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A COMMUNITY BASED STUDY TO ASSESS THE MEDICATION ADHERENCE IN PATIENTS WITH DIABETES MELLITUS IN ERODE

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ABSTRACT

Diabetes mellitus is the chronic metabolic disorder with the condition where there is abnormal high blood glucose level. Home medication review (HMR) is patient centered process which provides the effective and quality use of medication at patient's home. According to a study, nearly 50% of Type II diabetes fail to recite adequate glycemic control due to poor management of anti- diabetic medications. So, a community based interventional study was conducted in 150 subjects residing in various parts of Erode, with the aim to assess the knowledge, attitude and practices on management of anti-diabetic medications at home in diabetes patient through HMR after obtaining ethical committee approval. Information regarding medication adherence, medication errors and drug related problems was collected through systematically designed data collection form and patient information leaflet through home medication review. Questionnaires was prepared and given to patients before and after intervention. The low adherent patients were given with PIL and also counseled before the post interventional study. Among 150 subjects 85(56.6%) subjects in medication adherence, 135(90%) subjects in modification of dose, 115(76.7%) of subjects in time modification, 115(76.7%) subjects in knowledge of storage had shown improvement after the interventions (PIL and counselling). So, it was concluded that the pharmacist intervention was helpful in improving the overall diabetes management through HMR, thereby leading to a better health care outcome.

KEYWORDS: Home medication review (HMR), Medication adherence, Diabetes mellitus, Drug related problems (DRPs).

1. INTRODUCTION

Medication adherence is an important service in assisting the consumers living at home in preventing the problems related to medication and in maximizing the benefits of their medication regimen.

Medication adherence study includes the consumer, their clinicians, their pharmacy and their general practitioner with other relevant members of the health care team in the home setting of the medications.

Medication adherence study is considered as important due to the medication error, drug-food interactions which takes place due to the patients' irresponsibility of not taking the medications as prescribed and which could lead to the termination of the medication itself or causes the alteration of dose frequency. The inappropriate medication use by the consumer causes those ADRs which are the major burden to the patients. Therefore, HMR programs and several studies have been conducted in minimizing and preventing the drug related problems.

The goal of home medication review program is to enhance the patients' medication adherence by reducing the drug related problems (DRPs) that are caused due to the inappropriate use of medications.

Diabetes mellitus is a chronic metabolic disorder which is probably one of the oldest diseases known to man. Diabetes mellitus is the group of metabolic disease, a condition where there is abnormal high blood glucose level. Normally the food gets digested and the glucose is produced as one of the end products of carbohydrates. As a result, production of the insulin hormones takes place from the pancreas due to the increase in the blood glucose level. It converts the glucose to glycogen there by it reduces the blood glucose level to a normal range. There are many types of diabetes mellitus due to various reasons like, insulin is not all produced in the body, insulin is not sufficiently produced or not effective as it should be. Most common form of diabetes are, type 1 diabetes (5%), which is an autoimmune disorder, type 2 diabetes (95%), which is associated with obesity. The life style of a person is the main factor that results in diabetes including physical activities and balanced diet and genetic

factor (heredity).

Home medication review (HMR) is patient-centered process which provides the effective and quality use of medication at patients' home. It includes a systematic and detailed assessment of the patient's medication towards to identify and the medication- related needs with the aim to identify and prevent medication errors.

HMR service helps in identifying various potential DRPs which is ultimately beneficial for the patients. Adverse drug reactions (ADR), drug interaction, untreated indication, sub therapeutic dose, improper drug selection, alternative dosage forms, drug duplication are the DRPs which are addressed in HMR. This will help to improve medication adherence behavior and health related quality of life of the patients. Proper home medication administration plays a role in retaining drug efficacy and assure safe medication practices, which is a key to establish positive treatment outcomes.

According to International Diabetes Federation, India secures second position in having highest number of individuals with diabetes with 77 million individuals as of 2019. It is estimated that the number might increase to 134 million by 2045. It was also found that, since 2000, there was a drastic increase in the number of individuals having diabetes.

According to World Health Organization (WHO), diabetes is the ninth most leading cause of death. It was found that 74% of deaths were due to non-communicable diseases out of which 1.6 million death was due to diabetes. It is estimated that by 2035, nearly 592 million deaths may occur due to diabetes.

Current statistics show that 463 million people have diabetes and 374 million have impaired glucose tolerance (IGT) which is a pre-diabetic condition. There is an estimation that, by 2045, these number may increase to 700 million and 548 million in numbers respectively which implies a 51% increase when compared to 2019.

Statically data showed that nearly 50% of type 2 diabetics failed to achieve adequate glycemic control. It was due to various reasons but was largely due to poor adherence. A study showed that many discontinue the medication due to poor medication adherence.

Poor adherence to medication led to increased mortality, increased costs of outpatient care, emergency room (ER) visits, hospitalization and also management of complications of

diabetes. Hence it has become a necessity to approach the issue. A community-based home medication review is required to assess the medication adherence, to identify and resolve the drug related problems and thereby reducing the complications of diabetes and managing it.

Type 1: Diabetes mellitus

It is also called "Insulin Dependent Diabetes Mellitus"(IDDM)because in such patients, due to an absolute lack of insulin, regular injections of insulin are needed to save life. Earlier, it was called "juvenile-onset diabetes" because it most commonly develops either before puberty or in youngsters below 20 years of age and persists through out their life. IDDM is an autoimmune disease of the pancreatic beta cells (type-1A) resulting in their degeneration. It could also beidiopathic (type-1B).Viral infection such as echo-virus can also damage pancreatic beta cells (type-1B) .Approximately 10% of diabetics suffer with type 1 DM. These patients have a low degree of genetic predisposition, yet 15-20% of patients reveal appositive family history and the incidence in homozygous twins is about 50%.

Type 2: Diabetes mellitus

This is also called "Non Insulin Dependent Diabetes Mellitus" (NIDDM) or "Maturity Onset Diabetes" (As it occurs late in life). Approximately, 90-95% of diabetics have type-2diabetes. It usually occurs in people who are over 40 and over weight. Many type-2 diabetics, however, have a significant amount are elevated levels of insulin. For these people diabetes arises not forms hortage of insulin but because their target cells have become relatively in sensitive to insulin (Peripheral resistance to insulin). Genetic predis position, in type-2DM, is important as there Is greater than 94%concordancein identical twins.

Type 3: Diabetes mellitus

In this type, there are other causes of hyperglycemia, e.g., chronic pancreatitis or chronicdrug therapy with glucocorticoids, thiazide diuretics, diazoxide, growth hormone and with some protease inhibitors used to treat human immune deficiency virus infections (e.g.,saquinavir).

Type 4: Diabetes mellitus

It is also called "Gestational Diabetes Mellitus" (GDM). It is observed in approximately 4-5% of all pregnancies. Elevated blood sugar levels are usually observed in second or last trimester of pregnancy and usually resolved during the postpartum period. There is no genetic predisposition. The most plausible cause is that during pregnancy, the placental hormones promote insulin resistance (HL. Sharma, et.al.,2007).

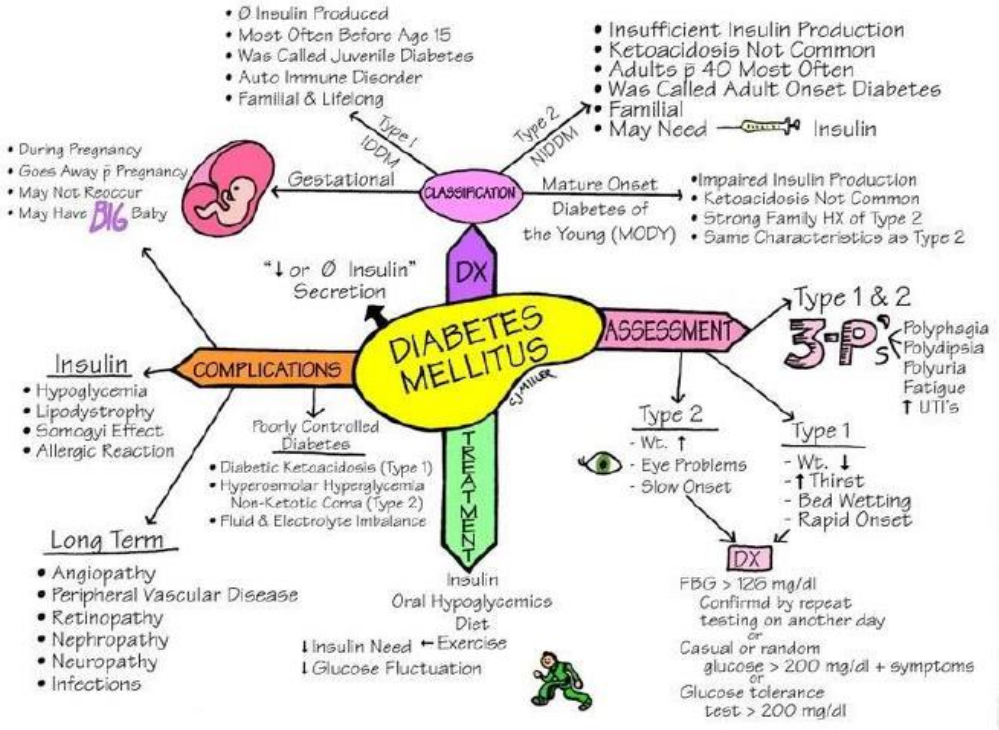

Figure No. 1: Overview of DM.

Etiology

The two main types of diabetes are type 1 diabetes and type 2 diabetes. A third type, gestational diabetes, develops only during pregnancy. Other types of diabetes are caused by defects in specific genes, diseases of the pancreas, certain drugs or chemicals, infections, and other conditions. Some people show signs of both type 1and type2 diabetes (T. R. Harisons, et. al., 2002).

Type 1: Diabetesmellitus

Type1diabetes is caused by a lack of insulin due to the destruction of insulin producing beta cells in the pancreas. In type1diabetes an auto immune disease the body's immune system attacks and destroys the beta cells. Normally, the immune system protects the body from infection by identifying and destroying bacteria, viruses, and other potentially harmful foreign substances. But in autoimmune diseases, the immune system attacks the body's own cells. In type 1 diabetes, beta cell destruction may take place over several years, but symptoms of the disease usually develop over a short period of time (Dimri S, et. al., 2009). Type 1 diabetes typically occurs in children and young adults, though it can appear at any age. In the past, type 1 diabetes was called juvenile diabetes or insulin- dependent diabetes mellitus (Mogensen C, et. al., 1984)

Latent autoimmune diabetes in adults (LADA) may be a slowly developing kind of type 1diabetes. Diagnosis usually occurs after age 30. In LADA, as in type 1 diabetes, the body's immune system destroys the beta cells. At the time of diagnosis, people with LADA may still produce their own insulin, but eventually most will need insulin shots or an insulin pump to control blood glucose levels. Genetic Susceptibility, Autoimmune Destruction of Beta Cells, Environmental Factors, Viruses and infections, Infant feeding practices also leads to DM (De Fronzo RA. et. al., 1988).

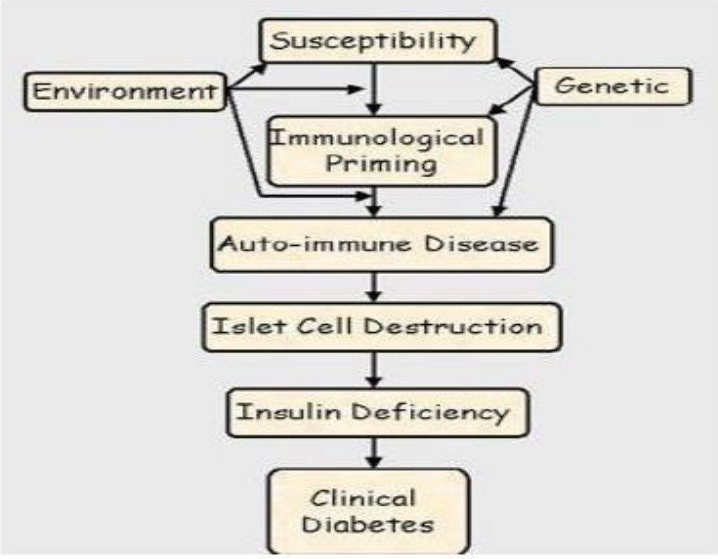

Figure No. 2: Diagram of possible mechanism for development of type 1 diabetes.

Type 2: Diabetes mellitus

Type 2 diabetes the most common form of diabetes is caused by a combination of factors, including insulin resistance, a condition in which the body's muscle, fat, and liver cells do not use insulin effectively. Type 2 diabetes develops when the body can no longer produce enough insulin to compensate for the impaired ability to use insulin. Symptoms of type 2 diabetes may develop gradually and can be subtle; some people with type 2 diabetes remain undiagnosed for years. Type 2 diabetes develops most often in middle-aged and older people who are also over weight or obese. The disease, on cer are in youth, is becoming more common in over weight and obese children and adolescents. Scientists think genetic susceptibility and environmental factors are the most likely triggers of type 2 diabetes. Genetic Susceptibility, Obesity and Physical Inactivity, Insulin Resistance, Abnormal Glucose Production by the Liver, Metabolic Syndrome, Beta Cell Dysfunction can lead to DM (New England Journal of Medicine. et. al., 1993).

Other types of diabetes

Other types of diabetes have a variety of possible causes. They include Genetic Mutations Affecting Beta Cells, Insulin, and Insulin Action, Other Genetic Diseases, Damage to or Removal of the Pancreas, Endocrine Diseases, Autoimmune Disorder Medications and Chemical Toxins and Lipodystrophy.

Pathophysiology

Type 1: Diabetes mellitus

Type-1 DM is an auto immune disease of the pancreatic beta cells (type-1A) resulting in their degeneration. It could also be idiopathic (type-1B).Viral infection such as echo-virus can also damage pancreatic beta cells (type1B). Approximately 10% of diabetic suffer with type1DM.Thesepatients have alow degree of genetic predisposition, yet 15-20% of patients reveal a positive family history and the incidence n homozygous twins is about 50%.

The clinical features of type-1 DM include hyper glycaemia with polyuria, poly dipsia, poly phagia and keto acidosis. These patients are generally not obese. Diabetic ketoacidosis isthe end result of insulin deficiency in uncontrolled type-1 diabetes (DeFronzo RA. et. al., 2009)

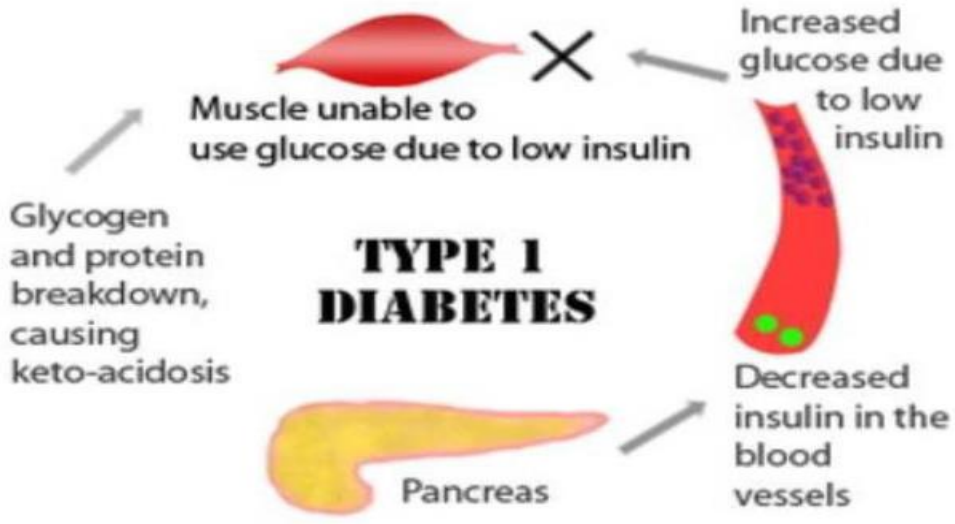

Figure No. 3: Pathophysiology of Type-I Diabetes.

Since insulin is not present to aid the entry of glucose in skeletal muscles and body cells, most cells now use fatty acids to produce ATP to compensate and to provide calories. This accelerated at break down generates Acetyl Co-A. But, due to DM, this acetyl Co-A can not be removed by Kreb`s cycle (to H_2O_2 and CO_2) and therefore gets accumulated. In absence

ofaerobic carbohydrate metabolism, two acetyl Co-A molecules join to form aceto acetic acid,beta hydroxyl butyaric acid and acetone, which are collectively called ketone bodies. These metabolic products cause metabolic acidosis or diabetic ketoacidosis, which decreases glucose utilization in brain and decreases pH of the blood leading to coma and death. Renal loses of glucose (Glycosuria), nitrogenous substances and ketone bodies (Ketoacidosis promote osmoticdieresis (Polyuria) that canresult indehydration andthirst (Polydipsia) (DeFronzo RA. et. al., 2009)

Type 2: Diabetesmellitus

Type 2 diabetes is caused by either inadequate production of the hormone insulin or a lack of response to insulin by various cells of the body. In type2 diabetes, the body either produces in adequate amounts of insulin to meet the demands of the body or insulin resistance has developed. Insulin resistance refers to when cells of the body such as the muscle, liver and fat cells fail to respond to insulin, even when levels are high. In fat cells, triglycerides are instead broken down to produce free fatty acids for energy; muscle cells are deprived of an energy source and liver cells fail to build up glycogen stores. This also leads to an overall rise in the level of glucose in the blood. Glycogen stores become markedly reduced and there is less glucose available for release when it may be needed. Obesity and lack of physical activity are thought to be major causes of insulin resistance (Geneva. et. al., 1999).

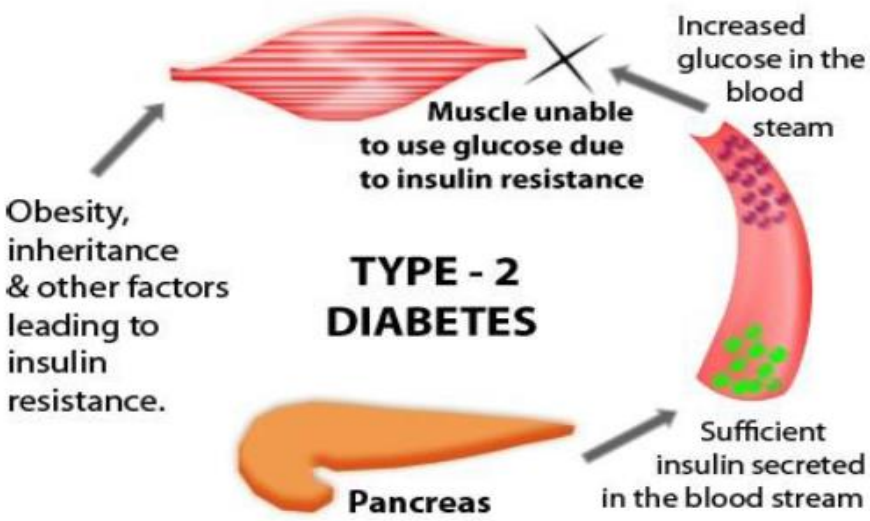

Figure No. 4: Pathophysiology of Type-II Diabetes.

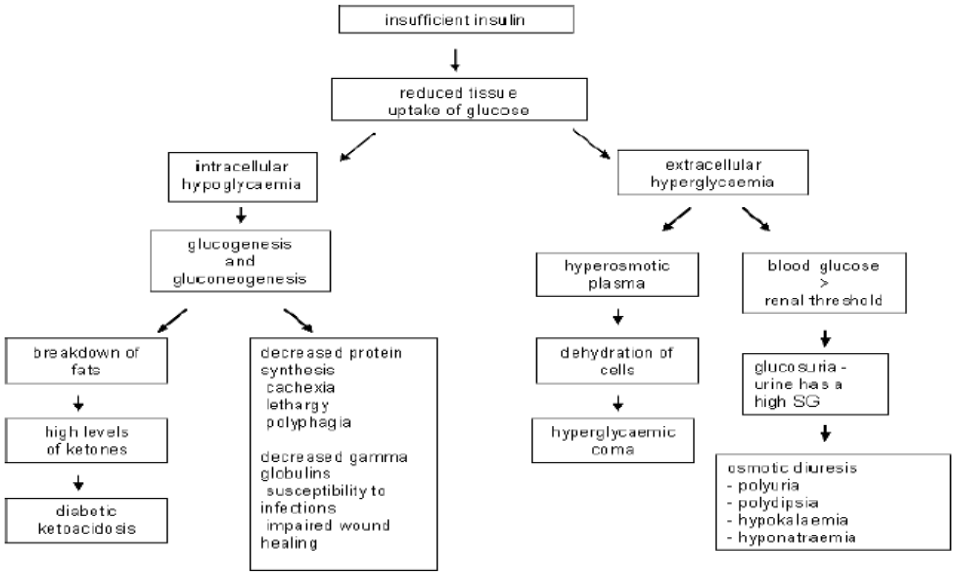

Figure No. 5: Diabetes mellitus is characterized by recurrent or persistent hyperglycemia.

Diagnosis

Diabetes mellitus is characterized by recurrent or persistent hyperglycemia, and is diagnosed by demonstrating any one of the following:

Fasting plasma glucoselevel ≥7.0mmol/l(126mg/dl)

Plasma glucose ≥ 11.1 mmol/l (200 mg/dL) two hours after a 75 g oral glucose load as in a glucosetolerancetest.

Symptoms of hyperglycemia and casual plasma glucose ≥ 11.1mmol/l(200mg/dl) Glycated hemoglobin(HbA1C)≥6.5%.

A positive result, in the absence of unequivocal hyperglycemia, should be confirmed by are peat of any of the above methods on a different day. It is preferable to measure a fasting glucose level because of the ease of measurement and the considerable time commitment of formal glucose tolerance testing, which takes two hours to complete and offers noprognostic advantage over the fasting test. Two fasting glucose measurements above 126mg/dl (7.0mmol/l) is considered diagnostic for diabetes mellitus.

Signs and Symptoms

Symptoms of type I diabetes

- Being very thirsty
- Feeling hungry
- Feeling tired all the time

- Having blurry eyesight
- Feeling numbness or tingling in your feet
- Losing weight without trying
- Urinating more often (Including urinating at night or bed wetting in children who were dry overnight before)

Symptoms of type II diabetes

- Frequent urination
- Increased thirst
- Increased hunger
- Blurred vision
- Slow-healing wounds or sores
- Prolonged and unexplained fatigue
- Numbness or tingling or burning sensation in the legs or feet
- Gynecological fungal infections in women
- Sexual impotence in men
- Musclecramps (Pratley RE, et. al., 2000).

Symptoms of retinopathy are minimal until advanced disease ensues with loss or blurring of vision. Signs of non-proliferative retinopathy include micro aneurysms, venous loops, retinal hemorrhages, hard exudates, and soft exudates. Proliferative retinopathy can include new vessels in the eyes or vitreous hemorrhage. The earliest sign of nephropathy is hypertension. Development of hypertension often coincides with the development of micro albuminuria. As nephropathy worsens, patients can develop edema, arrhythmias associated with hyperglycemia, and or symptoms related to renal failure. Signs and symptoms of neuropathy are dependent on the type of neuropathy that develops. Most commonly, patients develop symptomatic distal poly neuropathy. Signs include depression or loss of ankle jerks and vibratory sensation, with hyperalgesia and calf pain in some patients. The deficit is in a stocking glove distribution. Wasting of the small muscle of the hands and feet can also occur. Patients may present with focal neuropathies due either to mononeuritis or entrapment syndromes. These produce focal neurologic deficits confined to as in glenerve. A rare but severe form of diabetic neuropathy is diabetic amyotrophy, which begins with pain followed by severe weakness and spreads from unilateral to bilateral. It resolves spontaneouslyin18-24months.

Patients with coronary artery disease can present with stable an ginapectoris, unstable anginapectoris, or myocardialinfarction. Many patients have unrecognizable symptoms and can present with dysrhythmias. Patients with cerebral vascular disease can present with a sudden onset of a focal neurologicdeficit such as facial droop, hemiparesis, or isolated weakness of an arm or leg. Dizziness, slurred speech, gait difficulties, and visual loss can also be presenting symptoms. Stroke symptoms that last <24 hours are referred to as atransient ischemic event. Peripheral vasculardisease is recognized by exertional leg pain that can progress to rest pain and ischemic ulcers. Mostcases are asymptomatic.

Risk Factors and Complications

The major cause of the high morbidity and mortality rate associated with diabetes is a group of micro vascular and macro vascular complications affecting multiple organ systems. People with diabetes have agreatly increased risk for blindness, kidney failure, myocardial infarction, stroke, necessary limb amputation, and a host of other maladies. The onset and progression of these complications is strongly linked to the presence of sustaine dhyperglycemia. The complication rate and the severity of complications increase as the duration of diabetes increases. Other disorders (Such as hypertension and dyslipidemia) commonly seen in people with diabetes increase the risk form microvascular and macrovascular complications. There may also begenetic determinants of risk for diabetic complications (Medical pubs, et. al.)

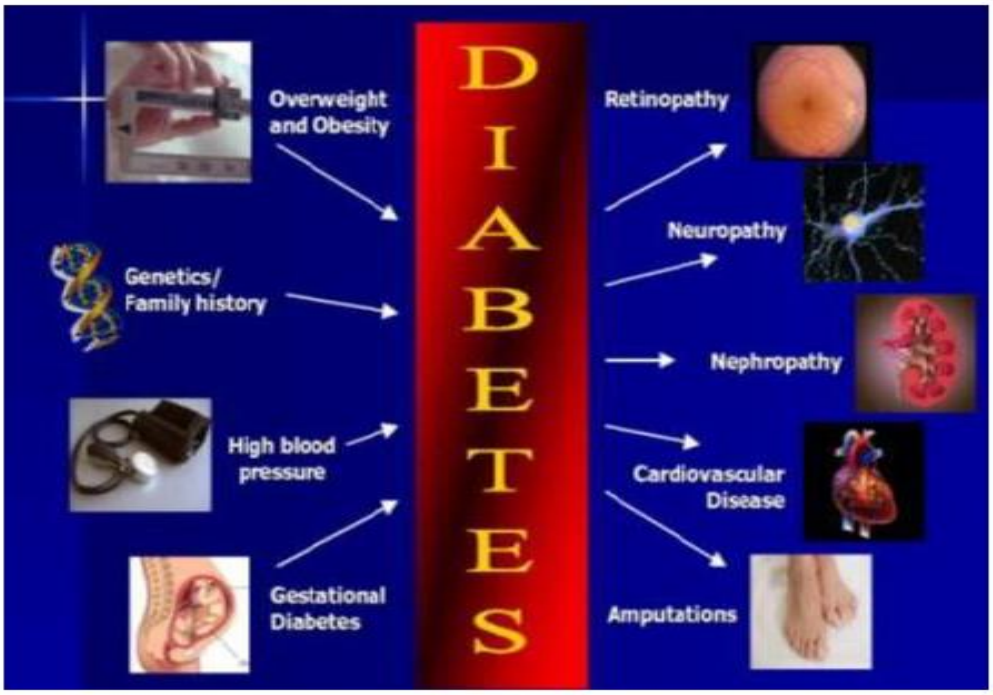

Figure No. 6: Risk Factos and Complications of diabetes.

Prevention

There is no known preventive measure for type 1 diabetes. Type 2 diabetes can often be prevented by a person being a normal body weight, physical exercise, and following a healthy diet. Dietary changes known to be effective in helping to prevent diabetes include a diet rich in whole grains and fiber, and choosing good fats, such as polyunsaturated fats found in nuts, vegetable oils, and fish. Limiting sugary beverages and eating less red meat and other sourcesof saturated fat can also help in the prevention of diabetes. Active smoking is also associated with an increased risk of diabetes, so smoking cessation can be an important preventive measure as well.

Management of diabetes

The main stay of non-pharmacological treatment of diabetes is diet and physicalactivity. Other methods of treatment includes acupuncture, hydrotherapy, mineral supplementation and conventional drugs which include sexogenous insulin, oral hypoglycemic agents and transplantation.

Oral glucose lowering drugs belong to five classes of oral agents approved for the management of diabetes mellitus. Oral therapy was indicated in any patient in whom diet and exercise fail to achieve acceptable glycemic control. Although initial response may be good, oral hypoglycemic drugs may lose their effectiveness in a significant percentage of patients. The drug category includes sulfonylurea, biguanide, α-glucosidase inhibitor, thiazolidinedioneand meglitinide and these drugs have various side effects. For instance; sulfonylurea causes weight gain due to hyperinsulinemia, biguanide cause body weakness, fatigue, lactic acidosis and alpha glucosidase inhibitor may cause diarrhea while thiazolidinediones may increaseLDL-cholesterol level.[33] Insulin is the commonly included in an oral agent when glucosecontrolissub-optimal at maximal dose of or all medication. Weight gain and hypoglycemia are the most common side effects of insulin. Vigorous insulin treatment may also carryan increase in atherogenesis (Ribes G., et. al., 1986).

Oralglucose-lowering agent sulfonylurea, tolbutamide and glyburide acts by enhancing insulin secretion from the pancreatic βcells. (KellyG.et.al., 1999). These action liver cells stimulating break down of glucose in glycolytic pathway and inhibiting glucose generation. Sulphonyl ureas acts by inhibiting the KATPchannels in plasma membranes of pancreatic βcells. The inhibition works to stimulate these cretion of insulin which is similar to that produced by glucose in the body but is of adistinct mechanism. They may be used as first-line

drugs in a case where oral hypoglycemic medication is required particularly in patients who cannot tolerate metformin. Newer drugs in this category such as glipizide and glimipramide appear to afford similar efficacy than older drugs such asgliclazide (Foye W.O., et. al., 1995).

All sulphonylureas drugs have a sulphonic acid-urea nucleus, and different chemical moieties are added at various positions on the nucleus to make different drugs. The action of the resultant drugs may have the desired effect, however, the potency and efficacy may differ significantly (Malender A. et. al., 2004).

Sulphonyl ureas drugs are typically not indicated for type 1 diabetic patients since they require the functioning of the β cells to produce the desired effect on blood glucose. They have been found to be most effective in non-obese patients with mild maturity onset diabetes and whose high glucose levels have not responded appropriately to diet alterations.

Biguanides such as metformin acts by increasing glucose transport across cell membrane of the skeletal muscle. They act in the presence of endogenous insulin, and are effective only where there are residual functioning pancreatic islet cells. Metformin is widely used in treatment of patients with insulin resistance because it can be used safely as an adjunct to diet therapy in obese patients to control their high glucose levels especially those who are not responsive to other therapies. The exact mode of action of metformin is disputable. Zhou et al indicated that it activates adenosine monophosphate proteinkinase (AMPK) in liver cells leading to increased fatty acid oxidation and glucose uptake by cells (Zhou G., et. al., 2001).

An overall reduction in lipogenesis and hepatic glucose production is normally observed. Metformin has antioxidant properties which are useful in its use in treatment of diabetes and cardiovascular disease. I has been demonstrated to inhibit xanthine oxidase and phosphor diesterase, advanced glycation end product formation and decreased production of tumour necrosis factor (Rahimi R., et. al., 2005).

The main problem with metformin is the risk of lactic acidosis which is particularly common in patients with renal insufficiency, cardiovascular disease, peripheral vascular disease, liver disease, pulmonary disease and in individuals over 65 years. Weakness, fatigue, shortness of breath, nausea, dizziness and kidney toxicity are the side effects.

Thiazolidinediones are known to act by increasing the sensitivity of peripheral tissues to insulin by affecting the expression of specific genes. They achieve this by binding and

activating peroxisome proliferator-activated receptor (PPAR-γ), a nuclear receptor. Some of the effects of this gene expression include the increase in the expression of the glucose transporters, decreased hepartic glucose output as well as the increased differentiation of pre-adipocytes in to adipocytes. The high affinity of this drug to PPAR-γ is important in the management of insulin resistance since large adipocytes that differentiate from smaller ones produce TNF-α which increase insulin resistance. Thiazolidinediones therefore suppresses the expression of these adipokines involved in insulin Resistance (Sharma A. M. et. al., 2007). Alpha-glucosidase acts by inhibiting alpha glucosidase enzyme in the brush border of the small intestine. This delays the absorption of glucose by decreasing the breakdown of complex carbohydrates by enteric digestive enzymes. Some of the most commonly used α-glucosidase inhibitors like acarbose have severe gastrointestinal side effects such as diarrhoea, flatulence and abdominal pains.

This raises the need for other sources of these inhibitors that have fewer side effects. The most obvious choice for these alternatives would be plants with ethnomedical uses in management of diabetes.

Introduction of streptozotocin

Streptozotocin is a permanent diabetes inducing drug. It is synthesized by a strain of the soil microbe *Streptomyces achromogenes* (Gram positive bacterium) with broad spectrum of antibacterialproperties. Streptozotocinisan un usual aminoglycoside containing an itrosoamino group discovered in 1959 as an antibiotic, now marketed as a generic drug. The nitrosoamino group enables theme tabolitet of nitricoxide (NO) donor. NO is an important messenger molecule involved In many physiological and pathological processes in the body. Streptozotocins widely used to induce diabetes in rodent models by inhibition of β-cellO-GlcNAcase.

Streptozotocin features four important biological properties as evidenced by its antibiotic, β-cell (beta)-cytotoxic, oncolytic, as well as oncogenic effects. This product is an antineoplastic antibiotic and is used mainly in the treatment of pancreatic (islet cell) tumors. It Is used for the treatment of malignant insulinoma. Current use of STZ is mostly as an investigational drug for diabetes research due to its specific toxicity associated with pancreatic β-cells. Low affinity glucose transporter- GLUT2 of βcells transports STZ into the cell and causes alkylation of DNA and irreversible necrosis of β cells. DNA synthesis in mammalian and bacterial cells is inhibited by action of STZ. STZ is widely used to induce both insulin-

dependent (IDDM) and non-insulin-dependent diabetes mellitus (NIDDM).STZ is an antibiotic and antitumor agent, induces diabetes mellitus a reduction of nicotinamide adeninedinucleotide in pancreaticβ-cells *invivo*. This review will summarize the chemistry of STZ and its β-cell toxicity through the link between STZ and free radicals. In addition, dosage, route of administration and metabolism of STZ in experimental animal models to study diabetes will be addressed (Busineni Jayasimha Goud et al., 2015).

Mechanism of action of streptozotocin

The range of the STZ dose is not as narrow as in the case of alloxan. The frequently used single intravenous dose in adult rats to induce IDDM is between 40 and 60 mg/kg b. w., but higher doses are also used. STZ is also efficacious after intraperitoneal administration of a similar or higher dose, but single dose below 40 mg/kg b.w. may be ineffective. For instance,when 50 mg/kg b.w. STZ are injected intravenously to fed rats, blood glucose (determined 2weeks after treatment) can reach about 15 mM STZ may also be given in multiple low doses. Such treatment is used predominantly in the mouse and the induction of IDDM is mediated by the activation of immune mechanisms. Streptozotocin action in B cells is accompanied by characteristic alterations in blood insulin and glucose concentrations.

Two hours after injection, the hyperglycemia is observed with a concomitant drop in blood insulin. About six hours later, hypoglycemia occurs with high levels of blood insulin. Finally, hyperglycemia develops and blood insulin levels decrease. These changes in blood glucose and insulin concentrations reflect abnormalities in B cell function. STZ impairs glucose oxidation and decreases insulin biosynthesis and secretion. It was observed that STZ at first abolished the B cell response to glucose. Temporary return of responsiveness then appears which is followed by its permanent loss and cells are damaged.

STZ is taken up by pancreatic B cells via glucose transporter GLUT2. A reduced expression of GLUT2 has been found to prevent the diabetogenic action of STZ. Intra cellular action of STZ results in changes of DNA in pancreatic B cells comprising its fragmentation Recent experiments have proved that the main reason for the STZ-induced B cell death is alkylation of DNA. The alkylating activity of STZ is related to its nitro soure a moiety, especially at the O6 position of guanine. After STZ injection to rats, different methylated purines were found in tissues of these animals. Since STZ is anitricoxide (NO) donor and NO was found to bring about the destruction of pancreatic islet cells, it was proposed that this molecule contributes to STZ-induced DNA damage. Pancreatic B cells exposed to STZ manifested changes

characteristic for NO action, i.e. increased activity of guanylyl cyclase and enhanced formation of cGMP. STZ is, however, not aspontaneous nitric oxide donor. This molecule is liberated when STZ is metabolized inside cells, but NO synthase is not required for this effect. On the other hand, the lowering of NO concentration in pancreatic isletcells by inhibition of the inducible form of nitric oxide synthase partially counter acted DNA cleavage induced by STZ. A similar effect can be attained by NO scavengers. However, the results of several experiments provide the evidence that NO is not the nly molecule responsible for the cytotoxic effect of STZ. STZ was found to generate reactive oxygen species, which also contribute to DNA fragmentation and evoke other deleterious changes in the cells. The formation of superoxide anions results from both STZ action on mitochondria and increased activity of xanthine oxidase. It was demonstrated that STZ inhibits the K rebscycle and substantially decreases oxygen consumption by mitochondria. These effects strongly limit mitochondrial ATP production and cause depletion of this nucleotide in B cells. Restriction of mitochondrial ATP generation is partially mediated by NO.

This molecule was found to bind to the iron-containing aconitase inhibiting enzyme activity. Augmented ATP dephosphorylation increases the supply of substrate for xanthine oxidase (B cells possess high activity of this enzyme) and enhances the production of uric acid – the final product of ATP degradation. Then, xanthine oxidase catalyses reaction in which the superoxide anions formed. As a result of superoxide anion generation hydrogenperoxide and hydroxyl radicals are formed. The inhibition of xanthine oxidase by allopurinol restricts the cytotoxic effect of STZ in vitro. Pretreatment of B cells with this inhibitor prevented the STZ-induced decrease of insulin secretion. It can be stated that potent alkylating properties of STZ are the main reason of its toxicity. However, the synergistic action of both NO and reactive oxygen species may also contribute to DNA fragmentation and other deleterious changes caused by STZ. NO and reactive oxygen species can act separately or form the highly toxic peroxynitrate.

There fore, intracellular antioxidants or NO scavengers substantially attenuate STZ toxicity. STZ-induced DNA damage activates poly ADP ribosylation. This process leads to depletion of cellularNAD+, further reduction of the ATP content and subsequent inhibition of insulin synthesis and secretion. The concept of unfavorable consequences of augmented poly ADP-ribosylation as a result of STZ action was confirmed by experiments revealing that the inhibition of this process prevents the toxicity of this diabetogenic agent. It was found that 3-

amino benzamide, a strong inhibitor of poly (ADP-ribose) synthase, protected against the action of STZ in rats, even when this substance was administered 45-60 min after STZ. Another inhibitor of poly (ADP-ribose) synthase, nicotinamide, which is also scavenging oxygen free radicals, exerted best protectionwhen it was administered shortly after STZ. The failure of protective action of nicotinamide administered after STZ is probably due to a potent reduction of the cellular ATP content by STZ since nicotinamide uptake is ATP-dependent. The protective effect of 3-amino benzamide and nicotinamide was also confirmed in vitro.

It has been suggested that some inhibitors of poly ADP-ribosylation may also exert aprotective effect due to their hydroxyl radical scavenging properties. However, in the case of STZ, recent investigations in poly (ADP-ribose) polymerased efficient mice demonstrated that the inhibition of poly ADP-ribosylation itself prevents STZ-induced B cell damage and hyperglycemia. Thus, it can be stated that the activation of poly ADP-ribosylation is of greater importance for the diabetogenicity of STZ than generation of free radicals and DNA damageperse. Calcium, which may also induce necrosis, does not seem to play a significantrole in the necrosis evoked by STZ since calcium channel antagonists do not protect B cells against streptozotocin, as they do in the case of alloxan. (SZKUDELSKI.et.al., 2001).

2. REVIEW OF LITERATURE

Review of literature on HMR of diabetes was carried out. The literature which was found relevant are as follows:

Uchenna I.H. Eze et al., 2022, conducted a Cross-sectional study to assess drug therapy for type 2 diabetes, glycaemic control and association of medication adherence with socio-demographic and clinical data, among adult diabetic patients attending a healthcare facility. The study included 200 adults with type 2 diabetes mellitus in a Nigerian healthcare facility. Data on patients clinical characteristics, diabetes drug therapy and medication adherence were collected, entered and anlaysed using SPSS version 24 ($P < 0.05$). Primary outcome measure was medication adherence among the patients, while secondary outcome measures was glycaemic control. A total of 200 (100%) respondents participated in the study and the majority 141(70.5%) were over 60 years old. Oral medications were mostly used 187(93.5%), particularly, metformin 199(99.5%) and pioglitazone 100(50.0%), while dipeptidyl peptidase-4 inhibitors were not used at all. Patients mostly had poor glycaemic control 159 (79.5%) and majority 152(76.0%) did not practice self-blood glucose monitoring. Moderate medication

adherence was predominant in the population.

Rosli MR *et al.,2022,* did a randomized controlled trail in Bandar Pasir Mas healthcare clinic in Kelantan, Malaysia, titled "Evaluation of home medication review for patients with type2 diabetes mellitus by community pharmacists: Randomized controlled trail". The study aimed to evaluate the effectiveness of HMR by community pharmacists (HMR-CP) in optimizing diabetes care, medication adherence and reducing medication wastage. A total of 166 patients with type2 diabetes mellitus agreed to participate and were then randomly assigned to either HMR-CP or control group. It was observed that there was a significant reduction in the Hb A1c-(0.91%) and FBG – (1.62mmol/L) over the study period ($p<0.05$). the study concluded that HMR-CP significantly improved the glycemic control, QoL, medication adherence and knowledge of T2DM patients as well as reduced the number of DRP and cost of medication wastage.

Neoh CF *et al., 2021*, Conducted the study as randomized controlled trial (RCT) titled as Economic evaluation of home medication review by community pharmacists (HMR-CP) for patients with type 2 diabetes mellitus (T2DM) The aim of this economic evaluation is to determine if home medication review by community pharmacists for patients with type 2 diabetes mellitus is a cost-effective intervention from the Malaysian healthcare provider point of view. The intervention and health services costs throughout the 6-month HMR-CP trial were RM121.45 [95%CI: RM115.89 to 127.08] per person. The study was concluded as HMR-CP was a budget friendly intervention that had significantly reduced the HbA1c among the T2DM patients, although related with higher mean total costs per participant

Liou W *et al., 2021*, did a six-month randomized controlled trial titled "The effects of a pharmacist- led medication review in a nursing home: A randomized controlled trial". Study was conducted at a nursing home in Taiwan which included 100 participants who were of age 65 years or above 65 years, with polypharmacy, and having ≥2 chronic diseases. Total 74.3% of potential inappropriate medication was observed. There were no differences in between 2 groups with the exception of medical problems, which showed a significantly higher prevalence in intervention group. The intervention group reported greater satisfaction with pharmacist visit and medication compliance and reduced drug related problems after the intervention. It was concluded that in this study, the intensive review of their medication revealed that the only significant effect of pharmaceutical care was on "all outcomes." It might be due to either their advanced age or the need of polypharmacy to cure chronic

conditions or may be due to small size of sample. It was concluded that those who received pharmacist intervention had higher satisfaction with medication reconciliation with fewer drug related problems.

Chandrashekar D *et al., (2019)* This study was conducted to identify, prevent and resolve the problems related to the potential medication. It is done to achieve the better outcomes for patients at home. It is a cross-sectional study conducted in different regions of Malappuram for a period of 6 months in 85 patients and the use of other medication and storage conditions of medicines were evaluated. Around 32% of the population undergone ADR on taking the medication. This study showed that the subjects were unaware of the HMR service and yet majority were accepting the program.

Sission E *et al., 2018,* conducted study of pharmacist role in the management of patient with type 2 diabetes. Where the purpose of the study is to summarize the current and future roles to pharmacist in providing care and educating patient with diabetes.

Studies which describe role, function and impact of pharmacist in diabetic care. As diabetics being rapidly increasing in population pharmacist should have the ability to respond to patient need. The study shows that coming years patient will engage more with coach educator or pharmacist and are vital for interdisciplinary diabetes care team. The role of pharmacist had expanded beyond dispensing of medicine to counselling and monitoring ADRs to optimize patient output.

Panda A *et, al.*, 2016, The cross-sectional, observational study was conducted on 1100 adult participants at a convenience sample of six retail private pharmacy counters. The data collection form was based on the Pharmaceutical Care Network Europe version 6.2 classification for DRPs. Descriptive statistics was used to represent the prevalence of DRPs. Chi-square test was used to find out the association between the type of medication and DRPs. Odds ratio (OR) with confidence interval (CI) was computed to find the factors determining the occurrence of DRPs. $P < 0.05$ was considered to be statistically significant. Data were analyzed using SPSS version 16.0.

Ahn J *et al., 2015*, conducted study to of patients centered care which seeks patient perspectives on understanding and perceived benefits and difficulties of HMR. HMR is important in-patient management of their medications. The studies shows that clear benefits

are seen when it is performed well. Also identified limitations and ineffectiveness of HMR. Training of doctors and pharmacists are needed for better results. In Australia, the percentages of hospital admissions due to adverse drug events range from 5.6% in the general population to 30.4% in the elderly population. Studies also show that patient compliance with medication is as low as 50–60%.2 Also, 59% of adults do not reach the minimum level of literacy required to understand health information. The results of this study are aggregated according to the three main themes – understanding and expectation of HMR, patient benefit and patient difficulties asses' benefits and difficulties of home medication review on patient perspective.

Kaveeshwar SA, Cornwall J *et, al.*, 2014, Diabetes is fast gaining the status of a potential epidemic in India with more than 62 million diabetic individuals currently diagnosed with the disease.1,2 In 2000, India (31.7 million) topped the world with the highest number of people with diabetes mellitus followed by China (20.8 million) with the United States (17.7 million) in second and third place respectively. According to Wild et al.3 the prevalence of diabetes is predicted to double globally from 171 million in 2000 to 366 million in 2030 with a maximum increase in India. It is predicted that by 2030 diabetes mellitus may afflict up to 79.4 million individuals in India, while China (42.3 million) and the United States (30.3 million) will also see significant increases in those affected by the disease.3,4 India currently faces an uncertain future in relation to the potential burden that diabetes may impose upon the country. Many influences affect the prevalence of disease throughout a country, and identification of those factors is necessary to facilitate change when facing health challenges.

Elina AN, Surta MC , *et,al.*, 2014, Ball PA, A comprehensive search was performed of PubMed, Scopus, Embase, and Web of Science for peer-reviewed, full- text articles published in the English language between January 1, 2008 and December 31, 2018. Relevant keywords such as "HMR," "home medicines review," "drug related problems," "pharmacist," and "elderly" were searched in diverse combinations with Medical Subject Headings (MeSH) terms by using Boolean operators to identify all relevant studies. The detailed search strategy interpretation using PubMed was as follows: ("HMR" [All Fields] OR "home medicines review" [All Fields]) AND "drug- related problems" [All Fields] AND "pharmacists" [MeSH Terms] OR "pharmacists" [All Fields] AND ("aged" [MeSH Terms] OR "aged" [All Fields] OR "elderly" [All Fields]) AND ("2008/01/01" [PDAT]: "2018/12/31" [PDAT]). Any further missing publications were searched by checking the references of the included studies.

ProQuest, Google Scholar, and Open Grey were searched for the grey literature.

Suji G, Sivakami S *et, al.*, 2013Diabetes related complications, if not treated, can be lethal. The basis of diabetes treatment is management of these complications by different approaches with the aim of providing a healthy life to diabetics. This article gives an overview of the various approaches currently in use to control hyperglycemia like pharmacological compounds and natural products. Many natural products have been used in traditional medicine, but only a few of them are discussed here. A combination therapy appears more useful for the treatment of diabetes rather than the use of a single compound.

3. AIM AND OBJECTIVES

Aim and Objective

To assess the medication adherence on management of Anti-diabetic medications at Home in diabetic patient through home medication review.

Specific objectives of the present investigation are

1. To assess and improve medication adherence in patients with diabetes mellitus using Morisky Medication Adherence scale-8 (MMAS-8).
2. To identify and resolve drug related problems in diabetic patients using Hepler-Strand classification.
3. To identify and prevent medication errors in diabetic patients.
4. To review the patient's method of storage of anti- diabetic medication at home.

4. PLAN OF WORK

The entire study was planned for a period of 9 months.

The proposed study was designed in three phases to achieve the objectives.

Phase I

- Literature review
- Identification of the need of work
- Preparation of protocol
- Obtaining institutional ethical committee approval

Phase II

- Designing the data collection form,

- Selection of study subjects
- Collection of data
- Documentation of collected data

Phase III

- Analysis of collected data.
- Statistical analysis of all collected data.
- Report preparation
- Submission

5. METHODOLOGY

Materials and Methods

Study design: Interventional Study.

Study site: The study was conducted at community level within Erode.

Study duration: The study was conducted for the duration of 9 months

Sample size: The study was limited for a sample of 150 based on the criteria included in the study.

Sample size was calculated by using RAO Software by keeping 5% margin error 90% of confidence interval and 50% response distribution the sample was found to be 150.

Margin error	5%
Confidence level	90%
Population size	20000
Response distribution	50%

Study criteria Inclusion criteria

a. Gender – Either male or female
b. Type –II diabetic millets patients from in patients department
c. Patient who are prescribed atleast one oral hypoglycaemic agent or insulin
d. Patients with gestational diabetes
e. Diabetic patients who are aged 18 year or above

Exclusion criteria

- Patients with incomplete data or record
- Any major surgical interventions in previous three months
- Pregnant and lactating women

- Patients who are not willing for the study
- People who are not diabetic

Source of data

Questionnaire was used to collect the data from the subjects of the community.

Study method

Preparation of subject information sheet: Subject information sheet was prepared in both Tamil and English language. Both were used in the study.

Preparation of informed consent form: Informed consent form was prepared in Tamil and English and the same was used in the study.

Before the selection of subjects, the subject information sheet was explained orally. Later consent form was orally explained to the participants before filling it taking their signature. Only the willing participants were used for the study

Data collection: Data were collected in the form of data collection form and questionnaires. Data collected included demographic details like age, gender, blood glucose level, comorbidity, treatment including drug name, its dose and frequency. It also included information regarding the medication management and medication adherence of the subjects. After the collection of the data, the study subjects were counseled using PIL. Later post interventional study was conducted.

Data analysis: The collected data were analyzed using Microsoft excel and paired t test.

Morisky Medication Adherence Scale-8 (MMAS-8

The Morisky Medication Adherence Scale-8 (MMAS-8) is a validated tool designed to assess medication adherence in patients:

- Questionnaire structure: MMAS-8 consists of eight items, with the first seven having dichotomous (yes/no) responses and the last item employing a 5-point Likert scale.
- Scoring system: Each affirmative response receives a score of 1, while negative responses score 0, except for the final item, which ranges from 1 to 5. The total score ranges from 0 to 8, with higher scores indicating better adherence.
- Interpretation:
- High Adherence (Score 8): Indicates excellent medication adherence.

- Medium Adherence (Score 6-7): Suggests moderate adherence but with room for improvement.
- Low Adherence (Score ≤5): Indicates poor adherence and the need for intervention or support.

Hepler-Strand classification

1. Identification of DRPs: Utilize the Hepler-Strand classification to identify various Drug related problem (DRPs) experienced by diabetic patients, such as adverse drug reactions, ineffective drug therapy, and drug interactions.
2. Categorization: Classify identified DRPs according to the Hepler-Strand framework, which includes categories like unnecessary drug therapy, dosage too low, and adverse reactions.
3. Resolution Strategies: Once DRPs are identified and categorized, develop intervention plans tailored to each specific problem. This may involve adjusting medication dosages, switching medications, or providing patient education.
4. Multidisciplinary Collaboration: Engage in collaboration with healthcare professionals, including pharmacists, physicians, and nurses, to address DRPs comprehensively. This teamwork ensures holistic patient care and better outcomes.
5. Regular Monitoring: Continuously monitor diabetic patients for any new or ongoing DRPs, especially considering the dynamic nature of diabetes management. Regular follow-ups and medication reviews are crucial to ensuring optimal therapeutic outcomes.

6. RESULT

Demographic details of the study population

The study was carried out in about 150 diabetic patients in the community level acquiring information from the patients. Among them 76 (51%) were male and 74 (49%) were female subjects. Here the figure 1 gives the percentage of male and female participants in the study. Among the diabetic patients participated in the study 10(6.6%) subjects were between the age group <40 years, 79(52.66%) subjects were between the age group 41-60 years 61(40.66%) between 61>years of age. Among the 150 patients who participated in the study, 2 were alcoholic, 9 were smokers and 3 consumed tobacco.

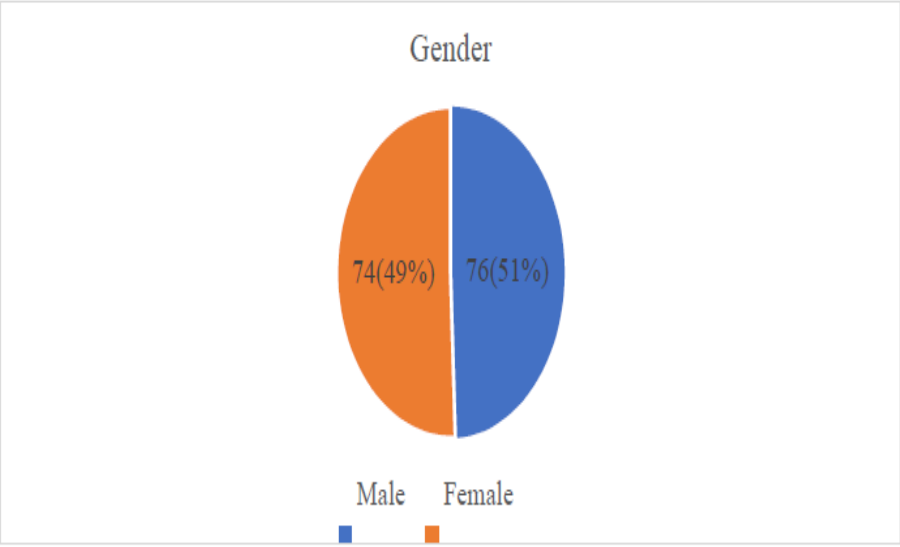

Figure No. 7: Gender distribution of the study participants.

Table 1.1: Demographic features of the patients.

Variables	Category	Frequency N=150	Percentage (%)
Gender	Male	76	51%
	Female	74	49%

Table 1.2: Demographic features of the patients.

Variables	Category	Frequency N=150	Percentage (%)
Age	< 40 years	10	6.6%
	41-60 years	79	52.66%
	age 61 and above	61	40.66%

Table 1.3: Demographic features of the patients.

Variables	Category	Frequency N=150	Percentage (%)
Social history	Alcoholic	2	1.4%
	Smoking	9	6%
	Tobacco	3	2%
	None	136	90.6%

Table 1.2 shows that majority 52.66% patients belongs to age group of 41-60 years of age followed by ≥60 years 40.66% and least among <40 years 6.6%. Similar study conducted by Uchenna I.H. Eze et al., of 200 (100%) respondents participated in the study and the majority 141(70.5%) were over 60 years old.

Number of participants from each area

The total number of participants in the study were 150 among which they are distributed in different areas of Erode.

Table 2: **Number of study participants from each area.**

Place	Number of participants
Pallipalayam	10
Bhavani	28
Kumarapalayam	12
Perundurai	20
Gobichettipalayam	30
Kodumudi	24
Chithode	26

The table shows number of participants each area there is different participant in different places, that is among 150 participants taken in different areas

Adherence of therapy among diabetic patients

Medication adherence of each study subject was recorded using Morisky medication adherence scale -8(MMAS-8) with the information obtained from the patients. Morisky medication adherence scale is a validated assessment tool which is used to check the adherence in the population. It consists of 8 questions with respective scores and as the score increases adherence and the maximum score that can be acquired is 8. It is divided into high adherence (=8), medium adherence (6<8) and low adherence (<6). It was found that 97(64.7%) of the population had low adherence, 30(20%) of the population had medium adherence and 23(15.3%) of the population were highly adherent. Hence, it was seen that more than half of the population had poor adherence during the pre- intervention study. Those who were low adherent to anti-diabetic medication were given PILs and patient counselling, patients who were medium and high adherent to anti- diabetic medication were given only PILs. After the intervention it was seen that 40(26.7%) of the population had low adherence, 25(16.7%) of the population had medium adherence and 85(56.6%) of the population were highly adherent. This observation was found significant with the help of paired t-test where p value was less than 0.05. The medication adherence of study subject was assessed with Morisky scale - 8 and is described in table number 3.

Table 3: **Morisky scale-8.**

Sl. no	Question	Yes		No	
		Pre	Post	Pre	Post
1.	Do you sometimes forget to take your medications?	81(54%)	40(26.6%)	69(46%)	110(73.3%)
2.	In the past 2 weeks, were there any days when you did not take your medications?	95(63.3%)	44(29.3%)	55(36.6%)	106(70.6%)

3.	Have you ever stopped your medications without telling your doctor, because you felt worse when you took it?	38(25.3%)	20(13.3%)	112(74.6%)	130(86.6%)
4.	When you travel or leave home, do you sometimes forget to bring along your medication?	67(44.6%)	38(25.3%)	83(55.3%)	112(74.6%)
5.	Did you take your medication yesterday?	140(93.3%)	148(98.6%)	10(6.66%)	2(1.33%)
6.	When your health condition is under control, do you sometimes stop taking your medications?	50(33.3%)	21(14%)	100(66.6%)	129(86%)
7.	Do you feel hassled about sticking to your treatment plan?	62(41.3%)	28(18.6%)	88(58.6%)	122(81.3%)
8.	How often do you have difficulty in remembering to take all your medication?	Pre-intervention	Post-intervention		
	a) Never/Rarely (1)	59(39.3%)	80(53.3%)		
	b) Once in a while (0.75)	36(24%)	60(40%)		
	c) Sometimes (0.75)	49(32.6%)	10(6.66%)		
	d) usually (0.25)	5(3.3%)	0		
	e) All the time (0)	1(0.66%)	0		

Table 4: Medication adherence level.

Medication adherence level	Pre intervention	Post intervention	P Value
Low adherence <6	97(64.7%)	40(26.7%)	< 0.05
Medium adherence 6-8	30(20%)	25(16.7%)	< 0.05
High adherence ≥8	23(15.3%)	85(56.6%)	<0.05

N value -150

Table 4.1

Age	Pre intervention study %	Post intervention study %	P value
< 40 years	18%	10%	<0.05
41-60 years	25%	20%	<0.05
age 61 and above	57%	50%	<0.05

Table shows

During pre interventional study tge category as less than 40 age the medication adheres as found to be a 18% and after post interventional study was found to be a 10 %. The 41-60 age was found to be a medication adherence as 25% after post interventional study 20 %. And the age as above 60 year the medication adherence as found to be pre interventional study in 57%

and post interventional study as 50%.

Identified drug related problems (DRPs) among the study participants

In the present study, ADRs were assessed with the help of Naranjo Scale. Out of 30 identified ADRs, 4 were definite, 17 were probable, 8 were possible and 1 was unlikely ADRs. The present study also identified 25 drug interactions. Among them 5 were major, 12 were moderate and 8 were minor interactions based on Medscape. The identified DRPs among the study participants were described in the table 6.

Table 5: Identified drug related problems among the study participants.

Sl No.	Types of DRPs	Pre-intervention	Post-intervention	P value
1	Untreated indication	5	1	< 0.05
2	Improper drug selection	2	0	< 0.05
3	Sub-therapeutic dosage	4	1	< 0.05
4	Failure to receive drugs	121	65	< 0.05
5	Over dosage	8	2	< 0.05
6	Adverse reactions	30	12	< 0.05
7	Drug interactions	25	10	< 0.05
8	Drug use without indications	0	0	< 0.05

Identified medication errors among the study participants

Prescribing error

During the pre-intervention prescribing error was found in 14(9.33%) of the study participants whereas after the intervention it was reduced to 3(2%) of the study participants. One example for prescribing error found in this study was prescription containing metformin 500mg for a lean study subject. This observation was found significant with the help of paired t-test where p value was less than 0.05.

Dispensing error

During the pre-intervention the dispensing error was found in 2(1.3%) of the study participants whereas after the intervention it was reduced to 0. One example for dispensing error found in this study was glimepiride and metformin hydrochloride tablets IP was dispensed instead of glimepiride and metformin hydrochloride (SR) tablets IP. This observation was found significant with the help of paired t-test where p value was less than 0.05.

Administration error

Administration error of the anti-diabetic drug

Own modification in the dose of anti-diabetic drug prescribed

During the pre-interventional study, it was found that 50 (33.3%) study participant were found to modify the dose of drug prescribed whereas it was found to be reduced after the intervention to 15(10%) participants. This result was found significant with the help of paired t-test where p value was less than 0.05.

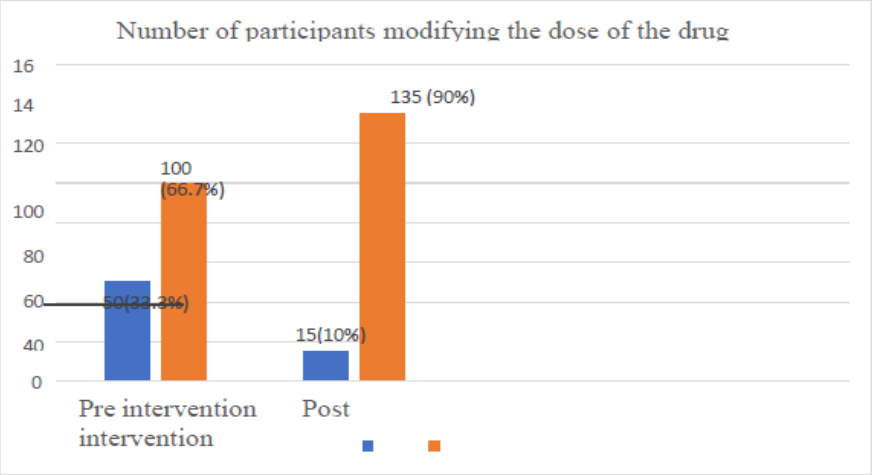

Figure no. 8: Number of participants modifying the dose of the drug prescribed.

Modification in the timings of anti-diabetic drugs

During the pre-interventional study, it was found that 80 (53.3%) study participant were found to modify the timing of anti-diabetic drug whereas during post interventional study it was reduced to 35 (23.3%) study participants. This observation was found significant with the help of paired t-test where p value was less than 0.05.

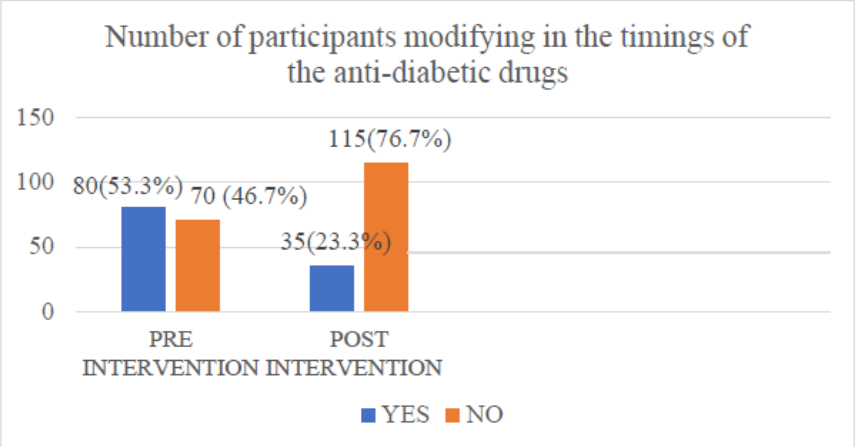

Figure no. 9: Number of participants modifying in the timings of the anti-diabetic drugs.

Wrong drug administered

During the pre-interventional study, it was found that 6 (4%) study participants were found to have administered wrong drug whereas it was decreased to 2 (1.3%) study participants after the post intervention study.

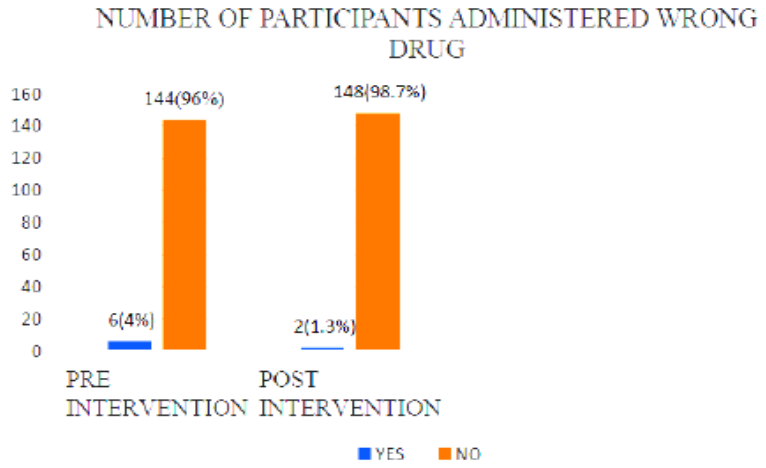

Figure no. 10: Number of participants administered wrong drug.

Checking the expiry date of the anti-diabetic medication before administration

During the pre-interventional study, it was found that 50(33.3%) of study participants were found to check the expiry date of the medications before administrating it whereas after the post interventional study, it was improved to 112(74.7%) of the study participants. This observation was found significant with the help of paired t-test where p value was less than 0.05.

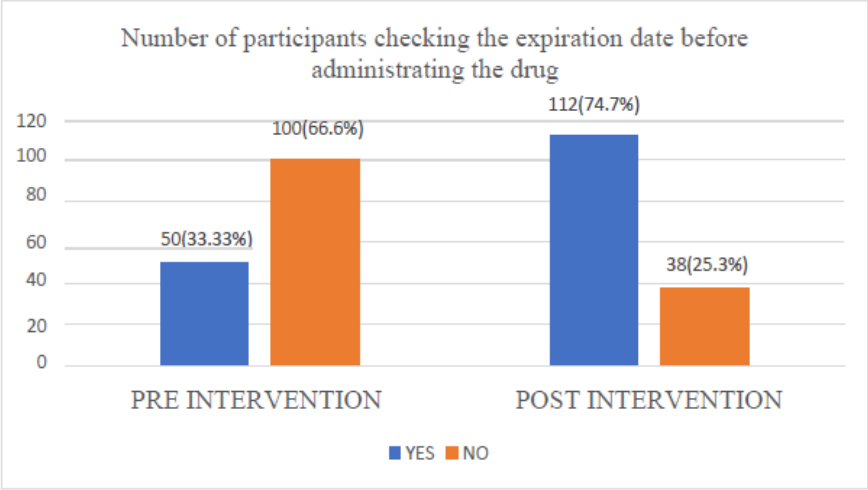

Figure No. 11. Number of participants checking the expiration date before administering the drug

Administration error found in the insulin administration usage of same syringe for multiple times during the administration of insulin

During the pre-interventional study, it was found that out of 150 study participants only 16 study participants were using insulin. Out of 16 study participants, 2(12.5%) of the study participants were found to use same syringe for 1 time, 4(25%) of the study participants were found to be using the same syringe for twice, 4(25%) of them were found to use the same syringe for 3-5 times and 6(37.5%) of the study participants were found to use the same syringe for 6-10 times. After the intervention it was improved as showed in the fig.5.

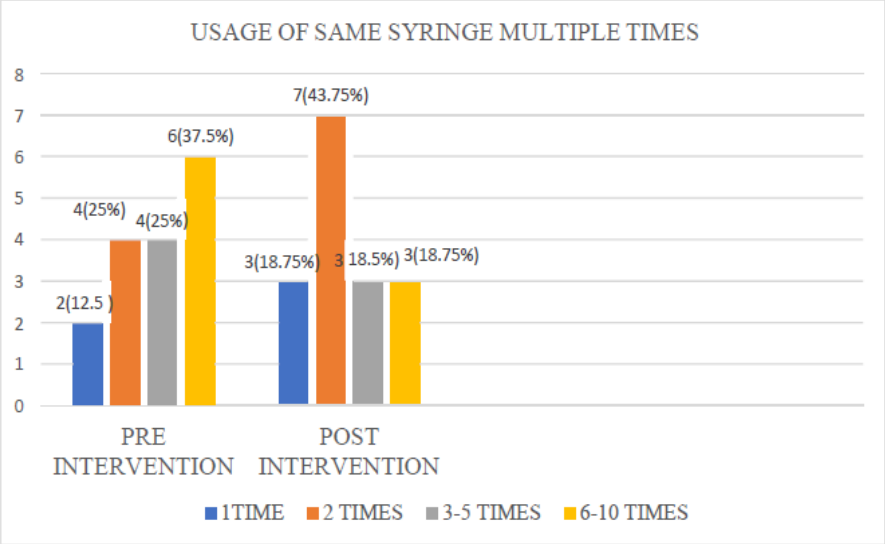

Figure No. 12: Usage of same syringe multiply times for administration of insulin.

Method of insulin administration by study participants

During the pre-interventional study, only half of the study participants who were taking insulin were administering the insulin properly which was improved significantly after the intervention.

Table 6: Method of insulin administration by study participants.

	Yes	No
Pre intervention		
Angle	10(62.5%)	6(37.5%)
Site	12(75%)	4(25%)
Post intervention		
Angle	15(93.75%)	1(6.25%)
Site	16(100%)	0

Monitoring error

During the pre-interventional study, monitoring error was found to be in 10(6.66%) of the study participants. After the intervention it was improved to 3(2%) of the study participants. This observation was found significant with the help of paired t-test where p value was less than 0.05. In this, study participants (10) were not regularly monitoring the blood glucose level.

Compliance error

During the pre-interventional study, the compliance error was found to be in 121(80.66%) of the study participants whereas after the intervention it was reduced to 65(43.33%) of the study participants. These study participants were non adherent to the anti-diabetic medications. This observation was found significant with the help of paired t-test where p value was less than The number of identified medication error was described in the table no 7.

Table 7: Identified medication errors among the study participants.

Sl. No.	Types of medication errors	Pre-intervention	Post-intervention	P value
1	Prescribing error	14	3	< 0.05
2	Dispensing error	2	0	< 0.05
	Administration error			
	a) Administration			
3	error of anti-diabetic drugs	186	164	
	b) Administration of insulin	24	14	< 0.05
4	Monitoring error	10	3	< 0.05
5	Compliance error	121	65	< 0.05

The table shows, When comparing the pre intervention and post interventional study as Prescribing error, Dispensing error, Administration error, Monitoring error and Compliance error as the preintervention study as higher than post interventional study. This observation is found significant with the help of p value of less than 0.05.

Storage of anti–diabetic medications: Storage of oral anti-diabetic medications

During the pre-intervention study it was found that study population about 13(8.6%) were storing the oral anti- diabetic drugs in kitchen, 8(5.3%) were storing in refrigerator,42(27.8%) of them were storing in house rooms, 83(55%) of them stored their medicines in cupboard whereas 5(3.3%) stored in the bathroom. After the post interventional study, it was found that majority of the study population 106(70.6%) stored their medication in the cupboard.

Table 8: Method of storing of oral anti-diabetic drugs by study participants.

Storage area	Pre-intervention	Post-intervention
Cupboard	83(55%)	106(70.6%)
Refrigerator	8(5.3%)	0
Ordinal house rooms	42(27.8%)	35(23.3%)
Kitchen	13(8.6%)	8(5.3%)
Bathroom	4(2.6%)	1(0.6%)

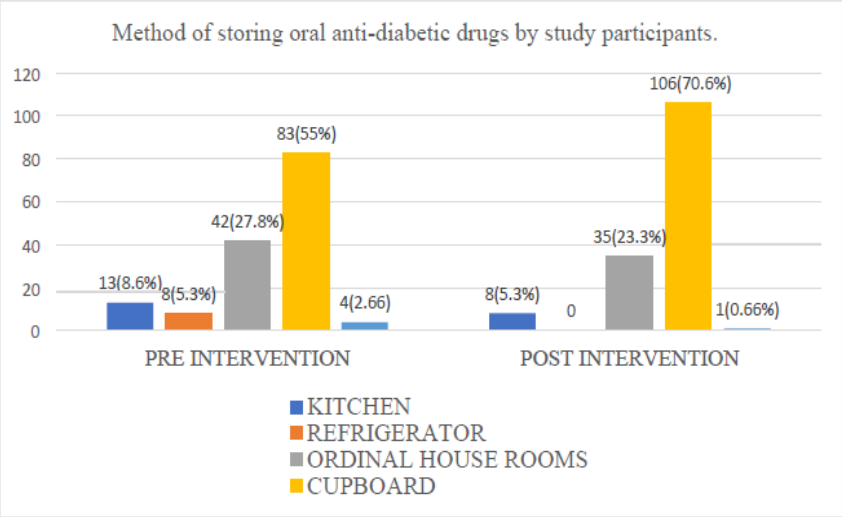

Figure 13: Method of storing oral anti-diabetic drugs by study participants.

Method of storing of insulin by study participants

During the pre-intervention study, only 16 were using insulin. Out of which it was found that about 2(12.5%) were storing the insulin in kitchen, 8(50%) were storing in refrigerator, 2(12.5%) of them were storing in ordinal house rooms, 3(18.75%) of them stored the insulin in cupboard whereas 1(6.25%) stored in the bathroom. After the post interventional, it was found that majority of the study population 13(81.25%) stored their insulin in the refrigerator.

Table 9: Method of storing of insulin by study participants.

Storage area	Pre-intervention	Post-intervention
Kitchen	2(12.5%)	0
Refrigerator	8(50%)	13(81.25%)
Ordinal house rooms	2(12.5%)	1(6.25%)
Cupboard	3(18.75%)	2(12.5%)
Bathroom	1(6.25%)	0

N=16

7. DISCUSSION

Home medication review (HMR) is an important service in assisting the consumers living at home in preventing the problems related to medication and in maximizing the benefits of their medication regimen in patients having diabetes mellitus. Diabetes mellitus is the chronic metabolic disorder with the condition where there is abnormal high blood glucose level. Home medication review (HMR) is patient centered process which provides the effective and quality use of medication at patient's home.[17] According to a study, nearly 50% of Type II diabetes fail to recite adequate glycemic control due to poor management of anti-diabetic medications.[18] A community based interventional study was conducted with the objectives of assessing and improving medication adherence in patients with diabetes mellitus using Morisky scale-8. This study also had few more objective that include identification and resolution of drug related problems (DRP) in diabetic patients using Hepler-strand classification, prevention of medication errors and reviewing of patient's method of storing of anti- diabetic medication at home.

A total of 150 of subjects who were suffering from diabetes mellitus were included in the study. Out of which 76 (51%) were male and 74 (49%) were female. While assessing medication adherence using Morisky scale-8, 97 people with low adherence (<6), 30 people with medium adherence (6-8) and 23 people with high adherence (>8) were found in pre interventional study. The reasons for low adherence found during the study was forgetfulness to take anti diabetic drugs, cost of the drug, multiple medication/ complex regimen, and unavailability of particular brand which may lead to hyperglycemia. As a part of the study, subjects with low adherence were given with PIL and patient counselling, whereas people with medium and high adherence were given with PIL only. The study showed a significant change in intervention in improving medication adherence i.e 40 people in low adherence, 25 people in medium adherence and 85 people in high adherence which were similar to the study done by Rozaini Rosli *et al.*, on Evaluation of HMR for patient with type 2 diabetes mellitus by community pharmacist.[19]

This study identified total of 195 DRPs in diabetic patients like untreated indication which included 5(7.5%) subjects. Here the patients were found to be in initial stage and the subjects used to modify their lifestyle without the medication. Improper drug selection was also identified here Metformin was given to diabetic patient who are lean in nature which shows the improper drug selection in study group of 2(3%) patients. sub therapeutic doses in the

study was found to be 4 (2.6%) which may lead to therapeutic failure. In the present study it was found that 8 study subjects were overdosed with anti-diabetic medication which can lead to hypoglycemia and other adverse effects. Among 150 study participants, 121(80.6%) showed failure to receive drugs which was caused due to non-adherence by the study subjects.. The study also showed Adverse drug reaction in 30(12%%) of study subjects which included unexplained weight gain in patient using glimepiride. The ADRs was classified based on Naranjo scale. Lipohypertrophy in patient administrating insulin. 25(10%) had experienced drug interactions mainly due to multiple drug therapy and co-morbid condition. No drug without indication was found during the study. In the Post interventional study, it was found that there was a significant reduction in the number of DRPs i.e., untreated indication was reduced to 1 (0.6%), improper drug selection was absent in the post interventional study, sub therapeutic dosage was reduced to 1(0.6%), failure to receive the drug was declined to 65(43.3%), overdosed in post interventional was found to be 2(1.33%), ADR was reduced to 12(8%), drug interaction was declined to 10(6.6%) in post interventional study. According to this study shows that failure to receive the drug was found to be the major type of drug related problem. Whereas the study conducted by Hasniza Zaman Huri *et al.,* on drug related problem in type 2 diabetes mellitus showed the most common DRPs found were potential interaction and drug not taken at all.[20]

The study results also showed data on medication errors, which are particularly prescribing errors, dispensing errors administration error, monitoring error and compliance error. During pre-intervention study prescribing error was found to be 14(9.33%) whereas after the intervention it was reduced to 3(2%). One example for a prescribing error that had come across during the study was prescription containing metformin 500 mg for a lean study subject. during the pre-interventional study only 2(1.3%) dispensing errors were identified which were reduced to 0 after the intervention.

One example for dispensing error was dispensing of normal tablets of glimepiride and metformin hydrochloride tablets IP rather than glimepiride and metformin hydrochloride (SR) tablets IP. While assessing administration error, own modification in the dose of anti-diabetic drugs was found to be 50(33.3%) study participants during pre - intervention study which was reduced to 15(10%) after the intervention. Administration error also included modification in the timing of anti- diabetic drug and wrong drug administration. Another reason for administration error included usage of same syringe for multiple times during the

administration of insulin. Here, during the pre- interventional study, it was found that out of 150 study participants only 16 study participants were using insulin in which 2(12.5%) of the patients were found to use same syringe for 1 time, 4(25%) of them using the syringe for twice and 6(37.5%) of the study participants were found to use the same syringe for 6-10 times, after intervention it had reduced. Other types of medication errors included monitoring errors and compliance errors. During the pre – intervention study, 10 (6.66%) subjects had monitoring errors and 121(80.66%) had compliance errors respectively. These outcomes were reduced to 3(2%) and 65(43.33%) respectively. The study had shown an improvement in reducing the medication errors by proper assessment which was similar tothe study done by Dilipchandrashekar *et al.*,.[21]

In the present study the storage of anti- diabetic drugs including both oral as well parenteral formulation was assessed. During pre-intervention study it was found that study population about 13(8.6%) were storing in refrigerator, 42(27.8%) of them were storing in house rooms, 83(55%) of them were storing in cupboards whereas 5(3.3%) were storing in bathroom. After the intervention study, it was found that majority of the study population 106(70.6%) subjects stored their oral anti-diabetic medication in cupboard. While assessing the storage of insulin by study participants shows during the pre- intervention study, only 6(37.5%) out of 16 study participants used to store insulin in refrigerator which were improved to 13(81.25%) after intervention. Thus, pharmacist intervention was found to be useful in reducing medication non- adherence, drug related problems, medication errors and improper storage of anti-diabetic drugs through home medication review study.

8. SUMMARY AND LIMITAION

Diabetes mellitus is the chronic metabolic disorder with the condition where there is abnormal high blood glucose level. Home medication review (HMR) is patient centered process which provides the effective and quality use of medication at patient's home. Home medication review (HMR) is an important service in assisting the consumers living at home in preventing the problems related to medication and in maximizing the benefits of their medication regimen. The general objective of the study was to assess the impact of pharmacist led home medication review in patients with diabetes mellitus in Erode.

The specific objectives were to assess and improve medication adherence in patients with diabetes mellitus using Morisky scale-8(MMS-8), to identify and resolve drug related problems in diabetic patients using Hepler-strand classification, to identify and prevent

medication errors in diabetic patients and to review the patient's method of storage of anti-diabetic medication at home. So an interventional study was conducted in different places of Erode for a period of 9 months. The study was limited for a sample of 150 based on the criteria included in the study and the study protocol was approved by the Institutional Ethics Committee (IEC).

Inclusion criteria included of patients of either gender, patients aged above 18years and volunteer people suffering from diabetes mellitus. Exclusion criteria included of patients below 18years, pregnant and lactating women and people who were not diabetic. According to a study, nearly 50% of Type II diabetes fail to recite adequate glycemic control due to poor management of anti-diabetic medications. Information regarding medication adherence, medication errors and drug related problems was collected through systematically designed data collection form and patient information leaflet through home medication review. Questionnaires was prepared and given to patients before and after intervention. The low adherent patients were given with PIL and also counseled before the post interventional study. Among 150 subjects 85(56.6%) subjects in medication adherence, 135(90%) subjects in modification of dose, 115(76.7%) of subjects in time modification, 115(76.7%) subjects in knowledge of storage had shown improvement after the interventions (PIL and counselling). So, it was concluded that the pharmacist intervention was helpful in improving the overall diabetes management through HMR, thereby leading to a better health care outcome.

Merits

- It is a community-based study where there is a gap between patient and healthcare provider because of lack of pharmaceutical care.
- It is an Interventional study where the subjects are educated with the basic knowledge of diabetes and diabetes management along with drug storage.
- Interventional study of home medication review in diabetes which is found rare in the community.

Limitations

- Small sample size.
- Information bias.

Future prospectives of the study

This study can be conducted in the large population in order to get more precise statistically evident data that will be useful in decision making.

9. CONCLUSION

This study was made to assess the pharmacist led home medication review in diabetes mellitus in Erode Tamilnadu. Medication adherence was calculated using Morisky scale -8. Drug related problems was evaluated using Hepler's Strand classification. Medication error was evaluated. Method of storage of anti-diabetic medication was reviewed using questionnaire. Questionnaire, PILs and counseling were used in the intervention to educate the study participants on anti-diabetic medication management. Microsoft Excel 2017 and paired t test were used in the study to evaluate and calculate the significant value. It was found that there was a significant improvement in the study results after the intervention. Hence it was concluded that the study was helpful in improving the overall diabetes management through HMR, thereby leading to a better health care outcome.

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