



A PROSPECTIVE STUDY ON DIFFERENT DRUGS USED IN DIABETES MELLITUS WITH CO-MORBIDITIES AND PATIENT COUNSELLING

Dr. G.Kiran^{1*}, Ch.Abidha², K.Praveen³, P.Abhinandana prem⁴ I.Divya⁵,

Abstract

Purpose: The purpose of the study is to assess the incidence of people using medication in diabetes mellitus with comorbid conditions and to achieve the therapeutic goals by the effective patient counselling.

Background: Diabetes mellitus is a condition caused due to the lack of insulin secretion to send the glucose from blood stream to cells. General process of diabetes occurs when the food turns into energy which is also called as glucose. These glucose molecules can be released into bloodstream and higher levels of glucose in blood stream causes diabetes mellitus or high blood sugar. In this process, the pancreas release a hormone called insulin which is used to send the glucose molecules from blood stream to cells to avoid DM.

Methodology: It is prospective observational study conducted in all the super specialities hospital in guntur. In this 200 patients with diabetes mellitus were selected for the study to evaluate the different types medications used in diabetes mellitus with comorbid conditions and the effect of patient counselling on patient health.

Results and discussion: A total number of 200 patients were enrolled in the study. Among them 45% were female and 55% were males of different age groups ranging from 21-60 years. It was found that 25% of them use Insulin therapy, 25% use combination of Oral Hypo glycemics along with Insulin, 25% of the patients use combination of Oral Hypoglycemics and Sulfonylureas. Out of 200 patients who were provided with patient counselling, 120 patients showed improvement.

Conclusion: According to the study, it was found that the use of Insulin, combination of Oral hypo glyceemic and Insulin, combination of Oral hypo glycaemic and Sulfonylureas was predominant.

Keywords: Diabetes mellitus, Dyslipidemia, Glucose, Insulin, Diabetic complications, Oral hypo glycemics.

^{1*} Associate Professor, Department Of Pharmacology, A.M Reddy Memorial College Of Pharmacy, Petlurivaripalem, Palanadu District, Guntur, A.P, Pin 522601.

^{2,3,4,5} Department Of Pharmacy Practice, A.M Reddy Memorial College Of Pharmacy, Petlurivaripalem, Palanadu District, Guntur, A.P, Pin 522601.

***Corresponding Author:** Dr. G.Kiran

*Associate Professor, Department Of Pharmacology, A.M Reddy Memorial College Of Pharmacy, Petlurivaripalem, Palanadu District, Guntur, A.P, Pin 522601.

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INTRODUCTION:

Diabetes mellitus is a chronic condition or a disease that affects the body's ability to use the energy found in food. It is referred to as Diabetes. It is the condition where the pancreas gland does not generate enough insulin required by the body to regulate glucose metabolism⁽¹⁾

There are several types of diabetes. The two most common are called type 1 diabetes and type 2 diabetes. An organ in the abdomen called the pancreas produces a hormone called insulin, which is essential to helping glucose get into the body's cells. In a person without diabetes, the pancreas produces more insulin whenever blood levels of glucose rise (for example, after a meal), and the insulin signals the body's cells to take in the glucose. In diabetes, either the pancreas's ability to produce insulin or the cells' response to insulin is altered.⁽²⁾

CLASSIFICATION:

Type 1 diabetes mellitus:

Type 1 diabetes is an autoimmune disease. This means it begins when the body's immune system mistakenly attacks other cells in the body. In type 1 diabetes, the immune system destroys the insulin-producing cells (called beta cells) in the pancreas. This leaves the person with little or no insulin in his or her body. Without insulin, glucose accumulates in the blood stream rather than entering the cells. As a result, the body cannot use this glucose for energy.⁽³⁾

Type 2 diabetes mellitus:

Type 2 diabetes occurs when your body's cells become less responsive to insulin's efforts to drive glucose into the cells, a condition called insulin resistance. As a result, glucose starts to build up in the blood. In people with insulin resistance, the pancreas "sees" the blood glucose level rising.⁽³⁾

Gestational diabetes mellitus:

Another kind of diabetes, called gestational diabetes, happens in women who have higher-than-expected blood sugar levels during pregnancy. Once it occurs, it lasts throughout the remainder of the pregnancy.⁽³⁾

ETIOLOGY OF DIABETES MELLITUS:

Type 1 Diabetes Mellitus:

Type 1 diabetes mellitus (T1DM) comprises several diseases of the pancreatic β cells which lead to an absolute insulin deficiency. This is usually considered to be the result of an autoimmune destruction of the pancreatic β cells

(type 1A).⁽⁴⁾

Type 2 Diabetes Mellitus:

Most patients with T2DM in the US and Europe are overweight or obese, however in India and China, most T2 DM patients have a lean body mass index (BMI), although it is with increased visceral and hepatic fat.⁽⁴⁾

Monogenic Diabetes:

Monogenic forms of diabetes are characterized by impaired secretion of insulin from pancreatic β cells caused by a single gene mutation. These forms comprise a genetically heterogeneous group of diabetes including, maturity onset diabetes of the young (MODY), permanent or transient neonatal diabetes, and mitochondrial diabetes.⁽⁴⁾

METHODOLOGY

MATERIALS AND METHODS:

SOURCE OF DATA: Data will be collected from 1. Case records of the patient's in hospital.

By evaluating the patient questionnaire collected from patients who are presented with D.M.

STUDY DESIGN:

The current study is a prospective study conducted over a period of 6 months from October 2022 to March 2023 at Lalitha Speciality Hospital in in-patient and out-patient department to assess the comorbidities in diabetic patients and its observational study on different drugs used in diabetic patients. Individuals who met the inclusion criteria are taken into consideration. The patients are included according to their interest and willingness in order to carry out the study

STUDY SITE:

Lalitha Super Specialty Hospital, Guntur

STUDY DURATION:

The study will be carried out for a period of 6 months.

STUDY POPULATION:

All patients of age 20-90 years.

STUDY CRITERIA:

The study will be carried out by considering the following criteria

INCLUSION CRITERIA:

- Patient with age group of 20-90 years.
- Both genders (male and female).
- All patients with co-morbidities like hypertension, diabetes, anemia, bone marrow disorders,

respiratory problems and hyper lipidemic diseases.

EXCLUSION CRITERIA:

- Patients with bacterial and viral infections.
- Patient with cancer.
- Pregnant women.
- Paediatrics.
- Excluding patients with other neurodegenerative disorders.

STUDY PROCEDURE:

- STEP -1: A Prospective study was carried out in the hospital with prior permission from both inpatient and outpatient departments.
- STEP -2: The patient visiting for the diabetes mellitus with co-morbidities and patient counselling was enrolled in the study considering the inclusion & exclusion criteria after taking their consent to participate in the study.
- STEP -3: From the enrolled patients, the data was collected by a specially designed patient data collection form.
- STEP-4: We conducted various educational programmes to all the patients regarding management of different drugs used in diabetes mellitus with co-morbidities and patient counselling.

STUDY METHOD:

The study will be conducted at Lalitha Super Specialty Hospital after obtaining ethical clearance from the Institutional Ethical Committee. All the patients who come under inclusion criteria will be monitored and data will be collected during the prospective study period.

DATA COLLECTION FORM:

Data collection was carried out by face-to-face interviews with the patients. The information collected includes demographic data (i.e., age and gender) History of the patient and clinical manifestations like fever, edema, hypertension, shortness of breath etc..., from the admission of the hospital to discharge. The data collection was pre-tested through a pilot study of 10 patients who were not included in the final analysis to check for the understandability and language clarity of questions, and all valid comments were taken into consideration by the principal researchers in the main survey.

The question was prepared in English and Telugu. It includes 7 questions which highlighted patients' baseline knowledge about transmission, prevention, and control of diseases, diet requirement, and various lifestyle modifications. The language of the questionnaire asked to the patients depends on the educational status of the patient. The questionnaire was given to the patient by the pharmacist at the point of enrolment (Prior to counselling) patient.

RESULTS AND DISCUSSION

A total of 200 patients were enrolled into the study. The data was taken from the patient who was during the 6 months duration. Detailed demographic data of all patients

1. GENDER DISTRIBUTION

Table:4 Gender categorization

S.NO	Sex	No. of Patients(N=200)	Percentage
1.	Male	120	60%
2.	Female	80	40%

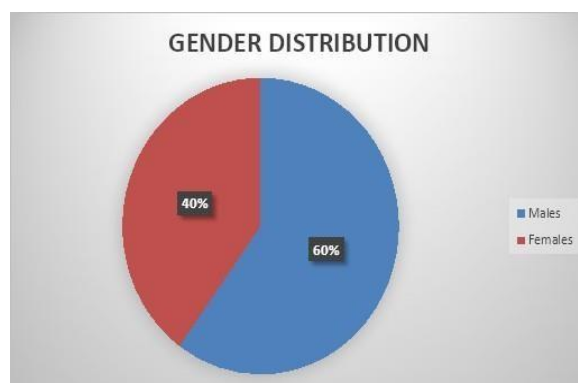


Figure:1 Gender wise distribution

The overall patient's demographics of sex distribution in the study are, 80 patients 40% of them were females and the remaining 120 patients 60% were males.

2. AGEDISTRIBUTION OF PATIENTS

Table: 5 Age distribution of the diabetic patients

S.NO	Age in Years	No. of Patients (N=200)	Percentage
1.	51-60	65	32.5%
2.	41-50	50	25%
3.	61-70	35	17.5%
4.	31-40	40	20%
5.	21-30	10	5%

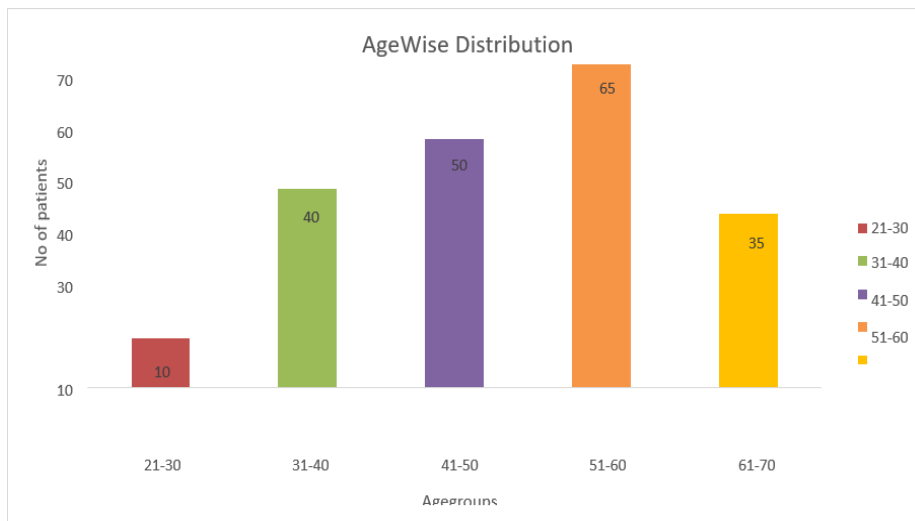


Figure:2 Age wise distribution patients of age group from 21 years to 70 years were included in the study.

3. DISTRUBUTIONOF PATIENTS

Table: 6 Distribution of patients

S.NO	Distribution of patients	No. of Cases (N=200)	Percentage
1.	IN PATIENT	160	80%
2.	OUTPATIENT	40	20%

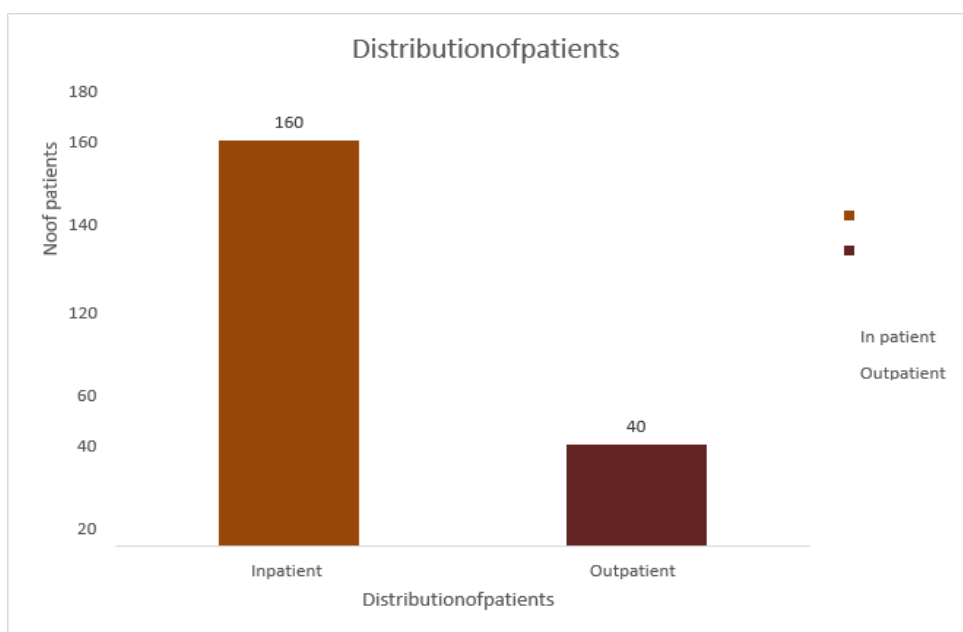


Fig: 3 distribution of patients The number of In-patients was found to be 160 patients (80%) and number of Out-patients was found to be 40 patients (20%).

4. CATEGORY OF DRUGS

Table:7 Category of drugs

S.NO	Categories	No of Cases(N=200)	Percentage
1.	Insulin Therapy	50	25%
2.	Oral Hypo glyceic Agent+ Insulin	50	25%
3.	Oral Hypo glyceic agents(Sulfonylurea+ Pioglitazone)	50	25%
4.	Sulfonylureas	25	12.5%
5.	Pioglitazone	25	12.5%

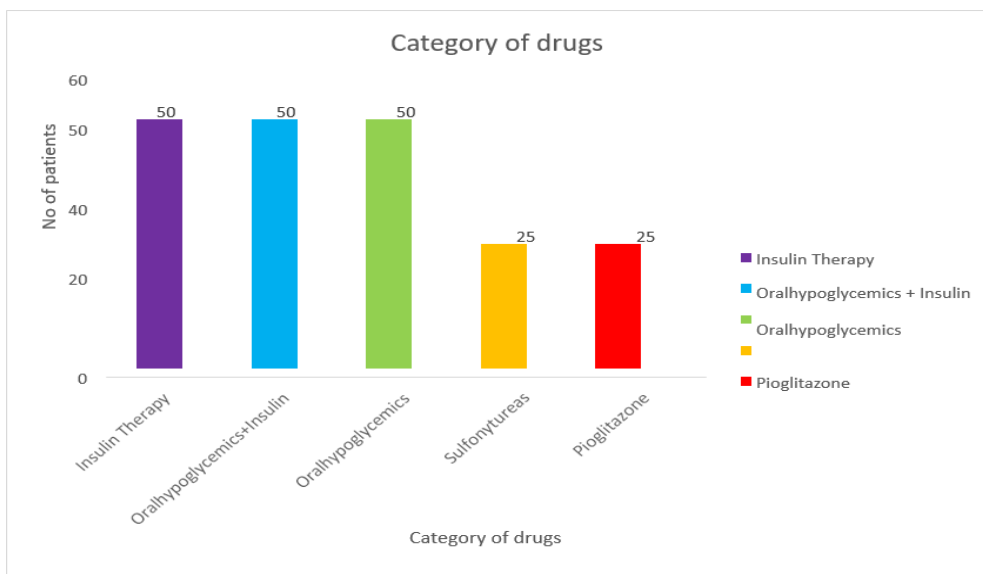


Fig:4 category of drgs used by the patients

The above graph explains that the use of Insulin for the therapy is found in 50 patients (25%), the combination of Oral Hypoglycemic agents and Insulin was found to be in 50 patients (25%), use of combination of SulfonylUreas and Oral

Hypoglycemic agents was found in 50 patients (25%), use of only SulfonylUreas was in 25patients (12.5%), use of Pioglitazone was found in 25 patients (12.5%).

5. MAJORCO-MORBIDITIES

Table:8 Major Co-morbidities along with Diabetes

S.NO	Type of co-morbidities	No of cases(N=200)	Percentage
1.	Nephrology	40	20%
2.	Cardiology(HTN& Other Cardiac diseases)	80	40%
3.	Hepatic Diseases	35	17.5%
4.	Neurology	35	17.5%
5.	General	10	5%

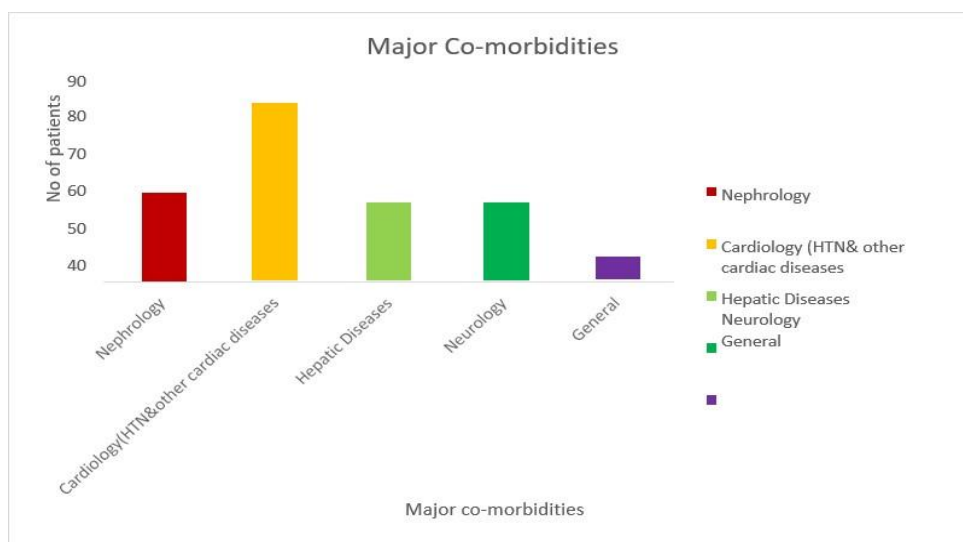


Fig: 5 Major Co-Morbidities Along With Diabetes

The above graph depict the occurrence of the co-morbidities along with diabetes. It is shown that among200(100%) patients the prevalence of the co-morbidities along with diabetes was found to be in cardiovascular events 80 patients (40%), Nephropathy 40 patients (20%), Hepatic disorders 35 patients (17.5%), Neurological disorders 35 patients (17.5%) and general 10 patients (5%).

6. PATIENT CATEGORIZATION

Table: 9 Patient categorization

S.NO	Categorization	No of cases(N=200)	Percentage
1.	Alcohol	115	57.5%
2.	Smoker	45	22.5%
3.	Alcohol+ Smoker	40	20%

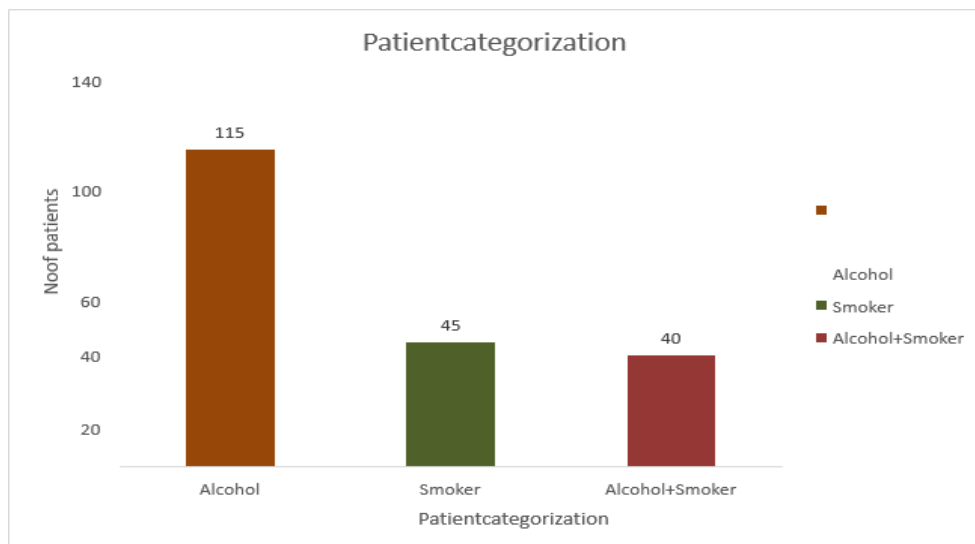


Fig: 6 patient categorization Out of 200 (100%) patients, 115 (57.5%) patients were alcoholics, 45 (22.5%) patient had the habit of smoking, and 40 (20%) patients had the habit of both smoking and alcohol consumption.

7. IMPACT OF PATIENT COUNSELLING

Table: 10 Impact of patient counselling

S.NO	Pre Counselling (N=200)	Post Counselling (N=200)	Improvement
1.	200	200	130

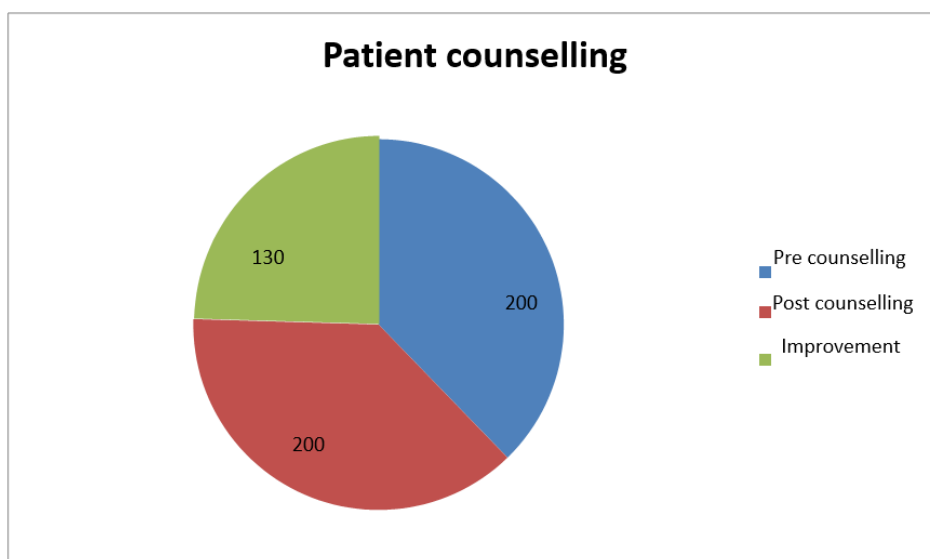


Fig:7 Patient Counselling Out of total 200 patients, counselling was provided to 200 patients and improvement was observed in 130 patients, which was observed through regular follow-ups.

STATISTICAL TEST:

To Assess the Occurrence of co-morbidities with different drugs used in the Diabetes Mellitus Chi

Square test is Performed.

NULL HYPOTHESIS:

There is no association between the co-morbidities

with different drugs used in the Diabetes Mellitus patients.

ALTERNATIVE HYPOTHESIS:

There is a significant association between the co-

morbidities with different drugs used in the Diabetes Mellitus patients.

Drugs	Insulin Therapy	Oral Hypo glycemics	Oral Hypo glycemics+ Insulin Therapy	Sulfonyl Ureas	Pioglitazone	Total
Males	20	45	38	12	5	120
Females	12	30	20	10	8	80
Total	32	75	58	22	13	200

$$\chi^2 = \frac{\sum(O - E)^2}{E}$$

Where O=Observed value E=Expected value.

O	E	O-E	(O-E) ²	(O-E) ² /E
20	19.2	0.8	0.64	0.03
45	45	0	0	0
38	34.8	3.2	10.2	0.29
12	13.2	-1.2	1.44	0.10
5	7.8	2.8	7.84	1
12	12.8	-0.8	0.64	0.05
30	30	0	0	0
20	23.2	-3.2	10.2	0.43
10	8.8	1.2	1.44	0.16
8	5.2	2.8	7.84	1.50

Table:11 Chi-Square table

(χ^2) TABULATED VALUE= 9.48(χ^2)

CALCULATED VALUE=3.56

(χ^2) Calculated value < (χ^2) tabulated value hence alternative hypothesis was accepted which states

that there is a significant association between the co-morbidities with different drugs used in the Diabetes Mellitus patients.

Co-Morbidities	Nephrology	Cardiology	Hepatic Diseases	Neurology	General	Total
Males	24	45	23	20	8	120
Females	16	35	12	15	2	80
Total	40	80	35	35	10	200

$$\chi^2 = \frac{\sum(O - E)^2}{E}$$

Where O=Observed value E=Expected value

O	E	O-E	(O-E) ²	(O-E) ² /E
24	24	0	0	0
45	48	-3	9	0.18
23	21	2	4	0.19
20	21	-1	1	0.04
8	6	2	4	0.06
16	16	0	0	0
35	32	3	9	0.28
12	14	-2	4	0.28
5	14	-9	81	5.78
2	4	-2	4	0

Table:12 Chi-Square table

(χ^2) TABULATED VALUE= 9.48(χ^2)

CALCULATED VALUE=6.81

(χ^2) Calculated value < (χ^2) tabulated value hence alternative hypothesis was accepted which states that there is a significant association between the

co-morbidities with different drugs used in the Diabetes Mellitus patients.

DISCUSSION

Diabetes is the most widely distributed metabolic syndrome in the world.

According to the study, the overall patient's demographics of sex distribution in the study are, 40% of them were females and the remaining 60% were males.

A wide range of patients were involved in the study whose age group ranges from the early age, i.e., 21 years to the very old stage, i.e., 70 years.

As Diabetes is a metabolic syndrome, there are chances of occurrence of many diseases along with it. Thus called as co-morbidities. Study was done on the prevalence of co-morbidities along with diabetes. It is shown that among 200 patients the prevalence of the co-morbidities along with diabetes was found to be in cardiovascular events 80 patients (40%), Nephropathy 40 patients (20%), Hepatic disorders 35 patients (17.5%), Neurological disorders 35 patients (17.5%) and general 10 patients (5%).

As the study is to evaluate the drug use pattern in the diabetics, the treatment preferred to the patients were studied. This explains that the use of Insulin for the therapy is found in 50 patients (25%), the combination of Oral Hypoglycemic agents and Insulin was found to be in 50 patients (25%), use of combination of Sulfonylureas and Oral Hypoglycemic agents was found in 50 patients (25%), use of only Sulfonylureas was in 25 patients (12.5%), use of Pioglitazone was found in 25 patients (12.5%).

The habit of smoking and alcohol consumption so affects the levels of blood glucose levels in the body. Thus study was also extended to sort out the habit of smoking, alcohol consumption and both. Out of 200 (100%) patients, 115 (57.5%) patients were alcoholics, 45 (22.5%) patients had the habit of smoking, and 40 (20%) patient had the habit of both smoking and alcohol consumption.

The study was done by collecting the information from both in-patients and out-patients. This is summarized as follows. The number of IP-patients were found to be 160 (80%) patients and the number of OP-patients were 40 (20%) patients.

The main aim of the study is to provide patient education regarding diabetes. This can be achieved by providing patient counselling and to find out

whether the provided patient education was use or not. This is done by regular follow-ups. Out of total 200 patients, counselling was provided to 200 patients, and improvement was observed in 130 patients, which was observed through regular follow-ups.

CONCLUSION

The present study identified few factors related to Diabetes. This involved the participation of both in-patients and out-patients. The distribution of Diabetes was in a wide range of age groups, i.e., aging from 21-70 years. The prevalence of diabetes is slightly more in males (80%), than in females (20%). The study also states that the presence of Hypertension as a co-morbid disease is the highest. It also states that the use of Insulin therapy, combination of Oral Hypoglycemics and Insulin, and the combination of Sulfonylureas and Oral Hypoglycemic were equally observed.

By providing the patient counseling, the improvement in the life styles of the patients was found to be in 130 patients, out of 200 patients.

LIMITATIONS

The following limitation can be observed by the conducted study:

- a) The study was done in a small population.
- b) The study was done for a limited period of time and was a single center study.
- c) The study did not involve the special populations.
- d) The study was not done in patients who were taking OTC.

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