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A STUDY ON MEDICATION USE EVALUATION IN PATIENTS WITH DIABETES MELLITUS AT A SUPER-SPECIALTY HOSPITAL

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ABSTRACT
Medication use evaluation is a crucial practice to be followed in different clinical studies. A prospective observational study was conducted for a duration of one year. The study includes a sample size of 100 patients. The study was designed to promote the utilization of standard treatment guidelines for patient care. The main objective of this study is to evaluate the quality of life in diabetic patients and to analyze the drug prescribing pattern observed in the hospital. A secondary objective of the study was patient counseling and to assess the patient's understanding of disease and medication utilization. Apart from that study also aided in reporting possible adverse drug reactions and drug interactions between the various prescribed drug. A standard questionnaire was used to assess the quality of life in patients suffering from diabetes mellitus which resulted in that there was the need for counseling was observed among the patients regarding disease and drug use.
Index terms: DUR studies, Diabetes Mellitus, prescribing pattern, quality of life, psychological effect.

INTRODUCTION

Drug utilization review (DUR) is a systematic and multidisciplinary performance improvement technique. Medical use evaluation(MUE), Drug use evaluation (DUE), and Drug utilization review (DUR) are sometimes used interchangeably, While DUE and DUR typically correspond to continuous, systematic, criteria-based, drug- or disease-specific evaluations that assure appropriate medication utilization at the individual patient's level, medication use evaluation (MUE) may be distinguished by emphasizing in improving patient health and wellbeing outcomes through clinical assessment outcomes via an interdisciplinary approach. [1-4]

Elements addressed in drug use evaluation: Having established the objectives, priorities, and emphasis, Establishing the usage standards for evaluation, acquiring usage statistics, examine and assess the information, Plan, and implement strategies to improve medicine utilization, Analyze the steps taken, Document the findings and share them with other healthcare providers. [5-7]

These studies include drug prescribing, dispensing, and dosing steps and focus primarily on therapeutic issues faced by large numbers of high-risk patients. DUE studies should analyze and evaluate this information implicitly, without prejudice of any kind, using predetermined criteria. It plans and implements the necessary programs after analyzing the information gathered in order to increase performance. Following the improvement of the necessary functions, the consequence of these alterations is collected and reported afterward executing the necessary follow-ups.[8-10] DUE primarily emphasize on rational drug use. [11,12].

The drug utilization studies use the various epidemiological approaches to analysis the clinical drug usage in a population. [13] It is mandatory to practice rational drug therapy for each patient receiving drug treatment. Consequently, it is obligatory to examine the drug usage pattern. [14,15]Drug utilization research (DUR) examines patterns of medication use and treatment adherence, as well as the factors that influence drug utilization. [16,17]

The goal of DUR is to promote the judicious use of drugs in the population. For the individual patient, prudent use of medicine means prescribing a rational medicine in the ideal portion for the correct indication, with the right information, and at a reasonable cost. [18]
They create a well-founded socio-medical and health-economic basis for decision-making in the healthcare system.[19] It is considered one of the most powerful tools for assessing physicians' prescribing patterns.[20] DUR studies are critical in steering toward appropriate prescribed medications, reducing the possibility of side effects and assisting in the increase of patient adherence and, as a result, their quality of life. [21,22]

Drug use evaluation can be enlisted in three categories. The first one is a prospective drug utilization review which implicates the analyzing the patient's prescription before the drug is given out to the patient. Prospective DUR studies allow pharmacists to detect and elucidate the issues using computerized systems. Pharmacists checks for drug-drug interactions, therapeutic duplication, or and contraindications that may occurs between drug and disease.

The second one is concurrent drug utilization review. It is usually performed throughout the treatment duration and entails ongoing monitoring of medication therapy to promote favorable outcomes for patients. It enables pharmacists to inform healthcare practitioners to possible concerns and intercede in areas of drug-drug interactions, duplication therapy, over or underutilization, and high or inadequate dose. This form of evaluation permits a patient's treatment to be changed if required.
Third and the last category is retrospective drug utilization study which evaluates the drug treatment prescribed once the person got the treatment. A retrospective study looks for trends in the prescription, distribution, or administration of medications. This study aids in the development of guideline and interventional standards to prevent the drug misuse and unfair drug usage means.
interventions can be developed to prevent the recurrence of improper medication use or abuse. Retrospective studies addressed the issues such as clinical drug abuse, incorrect drug dosage, and appropriateness of drug usage.[23] Table 1 shows the process of DUR studies.

Diabetes mellitus:
Diabetes mellitus is a lifelong complicated metabolic disorder associated with vascular (microvascular and macrovascular) complications. This condition usually happens as secondary to hyperglycemia.
In clinical practice, the use of dipeptidyl peptidase 4 (DPP-4) inhibitors in individuals with T2DM has increased due to low risk of hypoglycemia and weight neutrality. To achieve targeted glycemic control in type 2 DM patients, teneligliptin is currently used as a second or third supplement to the recommended treatment with other classes of oral hypoglycemic agents (OHAs)].
A common microvascular complication caused by uncontrolled chronic hyperglycemia is diabetic nephropathy [24,25] (also termed diabetic kidney disease [DKD]). DKD occurs in 20–40% of individuals with diabetes [26], generally within 10 years of diabetes onset. [27] Tight glycemic control, and the control of other risk factors like blood pressure, can prevent the occurrence and progression of microvascular complications in people with diabetes. [28,29]
Oral anti-diabetic agents predominate the prescribing pattern practices for type 2 DM but there was a shift in trend towards the use of fixed-dose combinations (FDC) in the management of type 2 DM, and the most of prescribing adherent to ADA treatment guidelines.
Different classes of drugs, oral and parenteral, are widely available and effective in treating type 1 and type 2 diabetes. They are classified according to their blood glucose-lowering mechanism and include incretin-dependent therapies such as insulin, biguanides, sulfonylureas (SU), meglitinides (glinides), α-glucosidase inhibitors (AGIs), thiazolidinediones (TZDs), and glucagon peptide 1 receptor agonists (GLP1a) and dipeptidyl peptidase 4 inhibitors (DPP4i), sodium glucose cotransporter type 2 inhibitors (SGLT2i), and combinations thereof. Newer agents such as SGLT2i and GLP1a have shown clinical benefits for patients with type 2 diabetes, including: [30-37] In contrast, there is evidence of clinical benefit for other classes (e.g., DPP4i). Another class of potential harms and unclear benefits (e.g., hypoglycemia due to SU in the elderly). [38-41]

Type 2 diabetes is indicated by insulin resistance and comparative deficiency in insulin secretion. Beta cell destruction and insulin deficiency get worsen with time. More sophisticated analyses of the beta-cell response and regulation have recently revealed that most people at risk for type 2 diabetes, i.e., those with impaired fasting glucose and impaired glucose tolerance, have already lost a significant amount of their pancreas' total insulin secretory capacity, close to 80%. People with type 2 diabetes have intra-abdominal (visceral) obesity, and it's part of a "ectopic fat" deposition pattern that's linked to insulin resistance along with elevated PAI1(Plasminogen activator inhibitor-1) level.[42] Type 2 diabetes was previously known as non-insulin-dependent diabetes, type 2 diabetes, or adult-onset diabetes, and it affects 90–95 percent of people with diabetes. Patients with this disease are more likely to have macrovascular and microvascular problems. Figure 1 depicts the progression of type 2 diabetes with age, obesity, and a lack of physical activity, the risk of acquiring this kind of diabetes rises. It affects women more frequently than men.[43] Figure 1 shows the progression of type 2 diabetes.

MATERIAL AND METHODS

Study Design: A prospective observational study was conducted in a super-specialty 300 bedded hospital on 100 patients. The inclusion and exclusion criteria of the study were explained to the patients and their representatives. An informed consent form was taken from the patients or their guardians who were willing to participate in the study. In addition, representatives have informed that refusal to participate in the study or withdrawal from it would not result in any kind of harm i.e., no blood samples were required.

Inclusion Criteria

Subjects must meet all the study Inclusion Criteria as outlined below:

1. Patients 18-80 years of age.
2. Patients suffering from Diabetes and Diabetes associated with Comorbidities

Exclusion Criteria

1. Pregnant and lactating women
2. Paediatric patients.
3. Psychiatric patients.

Source of data

1. Patient’s prescription
2. Patient case files.
3. Treatment chart
4. Discharge Summary.

RESULTS AND DISCUSSION

In the research study, a total of 100 inpatients were included. Prescribing patterns, drug interactions, and medical use evaluation were analyzed in these patients. Interviews with patients or his/her representative was conducted; information acquired was recorded in various forms and questionnaire and then analyzed.

Demographic Representation:

Demographic representation of 100 patients studied revealed that the majority of patients were male (62%) while females were 38%. Data showed majority of patients with diabetes and co-morbid conditions were either alcoholic or smoke. Majority of the patients were from middle class background and were unaware of disease, its progression, and complications. Figure 2 shows the graphical representation of gender- based prevalence of disease.

Age-wise diabetic prevalence:

Diabetes can occur at any age. Type 1 diabetes mellitus is generally seen in young age while type 2 diabetes mellitus is developed later in life. In our study we included people from the age group of 20yrs to 100 yrs. And we found that incidence of diabetes is seen majorly in age group of 41yrs to 60years of age. Followed by 61yrs to 80 yrs. and 21 yrs. to 40 yrs. The least number of patients were reported to be above 80 yrs. of age. This can be concluded that incidence of diabetes is higher within middle age groups. Figure 3 shows the age-wise prevalence of diabetes.

Co-morbid condition with diabetes:

It is assessed that half of patients suffering with diabetes are not aware of their disease and are predisposed to developing diabetes associated complications. Patients suffering from Type 1 and Type 2 Diabetes commonly show diabetic complications which are responsible for causing morbidity and mortality in such patients. In our study most of the patients were presented with co-morbid conditions. Out of which Hypertension, chronic

kidney disease, cancer, hypothyroidism, neurological disorders, infection, and anemia were observed in most of the patients. Among the entire patient studied, large numbers of patients were suffering from hypertension. (76) And the least number of patients reported hypothyroidism (8). Figure 4 shows the number of co-morbid conditions present among the patients.

Medication prescribed:

As patients admitted were also suffering from comorbid conditions, combination drug therapy was prescribed in order to improve patient's condition and standard of living. In majority of patients, oral hypoglycemic drugs were prescribed to manage diabetes mellitus.

Drugs used to manage Hyperglycemia included: glimepiride, metformin, teneligliptin, Linagliptin, and vildagliptin. Out of which glimepiride and metformin were excessively used among patients. Ecospirin AV, a combination drug of aspirin and atorvastatin was also given in almost half of the patients. It is given to manage hypertension which is present in more than 70% of the patients as co-morbid condition.

Insulin is also prescribed in combination therapy along with oral hypoglycemic drugs in the patients in which glycemic control was hard to achieve only by oral antidiabetic drug. Around 27 patients were given insulin co-therapy with oral hypoglycemic drugs. The least preferred anti-diabetic drug is linagliptin. Figure 5 shows the number of medications prescribed.

Antibiotics prescribed:

Antibiotics are the class of antimicrobial medications which are used to treat bacterial infection. Hospitalized patients require antibiotics in order to prevent the occurrence of infection. In this study patients received antibiotic treatment for various infections and for prevention of infection. Ceftriaxone is the maximum prescribed antibiotics among all the individuals (28) followed by piperacillin & tazobactam (13) and sulbactam/Cefoperazone (10). Figure 6 shows the number of antibiotics prescribed.

Drug interactions:

Drug interactions are the result of altered drug's mechanism of action due to concomitantly administered food or other drugs. Sometimes drug interactions can be life threatening and serious. In this study we have only studied drug-drug interaction.

Moderate drug interaction is seen in the majority of patients and number of moderate interactions reported were 152 and number of minor drug interaction reported were 20.

Major drug interactions are also seen in some patients.

All of these drug interactions seen among patients were either avoidable or was manageable by therapy modification, dosage modification or change in the timing or route of administration. Figure 7 shows the number of drug interactions reported.

Diabetes complications:

Both type 1 and type 2 diabetes are accompanied by other complications such as cardiovascular risks, neurological risks, ophthalmic problems like retinopathy and nephropathy. In this study we prepared a questionnaire where we asked patients about different complications they faced along with diabetes.

76 of 100 patients reported of various cardiovascular problems like hypertension, angina or arrythmia. 39 of the patients reported of ophthalmic issues like loss of vision and difficulty in focusing and blurry vision. 29 out of 100 patients suffered from lower libs problems that is peripheral neuropathy. Very few patients reported of gastrointestinal issues and 20 of them reported of nephropathy.

These complications can however be managed and if controlled can increase the life expectancy of the patient. Figure 8 shows the complications of diabetes.

Social history:

Social history of patient affects the overall health and healing time of patients and also effect the effectiveness of the medication. Social history like smoking, alcoholism and food allergy interferes with efficacy of oral hypoglycemic drugs by altering drug's ADME (absorption, distribution, metabolism, and excretion), and by effecting the drug response by altering pharmacodynamics of the drugs.

Through our questionnaire it is conclude that more than half of the patients were smoker that is 59% of the patients were chronic smoker. 33% of the patients were habitual drinkers and 8 % of the patients have certain kinds of food allergy.

Most of these patients were chronic alcoholic and smokers. Some of them have been drinking from more than 10 yrs.

Food allergies in patients were observed with peanuts, dairy products like milk, cottage cheese, curd etc. and gluten allergy. Figure 9 shows the social history of the patients.

Effect of insulin on patient's lifestyle:

Insulin is a naturally occurring hormone synthesized in the β cells of islets of Langerhans in pancreas. However, in type 1 diabetes and in certain complicated conditions of type 2 diabetes insulin injections are mandatory. Though it is essential but causes various side effects like redness, itching and swelling at the site of injection, GI irritation, weight gain and dependency.

In a questionnaire, we categorized the effect of insulin into 5 categories based on how much it has affected the patient's day to day life.

Out of 100 only 27 of the patients were on insulin. 8 patients out of 27 said that insulin effected their life 'quite a bit', 6 of them said it effected 'moderately' to them, other 5 of them said it 'effected a lot' and feel they are dependent on the insulin and can't have a meal without insulin injections. Other and this 5 people reported 'slight effect' and 3 of them have no issue with the insulin injection and they feel better with it. Figure 10 shows the effect of insulin on a patient's lifestyle.

Mode of insulin injection:

Insulin administration can be done by various methods like pens, injections and pumps based on the ease of application and budget friendly. 70 % of all the 27 patients taking insulin use injections and syringes, while only 4% use pumps. While the remaining 26% prefer insulin pen for administering insulin. Figure 11 shows the mode of insulin used.

Number of times syringe repeated:

It is recommended not to repeat the Insulin syringes used for administering insulin. Repetitive use of same syringe may lead to microbial contamination and thus may lead to infections, especially in patients with weak immunity.

When asked about if these patients repeated their insulin syringes categorized into 4 categories, never repeated, repeated twice, repeated thrice and repeated four times and more.5 patients never repeated their insulin injection and 4 patients admitted repeating the injects 4 times and more. Figure 12 shows the number of times the same syringe repeated by patient.

Psychological perception:

When asked about wheather patients are comfortable with or prefer oral hyopglycemic drugs over insulin or vise a versa, 81 prefered oral antidiabetic drug over insulin adminstration and 19 patient preffered insulin.

81 of the 100 patients state that insulin injetions are painfull and difficult to administer and 19 patients belive that insulin injections are necessory for maintaining their blood sugar level. Figure 13 shows the pyschological perception of insulin vs oral antidiabetic drugs.

Discussion

Diabetes mellitus is a metabolic disorder related to the body's inability to utilize glucose and to metabolize it. It is a chronic and lifelong disease-causing various morbidities and complications. It is ninth leading cause of mortality in the entire world in 2020. However, type 1 diabetes is much more prevalent than type 1 diabetes.

Various types of drug classes are used in the management of diabetes mellitus including biguanides, Sulfonylureas, SGLT-2 inhibitors,GLP-1 receptor agonists, inhibitors either as monotherapy or in

combination. As diabetes is a metabolic disorder, it is associated with multiple complications and comorbidities. This thus places a person in a vulnerable position to get infections and being hospitalized. Thus, this becomes important to analyse the drug used in comorbid conditions to prevent drug interactions and to estimate if quality of life in hospitalized patients improved after the intervention and patient counselling.

This current study tries to estimate the prescribing pattern in a territory care hospital and analysing the impact of disease in patients' day to day life. Various similar studies have been conducted in the recent past. A study took place in 2022 named treatment pattern trends for type 2 diabetes in British Columbia showed the result that metformin was the most used drug, and the use of combination drugs is increased over the years.

Similar study conducted in 2020 studied the effect of dapagliflozin in patients with chronic kidney disease as a comorbid condition to diabetes. Results shown significant improvement in the health of the patient and decline in mortality rate.

In this study we included various patients with multiple comorbid conditions along with diabetes mellitus. We found that majority of patients were suffering from cardiovascular disorders and kidney disorders particularly hypertension and chronic kidney failure. Other comorbidities observed during our study are neurological disorders, cancer, and infections. Out of total sample size only 7.39 % patients did not have any comorbid conditions. As many patients were also suffering from infections or were at the risk of infections, several antibiotics were also prescribed. Ceftriaxone was the most prescribed antibiotic. Talking about the gender-based disease distribution, disease prevalence is seen more in males than in females.

The study found out that glimepiride and metformin were the most prescribed antidiabetic drugs as a first line treatment. Most of the prescriptions followed the combination therapy whereas monotherapy was seen in few prescriptions. Alongside the hypoglycaemic drugs, a combination drug atorvastatin and aspirin were most abundantly prescribed to the patients with cardiovascular diseases. Among all the prescriptions, 27% prescribed for insulin therapy.

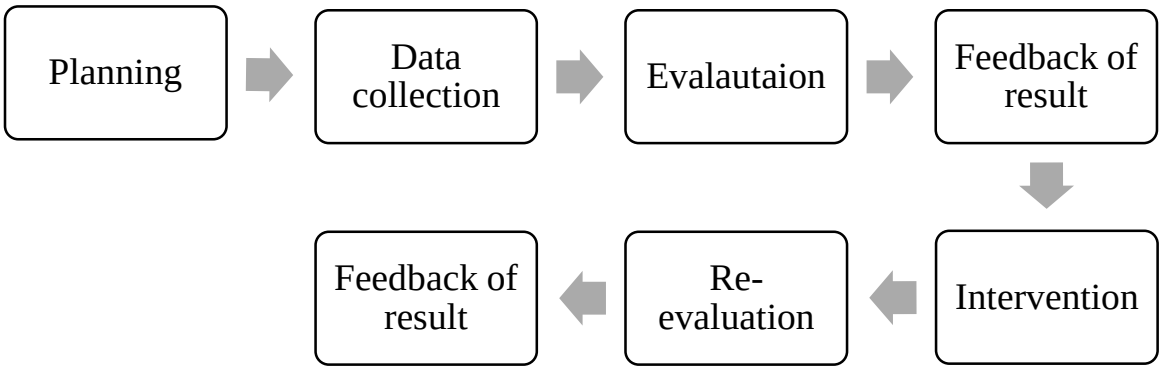
This study also focusses on the disease effect on lifestyle of the patient through a specifically designed questionnaire which is unique to this study and was not used elsewhere. Through questionnaire patients' understanding of the disease and drug use was also evaluated. Result of our questionnaire clearly denotes the need of counselling. Insulin use and prolong medication use has also affected the patient's psychological state of mind. Most of the patients were not comfortable with the insulin use and was in favour of oral hypoglycaemic medications. Many patients were keen to cease the continuous use of medications.

Numerous drug interactions were also found in the prescription which were confirmed with the use of trusted and reputed software's like Lexicomp, drugs.com, Medscape and WebMD.

Tables and figures

Tables:

Table 1: Steps in DUR studies



Figures:

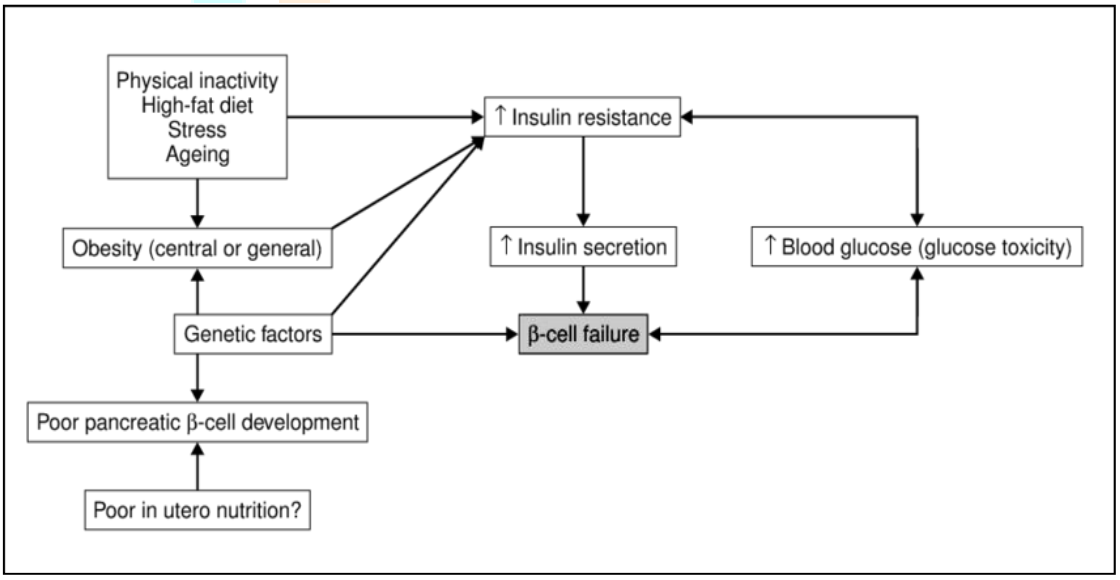


Fig. 1: Progression of type 2 diabetes

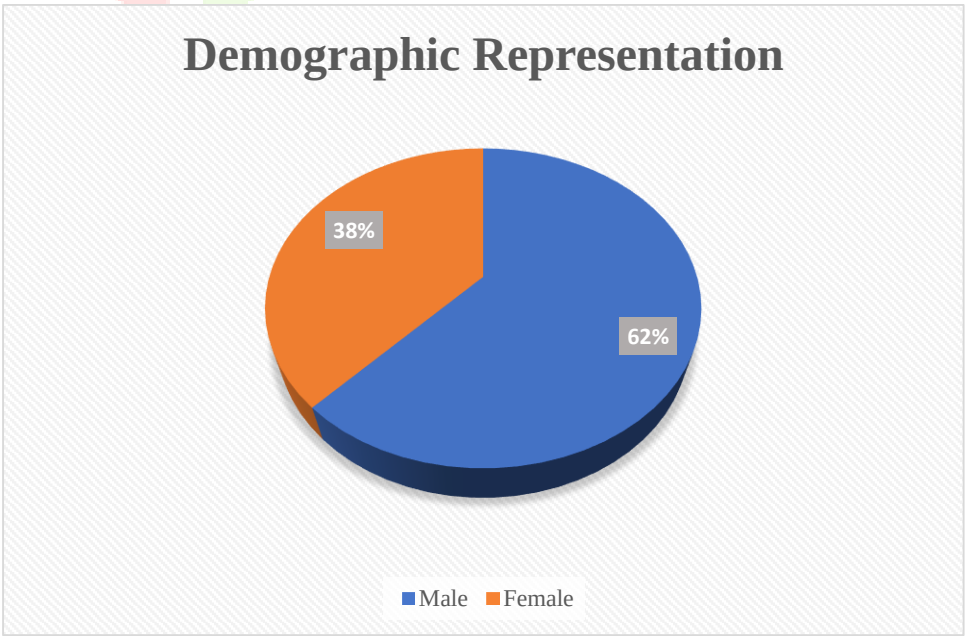


Fig. 2: Demographic representation

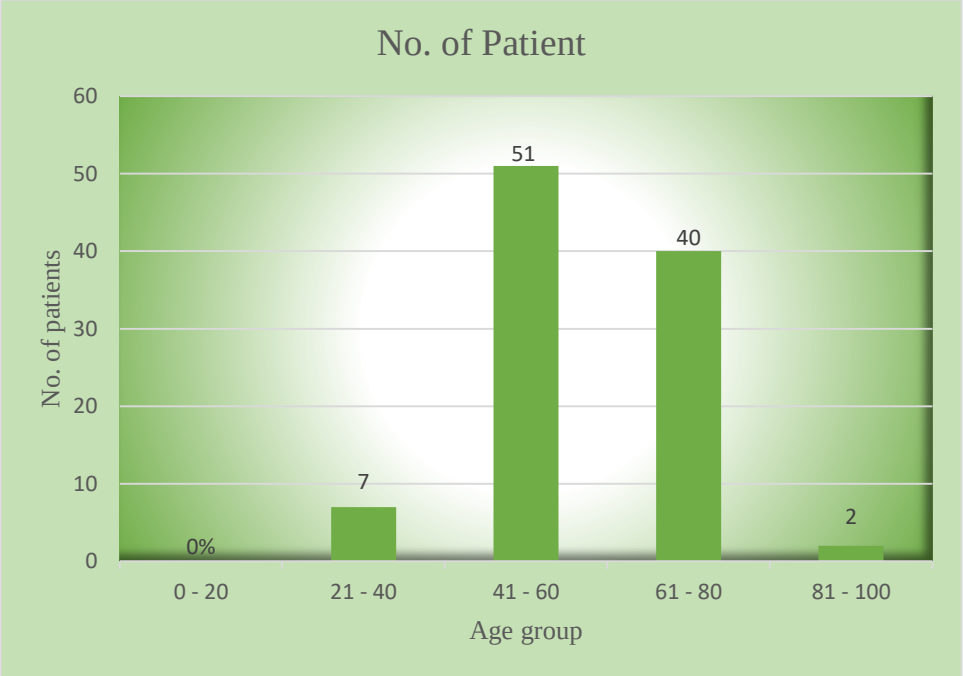


Fig. 3: Age-wise diabetes prevalence

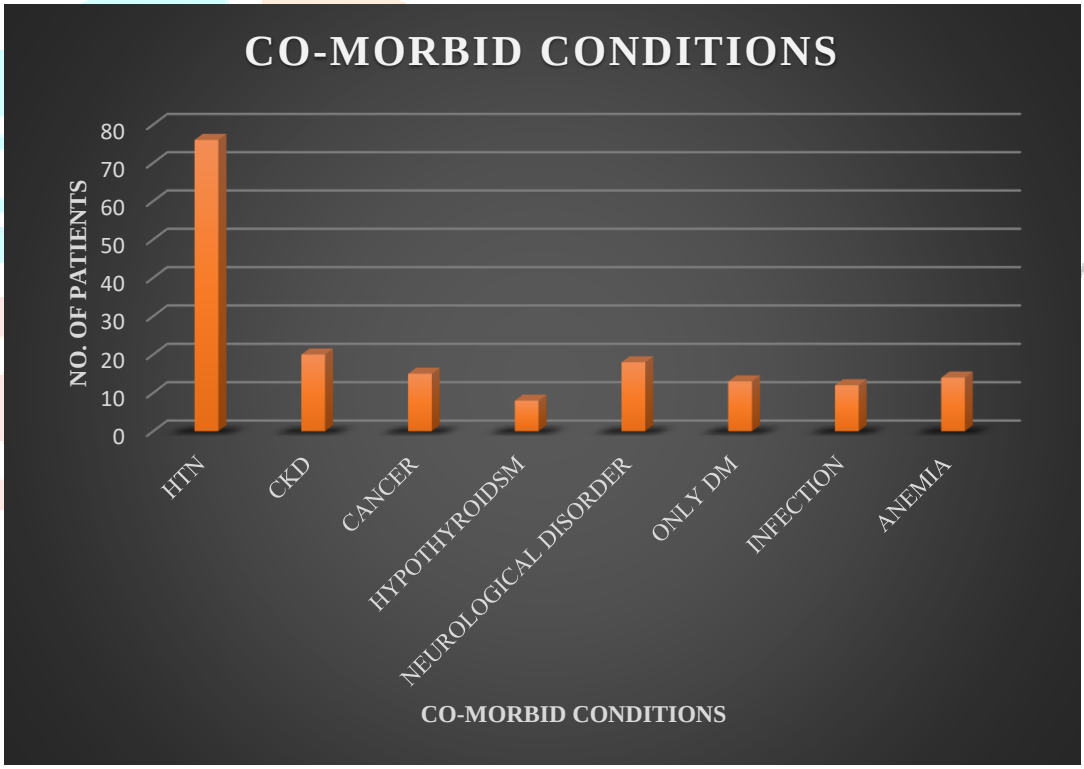


Fig. 4: Diabetes with different Co-morbid conditions

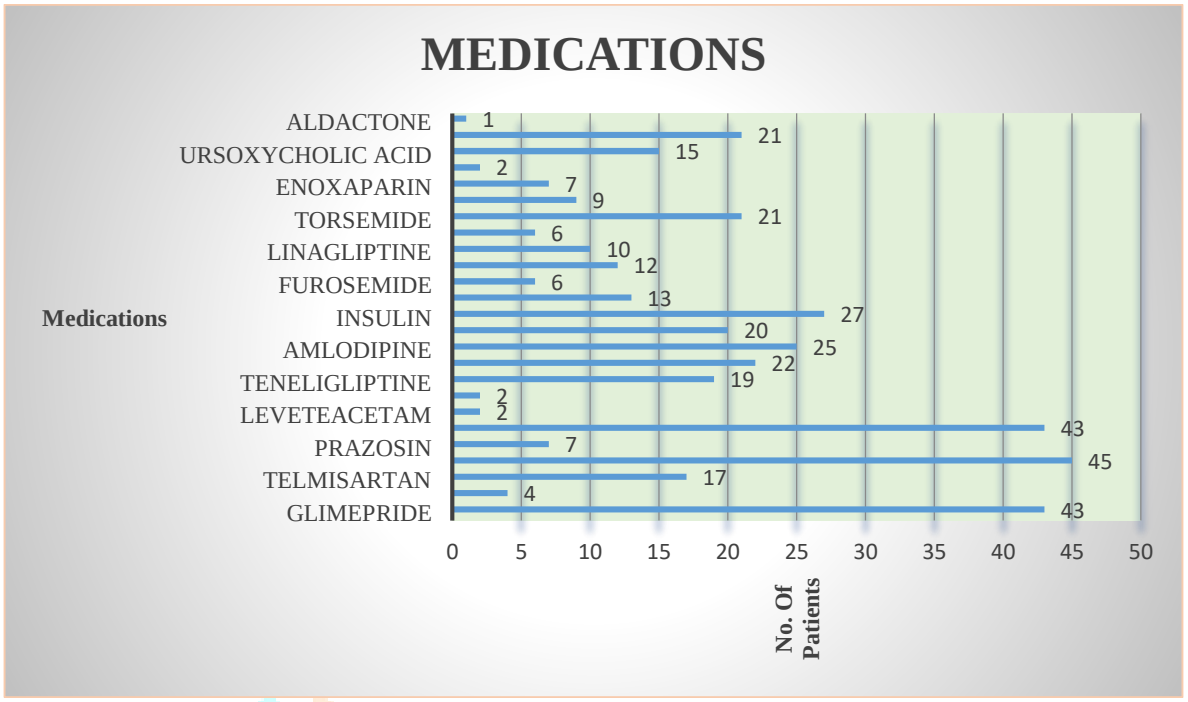


Fig. 5: Medications Prescribed

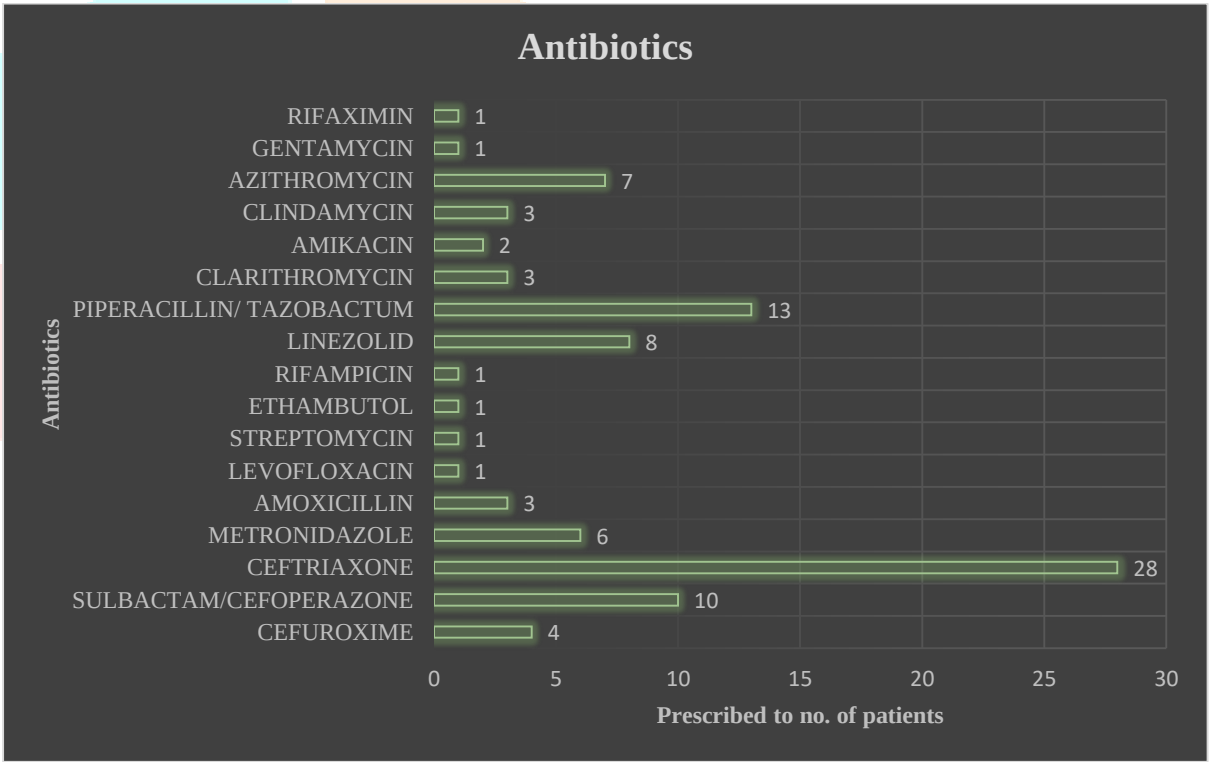


Fig. 6: Antibiotics prescribed.

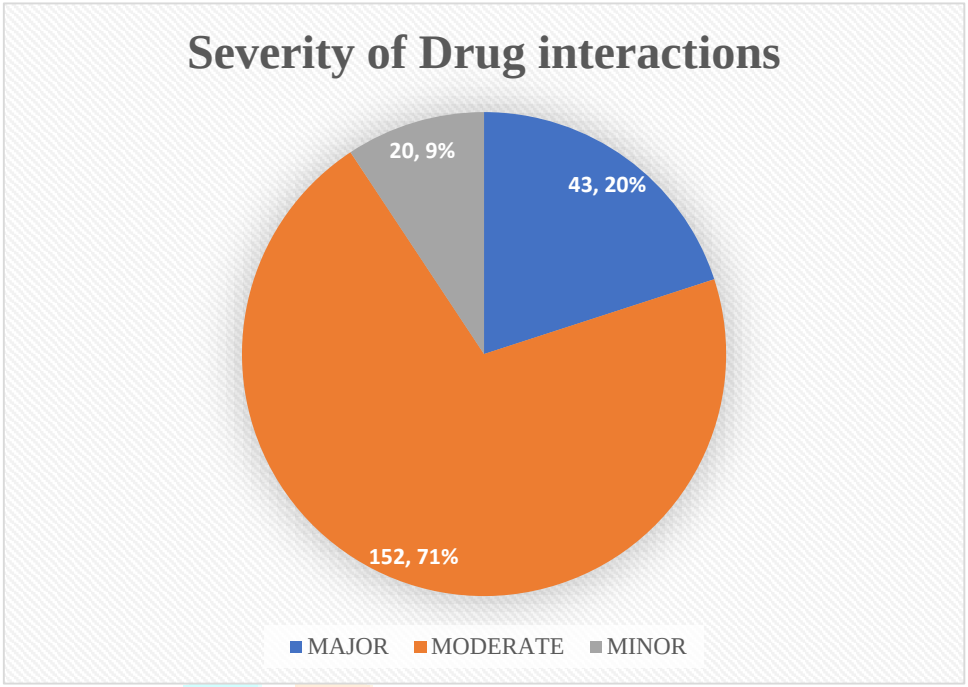


Fig. 7: Severity of Drug interactions

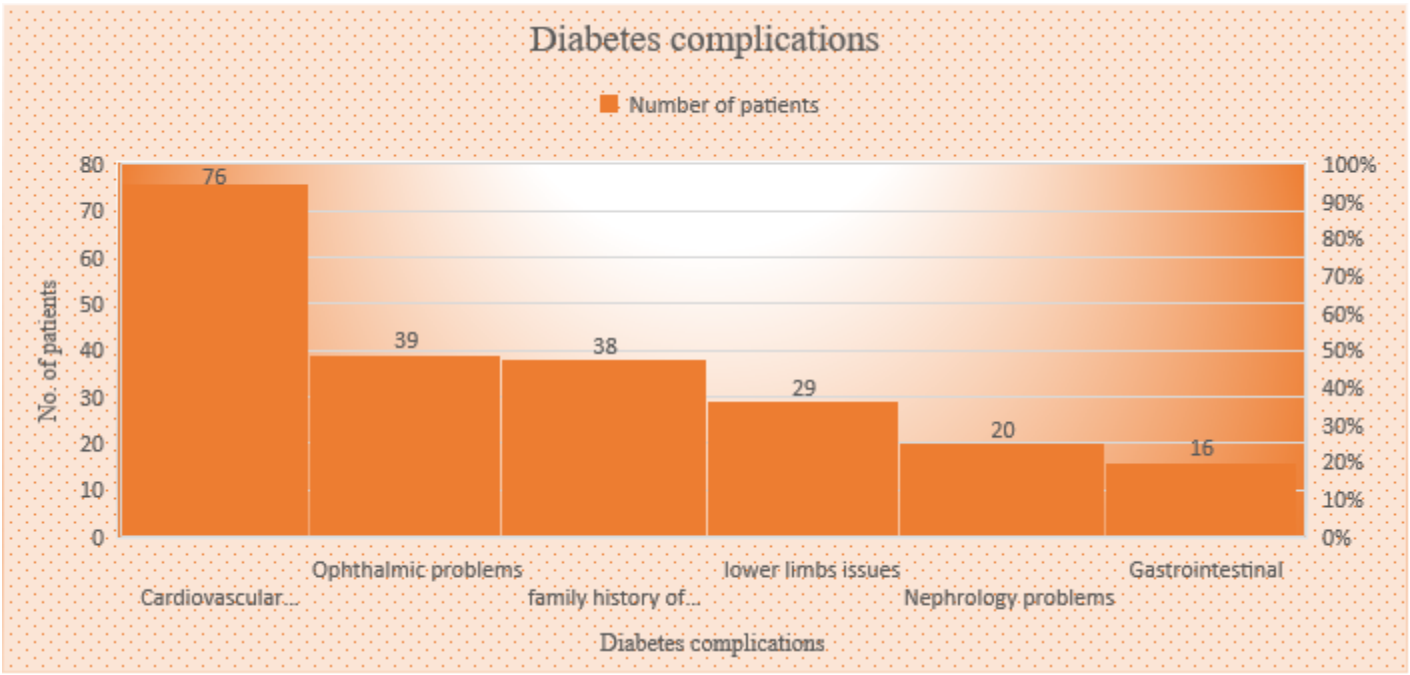


Fig. 8: Diabetes complications

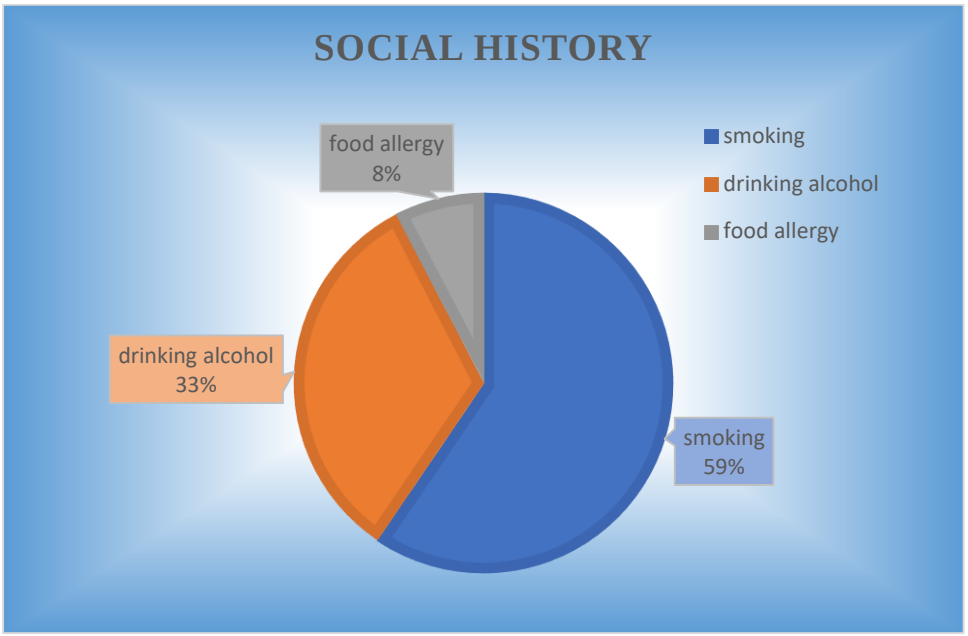


Fig. 9: Social history of patients

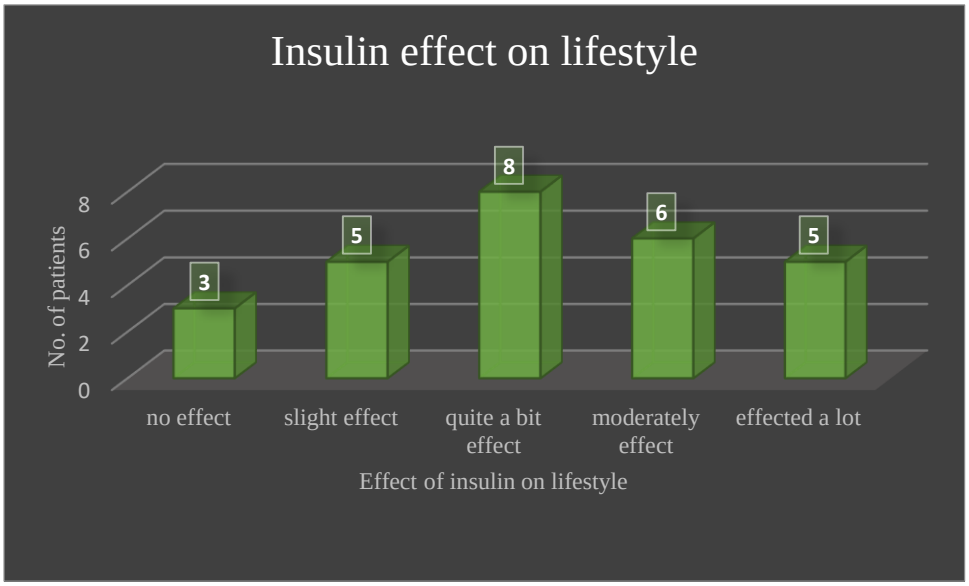


Fig. 10: Effect of insulin on patient's lifestyle

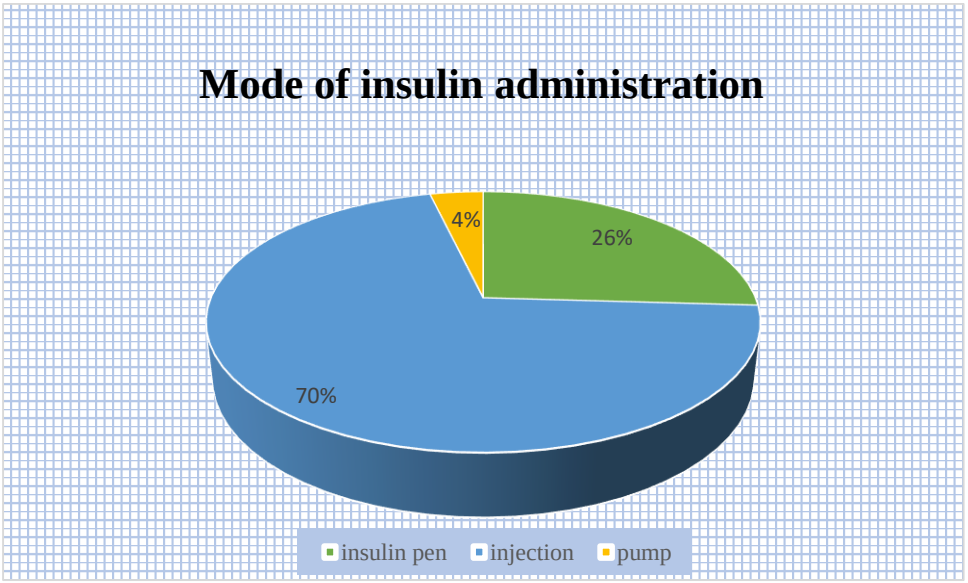


Fig. 11: Mode of insulin injection

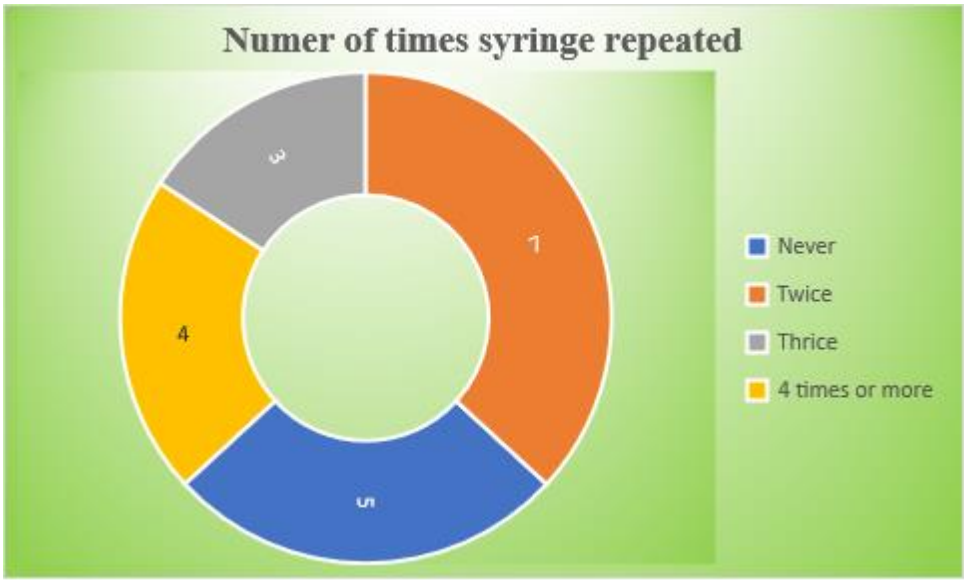


Fig. 12: Numer of times syringe repeated

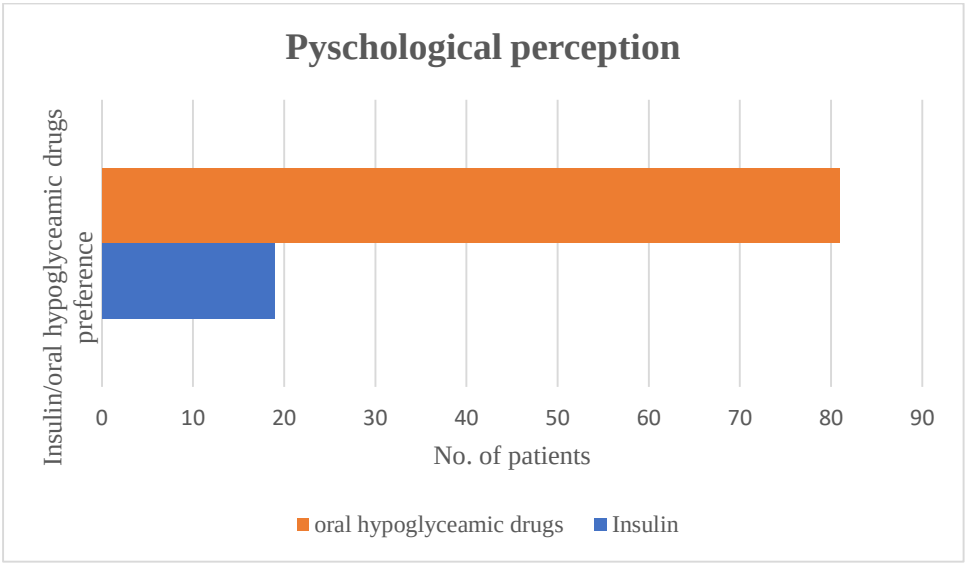


Fig. 13: Psychological Perception

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