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A STUDY ON PRESCRIBING PATTERN AND IMPLEMENTATION OF CLINICAL PHARMACY SERVICES IN PATIENTS WITH TYPE-2 DIABETES MELLITUS AND ITS COMPLICATIONS IN A TERTIARY CARE HOSPITAL, BANGALORE

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ABSTRACT

Objective: To conduct a study on prescription pattern and implementation of clinical pharmacy services in patients with Type2 Diabetes Mellitus and its complications. **Methods:** Prospective, observational studies were done in 150 patients with type-2 diabetes mellitus with complication were identified and enrolled for this study. Patient's demographic details, clinical data, drug prescriptions were collected and documented in a suitably designed case report form. **Conclusion:** The study has shown that in patients with type-2 DM with complications, insulin therapy was preferred over OHAs. INSULIN REGULAR was the first choice of insulin therapy and METFORMIN was the most prescribed OHAs. We also believe that patient education regarding lifestyle modification and diabetes is strongly advised to achieve the maximum control of glycemic levels in patients. **Result:** maximum number of patients were in the age groups of 40-49 yrs (34.67%) and 50-59 yrs (26.66%). 8% and 42% were suffering from microvascular and macrovascular complications respectively. 50% of patients had both micro and macro complications. Most of the patients needed insulin therapy (59.18%) to control their glucose levels. INSULIN REGULAR and HUMAN MIXTARD were most commonly prescribed insulins, whereas in OHAs METFORMIN followed by GLIMEPRIDE. The clinical services provided were: Identified drug interactions 39.33%, Adverse reactions (1.33%), Medication errors (9.33%), patient counsellings (50%).

KEYWORDS: Prevalence, complications,OHA'S.

INTRODUCTION

Diabetes mellitus (DM) is a chronic illness along with disturbance of carbohydrate, protein, and fat metabolism due to defects in insulin secretion and/or insulin response that requires life-long medical care and ongoing patient self-management and support to prevent acute complications and to reduce the risk of morbidity and mortality.

The level of morbidity and mortality because of diabetes and its possible micro-vascular or macro-vascular complications are tremendous and lead to considerable health care issues on both families and society. Optimal glycemic control will delay or prevent the progression of diabetes complication and improve the patient quality of life.

It is estimated that 366 million people had DM in 2011 and by 2030 it will risen to 552 million where number of people with type 2 DM is increasing in every country. DM caused 4.6 million death in 2011 and estimated that 439 million people would have type2 DM by the year 2030.[2]

Type 2 DM is a metabolic disorder which is characterized by high blood glucose in the context of insulin resistance and relative insulin deficiency and it also known as non-insulin dependent diabetes mellitus (NIDDM). Diabetes is often initially managed by increasing exercise and modifying diet.

NEED FOR STUDY

Oral medication for patients with Type-2 diabetes mellitus plays an important role in diabetes care and is associated with high level self-care behavior and self-management. However, poor adherence to diabetes treatment is common which causes severe health complications and increased mortality.

It is a major public health and health service challenge worldwide with global prevalence estimated to increase from 2.8% in 2000 to 4.4% in 2030, an increase from 171 million people to 366 million people in 30 years. The most recent Global Burden of Disease study estimates the diabetes is the seventh leading cause of years lived with disability worldwide. Diabetes is associated with reduced quality of life and life expectancy.

In India, the prevalence of diabetes among adults has reached approximately 20% in urban and approximately 10% in rural populations.

People with DM who wish to live normal life need to know a lot about their illness. Thus, awareness on DM and its complication has become an integral and essential part of DM care for both health professionals and the patients themselves. Consequently, educational efforts to improve self-management are central components of any effective treatment plan. There is increasing amount of evidence that patient adherence is the most effective way to lessen the complications of diabetes and its management.

OBJECTIVE

Primary Objective

To conduct a prospective and cross-sectional study on prescription pattern and implementation of clinical pharmacy services in patients with Type2 Diabetes Mellitus and its complications.

Secondary Objective

To evaluate rational use of anti-hypoglycemic drugs by analyzing the appropriateness of prescription with special reference to:

- Selection of anti-hypoglycaemic drugs in various clinical conditions
- Concomitant drugs used
- Dosage
- Route of administration

4. METHODOLOGY

4.1 Duration of Study

The study was conducted for a period of 6months.

4.2 Site of the Study

Study was conducted at tertiary care hospital. It is 300-bedded tertiary hospital having different specialties like medicine, surgery, orthopedics, pediatrics, obstetrics and gynecology.

4.3 Study Design

A hospital based prospective study.

4.4 Size of Study

Study was conducted in 150 patients.

4.5 Sources of Data and Materials

- Patient case sheet
- Medication/treatment chart
- Suitable design documentation form
- Laboratory data report

4.6 Study Criteria

Inclusion criteria

All the inpatient and outpatient in hospital who are treated for Diabetes mellitus in Tertiary care hospital.

Exclusion criteria

- Psychiatric patient
- Children
- Pregnancy

4.7 Study Procedure

Eligible patients were enrolled based on inclusion and exclusion criteria. Structured data collection was used for collecting the details. This form mainly contains demographic details, social habits, current medication, past medical and medication history, laboratory investigations, and other relevant data needed for present study were collected from patient's progress records, treatment chart, and laboratory reports. The data collected are subjected for various drug-drug interaction and ADR by using, primary Micromedex, 1mg, drugs.com, drug bank secondary and tertiary resources which are available in clinical pharmacy department.

RESULT AND INTERPRETATION

We had done analysis in 150 cases in tertiary care hospital in that

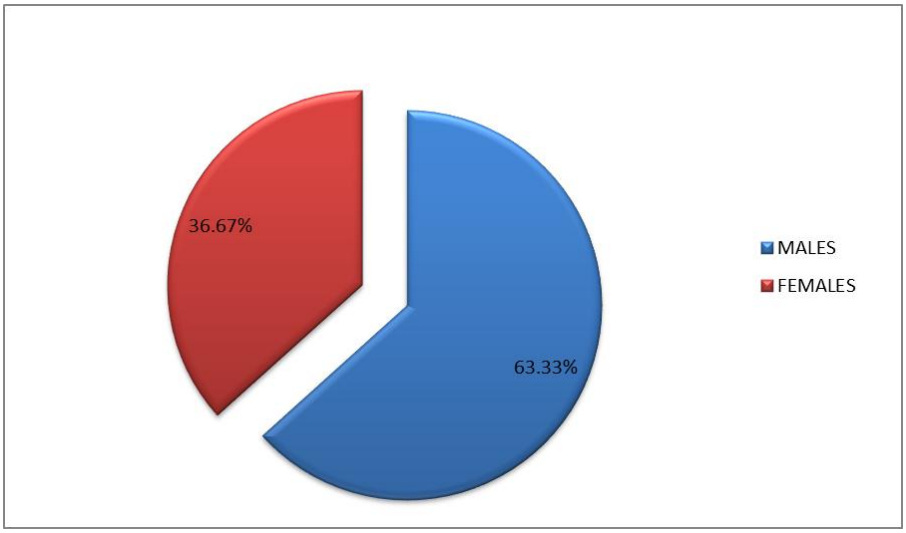

Figure 1: Male and female patients.

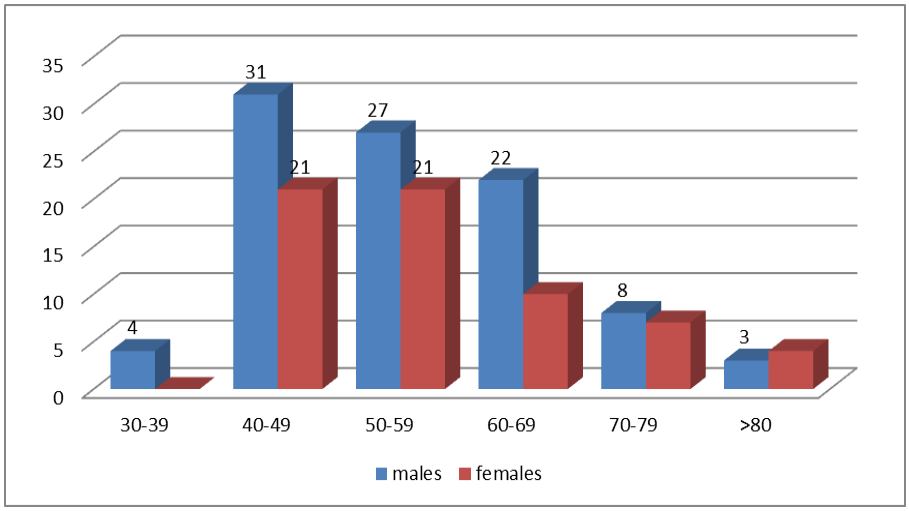

Figure 2: Age wise distribution of patients.

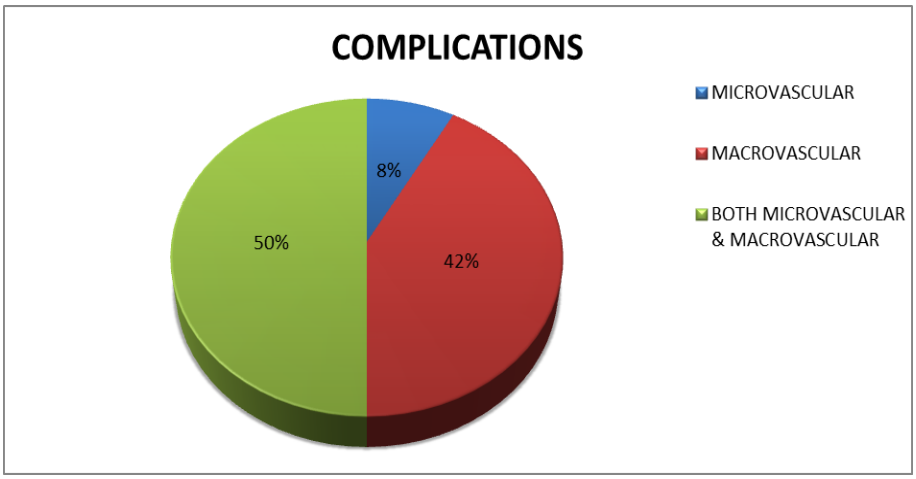

Figure 3: Graphical representation of frequency of complications in diabetes mellitus.

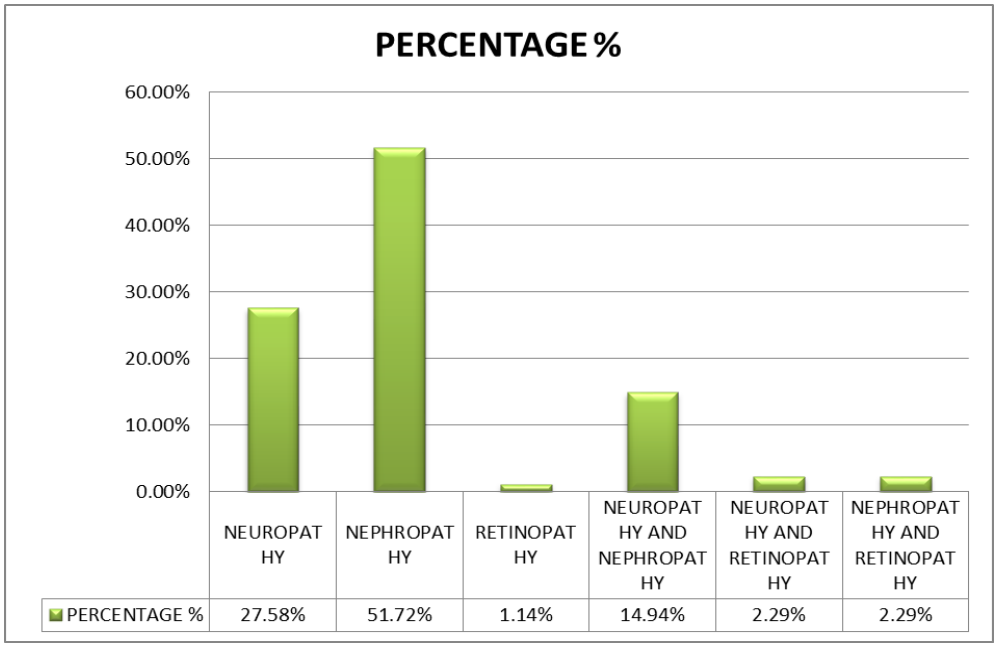

Figure 4: Graphical representation of frequency of microvascular complications.

Table 5: Frequency of macrovascular complications.

MACROVASCULAR COMPLICATIONS	NO. OF PRESCRIPTIONS	PERCENTAGE
HTN ONLY	73	52.89%
HTN +ANGINA	6	4.34%
HTN + IHD	11	7.97%
HTN + PVD	3	2.17%
HTN + CAD	8	5.79%
HTN + DYSLIPIDEMIA	2	1.44%
HTN + LV DYSFUNCTION	2	1.44%
HTN + CVA	1	0.72%
HTN + ANGINA + IHD	6	4.34%
HTN + MI + IHD	1	0.72%
HTN + PVD + IHD	2	1.44%
HTN + PVD + DYSLIPIDEMIA	1	0.72%
HTN + LV DYSFUCTION + IHD	3	2.17%
HTN + CAD + IHD	1	0.72%
HTN + IHD + PVD + CAD	1	0.72%
HTN + CAD + LV DYSFUNCTION + DYSLIPIDEMIA	1	0.72%
CAD	3	2.17%
CAD + ANGINA	1	0.72%
CAD + IHD + MI	1	0.72%
IHD	5	3.64%
IHD + LV DYSFUNCTION	4	2.89%
ANGINA	1	0.72%
PVD	1	0.72%
TOTAL NUMBER OF PRESCRIPTIONS	138	99.89%

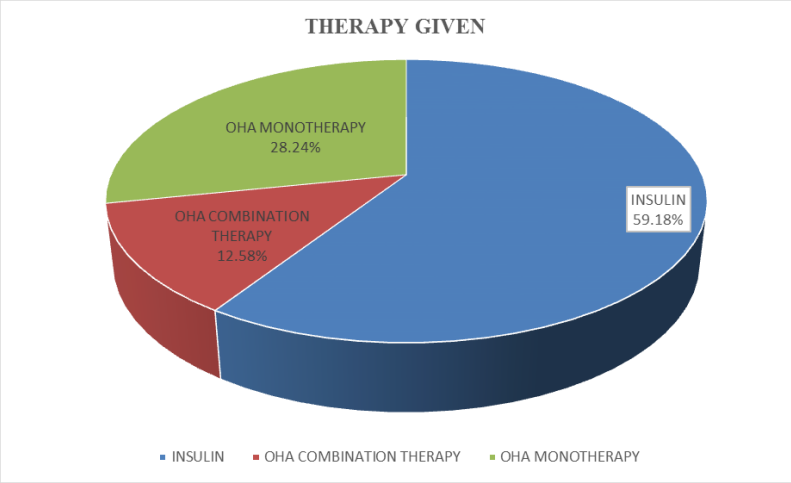

Figure 6: Graphical representation of drug therapy given in the subjects.

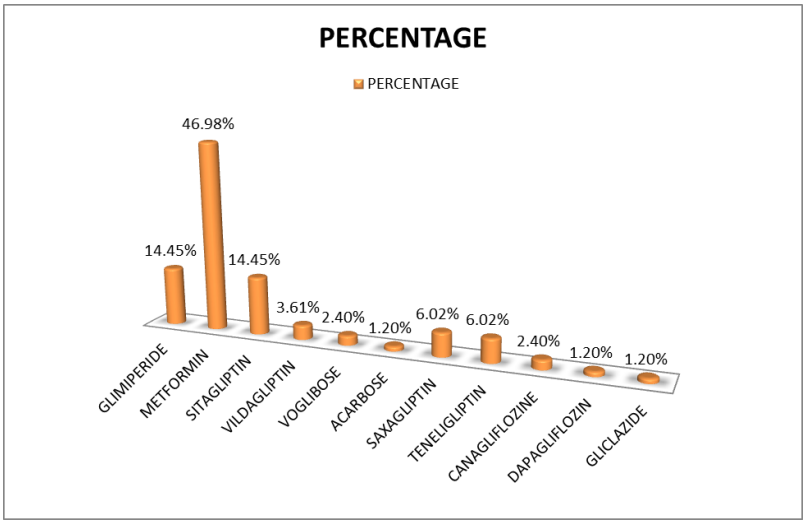

Figure 7: Graphical representation of mono therapy of oral hypoglycaemic agents (oha).

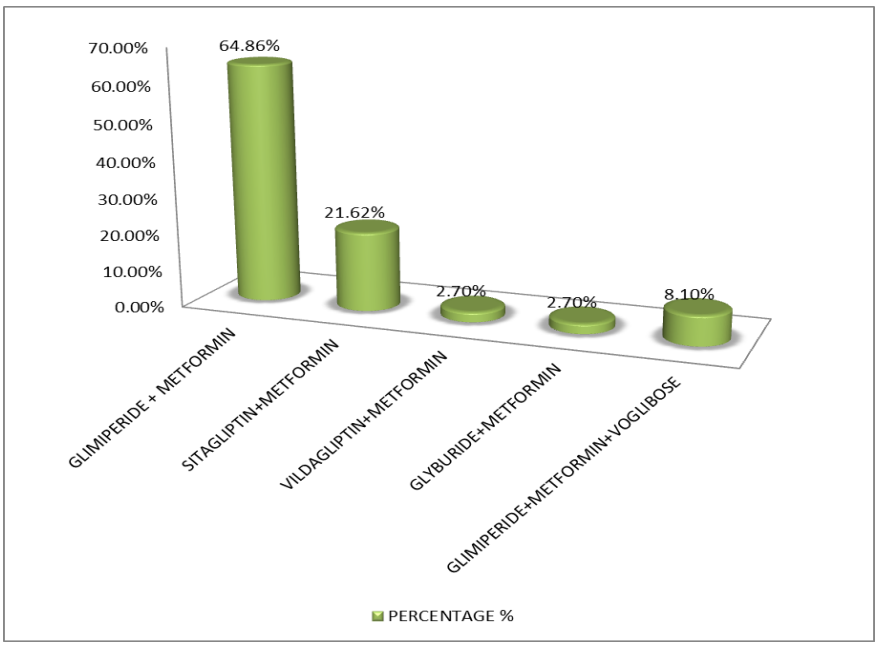

Figure 8: Graphical representation of combination therapy OHA.

Table 9: Insulin therapy given in the subjects.

INSULIN	FREQUENCY (NO. OF PRESCRIPTION)	PERCENTAGE
INSULIN REGULAR	73	41.95%
HUMAN MIXTARD	51	29.31%
INSULIN GLARGINE	19	10.91%
INSULIN ASPART	16	09.19%
INSULIN GLULISINE	2	01.14%
INSULIN DETERAIR	1	0.57%
INSULIN ASPART + INSULIN ASPART PROTAMINE	9	05.17%
INSULIN LISPRO + INSULIN LISPRO PROTAMINE	3	01.72%
Total number of prescription = 174		99.99%

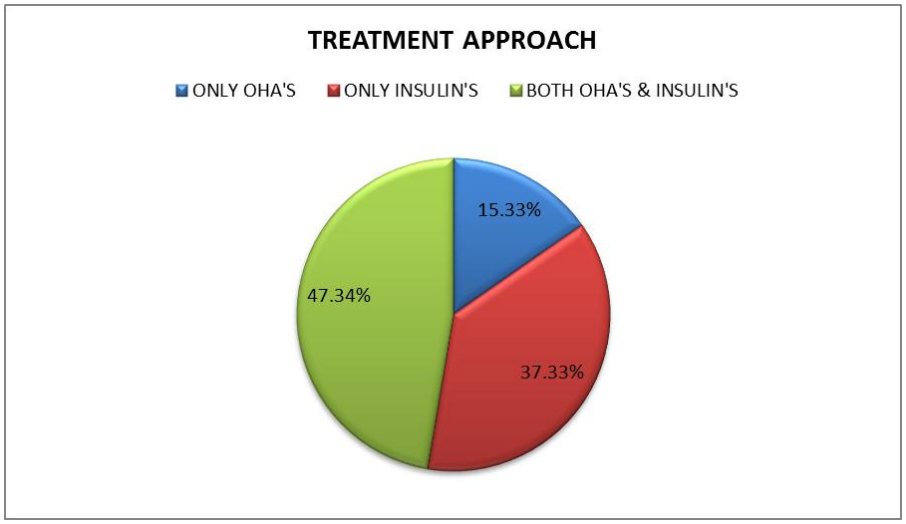

Figure 10: Graphical representation of treatment approach of hypoglycemic agents.

Clinical Pharmacy Services

Drug Interactions

Table 11: 24 Major drug interactions found in 150 prescriptions.

DRUGS	INTERACTING DRUGS	EFFECTS	NO. OF PATIENTS	PERCENTAGE (%)
GLIMEPRIDE	ASPIRIN	Increased risk of hypoglycaemia	07	29.16%
METFORMIN	ASPIRIN	Pharmacodynamic synergism	10	41.66%
INSULIN ASPART	ALCOHOL	Impaired glucose regulation	02	08.33%
INSULIN ASPART	LEVOFLOXACIN	Increased risk of hypoglycaemia or hyperglycaemia	03	12.5%
GLIMEPRIDE	LEVOFLOXACIN	Increased risk of hypoglycaemia or hyperglycaemia	01	4.16%
METFORMIN	LEVOFLOXACIN	Increased risk of hypoglycaemia or hyperglycaemia	01	4.16%
Total			24	99.97%

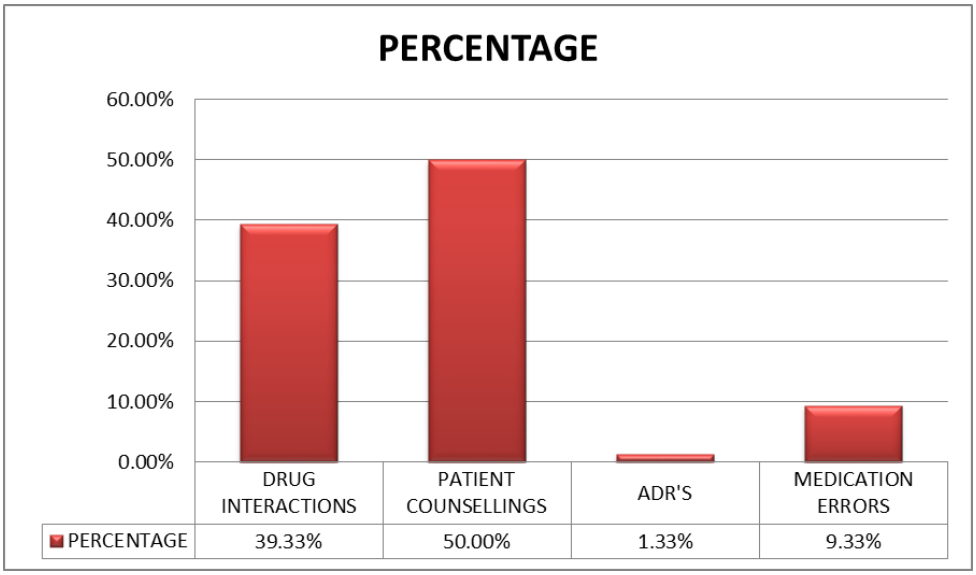

Figure 12: Graphical representation of clinical pharmacy services.

DISCUSSION

Diabetes mellitus (DM) is a chronic illness along with disturbance of carbohydrate, protein, and fat metabolism due to defects in insulin secretion and/or insulin response that requires life-long medical care and ongoing patient self-management and support to prevent acute complications and to reduce the risk of morbidity and mortality. It is a major public health and health service challenge worldwide with global prevalence estimated to increase from 2.8% in 2000 to 4.4% in 2030, an increase from 171 million people to 366 million people in 30 years. The most recent Global Burden of Disease study estimates the diabetes is the seventh leading cause of years lived with disability worldwide. Diabetes is associated with reduced quality of life and life expectancy.

In this study, an attempt has been made to evaluate the prescribing attitude of a physician along with the implimentation of clinical pharmacy services on patients with type-2 DM with complications in the hospital.The present study was based on ADA guidelines.The study procedure used here includes prospective and cross-sectional studies using the data collection forms and hospital information system.The analysis of the prescribing pattern of a physician promotes the rational use of drugs, also increases the efficacy of treatment.This also increases the safety of patients by promoting the decrease in morbidity and mortility rates in patients.

A total of 150 subjects were included in this study,our study suggests that out of 150 patients who were treated with the anti-diabetic drugs all of the subjects were having type-2 DM with complications in which male patients (63.33%) has more prevalence rate than female patients (36.67%).Our results provide a direct evidence of an increasing burden of type-2 DM with

complications especially among the middle aged population. Prevalance of type-2 DM with complications is mostly seen with in the age groups of 40-49 yrs (34.67%) and 50-59 yrs (26.66%).

Our study shows that 4% of the patients were obese who are leading an unhealthy lifestyle who have a major chance to be prone to diabetes at an young age along with the 10% of patients who were smokers and 13.33% were alcoholic, these results indicates the risk factors of type-2 DM with complications. Out of 150 subjects, only 8% were suffering from microvascular complications which are only seen in patients with type-2 DM,a majority of 42% were having macrovascular complications which are also seen in patients with cardiac disorders and 50% of patients had both micro and macrovascular complications.In microvascular complications nephropathy (51.79%) was most commonly seen and in macrovascular complications (52.7%) of hypertension cases were seen.

During our study period we have assisted with the clinical pharmacy services provided to the patient. The services provided were: Identifying the Drug interactions and reporting them, Adverse drug reactions, Medication errors, Counselling the patients. Some drug interactions found in the prescriptions were: GLIMEPRIDE+ASPIRIN(29.16%), METFORMIN+ASPIRIN(41.66%), METFORMIN+METOPROLOL (17.14%), INSULIN ASPART+METFORMIN (14.28%). Adverse reactions found were 1.33%, Medication errors found and rectified were 9.33%. Total patient counsellings done were to 75 subjects.

Our study suggests that most of the patients needed insulin therapy (59.18%) to control their blood glucose levels. This suggests that insulin therapy was more commonly used than that of the OHAs.This suggests that subcutaneous route were the most desired routes of administration of drugs than oral route.This study on prescribing pattern suggests that insulin therapy along with OHAs is the choice of most physicians in the treatment of type-2 DM. INSULIN REGULAR and HUMAN MIXTARD were the most commonly prescribed insulins, whereas in OHAs biguanides(METFORMIN) were the first choice followed by sulfonylureas (GLIMEPRIDE).The use of combination therapy is to achieve better glycemic control.

In monotherapy of insulin, INSULIN REGULAR(41.95%), HUMAN MIXTARD(29.31%), INSULIN GLARGINE(10.91%), INSULIN ASPART(9.19%), INSULIN GLULISINE(1.14%), INSULIN DETEMIR(0.57%) were the major choice. In combination

therapy, INSULIN ASPART+INSULIN ASPART PROTAMINE(5.17%), INSULIN LISPRO+INSULIN LISPRO PROTAMINE (1.72%) were the most common choice.

In monotherapy of OHAs, METFORMIN (46.98%), GLIMEPIRIDE (14.45%), SITAGLIPTIN (14.45%), SITAGLIPTIN (14.45%), VILDAGLIPTIN(3.61%), VOGLIBOSE (2.40%), ACARBOSE (1.20%), SAXAGLIPTIN (6.02%), TENELIGLIPTIN (6.02%), CANAGLIFLOZIN (2.40%) DAPAGLIFLOZIN (1.20%),GLICLAZIDE (1.20%) were most commonly prescribed. In fixed combination therapy of OHAs, METFORMIN + GLIMEPIRIDE (64.86%) were most commonly prescribed, SITAGLIPTIN + METFORMIN (21.62%), VIDAGLIPTIN + METFORMIN (2.70%), GLYBURIDE + METFORMIN (2.70%) were commonly prescribed. In triple therapy GLIMEPIRIDE + METFORMIN + VOGLIBOSE (8.10%) was mostly used.

In the analysis of the prescribing pattern, we found out that the drugs were prescribed based on the brand name instead of the generic name.This suggests the influence of pharmaceutical companies and the popularity of brands in the market.This study also suggests that in some hospitals still insulin based therapy is still dominant over the OHAs.

This study also suggests that monotherapy of insulin or OHAs was the most successful therapy and also shows success levels in the control of glycemic levels in the subjects. This also makes a strong point that insulin therapy is most commonly used rather than OHAs.

CONCLUSION

The analysis of our study has shown that in patients with type-2 DM with complications, insulin therapy was preferred over OHAs. In majority cases, insulin therapy was used in combination with OHAs for the better control of diabetes in presence of alarming levels of glycemic levels. INSULIN REGULAR was the first choice of insulin therapy and METFORMIN was the most prescribed OHAs. We also believe that patient education regarding lifestyle modification and diabetes is strongly advised to achieve the maximum control of glycemic levels in patients. We also believe that implementation of clinical pharmacy services plays important role in educating and following up of suspected drug interactions that promotes improved quality of life.

The result of our study suggest the need for comprehensive management of diabetic patients including dietary changes, life style modifications can control high blood sugar levels.

Effectiveness of therapy is influenced by selection of medication, as well as patients adherence with prescribed drug dosage regimens.

SUMMARY

The number of people with diabetes has risen from 108 million in 1980 to 422 million in 2014. The global prevalence of diabetes among adults over 18 years of age has risen from 4.7% in 1980 to 8.5% in 2014.The prevalence of diabetes has been seen increased in low income countries. Diabetes has been seen increased in middle aged people. Diabetes is more prevalent in people who smokes and consume alcohol .Diabetes is the major cause of blindness, kidney failure, heart attacks, stroke and lower limb amputation. An estimated 3.4 million deaths were reported in 2015 due to diabetes. Almost half the deaths were seen in patients before 70 years. In an article, WHO mentioned that diabetes will be the 7th leading cause of death in 2030.Healthy diet, regular physical activity, etc are some of the ways to prevent the onset of type-2 DM. Diabetes and its complications can be prevented with diet, regular physical activity, medication, regular screening of blood glucose levels.

The analysis of our study has shown that a few guidelines in prescribing pattern had been deviated by preferring insulin therapy over OHAs as per AMERICAN DIABETES ASSOCIATION. In majority of cases, insulin therapy was used in combination with OHAs for the better control of diabetes in presence of alarming levels of glycemic levels. INSULIN REGULAR was the first choice of insulin therapy and METFORMIN was the most prescribed OHAs. We also believe that patient education regarding lifestyle modification and diabetes is strongly advised to achieve the maximum control of glycemic levels in patients. We also believe that implementation of clinical pharmacy services by proper involvement of a clinical pharmacist is very important and also a slight change in the prescribing pattern will enhance better results in patient safety.

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