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A PROSPECTIVE STUDY ON PRESCRIPTION PATTERN OF ANTI-DIABETIC DRUGS IN TYPE2 DIABETES MELLITUS PATIENTS WITH OR WITHOUT COMORBIDITY IN TERTIARY CARE TEACHING HOSPITAL

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ABSTRACT

TYPE 2 DM is a increasing at an alarming rate and has been noticed as one of the leading cause of death and disabilities world wide. Hence this study focused on prescription pattern, quality of life and other comorbidities. To study the pattern and uses of major anti-diabetic class of given for diabetes and comorbities, the current use of Anti-diabetic and their rational use and to assess QOL in Type 2DM. A prospective observational study was carried out for a period of six months in inpatient medicine department of Chigateri district hospital, Davangere (Tertiary care teaching hospital) 157 case reports of patient with type 2 DM were reviewed, the details such as demographics, specified drug prescribed, QOL were recorded. Out of 157 patients, majority of patients diagnosed with type 2 DM were male (64%) the distribution of disease was higher in age group between 45-54 years, HbA1c range in between >7.65% and GRBS range in between 220-300 mg/dl, duration of type 2 DM was more in 1-5years(45.4%), HTN was most observed comorbid condition. Majority of patients received metformin as mono therapy (33.51%), and also combination therapy of various anti-diabetic drugs were prescribed. Average number of anti-diabetic drugs prescribed per prescription was 3, drugs prescribed by generic name accounted for 137 and drugs from essential drug list was 148. The study showed that metformin was predominantly prescribed oral anti-diabetic drug both as mono therapy and combination therapy. HTN was commonly found co-existing condition. Prescribing drug by brand names were high and from essential drug list were low. Number of drugs prescribed per prescription was decreased which is a

welcome sign and need to be encouraged. The information leaflet has significant impact on patients with diabetes and other comorbidities towards the diseases management showing the usefulness of PILS.

KEYWORDS: Type 2 Diabetic mellitus, Hypertension, Quality of life, Glycosylated Haemoglobin, General Random Blood Sugar, Patient Information Leaflet.

INTRODUCTION

Diabetes mellitus(DM) is a group of metabolic disorders characterized by hyperglycemia due to impaired insulin secretion with or without insulin resistance and abnormalities in carbohydrate, fat and protein metabolism.[1]

Type 2 DM is formerly known as non-insulin dependent diabetes mellitus(NIDDM), which is caused by the presence of insulin resistance with an inadequate compensatory increase progressive lower insulin secretion over time.[2] It is more common above the age of 40. Etiology of Type2 DM: Hereditary vulnerability, Fatness and physical sluggishness, Insulin resistance, Irregular Glucose production through the liver etc.[1]

The World Health Organization (WHO) has projected the global prevalence of T2DM will be more than double from 5 Million in 1995 to 300 Million by 2025. Regarding Indian scenario International Diabetes Federation (IDF) stated that 65.1 million of adults in India suffered from Diabetes in 2013. It was predicted that the prevalence of Diabetes in Adult population in India will be 6% by the Year 2025.[3] Therefore, the prevalence of diabetes in India is increasing at an alarming rate, which lead to increased awareness among people about causative factors for diabetes and its consequences.[7]

The treatment method of all physicians differs depending upon the available sources, the hospital set up and the patient related factors such as age, gender, BMI, tolerance, comorbid conditions. Therefore the present study aim to evaluate the prescription pattern of standard anti-diabetic drugs in tertiary teaching care hospitals.[1]

Prescription pattern analysis is defined as insight regarding the existing drug usage to ensure rational drug therapy. Prescription is the one of the most important tools that communicate between physician and patient and also a written order of medication schedule to the patient. Prescription pattern analysis is the assessment of current drug regimen.[2] Studying the Prescription Pattern of Antidiabetitic drugs is of great significance for optimising drug

therapy and drug control therefore the present study aim to evaluate the prescription pattern of standard Anti-diabetic drugs in tertiary teaching care hospitals.[1]

Factors affecting prescription pattern

Patient Related

- Age
- Gender
- Route of Administration
- Severity of Disease
- Experience on rational drug use
- Gaining of medical knowledge.

Drug Related

- Active ingredients
- Evidence of product effectiveness
- Patient characteristics
- Presence of adverse effects for the medication
- Successful self-use of drug
- Availability of drugs in community pharmacies
- Cost of drug for the patient.

Physician Related

- Physicians experience over the years
- Physicians consideration of the customers financial situation
- Patients trust in their physicians.[6]

WHO core prescribing indicators provide a measure of performance of healthcare providers in the area of prescribing practice.[9] It is used to check the rationality of the prescription.[6] Studying the prescribing pattern of antidiabetic drugs is of great significance for optimising drug therapy and drug control. Nowadays there are several classes of antidiabetic medication (ADM's) that are administered either orally or subcutaneously which differ in their mechanism of action and both glycemic and extraglycemic effects.[13]

Comorbidity refers to presence of at least one extra chronic disease for 6 months or longer. Prevalence of hypertension is high in diabetic patient. Hypertension and Diabetes are

interrelated disorders and independent causative factors associated with cardiovascular disease, cerebrovascular accidents, peripheral vascular disease, renal disorders and prevalence of various microvascular complications.[2]

Quality of life (QOL) is a multidimensional element of well being affected by physical, mental, emotional and social status of patients. It is increasingly used to access the health status of general public and patients as well as the impact of health care interventions. Patient with DM has significant impairement of all aspects of QOL due to its progressive nature and risk of developing complications. The subjects develop DM in the most productive years of their life, because of their lifestyle modification, increase in stress rates and various physical changes in the body.[2]

Optimal glycemic control still is the best strategy to manage the diabetes disorder: The currently antidiabetic drugs are effective, but a lot of factors such as patient adherence, education related to diabetes, lifestyle modification and type of medication has an association with glycemic control. Optimal glycemic control will delay or prevent the progression of diabetic complication and improve the patient Quality of life.[15]

MATERIAL AND METHODS

STUDY SITE: The study was conducted in the inpatients department General Medicine at Chigateri District Hospital, Davangere (A tertiary care teaching hospital) over a duration of 6 months.

STUDY DESIGN: It is a Prospective Observational Study.

SAMPLE SIZE: The study was conducted over 157 inpatients of General Medicine Department of the hospital.

STUDY CRITERIA: Study was carried out by considering the following inclusion and exclusion criteria.

INCLUSION CRITERIA

- Patients of both gender with age group of 25 and above years
- Patients with Diabetes along with other comorbidities are selected.

EXCLUSION CRITERIA

- Poisoning cases were excluded from study
- Pediatric patients were excluded from study

- Patient with Gestational Diabetes are also excluded from the study
- Patients with missing and insufficient data.

STUDY PROCEDURE

A prospective observational study was conducted in the Inpatients in medical ward on Type 2 Diabetes Mellitus patients in Chigateri General Hospital, Davangere. The patient detail was obtained along with comorbidities, current medication, relevant previous medical and medication histories. The data collected was recorded using specifically designed data collection format by reviewing patient medication charts. Demographic details, dose, route and frequency both during admission and discharge, information regarding the patients habit was recorded properly in designed data collection form and provided with patient information leaflet for improving quality of life.

RESULTS

1. GENDER WISE DISTRIBUTION

Out of 157 patients evaluated with Type 2 DM, majority were found to be Males (N=96,64%) when compared to Females (N= 61,38.8%).

Sl.No	Gender	No. Patient(%) (N=157)
1	Male	96 (64%)
2	Female	61(36%)

2. AGE-WISE DISTRIBUTION

Out of 157 patients, the distribution of disease tends to be higher in age group between 45- 54 years (N=46, 29.2%) and lower distribution is observed in the age group 25-34 years (N=4,2.5%)

Sl.No	Age in years	No. patients (%) (N=157)
1	25-34	4(2.5%)
2	35-44	12(7.6%)
3	45-54	46(29.2%)
4	55-64	37(24%)
5	65-74	41(27.2%)
6	>75	14(9.5%)

3. FAMILY HISTORY OF DIABETES MELLITUS PATIENTS

Out of 157 patients, (N=47,29.9%) have a family history of Type 2 DM whereas (N=98,62.4%) patients did not have a family history of Type 2 DM.

Estimation on family history of diabetes mellitus

Sl.No	Family history of diabetes mellitus	Number of patients(%) (N=157)
1	Present	53(33.7%)
2	Absent	104(66.3%)

4. BODY MASS INDEX DISTRIBUTION IN TYPE2 DM PATIENTS

Out of 157 patients, majority (N=67,42.6%) were found to be overweight and minority (N=3,1.97%) were found to be underweight.

Study of body mass index on Type 2 diabetes mellitus patients

Sl.No	Body mass index	Number of patients (%) (N=157)
1	Underweight	3 (1.97%)
2	Normal	25 (15.9%)
3	Overweight	67 (42.6%)
4	Obese	62 (39.6%)

5. SOCIAL HISTORY OF TYPE2 DIABETES MELLITUS PATIENTS

Out of 157 patients, majority (N=67, 42.6%) were found to be smokers and minority (N=25,15.9%) were found to be tobacco chewers.

Study of social history in Type2 Diabetes Mellitus patients

Sl.No	Social history	Number of patients (%) (N=157)
1	Alcoholic	65 (41.4%)
2	Tobacco chewing	25 (15.9%)
3	Smokers	67 (42.7%)

6. HbA1c WISE DISTRIBUTION

Out of 157 patients, majority of the patients had HbA1C range Fair control 6.8-7.6(N=108,68.7%) and minority of patients had Good Control in between 6-6.7 (N=13,18.2%).

Assessment of HbA1c levels

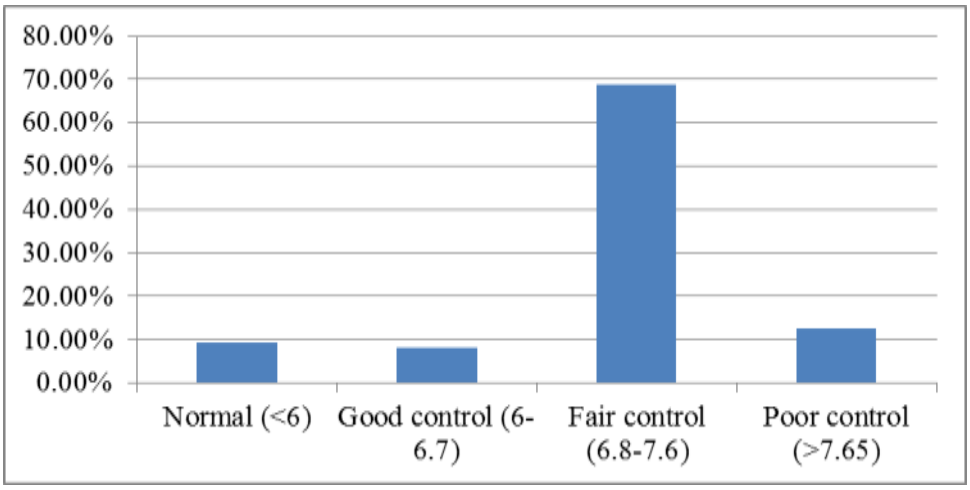

Illustration of HbA1c levels

7. GRBS WISE DISTRIBUTION

Out of 157 patients, majority of patients had GRBS range as diabetic which is in between 190-230 (N=116,73.8%) and minority had Normal 170-200 (N=19,12.1%).

Assessment of GRBS Range

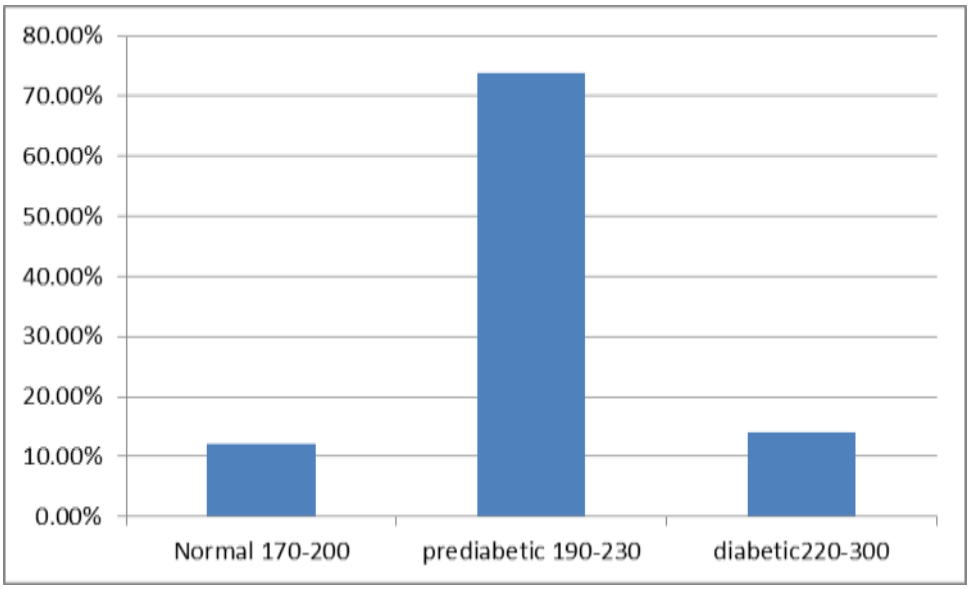

Illustration of GRBS Range

8. DURATION OF TYPE 2 DM

Out of 157 patient, duration of type 2 DM was found more in 1-5years(N=59,45.4%), followed by 6-10 years (N=38,29.2%), 11-15 years(N=17,13.0%), <1 year (N=13,10%),16-20 years (N=3,2.30%)

DURATION OF TYPE 2 DM

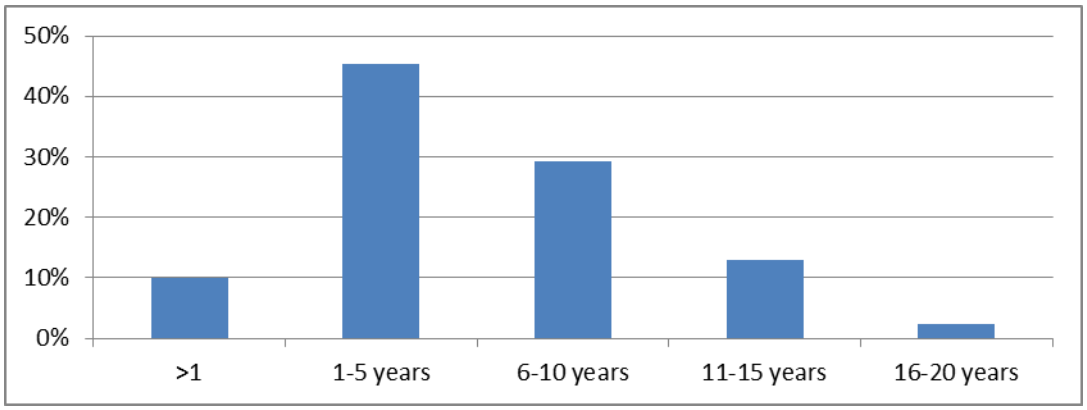

Illustration of duration of type 2 DM

COMORBIDITIES

(A) MONO COMORBIDITIES

Out of 157 Type 2 DM patients, N=29(43.9%) patients have HTN followed by N=17(25.76%) patients have pulmonary diseases. N=11(16.69%) patients have CVD, N=5(7.57%) patients have GI, N=4 (6.07%) patients have CKD.

MONOCOMORBIDITIES

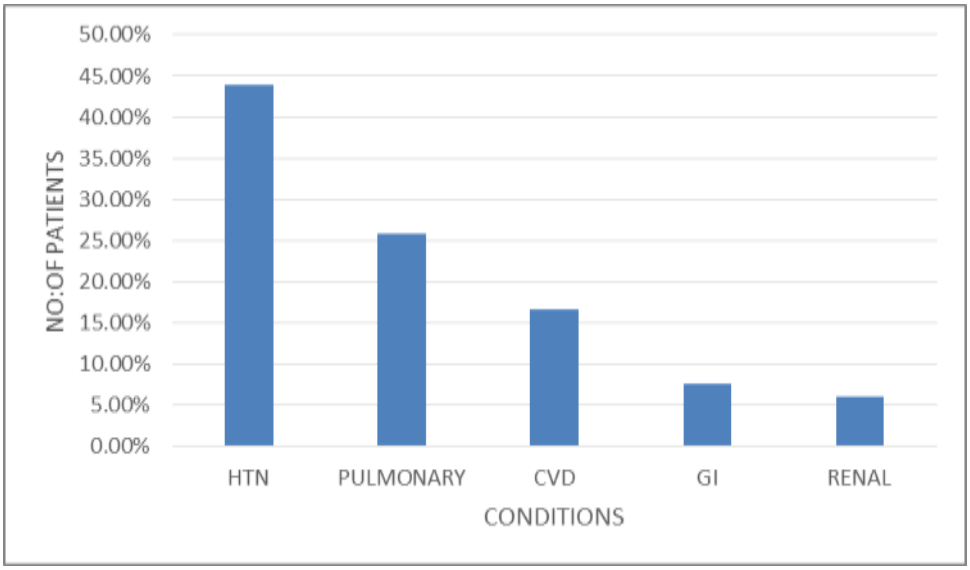

Illustration of monocomorbidities

(B) DUAL COMORBIDITIES

Out of 157 patients the most commonly observed dual comorbid condition were HTN +CVD(N=9, 25%).

DUAL COMORBIDITIES

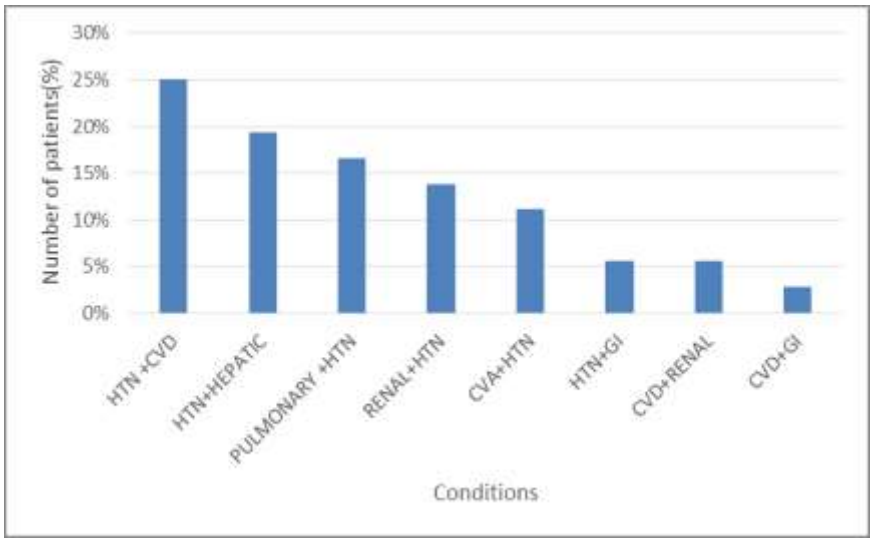

Illustration of dual comorbidities

(C)TRIPLE COMORBIDITIES

Out of 157 Type 2 DM patients the most commonly observed triple co morbid condition was HTN+CVD+RENAL (N=2,28.5%) and CVD+RENAL+PULMONARY (N=2,28.5%)

TRIPLE COMORBIDITIES

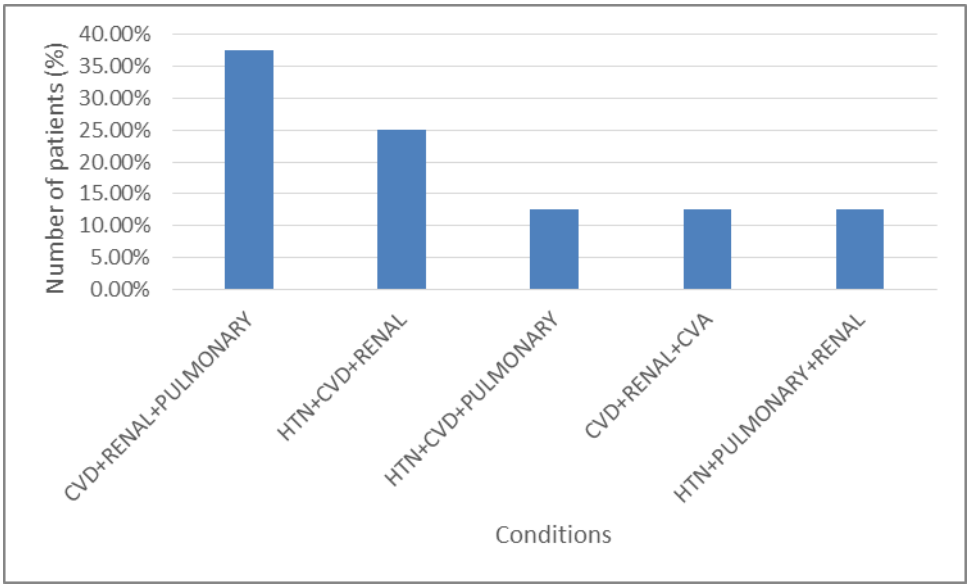

Illustration of triple comorbidities

DRUGS USED IN COMORBID CONDITION

Out of 157 patients, most commonly prescribed drugs are Antihypertensive(N=176,44.22%) followed by Antiplatelets (N=70,17.58%), Miscellaneous agents (N=68,17.08%), Multivitamins (N=60,15.07%) and Statins (N=19,4.77%).

DRUGS USED IN COMORBID CONDITION

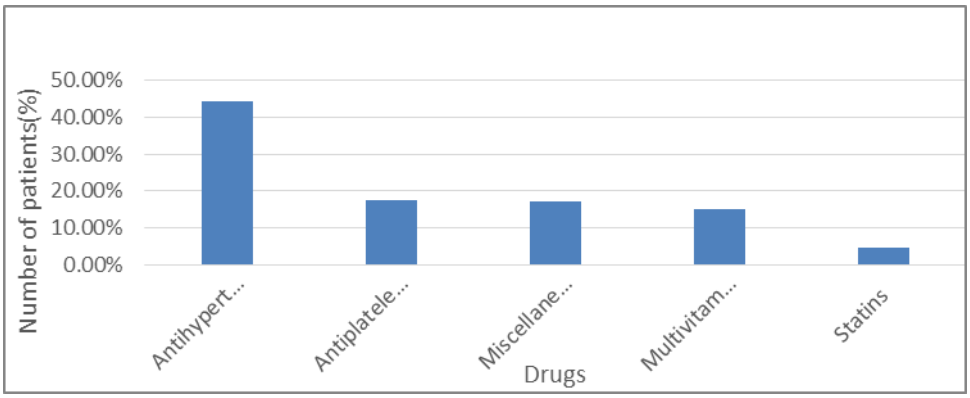

Illustration of drugs in comorbid condition

(A) MONOTHERAPY

Out of 157 patients with type 2 DM, most commonly prescribed Oral Hypoglycemic drug is Metformin(N=122,33.51%).

MONOTHERAPY

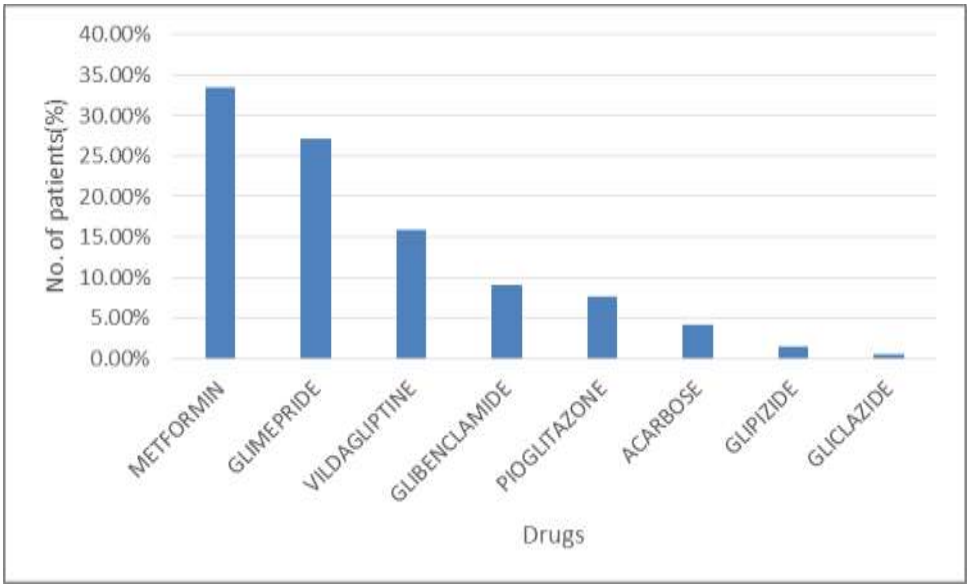

Illustration of monotherapy

(B) DUAL THERAPY

Out of 157 patients with type 2 DM, received Metformin +Glimepride as a dual therapy (N=19, 86.).

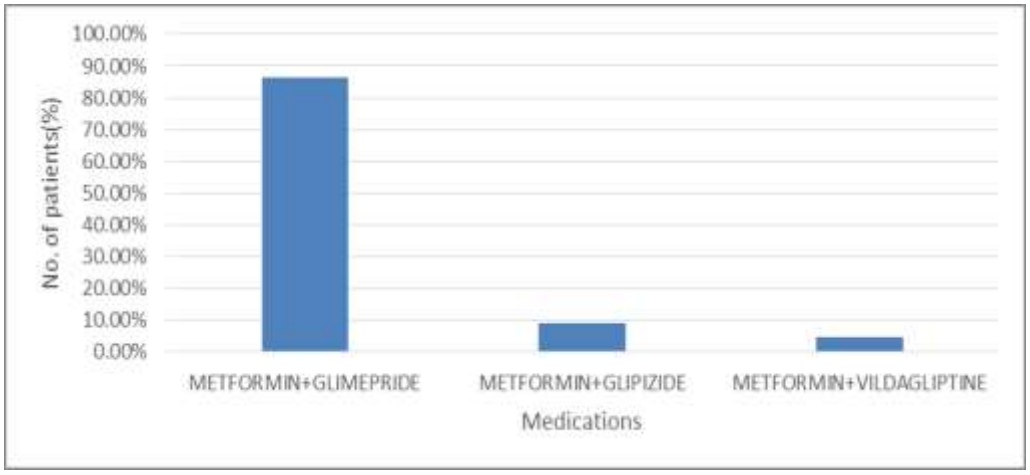

Illustration of dual therapy

(C) COMBINATION THERAPY

Out of 157 patients with type 2 DM, most commonly prescribed combination drugs were Metformin+glimepride+voglibose(N=44,56.41%).

COMBINATION THERAPY

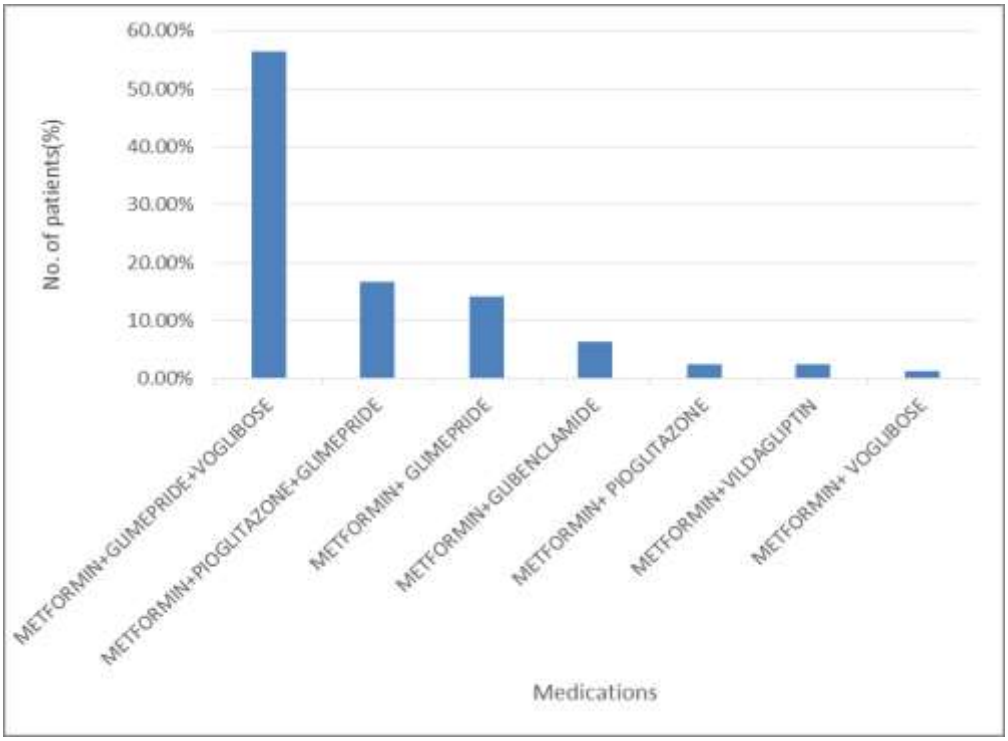

Illustration of combination therapy

(D) INSULIN THERAPY

Out of 157 patients with type 2 DM, most commonly prescribed insulin was Inj H. Actrapid (N=120,82.7%) and least prescribed was Inj. Aspart (N=1,0.68%).

INSULIN THERAPY

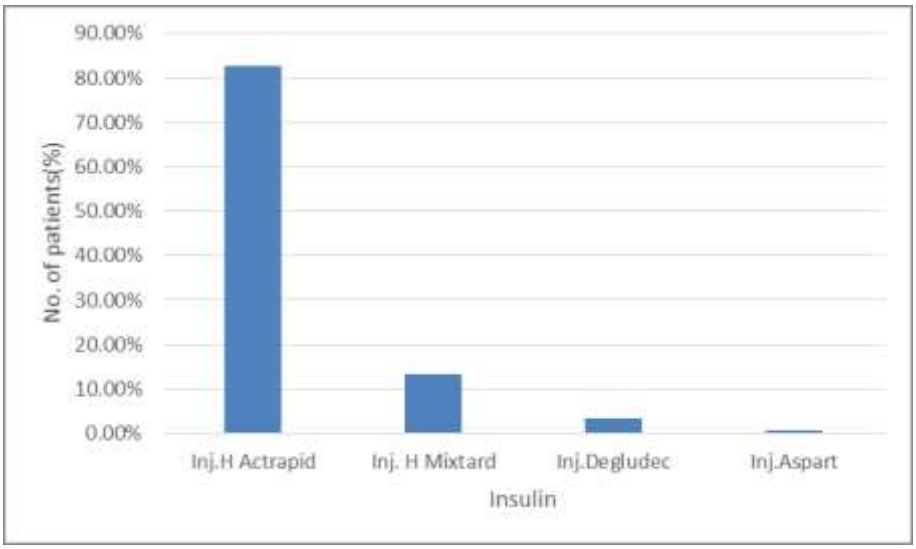

Illustration of insulin therapy

WHO Prescribing Indicators

Prescription Indicators

Sl.No	Prescription Indicators	Frequency
1	Total number of drugs prescribed	464
2	Average number of drugs prescribed per prescription	3
3	Number of prescription with monotherapy	364
4	Number of prescription with polytherapy	22
5	Number of drugs prescribed from the WHO essential drug list	148
6	Number of drugs prescribed by generic name	137
7	Number of prescriptions with parenteral preparation	145
8	Number of prescriptions with oral preparation	464

DISCUSSION

The purpose of this prospective observational study involving 157 patients with Type 2 DM over the course of 6 months in the patient General medicine Department, was to evaluate the Prescription pattiern of antidiabetic drug, co morbidities, quality of life(QOL) in Type 2 patients. In this study out of 157 patients enrolled, The proportion of male with Type 2 DM was significantly higher (N=96,64%) compared to female(N=61,36%) and the majority of Patient had history of Diabetes between 1-5 years(N=59, 45.4%) which is accordance with study conducted at Medical college, Kolkata by Alak K Das et al.[3] The result of present study with 157 diabetes patients, the majority of patient belong to the age group 45-54 years (N=46,29.2%), the BMI values were majoritively (N=67,42.6%) overweight and the study also revealed that they were mostly smokers(N=67,42.7%) this was in accordance with the study conducted at Tertiary Care Hospital in Uttarakhand by Kalpana Tiwari et al.[10] Among 157 patients (N= 104,66.3%) patients does not have a Family History of Type 2 DM, we also

evaluate that HTN was most common co-existing condition (N=29,43.9%). It was similar to the study conducted at Border Guard Hospital, Pikhana, a tertiary level Hospital in Dhaka by Nezrina S et al[11] and also we observed that patients with two or more conditions were found to be less. This trend is similar to that found in another report of the study conducted by Khalidi M et al.[14]

Out of the 157 cases reviewed, majority of the population had a HbA1c range between 6.8-7.6(N=108,68.9%) this was in agreement with study conducted at Aster CMI Hospital, Bangalore by Sonam Dolma et al.[6] and GRBS was most commonly found to be Pre-diabetic 190-230 (N=116,73.9%). this was also similar to the study conducted on East West college of Pharmacy, Bangalore by Nimisha Augustine et al.[11] We assessed that out of 157 patients with Type 2 DM, (N=364) received monotherapy, (N=22) received dual therapy as suggested by the result of the study conducted at RVM Hospital by Dr Mariyam et al.[1] The most commonly prescribed Combination therapy was Metformin+ Glimepride + Voglibose (N=44,56.41%) which is in agreement with study conducted at JSS Medical College and Hospital, Mysore by Pushpa V H et al.[8] In our study conducted among 157 Type 2 DM patients, Inj H. Actrapid (N= 120, 82.7%) were commonly prescribed Insulin Therapy which is in concordance with the result of the study conducted at MGM Medical College and Hospital, Maharashtra by Akshay A Agarwal et al.

In this study, we have Analyzed 157 prescriptions in which total number Antidiabetic Prescribed was 464, Average number of Antidiabetic drugs prescribed per prescriptions was 3 and drug prescribed by Generic name accounted for 137 and drugs from WHO Essential drug list were 148. Our study showed that 90% of patients received Oral Hypoglycemic medications and 30% of patients received Injections according to the Study conducted at JSS Medical College and Hospital, Mysore by Pushpa V H et al.[8]

CONCLUSION

Though, Diabetes Mellitus is a manageable disease yet it is high prevalent around the world. We carried out prospective study in a tertiary care Teaching Hospital to Assess the prescription pattern, quality of life, comorbidities in Type 2 diabetes patients. The present study diabetes was compared to females. Distribution of diseases tends to be higher in age group between 45-54 years and majority are suffering from Hypertension as a comorbid condition. Here the majority of patients were managed with insulin monotherapy as well as current prescribing trends on Anti Diabetic drug strategy to attain an optimal glycemic

control. Combination therapy of various oral Anti Diabetic drug (OAD) were prescribed for proper glycemic control in severe glycemic levels.

Prescribing drugs by essential drug list were low. Hence drugs from essential drug list have to be encouraged. Number of drugs prescribed per prescription was decreased which was a welcome sign and need to be encouraged. The information leaflet minimum readability met the patient education and comprehension. It was also observed that by providing, patient education with information leaflets. It had a significant impact on patients with diabetes and other comorbidities towards the diseases management showing the usefulness of Patient Information Leaflet(PIL).

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AUTHORS CONTRIBUTION

All the authors have contributed equally.

CONFLICT OF INTEREST

All authors declare that there are no conflict of interest.

ETHICS DECLARATION

The Instititutional Ethics Committee at SCS College of Pharmacy approved the protocol. All residents provided informed consent.

CONSENT FOR PUBLICATION

All authors have consent to the publication of their work.

COMPETING INTERESTS

The authors declares that they have no competin interests.

AUTHORS FUNDING

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