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A PROSPECTIVE OBSERVATIONAL STUDY ON EVALUATION OF ANTI-DIABETIC DRUGS AT A TERTIARY CARE TEACHING HOSPITAL

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ABSTRACT

Aim: the aim is to assess the safety and efficacy of anti-diabetic drugs. **Methodology:** a prospective observational study was carried out at the department of general medicine in a tertiary care teaching hospital for a period of 6months. All the patients above 18 years of either sex, with co-morbidities, diabetes was included. **Results:** it was observed that there was predominance of male(62%), female(36%) in the age group of <40–80 years, among that widely distributed in the age group of 51 –60 years with frequency of 37%. we noted, larger numbers of patients were prescribed with metformin (12%) as OHA. It was found that majority of patients were administered with regular insulin sc (64%) as an insulin analogue, (because of co morbid conditions, patients were often switched to insulin therapy in comparison with the metformin). Various other combinations of OHA and insulin analogues were also prescribed. The significant risk factor was found to be age (70%) followed by sedentary lifestyle (58%) and hypertension (47%). **Conclusion:** upon analysis it is reported that diabetes was more prevalent in the males and in the age group of 51–60years, with majority being prescribed with metformin and regular insulin. While counselling it was recognized that the majority of patients were illiterate about the disease and counselling for the diabetes lifestyle management had a positive impact in maintaining their blood glucose levels and improved their condition.

KEYWORDS: *diabetes mellitus, anti-diabetic drugs, counselling, risk factors.*

INTRODUCTION

Hyperglycemia (fasting glucose> 126 mg / dL and / or 200 mg / dL 2 hours after 75 g of oral

glucose), glycosuria, hyperlipidemia, negative nitrogen balance and sometimes ketonemia are hallmarks of diabetes, a range of metabolic diseases. Caused by errors in insulin sensitivity or action, or both.[1]

An estimated 26 million Americans over the age of 20 are estimated to have diabetes mellitus (DM) in 2010, and up to a quarter of these people are undiagnosed and another 79 million are at high risk of developing the disease. Better care for diabetic patients can reduce or prevent complications, reduce morbidity and mortality, while improving quality of life.[2]

Definition: The WHO has defined diabetes mellitus as a heterogeneous metabolic disorder characterized by the common feature of chronic hyperglycaemia with disorders of carbohydrate, protein and lipid metabolism. It is also important to understand another related term, metabolic syndrome (also known as syndrome X or insulin resistance syndrome), which consists of a combination of metabolic abnormalities that increase the risk of developing diabetes. Sugar and cardiovascular disease.[2]

Epidemiology: The biggest cause of sickness and mortality in the globe is diabetes mellitus. Due to its severe sequelae, including end-stage renal failure, ischemic heart disease, lower limb gangrene, and adult blindness, it is anticipated that it will continue to be a significant public health issue. India, China, the United States, Indonesia, and Japan are the five nations with the highest rates of diabetes prevalence.

A restricted diet and sedentary lifestyles among the expanding global middle class are the main causes of the occurrence, which is estimated at 7% of the adult population. Up to 90% of all instances of diabetes mellitus are caused by type 2 diabetes, which is more prevalent as people age and differs significantly by race and ethnicity. Native Americans, Asian Americans, African Americans, and Pacific Islanders have the highest rates of type 2 diabetes. In addition to genetic susceptibility, type 2 diabetes is frequently diagnosed in adolescence and is primarily linked to increased overweight/obesity and a sedentary lifestyle. In the United States, 7% of pregnancies are complicated by gestational diabetes mellitus, while the majority of women experience normoglycemia after giving birth. However, between 30% and 50% of people could eventually acquire type 2 diabetes or pre diabetes.

Etiological classification

1. Type 1 diabetes mellitus: (destruction of cells, usually leading to absolute insulin

deficiency).

2. Type 2 diabetes mellitus: (can range from predominant insulin resistance with insulin deficiency to a predominant secretory defect with insulin resistance).
3. Gestational diabetes mellitus
4. Other specific types.[3]

- Genetic defects of cell function and in the way insulin works.
- Diseases of the exocrine pancreas
- Endocrinopathies
- Induced by drugs or chemicals
- Infections
- Uncommon forms of immune-mediated diabetes
- Other genetic syndromes associated with diabetes

Glucose homeostasis: Normal glucose homeostasis is tightly regulated by three interrelated processes: glucose production in the liver; uptake and utilization of glucose by peripheral tissues, Mainly skeletal muscle and actions of insulin and counter-regulatory hormones, includingglucagon, on glucose absorption and metabolism.

Insulin and glucagon have opposite regulatory effects on glucose homeostasis. During fasting states, low insulin levels and high glucagon levels facilitate gluconeogenesis and hepatic glycogenolysis (glycogen breakdown), reducing glycogen synthesis, preventing hypoglycemia. Therefore, fasting plasma glucose levels are mainly determined by the production of hepatic glucose. After a meal, insulin levels rise and glucagon levels fall in response to the increased glucose load. Insulin promotes the absorption and utilization of glucose in the tissues. Skeletal muscle is the primary insulin sensitive site for postprandial glucose utilization and is critical for preventing hyperglycemia and maintaining glucose homeostasis.[4]

Regulation of insulin release: The main stimulus for insulin synthesis and release is glucose itself. An increase in blood sugar leads to the uptake of glucose into pancreatic β cells, which is facilitated by an insulin-independent glucose transporter, GLUT-2. β cells express an ATP- sensitive membrane K channel composed of two subunits: an inward-rectifying K channel and the sulfonylurea receptor (SUR-1), the latter being the site binding of oral hypoglycemic agents (sulfonylurea's). Glucose metabolism by glycolysis generates

ATP, resulting in increased cytoplasmic ATP/ADP ratios of β cells. This inhibits ATP-sensitive K channel activity, leading to membrane depolarization and extracellular calcium influx through voltage-gated calcium channels. The resulting increase in intracellular calcium stimulates the secretion of insulin, presumably from the hormone stored in the cellular granules. This is the immediate insulin release phase. If the secretory stimulus persists, a delayed and prolonged response follows which involves active synthesis of insulin. Other factors, including intestinal hormones and some amino acids (leucine and arginine), also stimulate the release of insulin, but not its synthesis.[4]

Insulin Action and Insulin Signaling Pathways: Insulin is the most potent anabolic hormone known with multiple synthetic and growth promoting effects. Its main metabolic function is to increase the rate of transport of glucose into certain cells of the body, thereby providing an increased source of energy. These cells are striated muscle cells (including myocardial cells) and to a lesser extent adipocytes, which together make up about two-thirds of total body weight. Glucose uptake in other peripheral tissues, particularly the brain, is independent of insulin. In muscle cells, glucose is then stored as glycogen or oxidized to create ATP. In adipose tissue, glucose is stored primarily as a lipid. In addition to promoting lipid synthesis, insulin also inhibits the breakdown of lipids in adipocytes. Likewise, insulin promotes amino acid absorption and protein synthesis, while inhibiting the breakdownof proteins. Therefore, the anabolic effects of insulin are due to the increase in synthesis and the decrease in the breakdown of glycogen, lipids and proteins.[4] Elucidation of the insulin signalling pathway has been central to our understanding of the pathogenesis of diabetes.

Pathophysiology

The two metabolic defects that characterize type 2 diabetes are

1. A reduced response of peripheral tissues to insulin (insulin resistance) and
2. Cellular satisfaction manifested as insufficient insulin secretion within the face of insulin resistance and hyperglycemia. Insulin resistance precedes the event of hyperglycemia and is sometimes related to compensatory cell hyperfunction and hyperinsulinemia early within the evolution of diabetes.[4]

Insulin resistance: Insulin resistance is defined as the inability of target tissues to reply normally to insulin. It ends up in reduced glucose absorption within the muscles, decreased glycolysis and oxidation of fatty acids within the liver, and therefore the inability to

suppress hepatic gluconeogenesis. A spread of functional defects is reported within the insulin signalling pathway in insulin resistance states, which impair signal transduction. Few factors also play an important role in the development of insulin resistance like obesity.[4] Obesity has profound effects on the sensitivity of tissues to insulin and, consequently, on systemic glucose homeostasis. The riskof diabetes increases with increasing obesity index. Not only absolutely the amount, but also the distribution of body fat affects insulin sensitivity. Central obesity is more related to insulin resistance than peripheral fatty deposits. Obesity can negatively impact insulin sensitivity in various ways through: non-esterified fatty acids (NEFA), adipokines, inflammation, peroxisome proliferator-activated receptor γ (PPARγ).[4]

Dysfunction of β cells: In type 2 diabetes, beta cells appear to exhaust their ability to adapt to the long-term demands of peripheral insulin resistance. In insulin resistant conditions like obesity, insulin secretion is initially over controls for any glucose level. This hyperinsulinemic state compensates for peripheral resistance and might often maintain normal plasma glucose levels for years. Eventually, however, cell compensation becomes insufficient and progression to hyperglycemia occurs. The observation that not all obese individuals with insulin resistance develop overt diabetes suggests that there must even be an intrinsic predisposition to cell failure. The molecular mechanisms underlying cell dysfunction in type 2 diabetes are multifactorial and in many cases overlap with those involved in insulin resistance. Thus,excessive NEFAs and reduced insulin signalling (lipotoxicity) predispose to both insulin resistance and cell failure. Substitution of amyloid islets is characteristic of people with long- term type 2 diabetes and is present in over 90% of the diabetic islets studied. Some believethat islet amyloid protein is directly cytotoxic to islets, almost like the role played by amyloid plaques involved within the pathogenesis of Alzheimer's disease.[4]

Clinical features: Patients are generally obese, Symptoms such as polyuria, polydipsia and polyphagia develop gradually, and the patient may have unhealed wounds, fungal infections, vulvar itching or balanitis, the patient may have frequent changes in refractory error and may have early cataractdevelopment; the patient may also be asymptomatic.[3]

Risk factors: Family history of diabetes mellitus, age, Physical inactivity and obesity, IGT previously identified, History of gestational diabetes mellitus and vascular disease, Birth of a large baby (>4kg), high blood pressure, HDL level < 35 mg/dl and TGL level > 250 mg/dl, Polycystic ovary syndrome, Acanthosis nigricans.[3]

Diagnosis

Table 1: Diagnostic Criteria for Type 2 Diabetes Mellitus.

Diagnostic Criteria for Type 2 Diabetes Mellitus:
Fasting (>8hours) blood glucose level >or= 126 mg/dl or
2 hour plasma glucose level > or = 200 mg/dl during oral glucose tolerance test with 1.75g/kg of glucose or
Hemoglobin A1c levels > 6.5 % is standardized to Diabetes Control and Complications TrialAssay or
Random plasma glucose levels > or = 200 mg/dl with following symptoms:
Sign and symptoms of Diabetes mellitus i.e., polyuria, polydipsia and unintentional weightloss.

TREATMENT

Therapeutic Lifestyle Modifications

1. **Dietary planning:** Diet control is the body's insulin guardian. The main therapeutic objective is weight loss in obese people; Weight reduction eliminates the need for oral antidiabetics or insulin, especially when normal body weight is achieved. Consistency in meal composition and timing is especially important for patients using fixed insulin regimens or oral antidiabetics. **Calorie:** Calorie calculations are performed for ideal body weight. Total calories should ideally be kept between 1000 and 1200 kcal/day. For obese people 20 kcal/kg of. For normal (sedentary) adults 30 kcal/kg. For normal (working) adults and growing children 40 kcal/kg. **Carbohydrates**: Carbohydrates should represent 50 to 60% of total calories. Concentrated sugars are avoided except in the treatment of hypoglycemia. **Fat:** The total fat content should be between 25 total calories. Skimmed or skimmed milk is recommended, only 2 to 3 eggs per week are allowed. Margarine should be taken instead of butter. Red and brown meat should be consumed in smaller quantities. You can take fish- based cheeses and skimmed milk. **Fibre:** about 25 grams of fibre per 1000 kcal is recommended. Fibre- rich complex carbohydrates are recommended (bran, whole grains, stews, legumes, vegetables and whole fruit). It is necessary to consume soluble fibre such as guar 15 g. **Protein:** The total protein content of the diabetic meal plan should be between 25 and 30%. **Meal plan:** Total calories should be consumed in three main meals and three snacks (breakfast 30%, snacks 10%, lunch 20%, evening snack 10%, dinner 20%, and snacks beforebed).
2. **Exercise:** Isotonic exercises such as brisk walking, swimming, or cycling are recommended. Exercise potentiates the beneficial effects of diet and other therapies. Aerobic exercise for 30-45 minutes/day, 5 times per week should be encouraged. The rest period between exercises should not exceed 48 hours. Exercise is less effective in

poorly controlled diabetics. Strenuous exercise in patients who have reduced insulin or increased carbohydrate intake can lead to hypoglycemia. **Light exercise:** One hour standing - 120 kcal/h, lying down - 70 kcal/h,sitting - 80 kcal/h, walking (4 km/h) – 180 kcal/h. **Moderate exercise:** swimming (0.25 mph) - 250 kcal/h, brisk walking (6.05 mph) - 250 kcal/h. **Intensive training:** tennis - 350 kcal/h, cycling (16 km/h) - 600 kcal/h, running (16km/h) - 800 kcal/h. **Physical activity:** Exercise can help you lose weight, lower your blood sugar levels, and increase your insulin sensitivity, which helps keep your blood sugar levels within a normal range. Goals to promote weight loss and maintain a healthy weight include: aerobic exercise, resistance exercise, and limited inactivity.[3]

Pharmacotherapy

Oral hypoglycemic agents

INSULIN SECRETAGOGUES

1. **Sulfonylureas**: Sulfonylurea's act by stimulating the release of insulin by the beta cells of the pancreas. It upregulates insulin receptors and increases the action of available insulin. The hypoglycaemic effect is due to a reduction in hepatic glucose release and a decrease in insulinresistance. Sulfonylurea's lower fasting blood sugar by about 70 to 80 mg/dL. In obesity, Sulfonylureas are only tried when a vigorous diet, biguanides, and exercise program have failed. Side Effects: Hypoglycemia, Sulfonylureas should not be used in patients with liver disease, kidney disease, allergic reactions to Sulfonylureas or during pregnancy. Patientsmay blush after ingesting alcohol.
2. **Meglitinide:** These are the new class of insulin secretagogues that modulate insulin secretion from beta cells by regulating potassium channels. The first member of the group is repaglanide - 0.25mg to 4mg before each meal. The duration of action is 4-5 hours. Due to its rapid onset of action and short duration, it is indicated for post-meal blood sugar control.
3. **Nateglinide:** It is a derivative of D-phenylalanine which acts directly on beta cells to stimulate the early secretion of insulin. Dose: 120 mg taken orally 10 minutes before each meal leads to insulin secretion within 15 minutes and returns to baseline in 3-4 hours.

INSULIN SENSITIZERS

1. **Biguanides:** Drugs during this group are phenformin and metformin. They're the drug of choice in type 2 diabetic obesity. They need no effect on insulin secretion. They improve the sensitivity of peripheral tissues to insulin, thereby improving the use of peripheral glucose. They suppress glucose production within the liver by reducing gluconeogenesis. It also increases glucose transporters in insulin sensitive cells. It is often taken orally or alone or with insulin. The initial dose of metformin is 500 mg/day with meals up to three g/day in 2-3 doses. Theymust be avoided in patients with renal or hepatic insufficiency, alcoholics, cardiopulmonary insufficiency and other known risks of lactic acidosis. Also, they ought to not be used duringpregnancy.
2. **Thiazolidinediones:** They improve insulin sensitivity in muscle, liver and fat. There's also a discount in hepatic glucose production. It appears to decrease plasma triglyceride levels and increase cholesterol levels. There's no hypoglycemia as they are doing not affect pancreatic insulin secretion. They'll be combined with other oral antidiabetic agents or with insulin. Pioglitazone 15-45 mg once daily, rosiglitazone 2-8 mg once daily.
3. **Alpha glucosidase inhibitors**: (acarbose) they require the action of a glucosidase, an enzyme round the intestinal brush, for absorption. Inhibitors of this enzyme, when taken before meals, cause a slower rise and a lower spike in glucose. A discount in glucose of 30-50 mg/dL and HbA1c of 0.5-1% has beenreported. It's administered at a dose of 50-100 mg TDS/day before meals. Side effects include: bloating, diarrhea, abdominal pain.
4. **Fatty acid oxidation inhibitors: (Acipiomax)** Acipiomax, a harder derivative of B-complex vitamin, reduces free fatty acids. And it also reduces fasting hyperglycemia and triglyceride levels. Insulinotropins: Glucagon-like peptides 1 (GLP-1): this can be under study. GLP-1 may be a fragment of the proglucagon molecule. And it appears to stimulate the discharge of insulin. Insulin-like protein 1 (IGF-1)or somatomedin.
5. **Dipeptidyl peptidase (DPP4) inhibitors**: it's an enzyme that breaks down GLP-1.The DPP4 inhibitor inhibits the degradation of GLP- 1 and thus increases the effect of incretin. Improves glucose-mediated insulin secretion Inhibits glucagon secretion.

1. **Sitagliptin:** could be a DPP4 inhibitor and increases insulin secretion and reduces glucagon secretion. The dose is 100 mg po once daily.
2. **Vildagliptin:** it's neutral and features a beneficial effect on lipids. The dose is 50 mg twicedaily with metformin, TZD, or insulin.

INSULIN

Principles of insulin therapy: Starting with a coffee dose, it may be given as one injection of an intermediate-acting insulin before breakfast or twice daily before breakfast and within the evening (0.3-0. 4 U/kg/day). Blood sugar should be monitored reception. If glucose testing facilities don't seem to be available, second urine samples are used. Insulin dose and treatment regimen are adjusted until adequate glycemic control is achieved. The frequency of blood sugar measurement is then reduced to 3-4 times daily, after which a glucose measurement once or twice per week is sufficient. Indications for insulin in type 2 diabetes: sulfonylurea deficiency, major trauma, surgery, stress, pregnancy, DKA, infarct, stroke, hepatic failure, renal and respiratory failure, and infections.[3]

OBJECTIVES

The principle aim of the study is to assess the safety and efficacy of anti-diabetic drugs, to identify and evaluate the effectiveness of the treatment in diabetic patients at tertiary care teaching hospital, Effective counselling of diabetic patients and to assess the possible risk factors associated with diabetes mellitus.

METHODOLOGY

Study design: A Prospective and Observational study.

Study location: Department of General Medicine, Osmania General Hospital, a Tertiary care teaching Hospital, Hyderabad.

Sample size: 100 patients.

Study population: Patients above 18 years of age.

Study period: 6 months.

Study criteria

INCLUSION CRITERIA

- Patients of both Genders.
- Patients above 18 years of age.
- Patients Diagnosed with type-2Diabetes Mellitus.
- Patients with co-Morbid Conditions.

EXCLUSION CRITERIA

- Pregnant and Lactating women.
- Subjects unwilling to participate in thestudies.

- Patients with type-1 Diabetes Mellitus
- COVID patients.

Statistical Analysis: Descriptive statistics was used for data analysis. Graphs and tables were generated using Microsoft Word and Microsoft Excel. We have used simple percentage calculations to arrive at a conclusion of our study.

Plan of work: All the relevant data has been taken from the patient's case notes, in a questionnaire, patient's prescription, laboratory tests etc. All the patients at the Osmania General Hospital are screened for diabetes. Each patients details regarding the age, sex, date of admission, date of discharge, physical activity, dietary intake, sugar consumption, laboratory investigations, historyof diabetes, and its treatment given, social habits and any co-morbidity were collected. Literatures which support the study are collected and are reviewed for the safety andefficacy of anti-diabetic drugs.

RESULTS

1. **Gender-Wise Distribution of Patients:** Based on the data collected from 100 cases of Type 2 Diabetes Mellitus, results were evaluated. We found that diabetes was prevalent among 64% Males followed by 36% Females as in figure 1.

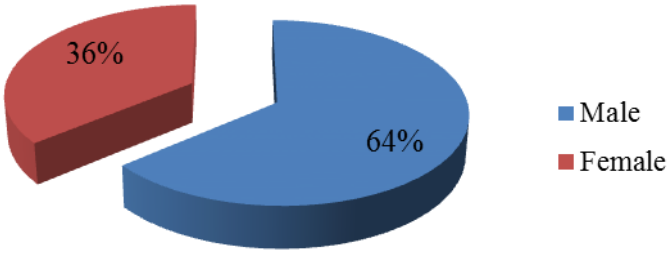

Fig. 1: Gender-Wise Distribution of Patients.

2. **Age-Wise Distribution of Patients:** All the patients were grouped as per the age. Majority of the patients in the study belonged to the age group of 51-60 years (37%) followed by age group of 41-50 years (23%) then 61-70 years (22%) as in figure 2.

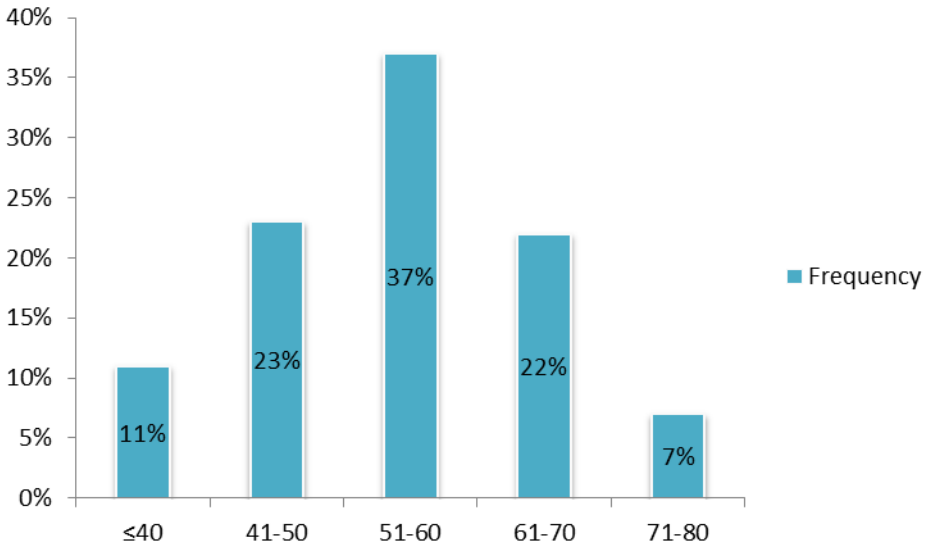

Fig 2: Age-Wise Distribution of Patients.

3. **Distribution Of Patients Based On Addiction:** Among the study population, 55% of the patients were with no addictions followed by 25% of alcoholics, 17% of smokers and 3% of tobacco chewers as in figure 3.

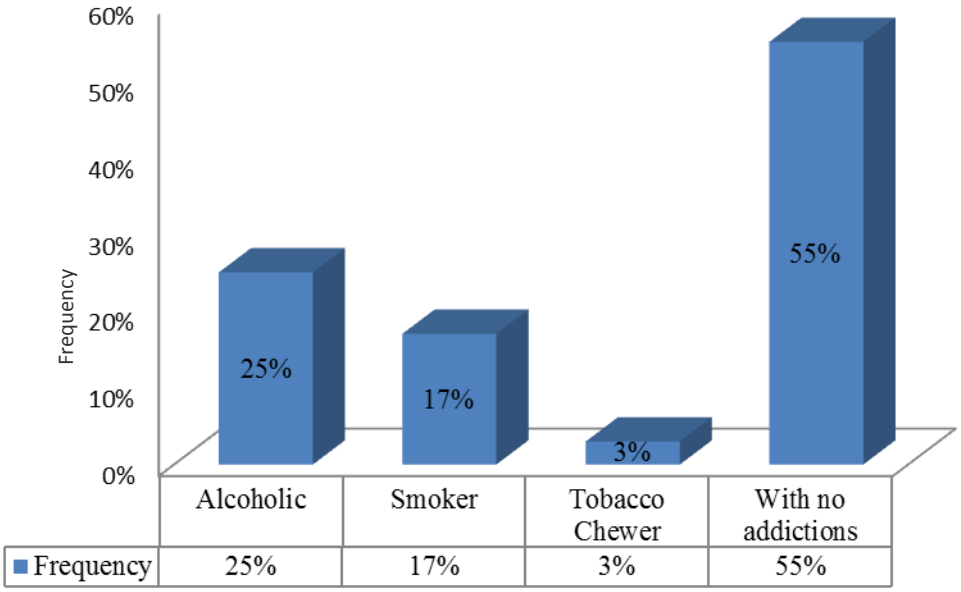

Fig. 3: Distribution of Patients Based On Addictions.

4. **Distribution Of Patients Based On Co morbidities:** among the study population, 62% of patients had cardiovascular diseases as co morbid condition followed by 17% patients with cns diseases, 17% with other infections, 15% with kidney diseases, 14% with respiratory tract infections and 12% with blood disorders as in figure 4.

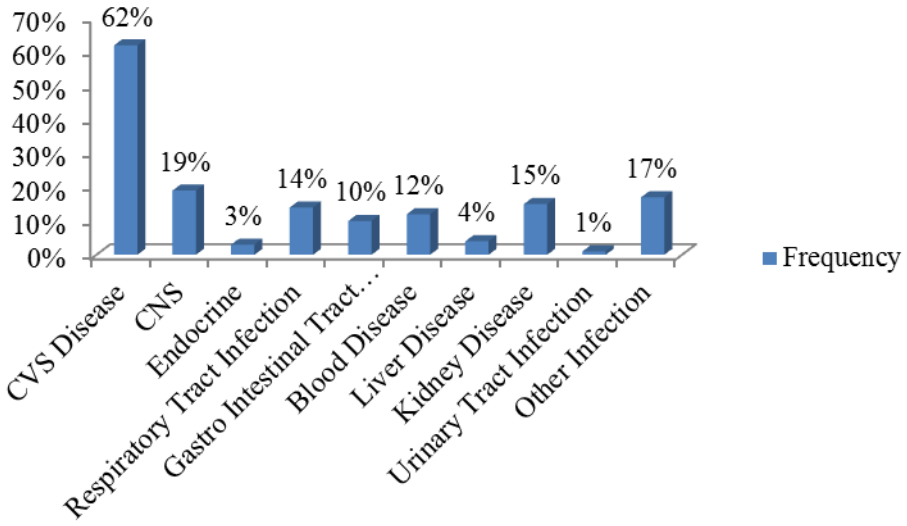

Fig. 4: Distribution Of Patients Based On Co morbidities.

5. **Distribution Of Anti-Diabetic Drugs Based OfRoute Of Administration: -** Within the study population. In 70% of diabetic patients subcutaneous route was the most preferred route of administration followed by oral route of administration in 30% of the patients as in figure 5.

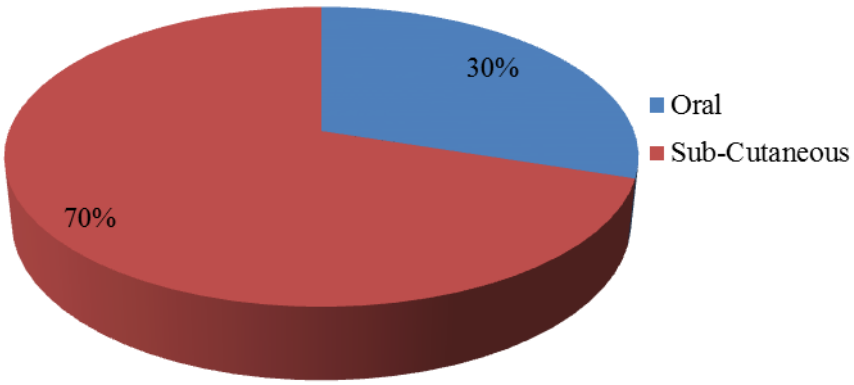

Fig. 5: Distribution of Anti-Diabetic Drugs Based OfRoute of Administration.

6. **Distribution Of Data Based On Oral Hypoglycemic Drugs:** Based on data collected during the study, It was found that most of the patients were on metformin which is an oral hypoglycemic drug accounting for 12%, followed by a combination of metformin + glimepride accounting for 8% and voglibose ((1%) followed by a dual combination of glimepride + Empagliflozine (1%) and triple combination of glimepride + metformin+voglibose (1%) as in figure 6.

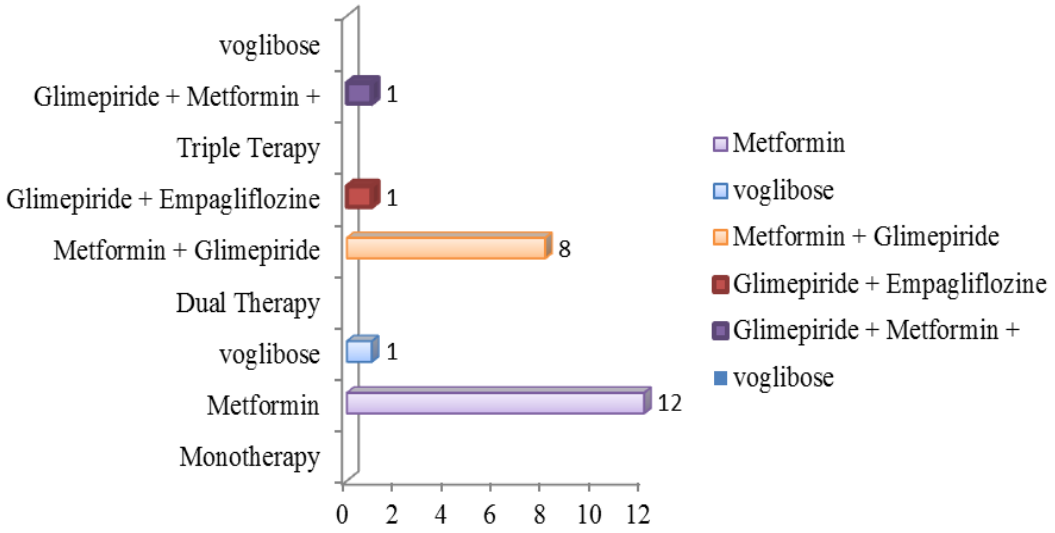

Fig. 6: Distribution of Data Based On Oral Hypoglycemic Drugs.

7. Distribution Of Data Based On Insulin Analogues: - Based on the 100 cases collected. It was found that most of the Diabetic patients were prescribed regular Insulin among Insulin analogs accounting for 64% as in figure 7.

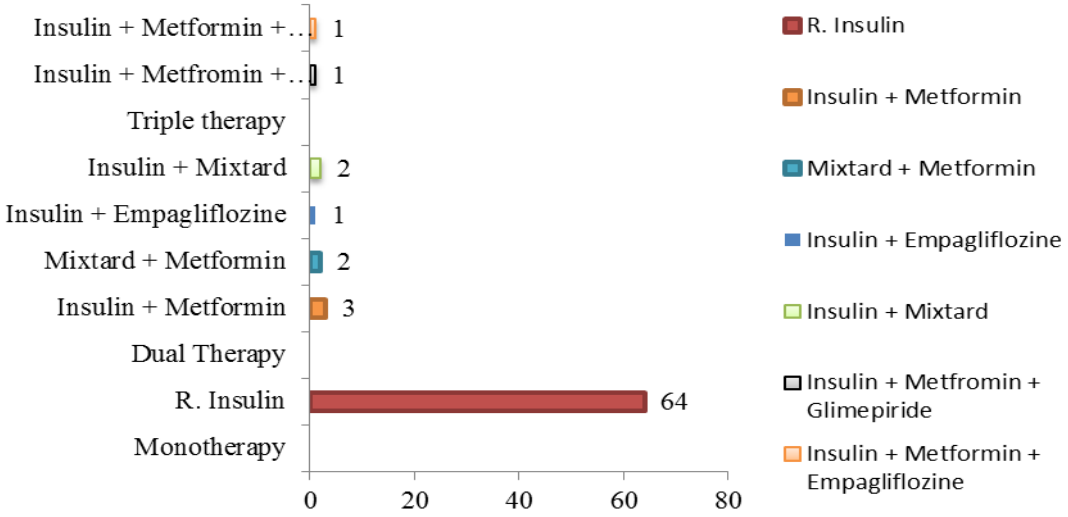

Fig 7: Distribution of Data Based On Insulin Analogues.

8. Distribution Of Patients Based On Their Duration Of Diabetes:- Among the study population, 53 patients had a diabetic history in between 1-10 years which accounts the highest (53%) followed by 15-25 years (7%) and less than 1% (11%) as in figure8.

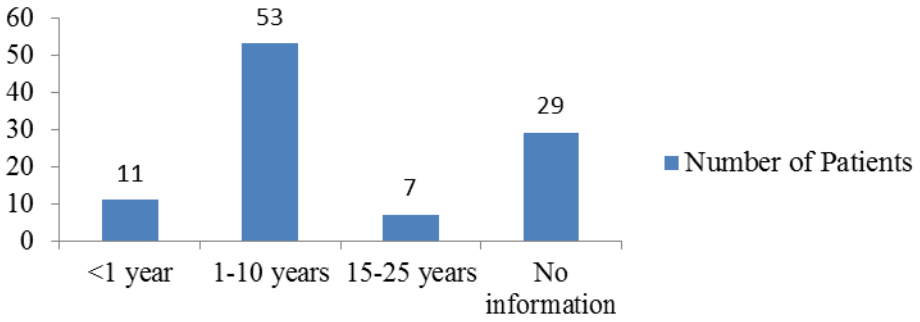

Fig. 8: Distribution of Patients Based On Their Durationof Diabetes.

9. Distribution Of Data Based On Hba1c Levels: - Based on the above data collected, 84% patients had not performed the HbA1C test whereas 14% had their Hb1AC >6.5 followed by 2% having their Hb1AC levels between 5.7-6.4 as infigure 9.

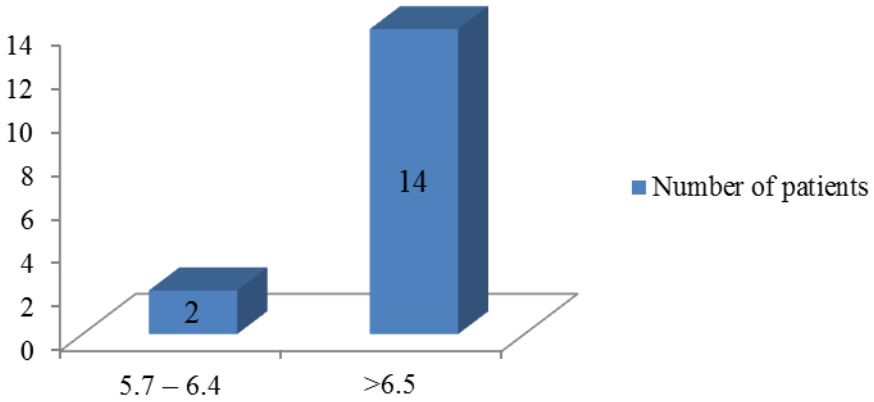

Fig. 9: Distribution of Data Based On Hba1c Levels.

10. Distribution Of Data Based On Complication Of Disease:- Among the study population, 73% of the patients were found to exhibit no complications followed by 10% exhibiting Diabetic Ketoacidosis and 8% Diabetic Foot Ulcers as in figure10.

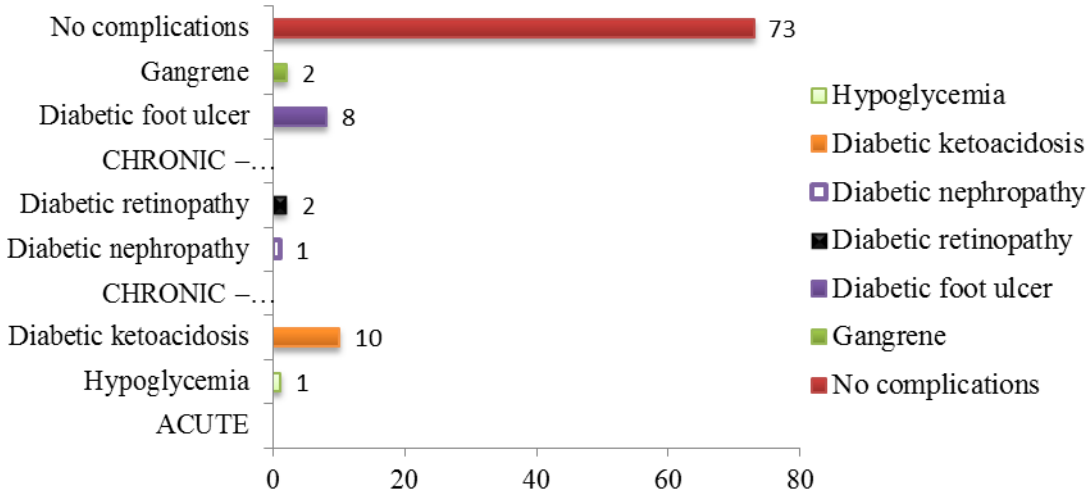

Fig. 10 Distribution of Data Based On Complication of Disease.

11. Distribution Of Patients Based On Risk Factors: - Upon the data collected, patients were classified based on risk factors. 70% of the patients were above 45 years of age, followed by 58% of the patients who were habituated to sedentary lifestyles and 47% of the patients having high blood pressure and 6% having highcholesterol levels as in figure 11.

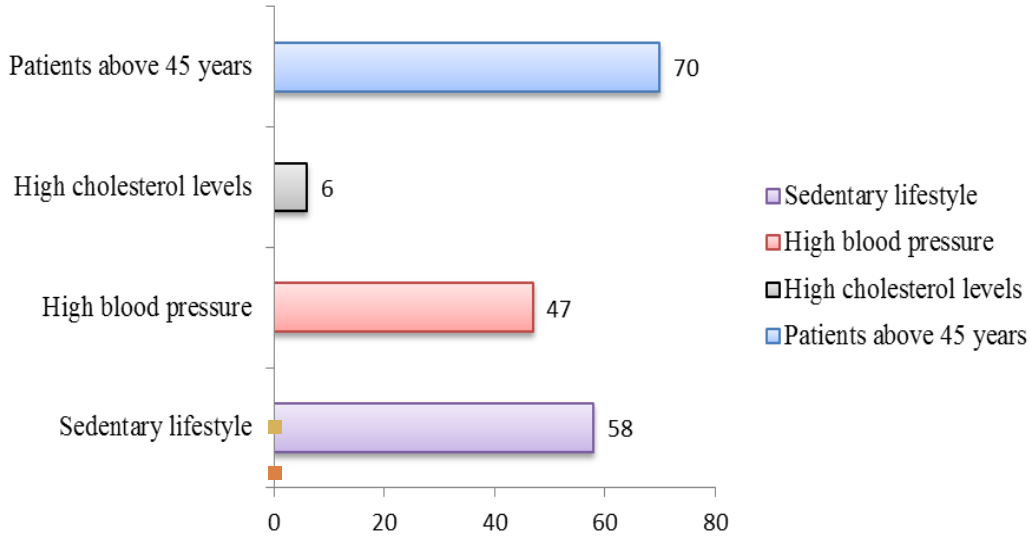

Fig. 11: Distribution of Patients Based On Risk Factors.

12. Distribution Of Patients Based On Adherence:- According to the data collected for analysis, most the subjects i.e., 60% had shown high adherence to the prescription, 21% showing low adherence and 19% medium adherence as in figure 12.

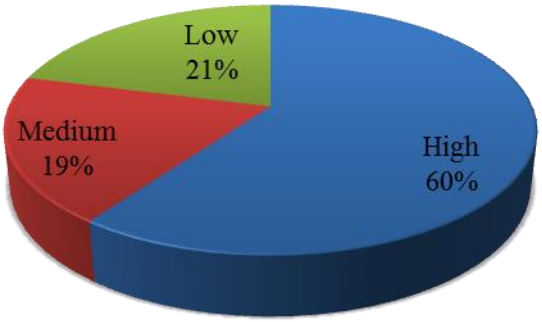

Fig. 12: Distribution of Patients Based On Adherence.

DISCUSSION

During a 6 month study period, 100 patients were evaluated. Results comprises of the following data: Among them 64% were males contributing to be majority with female 36% which was in accordance to the previous study (Pothuru Anil Kumaret al., 2021; Ashutosh Kakade et al., 2017; Khushali G. Acharyaet al., 2013) From the age of <40 to 80 years, majority of patients (37%) were in the age groupof 51 – 60 years. These results differ slightly from the previous study (Ashutosh Kakade et al., 2017; Lallu Mariam Jacob et al., 2018).

Among 100 patients, cardiovascular disorders such as HTN being the commonest co morbid condition (62%) followed by CNS (19%), respiratory tract infections (14%) (Because of the co morbid conditions patients were most often switched to insulin therapy in comparison with Metformin (12%) which was in accordance with the previous study (Lallu Mariam Jacob et al., 2018).

A total of 97 anti-diabetic drugs were prescribed out of which 76 were prescribed as monotherapy and 17 drugs as dual therapy and 3 as triple drug therapy. In monotherapy, OHA combinations were metformin (12%) and insulin therapy likeRegular insulin (64%) were prescribed. About the dual therapy, OHA combinations were metformin + glimepiride (8%), glimepiride +Empagliflozine (1%) and in case of insulin therapy, metformin + insulin (3%), metformin + mixtard (2%), Empagliflozine + insulin (1%), mixtard + insulin (2%). As for triple therapy, OHA combinations were glimepiride + metformin + voglibose (1%), andinsulin therapy like metformin + glimepiride + insulin (1%), metformin + Empagliflozine + insulin (1%) 30% of patients had their treatment

through oral route followed by 70% through sub-cutaneous route which is quite different fromthe previous study (Lallu Mariam Jacob et al., 2018).

Based on duration of diabetes among individuals, <1 year (11%), 1 – 10 years (53%), 15 – 25 years (7%) were found. When HBA1C levels were evaluated, 2% patients had 5.7 – 6.4 range, 14% had >6.5 range and 84% of patients did not complete the test.

Regarding complications, diabetic keto-acidosis (10%), hypoglycemia (4%) as an acute complication; diabetic retinopathy (2%), diabetic neuropathy (1%) and chronic microvascular complication; diabetic foot ulcer (8%), gangrene (2%) as chronic macrovascular complication and majority of patients (73%) had nocomplications. When we assessed the risk factors, 70% of patients were above 45 years of age, 58% had sedentary lifestyle, and 47% had hypertension which is quite similar with the previous study (Chinonyerem O Iheanachoet al., 2021). Among patients with addictions, alcoholics (25%), smokers (17%), tobacco chewers (3%) and with no addictions (55%) were found.

During our consultation, we encountered many patients who lacked understanding in managing their lifestyle, diet and physical activity. So, through this consultation, they learned many different ways to control their blood sugar besidestaking medicine.

CONCLUSION

In this study Effectiveness of the treatment was evaluated and diabetes mellitus associated risk factors were identified and efficient patient counselling was done for improving the quality of life in patients with diabetes.

It can be concluded from our findings that, male patients were more affected than female patients and those between the age group of 51-60 years are more prone totype 2 diabetes mellitus and the study also concludes that majority of the patients had a diabetic duration in between 1-10 years.

The study shows the incidence of various Risk factors, Among them Age >45 years of the age followed by sedentary lifestyle and hypertension were the major risk factors associated with diabetes, whose modification and Risk management could lead to positive health outcomes preventing further complications. We have also studied several

complications, among them the most prevalent one was Diabetic ketoacidosis followed by the Diabetic foot ulcer. Each diabetic patient in this study had one or more co morbid conditions; cardiovascular diseases were the most prevalent.

The most commonly prescribed drug for the treatment of T2DM in inpatients was insulin (Regular Human Insulin), followed by Biguanides (Metformin) and Sulfonylureas. Subcutaneous route of administration was the most preferred route for insulin. It was found that majority the drugs prescribed were according to AHA guidelines. The study also shows there is a high medication adherence of about 60%.

The current study have showed that involvement of clinical pharmacist in evaluating the best treatment outcomes with effective patient counselling can definitely have a positive impact on health outcomes and also improves the quality of life in patient.

Abbreviations

1. DM - Diabetes Mellitus
2. ADA - American Diabetes Association
3. GLUT 2 - Glucose Transporter 2
4. SUR 1 - Sulfonylureas Receptor 1
5. NEFA - Non Esterified Fatty Acid
6. PPAR - Peroxisome Proliferation Activated Receptor
7. DKA - Diabetic Keto Acidosis
8. BMI - Body Mass Index
9. GLP 1 - Glucagon Like Peptide 1
10. DPP 4 - Dipeptidyl Peptidase
11. HB1AC - Hemoglobin A1C
12. TZD - Thiazolidinediones
13. OHA - Oral hypoglycemic control

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