformin was prescribed to the category 140-150 mg/dl for only two times. This data were shown in the figure no.11.

The drugs used for infections in diabetic hypertensive patients were inj. Ceftriaxone Na (16%), inj. Metronidazole (13%), inj. Amikacin (14%), T. Amoxycillin+ clavulanic acid (17%), T. levofloxacin (10%), tab. Cefixim (13%), T. Azithromycin (6%), T. Piperacilline Na + tazobactam (8%), T. Artesunate+ mefloquine (3%). This data were shown in the figure no. 12.

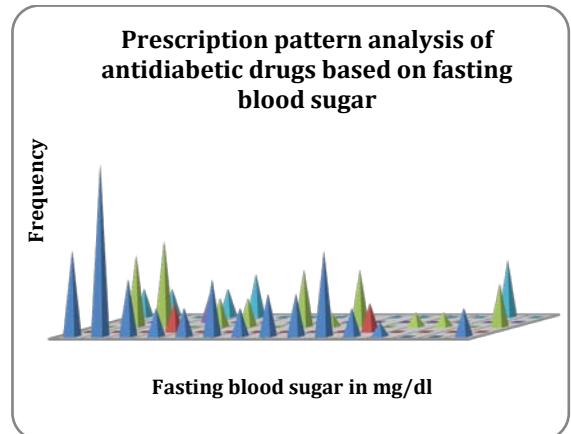


Fig. 11: Analysis of Anti-diabetic drugs based on fasting blood sugar level.

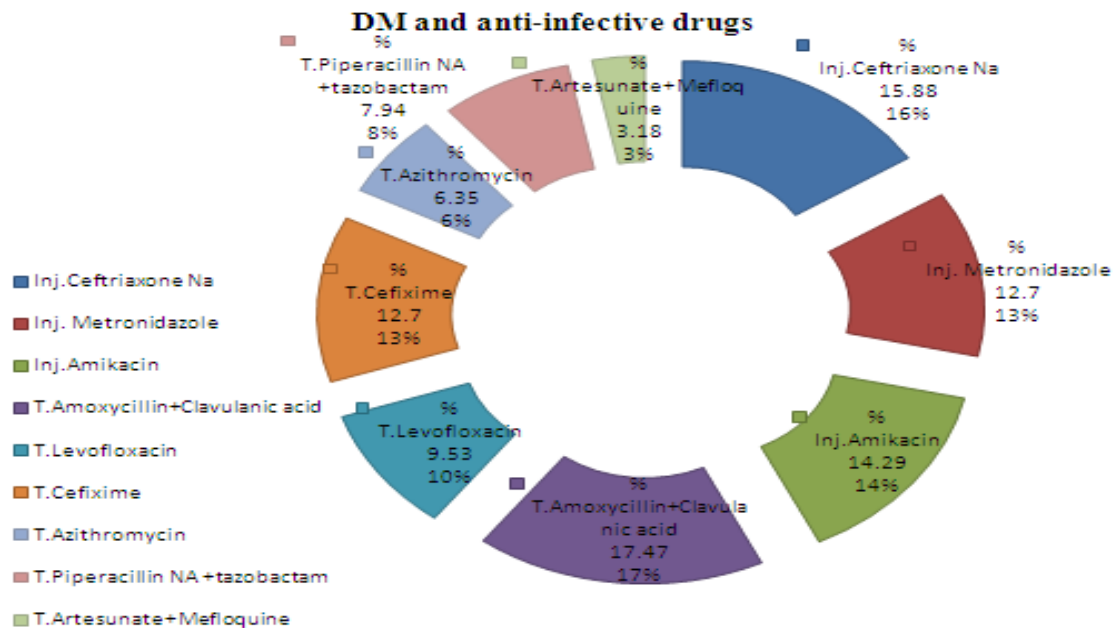


Fig. 12: Diabetes mellitus and anti-infective drugs (N=63)

Prescribing Errors

The following Prescribing errors were found in the study Untreated Hypertension: For 9 subjects who were having their blood pressure greater than 140/90mm of Hg, there was no anti-hypertensive drug prescribed.

Contraindicated drug prescribed: Metoprolol was prescribed for 1 subject suffering from Asthma. Illegible handwriting was observed in the prescription. Wrong route of administration: An Injection Insulin was prescribed for oral route.

Abbreviations

WT	Weight
HT	Height
IBW	Ideal Body Weight
BP	Blood Pressure

Chol	Cholesterol
Cl	Chlorine
Na	Sodium
K	Potassium
Zn	Zinc
DM	Diabetes Mellitus
HTN	Hypertension
HDM	Hypertensive Diabetes Mellitus
NHDM	Non Hypertensive Diabetes Mellitus
ATC	Anatomical, Therapeutical and Chemiacal Classification
Temp/ T	Temperature
GRBS	Glucose random blood sugar
FBS	Fasting blood sugar
PPBS	Post prandial blood sugar
SBP	Systolic blood pressure
DBP	Diastolic blood pressure
ADA	American diabetes association.
DPP	Dipeptidyl peptidase.
GLP	Glucagon like peptide
FDA	Food and Drug Administration
CNS	Central Nervous System
RAAS	Renin Angiotensin Aldosterone system
NSAIDs	Non Steroidal Anti-inflammatory disease.
SNS	Sympathetic Nervous System
VSMC	Vascular Smooth Muscle Cell
CO	Cardiac Output
HR	Heart rate
SVR	Sustained Virologic Response
CHF	Congestive Heart Failure
CV	Cardio Vascular
MI	Myocardial Infarction
CCF	Congestive Cardiac Failure
COPD	Chronic obstructive Pulmonary Disease.
GERD	Gastro-esophageal reflux disease
SIADH	Syndrome of inappropriate secretion of anti-diuretic hormone
Br Asthma	Bronchial Asthma
SSS	Sick sinus syndrome
SEAR	South East Asia region
SLE	Systemic lupus erythematosus
BPH	Benign prostatic hyperplasia.
HDL	High density lipid
LDL	Low density lipid
BMI	Body mass index
JNC	Joint National committee
GDM	Gestational diabetes mellitus
TZN	Thiazolidinedione
TG	Triglycerides
BUN	Blood urea nitrogen
DM	Diabetes Mellitus
ECG	Electro cardiogram
CT	Computer Tomography
ENT	Ear, Nose, Throat
UTI	Urinary tract infection
GIT	Gastrointestinal tract
LVF	Left Ventricular failure
Vit	Vitamins
WHO	World Health Organization
NCDs	Non communicable Diseases
SD	Standard Deviation
CCB	Calcium channel blocker
ACE	Angiotensin Converting Enzyme
I.V	Intra Venous
I.M	Intra muscular
Inj.	Injection
OD	once a day
BID	Twice a Day
TID	Thrice a day
QID	Four times a Day
PO	Per Oral
HS	On bed time
Stat	Immediate
HCTZ	Hydrochlorothiazide
ARB	Angiotensin II receptor blocker
OAs	Oral agents.

CONCLUSION

Hypertension is associated with diabetes largely independent of gender. 50-60 year age group patient have 40% risk to get diabetes. Hypertension is part of the metabolic syndrome, with a prevalence as high as 87.83% in patients who have type 2 diabetes. This study has shown Metformin as the predominantly prescribed oral hypoglycaemic drug in both combination and monotherapy. In the sulfonylureas, Glimperide is the most predominantly prescribed drug. Telmisartan is prescribed for hypertension in majority of the patients.

We have found prescribing errors like untreated indication, prescribing contraindicated drugs and illegible handwriting and route of administration. The adherence to the JNC VII Guidelines was good except in case of diuretics. Lacuna in the present prescribing pattern is underutilization of diuretics. Further studies from time to time are required in drug utilisation pattern and standard treatment guidelines to be circulated among practicing physicians. Our study was done for a short period of time and the number of patients studied was low. Hence, similar studies covering large number of patients are needed to confirm our findings.

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