ROLE OF CLINICAL PHARMACIST INTERVENTIONS IN THE MANAGEMENT OF DIABETES MELLITUS: A RANDOMIZED CONTROLLED STUDY

Thesis submitted to

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For the award of the degree of

Doctor of Philosophy

In the Faculty of Pharmacy

By

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2024

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Dedicated to my beloved parents, entire family & Almighty

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Dr. Sanatkumar Bharamu Nyamagoud

TABLE OF CONTENTS

LIST OF ABBREVIATIONS

SI NO	Abbreviations	Full Form
1.	2hPG	2-hour postprandial glucose
2.	4-IMAS	2. 4-item Medication Adherence Scale
3.	A1C	Glycated Haemoglobin
4.	ACC	American College of Cardiology
5.	ACE	Angiotensin-converting Enzyme
6.	ADR	Adverse Drug Reaction
7.	AE	Adverse Events
8.	AMP	Adenosine Monophosphate Protein
9.	AMPK	Adenosine Monophosphate Protein Kinesis
10.	ARB	Angiotensin-receptor Blockers
11.	ATC	Anatomical Therapeutic Chemical Classification
12.	BMI	Body Mass Index
13.	BP	Blood Pressure
14.	BPH	Benign Prostatic Hyperplasia
15.	CAC	Causality Assessment Committee
16.	CCI	Charlson Comorbidity Index
17.	CHF	Congestive Heart Failure
18.	COPD	Chronic Obstructive Pulmonary Disease
19.	CVD	Cardiovascular Disease
20.	CVD	Cerebrovascular Disease
21.	DCCT	Diabetes Control and Complication Trial
22.	DM	Diabetes Mellitus

23.	DMTAC	Diabetes Medication Therapy Adherence Clinic
24.	DPP-4	Dipeptidylpeptidase-4
25.	DTSQ	Diabetic Treatment Satisfaction Questionnaire
26.	DUE	Drug Utilization Evaluation
27.	DDI	Drug-Drug Interaction
28.	DoTS	Directly Observed Therapy Short Course
29.	DRP	Drug-Related Problem
30.	FBS	Fasting Blood Sugar
31.	FPG	Fasting Plasma Glucose
32.	GAD65	Glutamic Acid Decarboxylase 65-kilodalton isoform
33.	GDM	Gestational Diabetes Mellitus
34.	GH	General Health
35.	GFR	Glomerular Filtration Rate
36.	HEDIS	Healthcare Effectiveness Data and Information Set
37.	HDL	High-Density Lipoprotein
38.	HRQoL	Health-Related Quality of Life
39.	IAA	Insulin Autoantibodies
40.	ICA	Islet Cell Autoantibodies
41.	ICF	Informed Consent Form
42.	IDF	International Diabetes Federation
43.	IHD	Ischemic Heart Disease
44.	KAP	Knowledge, Attitude, and Practice
45.	LV Dysfunction	Left Ventricular Dysfunction
46.	MAQ	Medication Adherence Questionnaire

47.	MARS	Medical Adherence Rating Scale
48.	MH	Medical Health
49.	MI	Myocardial Infarction
50.	NICU	Newborn Intensive Care Unit
51.	PAD	Peripheral Arterial Disease
52.	PDC	Proportion of Days Covered
53.	PCSK9	Protein Convertase Subtilisin/Kexin Type 9
54.	PIS	Participant Information Sheet
55.	PIL	Patient Information Leaflets
56.	PR	Prolonged Release
57.	PSA	Pill Count Adherence
58.	RAS	Renin-Angiotensin System
59.	RCTs	Randomized Controlled Trials
60.	RLEP	Role Limitation Due to Emotional Problems
61.	RLPH	Role Limitation Due to Physical Health
62.	SF	Social Functioning
63.	SGLT2	Sodium-Glucose Co-transporter 2
64.	SNOSE	Sequentially Numbered, Opaque, Sealed Envelopes
65.	SBP	Systolic Blood Pressure
66.	TZD	Thiazolidinediones
67.	UKPDS	UK Prospective Diabetes Study
68.	VEGF	Vascular Endothelial Growth Factor
69.	69. WHO	World Health Organization
70.	E/F	Energy/Fatigue

71.	GAD65	Glutamic Acid Decarboxylase 65-kilodalton isoform
72.	HLA	Human Leucocyte Antigen
73.	IIT	Insulin Injection Technique
74.	IAA	Insulin Autoantibodies
75.	ICA	Islet Cell Autoantibodies
76.	LLN	Lipid-Lowering Medicine
77.	MARS	Medication Adherence Rating Scale
78.	PCMH	Patient-centered Medical Home
79.	PCA	Pill Count Adherence
80.	PF	Physical Functioning
81.	PIS	Participant Information Sheet
82.	PR	Prolonged Release
83.	RCTs	Randomized Controlled Trials

LIST OF TABLES

LIST OF FIGURES

LIST OF FLOWCHARTS

ABSTRACT

BACKGROUND

Diabetes mellitus, a chronic metabolic disorder, results in elevated blood sugar levels due to insulin impairment. Globally, 4.2 million deaths were reported in 2019, with 463 million adults affected. In India, over 7.1% of adults (62 million) suffer from diabetes. Poor understanding and medication adherence lead to psychological distress, decreased quality of life, and higher healthcare expenses. Clinical pharmacists can bridge the patient-doctor gap through patient counselling. The study proposes a pharmacist-led collaborative care initiative to enhance diabetes management and improve overall patient quality of life.

OBJECTIVES

Primary objective:

- To assess the impact of clinical pharmacist interventions in the management of diabetes mellitus.

Secondary Objective:

- To identify and assess drug related events in study population.

MATERIALS AND METHODS

The current work was a prospective randomized controlled study, which was conducted at Vivekananda General hospital, Hubballi. The sample size of the study population was 300. The diabetes mellitus patients of either gender, aged above 18 years with or without comorbid conditions and those who are admitted to in or out patient department were included in the study. Patients with mental incompetence, pregnant or lactating women and those who are not willing to participate in the study were excluded. Participants were randomly assigned by SNOSE method, either to the control group with usual therapy or the interventional group with pharmaceutical care

for the duration of 24 months. The study related data like KAP, MA, QOL, DUE, DRP, ADR, and clinical parameters have been collected and analyzed during the study period.

RESULTS

Total of 300 patients were enrolled in the study. The selected patients were randomly allocated into control group (n=150) and interventional group (n=150). During the study period, 26 patients in the interventional group and 22 in the control group were lost to follow-up and final analysis has been done on 252 patients. The KAP assessment showed, literate and subjects with disease duration of more than 5 years had better KAP results. The bivariate test results demonstrated that there is a significant difference ($P < 0.05$) in the domains of age, education, and duration of disease with respect to knowledge, attitude, and practice. DUE showed that 58.33% subjects were taking two and 27.33% were receiving three medications. A total of 321 DRPs were identified, in which 412 interventions were made of which 375 interventions were solved. Total of 104 ADRs were identified which were majorly seen in age group of >70. Multiple linear regression analysis revealed that age, gender, education, duration of diabetes, and comorbidities were significantly associated with HRQOL. The MA and clinical parameters were significantly improved in the interventional group compared to control group.

CONCLUSION

Clinical pharmacist-led collaborative care mediated patient counselling and pharmaceutical care services had a positive impact on patient's HRQOL, MA and clinical parameters which is a result of increased understanding of KAP towards DM. This reinforces the crucial role of clinical pharmacists in enhancing patient education,

promoting medication adherence, and addressing medication-related issues to achieve better health outcomes in individuals with diabetes.

KEYWORDS

Diabetes Mellitus; Patient Counselling; Drug Related Problems; Medication Adherence; Health Related Quality of Life.

1 INTRODUCTION

1.1 Background

Diabetes mellitus is a metabolic disorder exhibited by elevated amount of glucose in the blood (chronic hyperglycemia) condition occurs as a result of either a relative or absolute impairment in secretion of insulin, action of insulin, or both [1]. There are two primary categories of diabetes: Type 1, known as insulin-dependent diabetes mellitus, and Type 2, known as non-insulin-dependent diabetes mellitus. According to the American Diabetes Association and the World Health Organization (WHO), there are two subtypes of Type 1 diabetes: idiopathic diabetes with beta-cell blockage (1B) caused by impaired release of insulin or peripheral insulin resistance. Autoimmune/immune-mediated diabetes (1A) results from apoptosis of pancreatic beta cells due to antibodies (autoimmune related) [2].

Family history, race, and other autoimmune conditions increase type 1 diabetes risk; age, race/ethnicity, heredity, and history of gestational diabetes increases type 2 diabetes risk. Lifestyle risk factors include obesity (visceral fat accumulation), physical inactivity, dyslipidemia, hypertension, and a history of cardiovascular disease [3].

Diabetes over time leads to multiorgan complications, broadly divided into macrovascular and microvascular complications, leading to premature morbidity and mortality and increased financial burden on individuals [4].

Macrovascular complication which is common with type 2 diabetes includes coronary heart disease, cerebrovascular disease, and peripheral vascular disease which usually affects arteries in extremities and leads to gangrene. Microvascular complications include diabetic nephropathy, retinopathy, neuropathy, and diabetic foot [5].

As per the 10th edition of IDF (International diabetes federation) the prevalence of diabetes mellitus was assessed for the year 2021 and extrapolated to 2030 and 2045. It is estimated that around 537 million adults (20-79), constituting 10.5% of this age group globally, had diabetes in 2021. Predictions indicate that by 2030 the incidence will be 643 million and in 2045 it will be 783 million. This represents a 46% increase in the number of adults with diabetes, surpassing the 20% growth rate projected for the world's population during this period. In 2021, the estimates indicated that 74.2 million individuals in India had diabetes, and this number is anticipated to surge to over 134 million by 2045. Notably, India presents 1 in 7 of all adults living with diabetes globally [6].

Patients with type 2 diabetes often have comorbidities like obesity, hypertension, and hyperlipidemia [7]. Physical inactivity, smoking, alcohol, increased consumption of sugared beverages, and processed meat are the contributing factors [8].

Effective management of individuals with diabetes aims to minimize or prevent complications, enhance life expectancy, and improve overall quality of life. The patient's commitment in adhering to prescribed medications and making necessary lifestyle adjustments is crucial for successful diabetes management [9].

Diabetes is a complex disease to manage which requires patient involvement to be fully effective [10]. Despite the availability of a large number of pharmacotherapy modalities available for controlling blood glucose level, serum lipid, and blood pressure, recommended glycaemic targets are poorly achieved among the patients. This negative outcome may be due to patient unawareness about self-management of disease, lack of interventions by healthcare providers' or due to lack of patient compliance [11].

To manage these types of complex chronic diseases a collaborative, proactive, and integrated team of physician, dietician, nurse, and clinical pharmacist are required. The role of the pharmacist is prominent in diabetes care due to the complexity nature of the disease. MTM (Medication Therapy Management) is value service provided by pharmacists which involves medication chart review, providing therapeutic action plans for the individual patient, minimizing adverse drug reactions, managing polypharmacy, nonadherence and follow-up that reduces prescription errors and improving patients participation problems [12]. Pharmaceutical treatment is responsible domain of drug therapy that plays major role in improving patients quality of life by disease management. Pharmacists work with patients and other healthcare providers to design, put into practice, monitor, and adjust a treatment strategy that will achieve a specific therapeutic outcome [9].

Pharmaceutical care helps to enhance the health outcomes of patient through appropriate, effective, safe, and cost-effective management of drug therapy [13].

1. Recognizing existing issues related to drug therapy.

2. Resolving and managing ongoing medication-related issues. Taking steps to address and alleviate current challenges in drug therapy.

3. Proactively implementing measures to avoid potential issues linked to medication. Engaging in strategies to prevent future challenges in drug therapy [14].

As per the World Health Organization (WHO), adherence refers to the degree to which a person's actions, such as drug intake, compliance to a prescribed diet, and application of lifestyle modifications, align with recommendations given by the medical practitioners. Nevertheless, among individuals with diabetes, non-adherence to medication is notably prevalent, and insufficient adherence jeopardizes both safety

and the efficacy of treatment, ultimately resulting in surge in mortality and morbidity [15].

The responsibility of pharmacist is to optimize the therapy in consideration of patient needs and to educate the patients regarding medication and its effects [16]. Measures of health-related quality of life capture the emotional, physical, and lifestyle impacts associated with the illness, gaining growing recognition for their significance in the context of chronic illnesses [17].

Health related quality of life (HRQoL) incorporation into clinical practice to evaluate the importance of intervention by healthcare providers. Health research outcome also focuses on physiological measures and subjective factors. These subjective factors are essential because diabetes is mainly self-managed which affects daily life aspects [17].

A Drug-Related Problem (DRP) is characterized as an incident or condition related to pharmacological therapy that actively or possibly hinders the achievement of intended health outcomes [18]. Polypharmacy, advanced age, renal impairment, frequent alteration in medication chart, and severe illness increases the risk of DRP [19]. Collaboratively, pharmacists, alongside physicians, nurses, and administrators play a crucial role in ensuring patient safety [20]. Given the elevated risk of iatrogenesis, the identification, characterization, investigation of causes, and assessment of therapies related to DRPs are particularly vital in routine clinical practice, especially in hospital medical wards [19]. Clinical pharmacists can successfully identify, address, and avert clinically important drug-related problems, thereby positively influencing patient outcomes. This could impact positively in improved health, economy, and patient satisfaction, reduced medication-related issues, better quality of life, and decreased morbidity and mortality [13].

One of the most important roles in providing pharmaceutical care is patient counseling, which includes providing patients or their representatives either verbal or written information about the disease, treatments, and lifestyle modifications [13].

Educating patients will enhance the compliance, leading to a more efficient and economic healthcare delivery system. Facilitating patient-centered care, patient education encourages adherence to medications and therapies, ensuring seamless care, continuity and minimizing complications associated with illness [21]. Dietary counseling is an essential component of diabetes care. Continuous education initiatives and counseling support to diabetic patients in emphasizing the importance of risk factors, preventative measures, medication compliance, and behavioral changes to avoid the disease progression and ultimately reducing the need for hospitalization [13].

An adverse drug reaction (ADR) is defined as "A response which is noxious and unintended, and which occurs at doses normally used in humans for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function".

ADRs are of two types:

1. Type A reaction – Augmented Reaction, it is dose-dependent and predictable.

2. Type B reaction– Bizarre reaction, not predictable.

The comprehensive classification is DoTS i.e. Dose of the drug, Time course of the reaction and relevant Susceptibility factors [22]. In order to reduce the risks of ADRs, the role of pharmacist is to aid growth, maintenance, and assessment of ongoing programs by identifying and reporting suspected ADR. Clinical pharmacist plays a important role in ensuring that a greater number of adverse drug reactions (ADRs) are reported, which facilitates quick care, and results in decreased number of cases of morbidity and mortality [23]. Through education and training, pharmacists can play

more significant role in diagnosing, treating, and preventing adverse drug reactions. The significance of reporting an ADR must also be emphasized, particularly among healthcare providers and community pharmacists. Additionally, pharmacists play a key role in informing patients about their medication and counselling [24].

1.2 LITERATURE REVIEW

1.2.1 Diabetes Mellitus

1.2.1.1. Introduction to diabetes mellitus

1.2.1.2. Epidemiology

1.2.1.3. Pathophysiology

1.2.1.4. Risk Factors

1.2.1.5. Complications

1.2.1.6. Treatment Options

1.2.1.7. Pharmacist Interventions

1.2.1.7.1 Pharmaceutical Care

1.2.1.7.2 Medication Adherence

1.2.1.7.3 Health Related Quality of life

1.2.1.7.4 Drug Related Problems

1.2.1.7.5 Patient Education/Counselling

1.2.1.7.6 Adverse Drug Reactions

1.3 Justification

1.1.1 Diabetes Mellitus

1.1.1.1 Introduction to diabetes Mellitus

Type 2 Diabetes Mellitus (T2DM) is a prevalent metabolic disorder with a multifaceted origin, primarily attributed to the inadequacy in insulin secretion by pancreatic β-cells and peripheral tissue resistance to insulin leading to chronic hyperglycemia [25]. Such high blood glucose levels pave the way for a cascade of disruptions in the body's carbohydrate, fat, and protein metabolism, leading to various organ dysfunctions [25,26].

The repercussions of sustained hyperglycemia extend beyond mere blood glucose elevation. This metabolic imbalance affects multiple organs, impairing their structure and function. The normal vasculature within these organs experiences progressive damage at both micro- and macroscopic levels. The ramifications of these structural and functional disturbances manifest as complications in the body's crucial systems. These complications range from eye-related issues causing retinopathy and potential blindness, to kidney-related problems leading to nephropathy and the risk of renal failure. Additionally, the heart suffers, with complications like hypertension and emerging coronary heart disease. Nerve damage, especially peripheral neuropathy, contributes to a spectrum of difficulties, from autonomic neuropathy affecting cardiovascular, gastrointestinal, and genitourinary systems to long-term complications like foot ulcers and osteoarthropathy associated with peripheral nerve damage [27–29].

1.1.1.2 Epidemiology

Type 2 Diabetes Mellitus (T2DM) presents a substantial global health burden, as reflected in its epidemiological data. In 2019, the International Diabetes Federation (IDF) reported 4.2 million deaths attributable to diabetes, with an estimated 463 million adults between 20 to 79 years old living with the condition. Projections

suggest a potential increase to 700 million cases by 2045, accompanied by considerable health expenditure that surpassed 720 billion USD in 2019 [30].

The underdiagnosis of diabetes is a significant concern, with approximately 1 in 3 affected individuals equivalent to 232 million people likely not diagnosed. This disease predominantly affects those aged between 40 to 59 years, and its prevalence differs across regions, with over 80% of cases observed in low-to-middle-income countries, posing unique challenges for effective management [29].

Type 2 diabetes mellitus increases the risk of all-cause mortality by 16% [31]. Several studies concluded an association between T2DM and risk of cardiovascular disease, stroke and vascular disease.

Both genetic and environmental factors add up to the epidemiology of T2DM. Genetic influences interact with sedentary behavior and high-calorie intake, leading to the expression of various phenotypes and an increased susceptibility to several CVD risk factors such as hypertension, insulin resistance, and dyslipidemia. India represents a notable portion of the global diabetes burden, with an estimated 74.2 million cases in 2021, anticipated to exceed 134 million by 2045, making up 1 in 7 cases of adult diabetes worldwide [32].

1.1.1.3 Pathophysiology

Constituting 5-10% of diabetes cases, Type 1 Diabetes Mellitus (T1DM) is an autoimmune disorder marked by the targeted impairment of pancreatic β-cells. This process leads to deficiency of insulin and the onset of hyperglycemia. The pathogenesis involves a complex interplay of genetic and environmental factors. It is marked by immune-mediated destruction, identified by specific autoantibodies such as GAD65, ICAs, IA-2, IA2α, and insulin autoantibodies (IAAs), detectable in about 85-90% of patients with new-onset T1DM [33–36]. The varying rate of β-cell destruction

defines the disease progression, distinguishing abrupt cases in children, gradual onset in adults, and rare instances of retained insulin function for years. The autoimmune nature of T1DM manifests in association with other autoimmune disorders like myasthenia gravis, Addison's disease, celiac disease, and vitiligo, partly due to genetic influences linked to human leukocyte antigen (HLA) and other non-HLA genes [36,37].

Type 2 Diabetes Mellitus (T2DM) constitutes about 90-95% of diabetes cases, distinguished by insulin resistance and β-cell dysfunction. Its pathogenesis involves reduced cellular response to insulin in tissues like muscle, liver, and adipose tissue, with β-cell hyperfunction initially compensating for the resistance. Over time, this compensation falters, leading to insulin deficiency. T2DM progresses slowly, often remaining undiagnosed until advanced stages manifesting in symptoms like weight loss, blurred vision, and polyuria. Its etiology involves genetic predispositions and environmental factors such as obesity, family history, physical inactivity, and specific racial or ethnic backgrounds. Unlike T1DM, it lacks an immune-mediated pancreatic β-cell destruction, yet exhibits close associations with cardiovascular risk factors and diverse metabolic abnormalities like hypertension and lipid imbalances, often resulting in microvascular and macrovascular complications over time [38–44].

1.1.1.4 Risk Factors

1. Obesity:

- Increase Body Mass Index (BMI), even within the normal range, shows a relationship with T2DM onset, with a notable increase in risk beyond 30 kg/m^2.
- BMI's predictability for T2DM, however, varies when considering central obesity measures, which emerges as better predictors [45,46].

2. Central Obesity:

- Central or visceral obesity, irrespective of BMI, presents a strong correlation with T2DM, attributed to the unfavorable nature of adipocytes in visceral fat depots.
- Waist circumference is particularly vital and stands as an independent factor of T2DM, even after adjusting for BMI [47,48].

3. Weight Gain and Metabolic Syndrome:

- Weight gain across adulthood, particularly in early stages, influences T2DM risk. Metabolic syndrome components such as hypertension and dyslipidemia also play a role in enhancing T2DM risk [49].
- While weight changes exhibit a link to T2DM, they might not always independently influence T2DM risk beyond their impact on BMI [50].

4. Lifestyle Factors:

- Poor dietary habits, sedentary behaviors, and a lack of physical activity directly correlate with higher T2DM risk by promoting obesity and metabolic syndrome components.
- Lifestyle modifications, including balanced dietary habits and increasing physical activity are foundational for T2DM prevention [51–53].

5. Dietary Patterns:

- Increased consumption of sugared beverages, meat, and diet with low intake fruits, vegetables, fiber, and whole grains relate to higher T2DM risk [53,54].
- Dietary quality in terms of macronutrients (e.g., glycemic load, types of fatty acids) plays a significant role in T2DM prevention [51,54,55].

6. Physical Activity and Sedentary Behaviours:

- Physical inactivity and a sedentary lifestyle are directly linked to the risk of diabetes, as recommended preventive measures are a minimum of 150 minutes of moderate-vigorous physical activity per week [56,57].
- Reducing sedentary behaviours is equally crucial in curbing T2DM risk, particularly in high-risk populations [57,58].

7. Non-Modifiable Risk Factors:

- Factors such as aging, diabetes family history, ethnicity, and socioeconomic status are crucial in assessing T2DM risk, allowing for effective identification of high-risk groups and targeted interventions [59–61].

8. Aging, Family History, Ethnicity, and Socioeconomic Status:

- Older age significantly enhances T2DM risk due to impaired insulin regulation and reduced physical activity levels [30].
- Diabetes family history strongly correlates with T2DM risk, indicating a genetic predisposition to the disease.
- Certain ethnic groups exhibit inherently higher T2DM risks, attributable to genetic predispositions and body composition differences [62,63].
- Low socioeconomic status is an independent T2DM risk factor, influenced by various lifestyle and psychosocial aspects [64].

1.1.1.5 Complications

Diabetes exerts deleterious effects on diverse organ systems, giving rise to consequential complications over time. These complications are dichotomously categorized as microvascular and macrovascular. Microvascular ramifications encompass neuropathy, nephropathy, and retinopathy, indicating damage to the nervous, renal, and ocular systems, respectively. On the other hand, macrovascular complications entail cardiovascular maladies, strokes, and peripheral vascular

disorders, the latter potentially leading to non-healing injuries, gangrene, and eventual amputation [65].

Cardiovascular disease is a significant contributor, responsible up to 65% of mortality among individuals with diabetes. Diabetes is closely linked to heightened morbidity from ischemic heart disease and strokes, with individuals having 2 to 4 times higher mortality rates due to heart disease compared to those without diabetes. Additionally, diabetic individuals face 2 to 4 times higher likelihood of experiencing strokes. It's noteworthy that over 70% of diabetes patients have elevated blood pressure or are undergoing treatment for hypertension. The specific impact of hyperglycemia in triggering cardiovascular complications in individuals with diabetes is not yet fully understood.

Diabetes patients share the same risk factors for cardiovascular diseases as the general population, such as hypertension, hypercholesterolemia, and smoking. However, even a single risk factor can lead to poorer outcomes in individuals with diabetes compared to non-diabetic individuals [66]. A retrospective analysis spanning from 1950s to 2003, examining cardiovascular disease complications associated with diabetes across diverse populations, reveals a noteworthy decline in incidence rates. These reductions, especially notable during the 1980s and 1990s, align with the progress in pharmacological interventions targeting glycemic control, blood pressure, and blood cholesterol levels [66].

Peripheral Arterial Disease (PAD), manifests as the constriction of blood vessels supplying to the arms, legs, stomach, and kidneys [67]. Individuals with diabetes are at a increased possibility of developing PAD, which is influenced by various factors such as age, duration of diabetes, neuropathy, as well as associations with levels of C-reactive protein and homocysteine. Symptoms of PAD include intermittent

claudication, which refers to pain during exercise that subsides with rest, and pain at rest, indicating insufficient blood flow to the affected limb [67]. PAD increases the risk for amputation, occurring at higher rates in diabetic patients. The coexistence of PAD and diabetic foot ulcers is common, affecting approximately 50% of patients, emphasizing the importance of effective pain management to improve the quality of life for individuals dealing with these complications. In a study evaluating the efficacy of tapentadol prolonged release (PR) in treating chronic ischemic pain in patients with type 2 diabetes mellitus, the findings supported its effectiveness in reducing pain intensity, relieving neuropathic symptoms, and improving overall quality of life [68].

Diabetes retinopathy is a complication of diabetes characterized by a spectrum of retinal lesions encompassing impaired vascular permeability, capillary degeneration, and neovascularization. Categorized into non-proliferative and proliferative stages, the early non-proliferative phase involves hyperglycemia-induced pericyte death and basement membrane thickening, compromising blood vessel integrity without overt visual impairment [69]. As the disease progresses to the proliferative phase, neovascularization and macula edema occur, leading to visual impairment, bleeding, and potential complications such as retinal detachment [70].

Almost all patients with type 1 DM are vulnerable to diabetic retinopathy, and the majority of type 2 patients are at peril, later two decades of disease [71]. However, only a minority of affected individuals experience progression leading to impaired vision.

Managing diabetic retinopathy involves maintaining blood pressure and glycemic control, along with various treatments like laser photocoagulation, triamcinolone injection, vascular endothelial growth factor (VEGF) antagonists, and vitrectomy.

Despite available treatments, there is no universally agreed medical approach to slow down disease progression before resorting to more invasive interventions.

The incidence trends of diabetic retinopathy suggest a decrease in recent years, likely attributed to advancements in early identification, improved diabetes and retinopathy treatments, and reduced smoking rates. Population-based studies from the 1990s onward report a significant decline in the incidence of diabetic retinopathy compared to earlier studies. These positive trends are indicative of the impact in early detection and improved management strategies derived from research studies such as the UK Prospective Diabetes Study (UKPDS) and the Diabetes Control and Complication Trial (DCCT) [72].

Diabetic nephropathy is characterized by proteinuria and a gradual decline in GFR (glomerular filtration rate) over 10-20 years. Diabetic nephropathy is a significant risk factor for the development of macrovascular complications. Hypertension and uncontrolled glycaemic level pose a significant risk for diabetic nephropathy [73,74].

Identifying the most specific kidney function impacted by diabetes is challenging and beyond toxin filtration. The impact of hyperfiltration on instigating kidney damage remains a subject of debate, with recent findings proposing potential protective effects against end-stage kidney disease in diabetic individuals maintaining normal or elevated filtration levels [75].

Therapies aimed at treating diabetic renal disease primarily focus on controlling BP. Interventions that modify the RAS system, including ACE inhibitors and ARB antagonists, are commonly used as first-line treatments. However, the effectiveness of specific renin-angiotensin system interruption in preventing and managing early diabetic nephropathy is still a subject of debate, with recent studies showing less than promising outcomes in this regard [75].

1.1.1.6 Treatment Options

Metformin is commonly prescribed as a first-line treatment for individuals, recently diagnosed with type 2 diabetes mellitus(T2DM), with brand names including Glucophage, Glumetza, Riomet, and Fortamet. Administered in pill form, metformin enhances the body's response to insulin, thereby reducing elevated blood sugar levels. Typically, treatment begins with a once-daily dose during dinner, followed by the addition of a second daily dose during breakfast one to two weeks later. Subsequent adjustments are made based on individual response to ensure optimal therapeutic outcomes. Common side effects such as nausea, diarrhea, and flatulence are usually mild and transient, particularly when taken with food. However, individuals with severe kidney, liver, or heart disease, and those with excessive alcohol consumption, should avoid metformin. The decision to add a second medication alongside metformin is contingent on blood sugar and A1C levels, with various classes of medications available based on factors such as weight, risk of low blood sugar, and individual preferences. Metformin, with its multifaceted mechanisms of action including AMP-activated protein-kinase (AMPK) activation and inhibition of gluconeogenesis, is contraindicated in situations predisposing to lactic acidosis, such as renal dysfunction. While generally well-tolerated, side effects may include gastrointestinal symptoms and a reduction in vitamin B12 absorption. Notably, metformin demonstrates cardiovascular benefits, lowering the risk of macrovascular complications and exhibiting lipid-lowering effects without adverse cardiovascular impact [76–78].

Sulfonylureas, commonly prescribed for type 2 diabetes, present a cost-effective option with notable concerns, particularly for the elderly, due to a heightened risk of hypoglycemia. Long-acting sulfonylureas, including chlorpropamide, glibenclamide,

and glimepiride are associated with increased hypoglycemic risk in older adults. Therefore, it is recommended to avoid long-acting sulfonylureas in the elderly, favoring shorter-acting options like gliclazide and glipizide. Factors influencing sulfonylurea-induced hypoglycemia in the elderly include exercise, missed or inadequate meals, impaired renal or cardiac function, hospitalization, and certain medication associations. Additionally, sulfonylureas contribute to weight gain, limiting their use in renal failure due to the elevated hypoglycemia risk and extensive drug interactions, posing challenges, especially in the elderly population. Symptoms of low blood sugar, such as sweating, shaking, hunger, anxiety, and confusion, necessitate prompt consumption of fast-acting carbohydrates. Managing low blood sugar is crucial to prevent complications, and adjusting sulfonylurea usage based on meal schedules can reduce this risk. Careful consideration is essential, emphasizing caution, particularly in the context of kidney failure and advancing age [74,79].

Meglitinides, namely repaglinide (Prandin) and nateglinide (Starlix), are designed to manage postprandial glycemia, requiring more frequent administration with meals compared to sulfonylureas. Although their higher cost limits their utilization, especially among older individuals with polypharmacy, meglitinides pose a lower risk of hypoglycemia, particularly in patients lacking a fixed meal schedule, while exhibiting a comparable risk of weight gain to sulfonylureas. For individuals with acute to chronic renal impairment, repaglinide, which is mainly excreted through bile, may be used as a first-line treatment when metformin and sulfonylurea intolerance is not appropriate. Caution is advised against combining repaglinide with drugs affecting cytochrome P450, such as gemfibrozil, due to an elevated risk of hypoglycemia. Although meglitinides are not typically adviced as a first-line therapy

due to their higher cost compared to sulfonylureas, repaglinide may be a viable option for patients with kidney failure [80].

Alpha-glycosidase inhibitors, specifically acarbose (Precose) and miglitol (Glyset), are designed to regulate postprandial blood sugar level, making them theoretically appealing for older individuals. However, their gastrointestinal effects, relatively low efficacy, requirement for more frequent regular doses, and associated costs limit their widespread use. Operating by impeding carbohydrate absorption in the intestine, these medications contribute to lowering blood glucose levels, although not as effectively as metformin or sulfonylureas. They can be employed in combination with other medications if the initial treatment proves insufficient. The primary side effects of these inhibitors include diarrhea, and abdominal pain, which may be mitigated by initiating treatment with a low dose. Typically administered three times daily with the first bite of each meal, these inhibitors present a therapeutic option with certain limitations and considerations in diabetes management [69].

Thiazolidinediones (TZD), encompassing pioglitazone (Actos) and rosiglitazone (Avandia), operate by enhancing the peripheral tissue sensitivity to insulin, thereby lowering blood sugar levels. Despite not elevating the risk of hypoglycemia, their utilization in the elderly is constrained by factors such as high cost and notable side effects. Pioglitazone, potentially beneficial in secondary prevention, is associated with drawbacks including increased weight, macular edema, fluid accumulation, an increased adversities of heart failure, bone fractures, and a potential link to bladder cancer. Typically administered in pill form and often in combination with metformin, a sulfonylurea, or insulin, the limitations posed by these side effects influence the cautious use of TZDs in the elderly population [81]. Dipeptidyl peptidase-4 (DPP-4) inhibitors, like sitagliptin, saxagliptin, linagliptin, alogliptin, and vildagliptin, provide

a safe once-daily oral option for elderly individuals managing type 2 diabetes. These agents effectively control hyperglycemia with minimal risk of hypoglycemia and negligible impact on body weight. Dose adjustments are generally unnecessary for age, making them well-suited for the elderly population. While vildagliptin has shown efficacy and safety in patients aged 75 and above, safety data for this age group are limited. These inhibitors, fostering insulin release, can be prescribed independently or in combination with other oral medicines for those intolerants to metformin or requiring additional glycemic control. They do not induce hypoglycemia or significant weight changes, although rare reports note joint pain, pancreatitis, and severe skin reactions. Regular liver function monitoring is required for vildagliptin use [82].

Sodium-glucose co-transporter 2 (SGLT2) inhibitors, like dapagliflozin, empagliflozin, canagliflozin, are innovative oral hypoglycemic agents. They lower blood glucose by increasing urinary glucose excretion, independent of insulin, offering reduced hypoglycemia risk and mild diuresis. These agents, beneficial for weight and blood pressure control, appeal to elderly individuals managing type 2 diabetes. Caution is advised, as their use is contraindicated with an estimated GFR< 60 mL/min, potentially causing dehydration, electrolyte imbalances, and weight loss especially in frail elderly patients. They may elevate the risk of genital and urinary infections, urging careful use in those susceptible. Notably, SGLT2 inhibitors may be advantageous for individuals with heart failure or chronic kidney disease due to demonstrated cardiovascular, renal, and mortality benefits [38,83].

Insulin treatment is a viable option for glucose regulation in selected geriatric patients with type 2 diabetes (T2DM), offering comparable efficacy and hypoglycemia risks as in younger individuals. Various regimens, such as multiple daily injections and

continuous subcutaneous infusion, prove effective with low hypoglycemia rates in healthy elderly subjects. Incorporating long-acting insulin in elderly T2DM patients demonstrates effectiveness without heightened hypoglycemia risks. Challenges like visual or manual dexterity issues can complicate insulin therapy, but tailored delivery devices ease the process. Insulin analogues are preferred in the elderly due to lower hypoglycemia and weight gain risks, especially in frail individuals. Initiation of insulinization in elderly individuals should begin cautiously with a individual regular dose of long-acting insulin to mitigate hypoglycemia risks. While traditionally considered for later stages, recent evidence supports insulin use at earlier stages to enhance overall diabetes management. Side effects, including hypoglycaemia and weight gain, can be managed by adjusting insulin doses. In specific cases, insulin injections may be used as a first-line treatment or added to oral medications [30,73,84].

1.1.1.7 Pharmacist Interventions

Effective treatment for diabetes mellitus demands strict adherence and active patient involvement in self-medication. Pharmacists play a pivotal role in providing self-management support. Pharmacist-led interventions, encompassing education on diabetes, medication adherence, lifestyle, and self-management skills, demonstrated a significant mean reduction of 0.75% in glycated hemoglobin (HbA1c) levels. They actively engage in medication management by educating patients about proper drug usage, addressing potential side effects, and collaborating with healthcare providers to adjust treatment plans as needed. Lifestyle counseling is a key aspect, with pharmacists offering guidance on dietary choices, exercise routines, and smoking cessation to support optimal blood glucose control. Preventive care measures, including advocating for regular eye and foot examinations, are crucial in minimizing complications. Pharmacists also emphasize the importance of consistent blood

glucose monitoring and help patients interpret and act upon the results. However, variability in intervention methods and a lack of standardization contributed to outcome variations. The studies underscored the substantial improvement in diabetes outcomes through pharmacist-led interventions, underscoring the valuable contribution of pharmacists to the global healthcare system. Additionally, a prospective observational study conducted in New Delhi hospital highlighted adverse drug reactions (ADRs) in type 2 diabetes patients, emphasizing the need for more information on prescribed drugs and their side effects to ensure patient safety. In managing complex chronic diseases like diabetes, a collaborative team of healthcare professionals, including physicians, dieticians, nurses, and clinical pharmacists is essential. The pharmacist's role is significant in diabetes care, with Medication Therapy Management (MTM) providing valuable services in minimizing adverse drug reactions, managing polypharmacy, and improving patient participation [85].

1.2.1.7.1 Pharmaceutical Care

Effective pharmaceutical care is important to improve quality of life. In this approach, pharmacists work in cooperation with patients and other medical practitioners to develop, execute, and oversee a therapeutic plan with targeted outcomes. The pharmaceutical care plan involves three fundamental functions: recognizing both potential and existing medication-related issues, addressing current medication-related problems, and proactively preventing potential medication-related problems [86].

1.2.1.7.2 Medication Adherence

The World Health Organization (WHO) defines adherence as the degree to which an individual's behavior aligns with agreed recommendations from healthcare providers, encompassing medication, diet, and lifestyle changes. Non-adherence, especially prevalent among patients with diabetes, poses risks to safety and treatment

effectiveness, leading to increased mortality and morbidity. Pharmacists bear the responsibility to optimize therapy considering patient needs and educate them about medication and its effects.

1.2.1.7.3 Health Related Quality of life

In chronic illnesses, health-related quality-of-life measures are essential indicators that capture the emotional, physical, and lifestyle ramifications of illness. Within the realm of diabetes, HRQoL is shaped by the disease's nature, its complications, and the patients' comprehension, impacting diverse facets of patients' overall health. The incorporation of HRQoL assessment into clinical practice provides healthcare providers with a valuable tool to assess the success of interventions, taking into account both objective and subjective factors crucial in the self-management of conditions such as diabetes.

1.2.1.7.4 Drug Related Problems

Drug-related problems (DRPs) are issues that arise from drug therapy and can hinder health outcomes and pose a higher risk in certain patient groups. Clinical pharmacists play a crucial role alongside physicians, nurses, and administrators in ensuring patient safety by identifying, solving, and preventing clinically significant DRPs. This proactive approach positively impacts patient outcomes, improving health, economic outcomes, satisfaction, medication appropriateness, reducing adverse events, and enhancing overall quality of life, thus reducing morbidity and mortality [87].

1.2.1.7.5 Patient Education/Counselling

Patient counselling is a crucial aspect of providing pharmaceutical care. It involves communicating disease, medication, and lifestyle-related information to patients or their representatives, either orally or in written form. Patient education is also essential for ensuring compliance, promoting patient-centered care, adherence to

medications and therapies, ensuring continuity of care, and reducing illness-related problems. Nutritional counselling is an integral part of diabetes management, emphasizing the importance of diet and preventing hypoglycaemic episodes.

1.2.1.7.6 Adverse Drug Reactions

An Adverse Drug Reaction (ADR), defined as a noxious or unpleasant response related to the use of medicine, that is categorized into Type A (augmented, dose-dependent, and predictable) and Type B (bizarre, not predictable) reactions. The comprehensive classification, DoTS (Dose, Time course, and Susceptibility factors), aids in reducing ADR risks. Pharmacists play a important role in recognising and reporting suspected ADRs, contributing to the growth, maintenance, and assessment of ongoing programs. Their involvement ensures quick care, and consequently, a decrease in the number of morbidity and mortality cases. Education and training empower pharmacists to play a more significant role in diagnosing, treating, and preventing adverse drug reactions, with an emphasis on the importance of reporting ADRs, particularly among community pharmacists. Additionally, pharmacists play a vital role in informing patients about their medication [88].

Review of Literature

Firkus, D. et al. (2023) conducted a study to assess the impact of pharmacist participation in diabetes patients through Medication Management Services in the improved primary care model. Using a retrospective cohort design, patients who were referred to a pharmacist and propensity score-matched controls, who did not receive such services were compared for the quality of diabetes care in the study. A composite of four diabetes management goals-BP, use of aspirin, use of statin, and haemoglobin A1c (HbA1c) control were the main outcomes to be attained at six months. Results indicated a higher proportion of patients achieving these goals when

receiving pharmacist e-consults compared to controls. The study's findings supported the conclusion that integrating pharmacists into enhanced primary care teams contributes to improved diabetes management. The study encourages the involvement and utilization of pharmacists in interdisciplinary activities to enhance the overall quality of diabetes care [89].

AlAhmad, M.M. et al. (2023) The primary objectives of the study were to evaluate how the 2018 American College of Cardiology/American Heart Association (ACC/AHA) guidelines for cholesterol treatment are really put into practice and if clinical care interventions affect patients' adherence to these guidelines. ACC/AHA guidelines were used to recommend statin medication to 272 participants who visited internal medicine clinics for the research. The study measured patients' adherence to recommendations both before and after clinical pharmacist intervention. Following pharmacist intervention, there was a significant improvement in adherence to recommendations, with a notable increase in the percentage of patients placed on statin therapy. The use of other lipid-lowering agents decreased, aligning with guideline recommendations, and there was an increased utilization of combination therapy involving statins with non-statin agents like ezetimibe and PCSK9 inhibitors. The findings underscored the importance of collaborative teamwork between clinicians and clinical pharmacists in enhancing patient care and improving health outcomes, particularly for individuals with dyslipidaemia [90].

Lim, P.C. et al. (2023) This study examined how patient default rates, follow-up frequency, and pharmacist interventions affected glucose control in the Diabetes Medication Therapy Adherence Clinic (DMTAC) programme. The key objectives were to assess how pharmacist-led DMTAC affects glycemic control and to compare the results of glycemic control in primary health clinics vs hospitals, and analyze

differences in control between patients who defaulted and those who did not. The study revealed a noteworthy enhancement in glycemic control within the first year of pharmacist-led DMTAC. Poor glycemic control was observed in defaulters, emphasizing the significance of regular DMTAC visits. Both the frequency of visits and pharmacist interventions exhibited a positive influence on glycemic control. The findings underscore the effectiveness of DMTAC, particularly in improving HbA1c management, suggesting the incorporation of these approaches in the development of future diabetes management programs [91].

Schwenka, N et.al. (2023) The objective of the research was to assess whether individuals with type 2 diabetes mellitus (T2D) getting care at clinics attached to academic medical centres, where a patient-centered medical home (PCMH) is present, and who have a pharmacist on their care team, have a higher chance of meeting a composite of diabetes quality care measures than patients receiving standard care without a pharmacist. The key objective was to maintain the most recent recorded A1C level below 9%, to achieve a composite A1C level below 9% and complete annual laboratory testing, and to get a composite A1C level below 9%, complete annual laboratory testing, and a prescription for statins for people between the ages of 40 and 75. The study's findings indicated that the group with pharmacists in their care team outperformed the usual care group, particularly in achieving A1C levels below 9% and meeting the specified criteria for patients aged 40 to 75 years [92].

Osoro I et al. (2023) conducted a study to assess pharmacist interventions for minimizing DRP in diabetes with co-existing hypertension. The study was a prospective observational study that aimed to determine how well pharmacist interventions worked to reduce medication-related problems in people with diabetes and concurrent hypertension. A total of 628 therapies were indicated for the 1,914

participants who were enrolled in the trial throughout a five-year period. "Substituting the drug" (39%), "changing the frequency of administration" (25%), and "adding the drug" (14%), were the majority of recommended interventions. A significant improvement in patient compliance status was seen in the study (p = 0.29 0.07). The results highlighted the critical role clinical pharmacists play in lowering drug-related issues, emphasizing the value of patient counselling and follow-up treatment in this particular setting [93].

Wagner, M. L.et al (2022) In a randomized controlled study titled "Pharmacists Improve Diabetes Outcomes," the research aimed to determine patient satisfaction with pharmacist services as well as the effect of incorporating pharmacists into an interprofessional team on diabetes treatment outcomes. The primary objective was on changes in baseline A1C levels; correction of medication mistakes, adherence, satisfaction surveys, use of healthcare, and self-rated health were considered secondary outcomes. In this two-phase trial, diabetic patients were randomised to receive standard care (control arm) or standard care plus a pharmacist's intervention (intervention arm) over the period of 12 months. Results revealed a important contrast in mean A1C levels from baseline between the control and treatment arms, indicating that the interventional group demonstrated greater adherence to preventive care visits. The study concluded that incorporating pharmacists into a collaborative healthcare team can substantially enhance diabetes control and patient satisfaction [94].

Wang, W.et al (2022) In a randomized controlled trial the objective was to assess the impact of pharmaceutical care provided after discharge on adherence to treatment in patients who have both hypertension and T2DM. Primarily, the study aimed to maintain medication adherence for three months. Secondary objectives were to meet target blood pressure of less than 130/80 mmHg, haemoglobin A1c, fasting plasma

glucose, and 2-hour postprandial glucose levels. Results indicated that the intervention group adhered to medications than the control group, and there were changes in the secondary outcomes attained. The study concluded that providing pharmaceutical care post-discharge contributes to better treat-to-target rates for blood glucose and BP, along with improved medication adherence [95].

Narain KDC et al. (2022) A study was carried out to determine the efficacy of UCMyRx, a clinical pharmacist-led intervention embedded in primary care, among individuals with T2DM and Medicaid coverage. The study aimed to evaluate the effects of UCMyRx versus standard medication on haemoglobin A1c and BP control. With a 2:1 propensity-matched comparison group and data from Electronic Health Records, the study used a Difference-In-Differences trial design to find that, although there was no noteworthy effect on systolic blood pressure (SBP), at least one UCMyRx clinical pharmacist visit was associated with a significant decrease in HbA1c by 0.27% (P-value = 0.03). Subgroups with baseline SBP > 150 mmHg or HbA1C ≥ 9% did not exhibit different UCMyRx effects on SBP or HbA1C. Charlson Comorbidity Index (CCI)-stratified research revealed that those with the lowest comorbidity score (CCI 0-5) had larger UCMyRx effects on HbA1c (0.47%, P-value = 0.02). Notably, only Medicaid recipients without Medicare demonstrated a significant UCMyRx effect on HbA1c (0.35%, P-value = 0.02). In conclusion, the study highlighted that individuals with T2DM and Medicaid can benefit from the UCMyRx intervention, particularly in improving HbA1c control [96].

Zhuo Y et al. (2022) The efficacy of a smartphone application led by a clinical pharmacist in improving insulin injection technique (IIT), glycemic control, and medication adherence for women with gestational diabetes who get numerous daily insulin injections was investigated in a randomized clinical trial. There were 119

participants in the study: 61 people were of control group and 58 people were in intervention group. In addition to several other noteworthy advantages, such as enhanced IIT, decreased pre-prandial insulin dosage, improved fasting plasma glucose (FPG) and 2-hour postprandial glucose (2hPG) levels, and decreased rates of hypoglycemia, the intervention group showed significantly higher medication adherence (69.0% vs. 34.4%, p = 0.000). The intervention group also displayed a lower rate of admissions to the newborn intensive care unit (NICU). However, the intervention group had a greater rate of caesarean delivery (p > 0.05). The study found that a smartphone app led by a clinical pharmacist could be a useful tool for controlling gestational diabetes mellitus (GDM) when combined with normal therapy. This could lead to better outcomes for medication adherence, insulin injection technique, and glycemic control [97].

Parsiani R et al. (2022) An evaluation was conducted to assess the impact of the introducing pharmacist-led diabetes treatment programme within an endocrinology clinic. Assessing the average change in haemoglobin A1c (HbA1c) levels among patients receiving clinical pharmacist-assisted short-term diabetes care services was the primary objective. Patients who were sent to the clinical pharmacist participated in this retrospective, single-center study. The findings showed that at 3-6 months, individual HbA1c levels decreased significantly by 2.0% on average. Particularly, at 3-6 months, patients with a baseline HbA1c of at least 8.5% saw a significant 2.5% decline in HbA1c levels (P < 0.001). According to the study's findings, glycemic control was improved when a clinical pharmacist was added to the endocrinology practice, especially for patients who were referred. The results demonstrated the efficacy of this brief, intense treatment strategy by indicating that individuals might

decrease their HbA1c significantly with short-term assistance from a clinical pharmacist [98].

Oñatibia-Astibia, A.et al. (2021) conducted a systematic review to assess the effectiveness of community pharmacist interventions on promoting adherence to lipid-lowering medicine (LLM) and how these interventions affected clinical outcomes. The study aimed to evaluate how well these interventions worked to increase patient adherence to prescribed LLM and how that affected clinical outcomes. The review methodically looked through databases like SCOPUS, MEDLINE, and EMBASE. Adherence to the treatment was better than that of the control group, according to a meta-analysis of four studies. In conclusion, the study found that pharmacist-led interventions had a good impact on LLM adherence; however, additional investigation is required to determine the exact methods in which these interventions lead to better clinical results [99].

Daly, C. J. et al (2021) A research investigation was carried out on the "Effect of Managed Care-Integrated Community Pharmacist Interventions on Enhancing Medication Adherence." The study aimed to assess the influence of community pharmacists engaging in adherence-focused interventions. The predominant intervention involved providing counselling to patients regarding the advantages of medication and subsequent follow-up. Notably, there was a substantial rise in the proportion of days covered (PDC) among individuals who were previously nonadherent to their medication regimen. In summary, the study found that collaborative efforts led by community pharmacists in promoting adherence had a favourable outcome on patients [100].

Marcum, Z. A.et al. (2021) Pharmacist-led interventions to promote medication adherence in older individuals was a study that conducted a systematic review and

meta-analysis by searching multiple databases, including PubMed, Scopus, and Cochrane, for randomized controlled trials (RCTs) that centered on pharmacist-led medication adherence advancement. After 40 RCTs were analyzed, the impact of pharmacist-led treatments was found to have a significant mean effect size. The research findings indicate that pharmacist-led interventions had a significant and beneficial impact on elderly patients' medication adherence [101].

Phillips, S.et al. (2021) A study titled "Multidisciplinary Diabetes Clinic Improves Clinical and Behavioural Outcomes in a Primary Care Setting" was conducted to evaluate the impact of a collaborative approach on behavioural outcomes and the mean change in A1c between intervention and control groups. The self-efficacy scale was used to evaluate behavioural outcomes, and A1C levels were checked every three months. Results revealed that, in comparison to the control group, the interventional group's A1C levels had dropped considerably from baseline. Results of the study showed that compared to the control group, patients with T2DM who received the interdisciplinary team approach had improved mean A1c control and behavioural outcomes [102].

Besemah NA et al. (2021) carried out research to determine the influence of pharmacist-led programs on outpatients with T2DM in primary healthcare settings in Indonesia. The objective was to evaluate how a pharmacist’s intervention affected clinical outcomes and adherence to medications. A pretest-post-test design was employed, involving counselling sessions, and adherence to medication was evaluated using a Medication Adherence Questionnaire (MAQ) and pill count adherence (PCA). Clinical outcomes, including A1C, blood pressure, and lipid levels, were measured. The results indicated significant improvements in most outcomes within the intervention group, with the exception of HDL cholesterol and blood pressure.

Pharmacist intervention demonstrated a substantial positive effect, leading to significant improvements in A1C, cholesterol, LDL, and triglyceride levels, as well as enhancing medication adherence in patients with diabetes [103].

Simon MA et al. (2021) A randomized controlled trial was conducted to assess patient satisfaction with the care they received and investigate the effects of pharmacist-led interventions on the management of type 2 diabetes mellitus. Utilizing the diabetic treatment satisfaction questionnaire (DTSQ) and the medication adherence rating scale (MARS) as the main end measures for evaluating patient satisfaction with treatment, a six-month study, which included 97 patients with T2DM. Assessments of knowledge, attitude, perception, and laboratory measurements were examples of secondary outcomes. After six-month of follow-up, group A's glycaemic parameters showed a substantial improvement over group B's, according to data analysis using paired and unpaired T-tests. Additionally, group A's mean MARS and DTSQ scores improved relative to group B (P-value 0.05). The study found that patient compliance, quality of life, and satisfaction with care are all improved when diabetic patients received counselling from pharmacists [104].

Desse TA et al. (2021) To assess the influence of clinical pharmacy interventions on health and economic results for people with T2DM in hospital settings, a systematic review and meta-analysis were conducted. The study involved a thorough search of EMBASE, MEDLINE, CINAHL, PsycInfo, and the COCHRANE Library databases, along with an examination of significant articles' citation and reference lists. Health-related quality of life, major cardiac events, mortality from all causes, adverse events (AEs), and economic outcomes were the main outcomes that were considered. Of the 11,853 studies that were first found, 44 were reviewed, and 29 randomized controlled trials (n = 4055) were taken into consideration for the meta-analyses. The results

showed that clinical pharmacy interventions significantly reduced the incidence of adverse events and significantly lowered HbA1c levels when compared to normal treatment. Despite a lack of evidence on the effects of clinical pharmacy treatments on major cardiovascular events, one study indicated a non-significant reduction in all-cause mortality. Furthermore, when comparing type 2 diabetes care with standard care, there was a noteworthy enhancement in QoL and a substantial decrease in economy. The study concluded that clinical pharmacy interventions had a positive effect on glycaemic control, QoL, and resulted in a decrease in adverse events and the overall cost of T2D [105].

Abubakar M et al. (2021) A community pharmacy in Pakistan conducted a randomized controlled study to evaluate the impact of pharmacist-led interventions on the management of diabetes. A control group and an intervention group were randomly allocated, with the latter group receiving both pharmaceutical and non-pharmacological therapies. The study found that there were notable increase in both groups' medication adherence, glycemic management, and health-related quality of life (HRQoL). There was no remarkable difference in blood glucose levels or HRQoL between the two groups; however, pharmacist intervention was associated with improved glycemic control adherence to medication, HRQoL, according to those in the intervention group who had clinically significant correlations. The results revealed the beneficial effects of pharmacist-led interventions by showing that a significant percentage of patients with type 2 diabetes mellitus in the intervention group reached desired levels of HRQoL, adherence to medication and glycemic control [106].

Andanalusia M et al. (2021) At a Matara Primary Health Care Centre, a study was conducted to examine the effects of pillbox use and pharmacist education on diabetes mellitus patients' adherence to their medication regimens. The objective was to assess

how the combination of pillbox utilization and pharmacist guidance influenced medication adherence in these patients. The study utilized a medication scale questionnaire to measure adherence, and the participants were divided into three groups, each consisting of 11 patients. The results indicated an increase in medication adherence among patients who received education and pillbox intervention, while there was no change in adherence scores among those who received education only or were in the control group. Notably, factors contributing to improved compliance included medication refilling and intentional non-adherence. In conclusion, the study suggested that medication adherence could be enhanced through a combination of patient education and the use of pillboxes facilitated by pharmacists [107].

Hirsch JD et al. (2021) A study was conducted to evaluate patient satisfaction, HbA1c, and medication adherence outcomes in an interdisciplinary care diabetes 'Tune-Up' clinic run by a pharmacist, with the goal of assessing the impact of the intervention. The results revealed significant improvements in medication adherence scores, HbA1c levels, and patient satisfaction scores. Pharmacist personalized intervention improved patients' glycemic control, adherence and satisfaction [108].

Ting CY et al. (2021) A RCT was carried out to determine how well a pharmacist-led structured group-based intervention called MEDHEALTH could improve patients with type 2 diabetes mellitus glycaemic control and medication adherence. The primary focus of the study was to assess the impact of MEDHEALTH on improving HbA1c levels and medication adherence. The results indicated a decrease in HbA1c levels within the MEDHEALTH group, along with an increase in SEAMS score compared to the control group. The study's conclusion highlighted that, among Malay patients with T2DM, MEDHEALTH has the potential to enhance both medication adherence and glycemic control [109].

Hale G et al. (2021) A study, conducted as part of the ACORN SEED initiative, aimed to determine the impact of a pharmacist-led clinic on adherence to medication in an ACO primary care office. The assessment was specifically concerned with the adherence to statins, diabetic drugs, and RAS antagonists as shown in the Healthcare Effectiveness Data and Information Set (HEDIS) Medicare Star Ratings. This retrospective cohort study focused on Medicare beneficiaries covered by Humana HMO who were qualified and had at least one chronic condition that was being treated with a statin, diabetic medicine, or RAS antagonist. Out of the 102 patients referred to Medication Therapy Management (MTM), 32 attended follow-up visits, resulting in 25 interventions. The study's findings indicated an improvement in Medicare Star Ratings for patients, highlighting the positive impact of implementing a pharmacist-led MTM clinic [110].

Shi FH et al. (2021) A research study was conducted to examine the effects of clinical pharmacist intervention on blood sugar level variations in individuals suffering from acute myocardial infarction and diabetes, with the primary objective of determining whether such intervention could effectively reduce blood glucose levels and fluctuations in these vulnerable individuals. This retrospective study focused on patients with both diabetes and acute myocardial infarction. Following pharmacist intervention, there was a significant progress observed in blood glucose levels and a reduction in glucose fluctuations. Propensity score matching (PSM) was employed to minimize the influence of patient characteristics on the study outcomes. The study's findings led to the conclusion that clinical pharmacist intervention played a crucial role in improving outcomes by reducing blood glucose fluctuations and mitigating the risk of potential hypoglycemia [111].

Al-Qerem W et al. (2021) A study was conducted to examine factors correlated with non-adherence to medications in patients with T2DM, with the objective of assessing medication adherence and identifying its predictors in this patient population. This cross-sectional study utilized a four-item medication adherence scale (4-IMAS). Among the 287 diabetic patients included in the study, half exhibited moderate adherence. Notably, the necessity score, concern score, and frequency of medication administration emerged as significant predictors of adherence. The study's conclusion emphasized that to enhance medication adherence and subsequently improve glycemic control in diabetic patients, future intervention programs should concentrate on simplifying medication regimens, emphasizing the essential nature of medications, and addressing concerns related to drug use [112].

Norton MC et al. (2020) An observational cohort study that was carried out retrospectively (n=385) to compare the outcomes of physician-managed care and pharmacist-collaborative care, evaluating the impact of collaborative disease-state management on diabetes outcomes in primary care. In the collaborative care group, there was a notable mean reduction of 1.75% in HbA1c, compared to a 0.16% reduction in the usual care group (P .0001). Follow-up assessments revealed a higher proportion of patients in the collaborative care group achieving HbA1c levels below 8% (P =.0049). Other positive outcomes in the collaborative care group included decrease in total cholesterol (P =.0023) and triglycerides (P =.0016), along with an increased uptake of PPSV23 pneumococcal vaccines (P =.0255). Conversely, the usual care group exhibited an increase in PCV13 pneumococcal vaccinations (P =.0075). The collaborative care group demonstrated significant reductions in both emergency room visits (P =.0162) and hospitalizations (P =.0225), leading to estimated savings of $633,015. The study underscores the efficacy of pharmacist-

physician collaboration in primary care, yielding improved diabetes outcomes and substantial cost savings through reduced healthcare utilization [113].

Correr, C.J et al. (2020) conducted to determine the involvement of pharmacist in national campaign and incidence of diabetes screened through community pharmacy. This cross-sectional study revealed that 18.4% of participants had high blood glucose, with identified risk factors including abdominal circumference exceeding 94cm for men and 80cm for women, a body mass index over 25kg/m2, history of hypertension, decreased consumption of daily vegetables, family history of diabetes. This was the largest Brazil pharmacy screening program that focuses on role of pharmacist in patient education [114].

Fajriansyah et al. (2020) A cluster randomized controlled study was conducted to explore the influence of pharmacist counselling on the health-related quality of life (HRQoL) of patients with T2DM, specifically those enrolled in Prolanis T2DM. The research employed a cluster randomized controlled trial design with control and intervention groups, incorporating pre- and post-test procedures. The EQ-5D-5L questionnaire in Bahasa Indonesia was utilized for data collection, and analysis involved EQ-5D preference weights for individual health states. HbA1c levels were also assessed. In the control and intervention groups, respectively, the change in the EQ-5D-5L index score. The control group exhibited a VAS score change of 0.07 (post-pre), while the intervention group showed a change of 2.66 (P = 0.000). The study's findings suggested that pharmacist counseling has the potential to enhance HRQoL [115].

Masuda C et al. (2020) Conducted a pilot study; the research focused on assessing the impact of pharmacist-provided medication recommendations for diabetes mellitus patients to medicine residents. By offering medication suggestions to medical

residents ahead of the patient's appointment, pharmacists aimed to contribute to better diabetes management and enhance prescriber understanding and utilization of diabetic drugs. Although the study acknowledged the limitation of a small sample size that hindered the demonstration of statistical significance, it indicated that implementing the recommendations provided to family medicine residents during patient office visits contributed to a reduction in A1C levels. The study's outcomes suggest the need for a larger-scale investigation to assess the impact of pharmacist intervention in lowering glycaemic level [116].

Presley, B. et al. (2019) conducted a systemic review and meta-analysis which aimed to evaluate the efficacy of interventions led by pharmacists in improving medication adherence. The meta-analysis involved a thorough review of articles from diverse databases, with a total of 59 studies being incorporated. The findings indicated a substantial positive effect of pharmacist-led interventions on individuals with diabetes. Notably, materials provided by pharmacists during counselling were found to be more effective compared to other intervention [117].

Toroski, M.et al. (2019) carried out a systematic review of patient and physician for type 2 diabetic medicines. The study aimed to evaluate patients' and physicians' preferences for T2DM medications. Several databases were searched to systematically review articles. The study included 3346 studies, and 27 attributes of type 2 anti-diabetic were included. The study concluded that the patient and physician prefer the anti-diabetic which reduces A1C and blood sugar level, and have fewer side effects. Focusing on these attributes may help in improving patient adherence and better management of diabetes [118].

1.3 Justification

According to the International Diabetes Foundation, India had more diabetics than any other nation in the world until very recently. More over 62 million Indians, or more than 7.1% of the adult population, suffer from diabetes at this point in time. Each year, diabetes claims the lives of around one million Indians [119].

A higher risk of developing disease at a relatively younger age is associated with Indians' higher insulin resistance, greater abdominal adiposity (higher waist circumference despite lower body mass index), lower adiponectin, and higher levels of high-sensitive C-reactive protein. This risk is further increased by environmental variables, economic growth, physical inactivity, unhealthy eating habits, and epidemiological change [120].

Indian patients and healthcare providers are confronted with a multitude of obstacles including clinical inertia in attaining glycaemic control, insufficient follow-up, and low disease knowledge. Numerous studies have revealed that Indian T2DM patients had higher mean HbA1c values, indicating inadequate glycaemic control, and fail to meet treatment goals. Widespread differences in treatment preferences within the nation are also caused by inadequate Indian guidelines [120].

Many people with diabetes and their families find it difficult to manage the financial, psychological, and social effects of the disease because of the lifetime expenses involved. The onset of diabetes could be prevented or delayed considerably with the early identification of those who are at-risk and the implementation of appropriate lifestyle modifications and interventions [120].

Patients' adherence to stringent dietary, exercise, self-care, and medication regimens is crucial for treating diabetes. Patients with diabetes who also have other medical conditions are more likely to use polypharmacy; the more drugs a patient takes, the

higher their risk of developing drug-related side effects, interactions, non-compliance with prescribed dosages, lack of a legitimate medical reason, and so forth. Positive clinical results for patients with type 2 diabetes appear to be significantly hampered by poor drug compliance, in both developed and developing nations [121].

There is an enormous need for patients to practice committed self-care behaviors in a variety of areas, such as healthy eating, exercise, taking their medications as prescribed, and blood glucose monitoring, in order to reduce diabetes-related morbidity and mortality. Health care providers have a critical and underappreciated role in encouraging diabetic patients to practice self-care, even if a variety of demographic, socioeconomic, and social support characteristics may be seen as helpful contributions [122].

One of the well-known responsibilities of pharmacists is medication therapy management (MTM), which may be a useful strategy for enhancing health outcomes and adherence to anti-diabetic drugs. Additionally, because of their expertise in patient-centered care and pharmacotherapeutic knowledge, clinical pharmacists are in a unique position to educate, elaborate, implement and monitor patients' prescription regimens, all of which contribute to improved health outcomes [123].

Patient counselling is also one major domain where clinical pharmacist can play a significant role in educating the patients to improve the health outcomes. In India, doctors per patient’s ratio is very less compared to the WHO recommended guidelines. Hence the doctors consulting and counselling time for per patient is very limited and unable to provide the insights of the disease and medications. Hence there is a need for proper and well-established patient counselling centre where a clinical

pharmacist can bridge the gap between patient and doctor, which ultimately improves the overall quality of life of patients.

India is quickly approaching the status of a possible diabetes epidemic [124]. Poor understanding of diabetes and inadequate adherence to medication can result in psychological distress, decreased quality of life, higher hospital stays and overall healthcare expenses, and a greater risk of mortality and morbidity. Due to the need for additional medical visits and hospital stays, problems associated with anti-diabetic medications result in both needless suffering and significant costs for society. Research shows that twice as much money is spent on DRPs and adverse drug occurrences as it is spent on the drugs themselves [125]. According to the study, clinical pharmacists are required to provide patient education, counseling, and other interventions to enhance patients' understanding of diseases, encourage adherence to antidiabetic treatment, and reduce DRPs. All of these strategies may enhance patients' overall quality of life as it relates to health.

Hence, there is a need of clinical pharmacist in the management of diabetes and also to assess drug related problems in order to improve the health-related quality of life and overall patient health outcome.

1.4 Objectives

1.4.1 Primary objective

- To assess the impact of clinical pharmacist interventions in the management of diabetes mellitus.

1.4.2 Secondary Objective

- To identify and assess drug related events in study population.

2 MATERIAL AND METHODS

2.1 Study Site

2.2 Study Design

2.3 Study Sample Size

2.4 Eligibility Criteria

2.4.1 Inclusion Criteria

2.4.2 Exclusion Criteria

2.5 Informed Consent

2.6 Study Procedure

2.6.1 Participant selection and recruitment

2.6.2 Randomization

2.6.3 SNOSE method

2.7 Data Collection

2.7.1 Assessment of Knowledge, Attitude and Practice

2.7.2 Drug Utilization Evaluation

2.7.3 Drug related problems

2.7.4 Assessment of Drug-Drug Interaction

2.7.5 Adverse Drug Reactions

2.7.6 Patient Counselling

2.7.7 Assessment of Health-Related quality of life

2.7.8 Assessment of medication adherence

2.8 Study Outcome Measures

2.9 Study Material

2.1 Study site

The study was conducted at Vivekananda general hospital, Deshpande Nagar, Hubballi.

2.2 Study design

It was a prospective, stratified randomized controlled study where the participants were randomized into two categories i.e. interventional or study group and control group. Ethical clearance (No - KAHER/ EC/19-20/290619004) was obtained from Institutional Ethics Committee for Human, KLE Academy of Higher Education and Research Belagavi.

2.3 Study Sample Size

The pilot study has been conducted on 10 patients (n=5 patient at each group). The SD of medication adherence in-

Group A (Intervention group) is $S_1 = 1.02$

Group B (Control group) is $S_2 = 1.55$.

$$S = \frac{S1 + S2}{2}$$

The sample size of the study will be calculated using the below mentioned formula:

$$n = \frac{2S^2(Z_{1-\alpha/2} + Z_{1-\beta})}{d^2}$$

- $Z_{1-\alpha/2}$ = 1.96 at 5% of α-error
- $Z_{1-\beta}$ = 1.68 at 95% power of test

As per formula n=150 patients in each group.

2.4 Eligibility Criteria

2.4.1 Inclusion criteria

1. Patients of both gender and age above 18 years.

2. Patients diagnosed with diabetes mellitus including out and in-patient of general medicine department.

3. Diabetes with or without co-morbid conditions.

4. Patients ready and willing to participate in the study.

2.4.2 Exclusion criteria

1. Patients who are very ill.

2. Patients with mental incompetence.

3. Pregnant or lactating women.

2.5 Informed consent

Informed consent form (ICF)/Assent Participant information sheet (PIS) in English or in other patient preferred local languages like Kannada, Marathi and Hindi was provided for the eligible patients. Concise information regarding the study, its motive, benefits and risks involved in taking part in the study, duration of the study, randomization, monitoring, confidentiality, rights of the participants to withdraw from the study was informed to the patient. Patient understanding of the study was cross verified. Concerns and queries regarding the study was addressed. Once the individual agreed to take part in the study, two forms of ICF was signed by the patient, out of which one was given to the patient or care giver reference and one was taken by the investigator for documentation.

2.6 Study procedure

The target population for this study includes, individuals identified with diabetes. The primary requirement to enroll the patients to this study was that, patients should be newly diagnosed and past medication history with antidiabetic drugs. Population with diabetes mellitus, above 18 years of age, patients from the general medicine ward's outpatient and inpatient departments were enrolled during the study period.

After meeting the eligibility requirements and giving their agreement, patients were randomly assigned to either the trial or the control group.

2.6.1 Participant selection and recruitment

Information regarding target population were collected from out and in-patient department of general medicine. Patients were screened for eligibility to the study, and those who satisfy the eligibility criteria and willing to participate in the study were recruited.

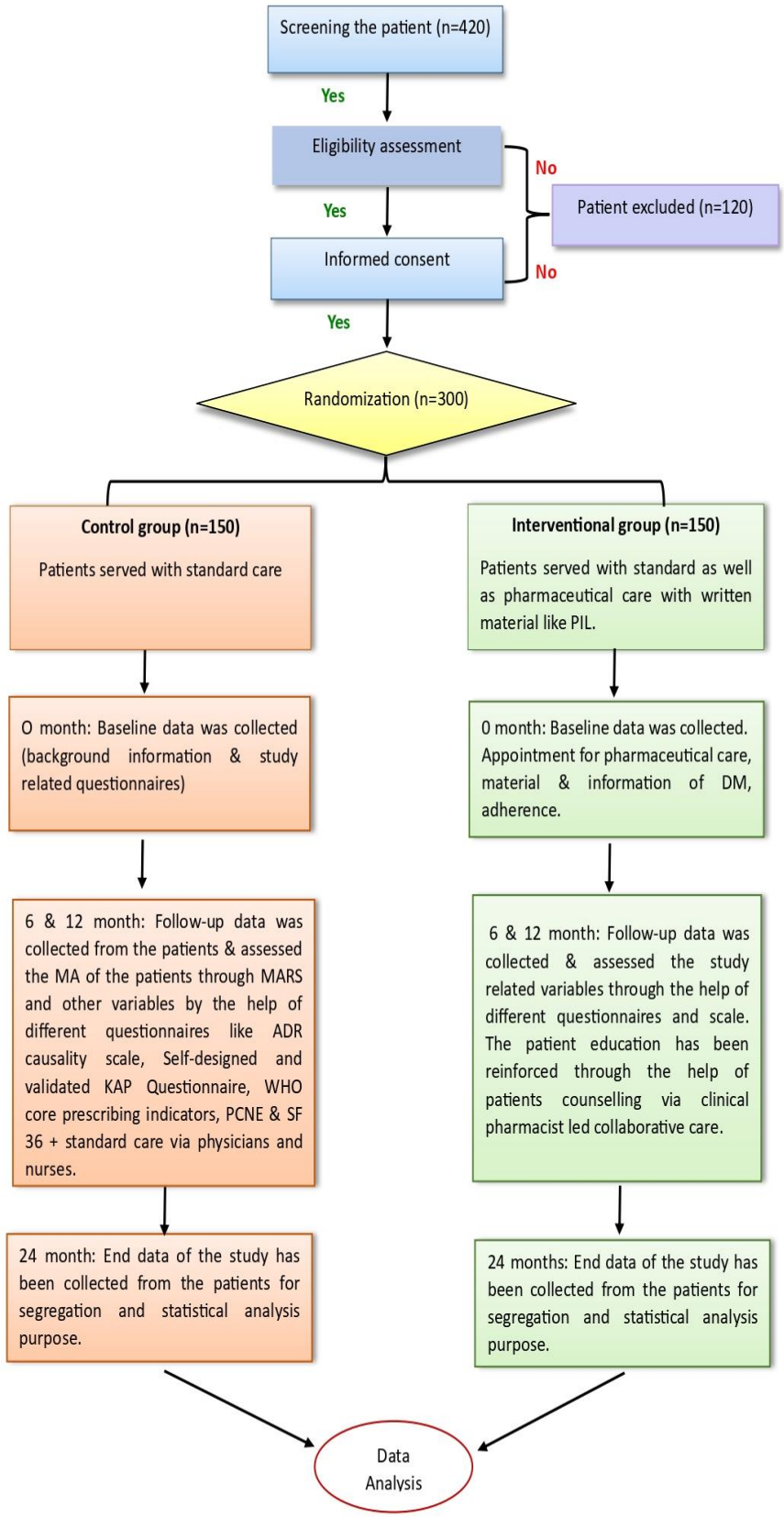
2.6.2 Randomization

Participants were assigned at random to either the study group or the control group using the SNOSE method and computer-generated simple randomization. The label was opened once the details of the patients were filled on envelop. After a patient was recruited for the trial and their details were completed on a closed envelope, the randomization numbers were kept a secret.

2.6.3 SNOSE method

The method of concealing known as sequentially numbered opaque sealed envelopes (SNOSE) was employed. Only after participant details were written on each envelope were they opened in order. The carbon paper or pressure-sensitive material within the envelope sends that data to the assignment card. Strong light cannot pass through an envelope that has cardboard or aluminum foil inside of it.

Flow chart No 1: Schematic diagram of detailed study plan



Participants under control group: Participants were interviewed for questionnaire to assess the knowledge, attitude and practice (KAP) of antidiabetic therapy and also required data were collected from patient case sheet/ laboratory reports and also by interacting with the patient. Further, participants of the control group were monitored for study outcomes. Adverse drug reaction, medication adherence, quality of life using the SF-36 questionnaire was recorded during baseline and whenever the test was done further during monitoring. Study outcomes were recorded during monitoring period. Telephonic interview, E-mail, social media were also done wherever required to record the study outcomes. If any adverse outcomes were noticed or informed, participants were referred to the consulting clinicians. The DUE of antidiabetics were carried out and categorized with respect to WHO Core prescribing indicators.

Participants of study/Interventional group: Numerous interventions, including patient counseling, the pill count method, the use of a special medication container, self-recording of medication intake, mail remainder, and telephone contacts to pick up prescription refills and attend clinic appointments, can improve adherence to antidiabetic drugs. Many factors, including length of drug use, amount of tablets taken, use of alternative treatments, support from family, and financial restraints, might affect adherence to antidiabetic medications. The MARS for assessing medication adherence, SF-36 questionnaire for assessing quality of life and ADR assessment scales were used for the study. The possible DRPs were identified, their different causes were categorized according to PCNE V9.1 and resolved accordingly. The clinical pharmacist interventions and outcomes were documented. The DUE of antidiabetics were carried out and categorized with respect to WHO Core prescribing indicators. The outcomes of clinical pharmacist led patient counselling were measured

and documented with respect to changes in their clinical parameters, quality of life, KAP of diabetes mellitus and medication adherence.

2.7 Data Collection

Data were collected in well-designed patient data collection forms. Laboratory reports, case sheets, prescriptions, participant interviews were considered as sources of data. Base line data involves demographic details and antidiabetic therapy.

2.7.1 Assessment of Knowledge, Attitude and Practice

A self-made and validated questionnaire was developed utilizing the most recent data from reliable sources, including the World Health Organization, the Centers for Disease Control and Prevention, and the Indian Ministry of Health and Family Welfare, following a thorough literature search. The survey was divided into two sections: the first evaluated participant demographics, and the second evaluated KAP in relation to diabetes. Eleven knowledge questions, seven attitude questions, and seven practice questions made up the KAP part. A basic yes/no response technique was used for the majority of the knowledge questions, which assessed the participant's understanding of clinical signs and symptoms, risk factors, severity, prevention, control, and management. Specific response options pertaining to blood glucose monitoring, exercise, medication adherence, meals, and follow-up were offered by the attitude and practice questions. Three doctors independently reviewed and validated the KAP questionnaire and only minor grammatical adjustments were advised, which were swiftly rectified.

2.7.2 Drug Utilization Evaluation

Drug utilization evaluation (DUE) is process that analyzes and evaluates the patterns of drug use including prescribing pattern, dispensing and use of medications for providing safe, effective and cost-effective treatment.

In our study, we used WHO and Anatomical Therapeutic Chemical classification system (ATC). The study's objective was to assess the tertiary care hospital in Hubballi's prescribing trend for antidiabetic medications.

Utilizing the WHO ATC Code and adjusted WHO prescribing key indicators, the data were examined as follows,

1. Average number of drugs per encounter = total number of drugs prescribed/total number of encounters.

2. Percentage of drugs prescribed by generic name = (number of drugs prescribed by generic name/total number of drugs prescribed) x 100.

3. Percentage of antidiabetic prescribed = (number of patients encounter with antidiabetic/total number of drugs prescribed) X100.

4. Percentage of encounters with an injectable drug prescribed = (number of patients encountered with injections/total number of drugs prescribed) x100.

5. Percentage of drugs prescribed from NLEM = (number of drugs prescribed from NLEM/total number dug prescribed) x100.

2.7.3 Drug related problems

The clinical pharmacist who intervened was a scholar of research. The internal physician co-guide and the research and academic guides led all of the interventions that the intervening clinical pharmacist made. The researcher, a clinical pharmacist, examined every patient with diabetes mellitus who was hospitalized or outpatient and had additional comorbidities. The data and DRPs were then assessed and its associated factors were identified using PCNE Version 9.1 Guidelines and recorded in DRPs documentation forms and were resolved to improve patients' health-related outcome. The DRPs include Drug-Drug Interactions (DDIs), ADR, drug duplication, therapeutic drug duplication, drug without indication, indication without drug,

contraindication etc. The patient's chief complaints were assessed in relation to drug therapy as a component of the disease itself, and those symptoms linked to therapy were reported as drug-related problems. Utilizing resources like Micromedex (Drugdex), Lexicomp drug information handbook and British National Formulary for any drug-related problems, the patient's drug treatment, including the dosage, duration, frequency, adverse drug reactions, and contraindications were examined for their appropriateness.

The detected drug-related problems were then addressed with the co-guide (inhouse physician), and after reaching a consensus on interventions, they were communicated to the appropriate doctor along with the recommended course of action to address drug-related problems during the following day's ward round visits.

The recognized drug related problems were classified as per the PCNE V9.1 category and the clinical pharmacist interventions were recorded by the research scholar in the well-designed pharmacist interventions record form. The undertaking level of physicians for the specific interventions were also recorded as either accepted or not approved according to the strategy of the consulting physician. Similarly, the results of the interventions and the clinical importance and correlation of drug related interventions were also documented by the research person. Every information's were then assessed by the team, using the descriptive statistics to assess the impact of clinical pharmacist interventions in patients with T2DM.

2.7.4 Assessment of Drug-Drug Interaction

The patient treatment charts were analysed for the DDI's. We used drug databases such as Micromedex to obtain information on potential drug interactions and categorized them based on their severity of interaction as major, moderate, and minor.

2.7.5 Adverse Drug Reactions

The suspected adverse drug reaction reporting form version 1.4 released by the Indian Pharmacopeia Commission, PvPI, were used as materials and data sources. ADR reporting form collects all pertinent data on patient information and adverse effects such as, suspected adverse reaction, suspected medication(s), and reporter information etc. All suspected adverse drug reactions were collected, analyzed, and confirmed by the doctor and inhouse medical officer-in-charge and were assessed by the Causality Assessment Committee (CAC) for causality using WHO-UMC Causality Categories, Naranjo's causality assessment scale, preventability using Modified-Schumock and Thornton scale, and severity using Modified Hartwig and Siegel scale.

Adverse Drug Reactions were assessed using Schumock and Thornton Scale which has 3 sections definitely preventable, probably preventable, and non-preventable where section A has 5 questions and B has 4 questions. Each of the responses were categorized as No or Yes.

Hartwig's Severity Assessment Scale was also used which includes,

Mild- levels 1 and 2

Moderate- levels 3 and 4

Severe- levels 5 and 6

Causality Assessment

WHO causality assessment scale has been divided into 6 groups which have 4 requirements in each category,

a) Temporal relationship

b) Plausibility and absence of other factors

c) Laboratory findings and

d) De-challenge and re-challenge.

WHO-UMC causality categorized into 6 different term such as Certain, Probable/ Likely, Possible, Unlikely, Conditional/Unclassified and Unassessable/ Unclassifiable. Naranjo's causality assessment scale was also used to assess the causality of ADRs. It consists of 10 questions that are answered as Yes, No and Don't Know. Based on the answers the scores were categorized into

a) Definite

b) Probable

c) Possible

d) Doubtful

2.7.6 Patient Counselling

The patient counselling centre was established in the hospital to provide patient education regarding diabetes mellitus, comorbidity, risk factor, lifestyle modifications, and treatment. In interventional group, the patient clinical pharmacist facilitated patient counselling sessions verbally and patient information leaflet (PIL) regarding DM was provided to the patients. Patient education was provided in patient preference language mainly Kannada, as a major language. The PIL contains all the necessary information regarding DM which helped the patients for the better understanding of the disease. It also contains lifestyle modifications to reduce the micro and macrovascular complications and manage the same. The patients were followed up for baseline, 6^{th} month,12^{th} month and 24^{th} month. In interventional group, the outcomes of patient education were evaluated by mainly in three vital domains: health-related quality of life, medication adherence, and clinical parameter outcomes.

2.7.7 Assessment of Health-Related quality of life

Chronic disease patients are increasingly acknowledging the significance of Health-Related Quality of Life (HRQoL) assessments, which capture the psychological, physical, and behavioral effects of a disease.

To assess Health -Related Quality of Life SF-36 scale was used. It includes domains of physical, mental, and social health status. The short-form -36 survey consists of 36 items in 8 domains measuring Physical Functioning (PF-10), Social Functioning (SF-2), Role Limitation due to Physical Health (RLPH-4), Role Limitation due to Emotional Problems (RLEP-3), Mental Health (MH-5), Energy/Fatigue(E/F-4), Pain (2), and General Health (GH-6). The HRQoL was assessed in the control group and interventional at baseline, 6^{th} month,12^{th} month and 24^{th} month respectively.

2.7.8 Assessment of medication adherence

Medication adherence was assessed using Medication Adherence Rating Scale (MARS) questionnaire that had total of 10 questions. It was scored as following; for questions 1-6 and 9-10 as 'No' result is indicative of adherence and was given a score of 1. While questions 7 & 8 'Yes' result indicates adherence and was given score of 1. Total score ranges from 0-10 and individuals with a score of ≥ 6 is identified to have good adherence and individuals who has a score of < 6 indicates bad adherence. Medication adherence was assessed in control and interventional group at baseline (0 month), 6^{th} month and 24^{th} month respectively.

2.8 Study outcome measures

- **Primary outcomes:** Counseling the patients about diabetes mellitus and its treatment. Educating the importance of medication adherence because non-adherence is very common in patients with chronic diseases and multiple treatment which leads to frequent and prolonged hospitalization.

- **Secondary outcomes:** Diabetes requires long-term antidiabetic drug therapy. Assessment and prevention of drug related interventions and adverse drug reactions to improve the health-related quality of life.

2.9 Study Materials

1. Informed Consent Form (ICF).
2. Patient Data Collection Forms.
3. Patient Information Leaflets (PIL).
4. Patient Counseling Documentation Form.
5. Suspected adverse drug reaction reporting and assessment form.
6. Suspected adverse drug reaction notification form.
7. Drug Interaction Documentation Form.
8. Pharmacist Intervention Documentation Form.
9. Patient medication history interview form.
10. Medication Adherence Rating Scale.
11. SF-36 questionnaire.
12. ADR assessment scales by Naranjo, Hartwig and Siegel and modified Schumock and Thornton scale.
13. DRP's were classified using PCNE V9.1.
14. DUE of antidiabetic therapy using WHO core prescribing indicators and WHO ATC Code.
15. KAP was assessed by self-designed and validated questionnaires.

3 DATA ANALYSIS PLAN

The patients sample size has been through sample pilot study to get the proper study outcomes. At 95% confidence interval, probability was considered $P<0.05$ for statistical significance. The data of the present study was entered and analyzed by IBM SPSS Statistics Version-26. A KAP study was conducted using a self-made and validated questionnaire. The questionnaire was developed based on the latest data from reputable sources such as the World Health Organization, the Centre for Disease Control and Prevention, and the Indian Ministry of Health and Family Welfare, following an extensive literature search. Student t-test to evaluate the Knowledge, Attitude, and Practice levels between a control group and an interventional group over two years.

In our Drug Utilization Evaluation (DUE) study, we assessed the prescribing trends for antidiabetic medications using the WHO ATC Code and adjusted WHO Core Prescribing indicators to analyse the data. In the process of identifying Drug-Related Problems (DRPs), our study focused on patients with diabetes mellitus and additional comorbidities. Data and DRPs were systematically assessed following the guidelines outlined in PCNE Version 9.1. The identified DRPs encompassed various issues, including Drug-Drug Interactions (DDIs), Adverse Drug Reactions (ADRs), drug duplication, therapeutic drug duplication, drug without indication, indication without drug, and contraindications. Detected DRPs were collaboratively discussed with the in-house physician co-guide, and interventions were communicated to the treating physician. The interventions were categorized according to PCNE V9.1 and

meticulously recorded, including the level of acceptance by physicians. Our study employed descriptive statistics to assess the impact of clinical pharmacist interventions on patients with diabetes mellitus, documenting results and the clinical significance of the interventions. This comprehensive approach aimed to enhance patient outcomes and ensure the appropriateness of drug therapy in this specific population.

In our study, the assessment of DDIs involved analyzing patient treatment charts for potential interactions, utilizing drug databases like Micromedex and categorizing interactions based on severity (major, moderate, minor). For ADRs, we employed the suspected adverse drug reaction reporting form provided by the Indian Pharmacopeia Commission, PvPI. Confirmed ADRs underwent assessment by the Causality Assessment Committee (CAC) using various scales: Schumock and Thornton for preventability, Hartwig's Severity Assessment Scale for severity, and WHO, WHO-UMC, and Naranjo's scales for causality.

To measure HRQoL, we employed the SF-36 scale, encompassing domains of physical, mental, and social health status. The SF-36 survey comprises 36 items distributed across 8 domains, including Physical Functioning (PF-10), Social Functioning (SF-2), Role Limitation due to Physical Health (RLPH-4), Role Limitation due to Emotional Problems (RLEP-3), Mental Health (MH-5), Energy/Fatigue (E/F-4), Pain (2), and General Health (GH-6). HRQoL assessments

were conducted at baseline, 6th month, 12th month, and 24th month for both the control and interventional groups. We utilized bivariate regression analysis to assess the factors affecting HRQOL and to compare the HRQOL between patients in the control and interventional groups over two years.

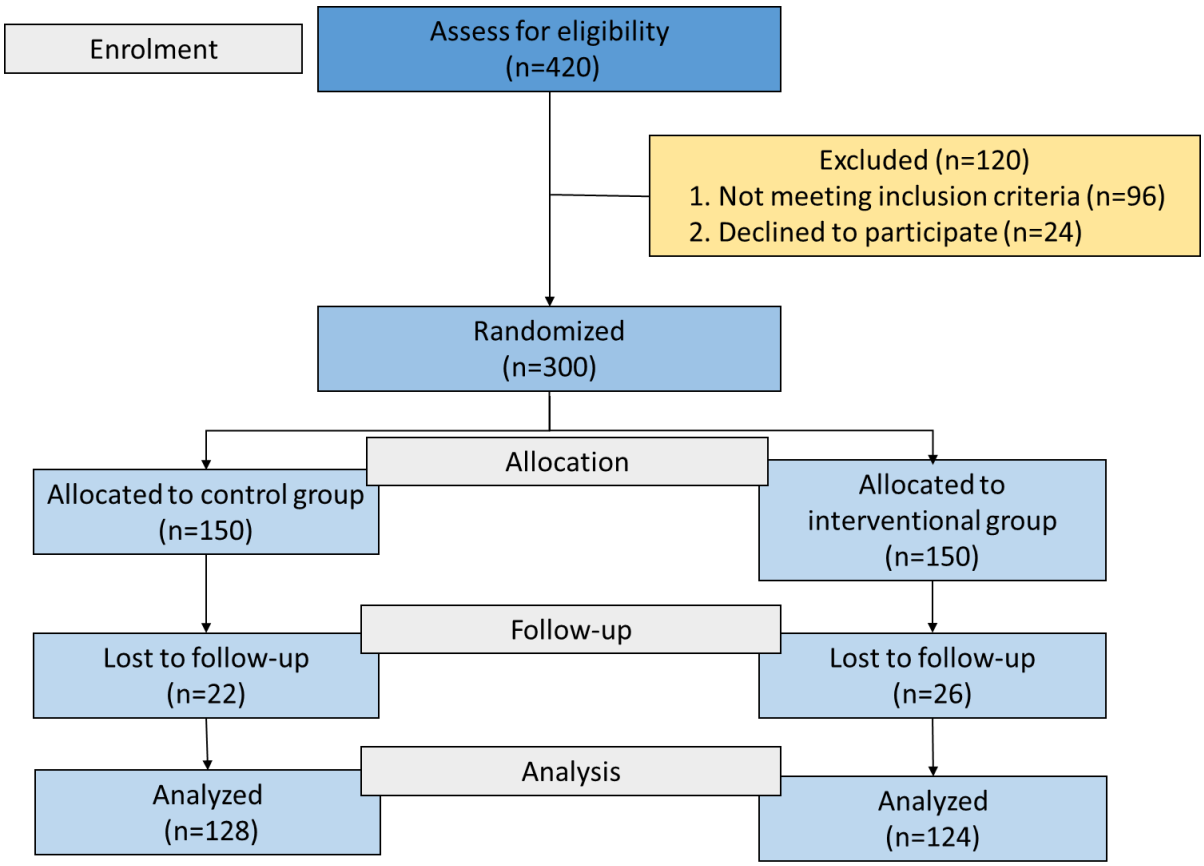
In our study, Medication Adherence was evaluated using the MARS questionnaire, comprising a total of 10 questions. The total score ranged from 0 to 10, and individuals with a score of ≥ 6 were identified as having good adherence, while those with a score of < 6 indicated poor adherence. Medication adherence was systematically assessed in both the control and interventional groups at baseline (0^{th} month), 6^{th} month, and 24^{th} month, and One-Way Analysis of Variance (One-Way ANOVA) was employed to analyse any significant differences in medication adherence between the control and interventional groups at baseline, 6^{th} month, and 24^{th} month.

The clinical outcomes of the study participants were assessed by examining various clinical parameters in both the control and interventional groups at baseline and the 24^{th} month. The status of diabetic health was monitored through different laboratory parameters, including Fasting Blood Sugar (FBS), Random Blood Sugar (RBS), Postprandial Blood Sugar (PPBS), HbA1c, and others. To evaluate the variations in these parameters between the control and interventional groups at baseline and after 24 months, we employed the Independent Student t-test. This statistical analysis allowed us to determine if there were significant differences in clinical outcomes between the two groups throughout the study.

4 RESULTS

Total of 420 diabetes mellitus patients were screened for the current study. Study participants were enrolled after screening and provide their willingness to sign informed consent were randomized into two distinct groups. (Flowchart 1)

Flowchart No 2: Distribution of patients, the usual care based on the control group and the pharmaceutical care based interventional group



Total of 300 patients were enrolled in the study. At each group, 150 were enrolled of which control group was served as usual care and the interventional group was served with pharmaceutical care. In control group, 22 patients were withdrawn from the study whereas in interventional group 26 patients left the study. Finally, the complete data analysis has been done on 252 patients.

4.1 Demographic Data

Out of 300 participants, 218 were men (72.60%) and 82 were women (27.30%). The age group distribution of 61-70 years was the highest, with 82 (27.33%) participants. While, age group 21-30 years, had the lowest participants 6 (02.00%). The participants BMI distribution were of 85 (28.33%), 108 (36.00%), and 33 (11.00%) respectively, revealing obese, overweight and underweight conditions. The majority of participants, 174 (58%) and 187 (62.33%) were linked to alcohol and smoking. There were 91 (30.33%) and 51 (17.00%) participants who didn't smoke or drink alcohol, respectively. Total of 183 participants were literate (61%) while 117 were illiterate (39%). To determine the socioeconomic class of the individuals, Kuppuswamy's scale was used. The majority of participants, 121 (40.33%), belonged to the lower middle class, while the least was 27 (9.00%) from the upper class. The majority of study subjects (102, 34.00%) had diabetes for more than ten years, whereas just 28 (9.33%) of the patients had the diabetes for less than a year. Out of 300 participants, 258 patients were from inpatient and 42 were from outpatient department. The complete breakdown of the categorical demographics of the study participants, expressed in percentage, is provided in Table 1.

Table 1: Demographic characteristics of study participants

Sl. No.	Demographics	Category	Control Group	Interventional Group	Total Number	Percentage
1	Age	21-30	2	4	6	2.00
		31-40	22	14	36	12.00
		41-50	30	22	52	17.33
		51-60	31	43	74	24.67
		61-70	42	40	82	27.33
		>70	23	27	50	16.67
2	Gender	Male	112	106	218	72.67
		Female	38	44	82	27.33
3	Body Mass Index (BMI)	Under Weight	20	13	33	11.00
		Normal Weight	33	41	74	24.67
		Over Weight	59	49	108	36.00
		Obese	38	47	85	28.33
4	Socioeconomic Status	Upper	16	11	27	9.00
		Upper Middle	22	26	48	16.00
		Lower Middle	60	61	121	40.33
		Upper lower	30	38	68	22.67
		Lower	22	14	36	12.00
5	Duration of Diabetes	<1 Year	16	12	28	9.33
		1-5 Years	35	41	76	25.33
		6-10 Years	42	52	94	31.33
		>10 Years	57	45	102	34.00

6	Marital Status	Married	128	133	261	87.00
		Unmarried	12	09	21	7.00
		Widowed	10	08	18	6.00
7	Literacy Status	Literate	93	90	183	61.00
		Illiterate	57	60	117	39.00
8	Occupation	Employed	90	83	173	57.67
		Unemployed	60	67	127	42.33
9	Smoking	Non-smoker	42	49	91	30.33
		Smoker	92	82	174	58.00
		Recently quit	16	19	35	11.67
10	Alcohol	Alcoholic	97	90	187	62.33
		Non-Alcoholic	26	25	51	17.00
		Recently quit	27	35	62	20.67
11	Diabetic complications	Coronary artery disease	20	36	56	46.67
		Cerebrovascular disease	9	9	18	15.00
		Retinopathy	11	10	21	17.50
		Neuropathy	12	15	27	22.50
		Chronic Kidney Disease	16	17	33	27.50
		Diabetic Foot	7	7	14	11.67

4.2 Assessment of Knowledge, Attitude and Practice of the study participants

Assessment of Knowledge

The study result depicted that, out of 300 subject's majority of the subjects heard of diabetes and also knew that obesity is the major cause. Only 18 (6.00%) subjects were aware of glucose tolerance test and only 38 (12.67%) subjects were ever participated in a diabetes awareness program was as shown in the table 2.

Table 2: Overall responses for Knowledge based questionnaires

Sr. No.	Questionnaires	Yes	Percentage	No	Percentage
1	Have you ever heard of Diabetes?	264	88.00%	36	12.00%
2	Is obesity the major cause of diabetes?	226	75.33%	74	24.67%
3	Do you know how to measure Diabetes?	162	54.00%	138	46.00%
4	Do you know what is Glucose Tolerance Test?	18	6.00%	282	94.00%
5	Is lifestyle modification required for a diabetic patient?	186	62.00%	114	38.00%
6	Do you know that exercise can help you manage your diabetes?	212	70.67%	88	29.33%
7	Can high blood pressure worsen the disease?	86	28.67%	214	71.33%
8	Is Fibre rich diet good for Diabetes?	147	49.00%	153	51.00%
9	Can medicines alone be used for the treatment of diabetes?	132	44.00%	168	56.00%
10	Does diabetes have the potential to harm the body's other organs?	84	28.00%	216	72.00%
11	Have you ever participated in a diabetes awareness program?	38	12.67%	262	87.33%

Table 3: Responses for Knowledge based questionnaires in Control and Interventional groups

Sr. No.	Questionnaires	Control Group		Interventional Group		Total (%)	
		Yes (%)	No (%)	Yes (%)	No (%)	Yes (%)	No (%)
1	Have you ever heard of Diabetes?	129 (43.00)	21 (7.00)	135 (45.00)	15 (5.00)	264 (88.00)	36 (12.00)
2	Is obesity the major cause of diabetes?	120 (40.00)	30 (10.00)	106 (35.33)	44 (14.67)	226 (75.33)	74 (24.67)
3	Are you familiar with measuring diabetes?	87 (29.00)	63 (21.00)	75 (25.00)	75 (25.00)	162 (54.00)	138 (46.00)
4	Are you familiar with what is Glucose Tolerance Test?	8 (2.67)	142 (47.33)	10 (3.33)	140 (46.67)	18 (6.00)	282 (94.00)
5	Is lifestyle modification required for a diabetic patient?	85 (28.33)	65 (21.67)	101 (33.67)	49 (16.33)	186 (62.00)	114 (38.00)
6	Do you know that exercise can help you manage your diabetes?	98 (32.67)	52 (17.33)	114 (38.00)	36 (12.00)	212 (70.67)	88 (29.33)
7	Can high blood pressure worsen the disease?	54 (18.00)	96 (32.00)	32 (10.67)	118 (39.33)	86 (28.67)	214 (71.33)

8	Is Fibre rich diet good for Diabetes?	93 (31.00)	57 (19.00)	54 (18.00)	96 (32.00)	147 (49.00)	153 (51.00)
9	Can medicines alone be used for the treatment of diabetes?	52 (17.33)	98 (32.67)	80 (26.67)	70 (23.33)	132 (44.00)	168 (56.00)
10	Does diabetes have the potential to harm the body's other organs?	28 (9.33)	122 (40.67)	56 (18.67)	94 (31.33)	84 (28.00)	216 (72.00)
11	Have you ever participated in a diabetes awareness program?	18 (6.00)	132 (44.00)	20 (6.67)	130 (43.33)	38 (12.67)	262 (87.33)

Assessment of Attitude

The study illustrated that, out of 300 subject's majority of the subjects i.e., 82.67% (n=248) had the positive attitude of taking the medications regularly. Whereas, 16.33% subjects believe that regular check-ups with their doctor are required. Remaining results regarding the assessment of attitude in patients with DM in a secondary care hospital are mentioned in Table 4.

Table 4: Overall responses for Attitude based questionnaires

Sr. No.	Questionnaires	Yes	Percentage	No	Percentage
1	Do you prefer to exercise every day?	125	41.67	175	58.33
2	Do you prefer to monitor Fasting Blood Sugar (FBS) and Post Prandial Blood Sugar (PPBS) levels every month?	136	45.33	164	54.67
3	Do you think taking two doses will help your diabetes get under control faster?	36	12.00	264	88.00
4	Do you prefer to take medications regularly?	248	82.67	52	17.33
5	Do you believe that regular check-ups with your doctor are required?	251	83.67	49	16.33
6	Do you believe that long-term treatments will inevitably lead to organ failures?	112	37.33	188	62.67
7	Do you prefer to take HbA1c (Glycated hemoglobin) test once in every 3 months?	62	20.67	238	79.33

Table 5: Responses for Attitude based questionnaires in Control and Interventional groups

Sr. No.	Questionnaires	Control Group		Interventional Group		Total (%)	
		Yes (%)	No (%)	Yes (%)	No (%)	Yes (%)	No (%)
1	Do you prefer to exercise every day?	48 (16.00)	102 (34.00)	77 (25.67)	73 (24.33)	125 (41.67)	175 (58.33)
2	Do you prefer to monitor Fasting Blood Sugar (FBS) and Post Prandial Blood Sugar (PPBS) levels every month?	74 (24.67)	76 (25.33)	62 (20.67)	88 (29.33)	136 (45.33)	164 (54.67)
3	Do you think taking two doses will help your diabetes get under control faster?	20 (6.67)	130 (43.33)	16 (5.33)	134 (44.67)	36 (12.00)	264 (88.00)
4	Do you prefer to take medications regularly?	112 (37.33)	38 (12.67)	136 (45.33)	14 (4.67)	248 (82.67)	52 (17.33)
5	Do you believe that regular check-ups with your doctor are required?	138 (46.00)	12 (4.00)	113 (37.67)	37 (12.33)	251 (83.67)	49 (16.33)

6	Do you believe that long-term treatments will inevitably lead to organ failures?	48 (16.00)	102 (34.00)	64 (21.33)	86 (28.67)	112 (37.33)	188 (62.67)
7	Do you prefer to take HbA1c (Glycated hemoglobin) test once in every 3 months?	39 (13.00)	111 (37.00)	23 (7.67)	127 (42.33)	62 (20.67)	238 (79.33)

Assessment of Practice

The study results demonstrated that, out of 300 subjects 61.00% (n = 183) had good practice of taking medications regularly. There was least practice of 23.67% (n=71) HbA1c testing and monitoring blood glucose level monthly in 49.33% (n=148) of respondents. The results regarding the practice are detailed in table 6.

Table 6: Overall responses for Practice based questionnaires

Sr. No.	Questionnaires	Yes	Percentage	No	Percentage
1	Do you exercise for 30-60 minutes every day?	128	42.67	172	57.33
2	Do you monitor Blood Glucose Level every month?	148	49.33	152	50.67
3	Do you always eat small and frequent meals?	67	22.33	233	77.67
4	Do you exclude rice from meals?	129	43.00	171	57.00
5	Do you take medications regularly?	183	61.00	117	39.00
6	Do you get your HbA1c test done every 3 months?	71	23.67	229	76.33
7	Do you have habit of Alcohol consumption?	187	62.33	113	37.67

Table 7: Responses for Practice based questionnaires in Control and Interventional groups

Sr. No.	Questionnaires	Control Group		Interventional Group		Total (%)	
		Yes (%)	No (%)	Yes (%)	No (%)	Yes (%)	No (%)
1	Do you exercise for 30-60 minutes every day?	48 (16.00)	102 (34.00)	80 (26.67)	70 (23.33)	128 (42.67)	172 (57.33)
2	Do you monitor Blood Glucose Level every month?	80 (26.67)	70 (23.33)	68 (22.67)	82 (27.33)	148 (49.33)	152 (50.67)

3	Do you always eat small and frequent meals?	31 (10.33)	119 (39.67)	36 (12.00)	114 (38.00)	67 (22.33)	233 (77.67)
4	Do you exclude rice from meals?	60 (20.00)	90 (30.00)	69 (23.00)	81 (27.00)	129 (43.00)	171 (57.00)
5	Do you take medications regularly?	89 (29.67)	61 (20.33)	94 (31.33)	56 (18.67)	183 (61.00)	117 (39.00)
6	Do you get your HbA1c test done every 3 months?	40 (13.33)	110 (36.67)	31 (10.33)	119 (39.67)	71 (23.67)	229 (76.33)
7	Do you have habit of Alcohol consumption?	92 (30.67)	58 (19.33)	95 (31.67)	55 (18.33)	187 (62.33)	113 (37.67)

Table 8: Demographics of the study population and prevalence of superior knowledge, attitude and practice among the study population

Sl No	**Demographic Details**		**Total Number (Percentage)**	**Participants with better knowledge ≥ 6**	**Participants with better attitude ≥ 4**	**Participants with better practice ≥ 4**
1	Age	21-30	06 (2.00)	3 (2.29)	2 (1.39)	2 (1.31)
		31-40	36 (12.00)	13 (9.92)	10 (6.94)	12 (7.84)
		41-50	52 (17.33)	20 (15.27)	23 (15.97)	41 (26.80)
		51-60	74 (24.67)	36 (27.48)	32 (22.22)	41 (26.80)
		61-70	82 (27.33)	28 (21.37)	41 (28.47)	36 (23.53)
		>70	50 (16.67)	31 (23.66)	36 (25.00)	21 (13.73)
		Total	300 (100.00)	131 (43.67)	144 (48.00)	153 (51.00)
2	Gender	Male	218 (72.67)	89 (67.94)	102 (70.83)	92 (60.13)
		Female	82 (27.33)	42 (32.06)	42 (29.17)	61 (39.87)

3.	Education	Literate	183 (61.00)	91 (75.83)	61 (61.62)	28 (60.87)
		Illiterate	117 (39.00)	29 (24.17)	42 (38.38)	18 (39.13)
4.	Duration of Diabetes	<1 Year	28 (9.33)	11 (7.80)	15 (11.81)	13 (8.55)
		1-5 Years	76 (25.33)	29 (20.57)	27 (21.26)	31 (20.39)
		6-10 Years	94 (31.33)	48 (34.04)	39 (30.71)	52 (34.21)
		>10 Years	102 (34.00)	53 (37.59)	46 (36.22)	56 (36.84)

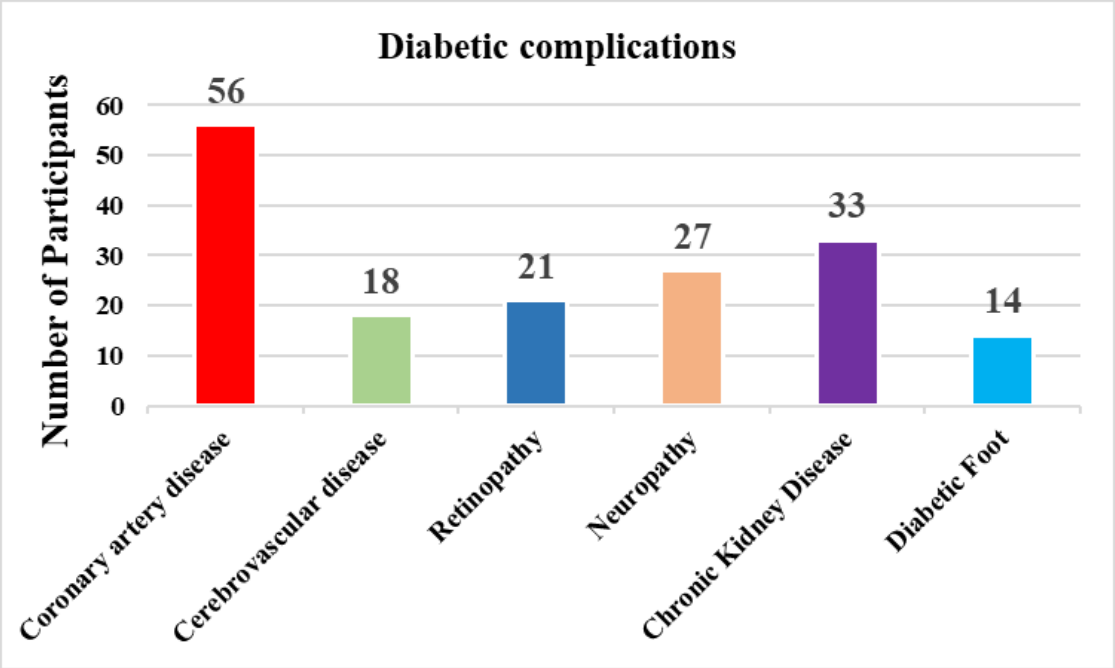
Out of 300 subjects, 131 (43.67%) patients were had better knowledge, 144 (48.00%) had better attitude and 153 (51.00%) had better practice. The majority of the patients in the study population were over 60 years old. Out of 218 males, 89 (68.46%) patients were had better knowledge, 102 (75.56%) had better attitude and 36 (60.00%) had better practice. Out of 183 literate patients, 91 (75.83%), 61 (61.62%) and 28 (60.87%) patients had better knowledge, attitude and practice respectively. The patients with diabetes duration more than 10 years were 102, in which 53 (37.59%) patients had better knowledge, 46 (36.22) patients had better attitude and 56 (36.84%) patients had better practice.

Table 9: Study population demographics and the frequency of improved knowledge, attitudes, and practices in the intervention and control groups

Demographic Details		Total Number (Percentage)	Participants with better knowledge ≥ 6			Participants with better attitude ≥ 4			Participants with better practice ≥ 4		
			Control	Interventional	Total	Control	Interventional	Total	Control	Interventional	Total
Age	21-30	06 (2.00)	1 (0.76)	2 (1.53)	3 (2.29)	1 (0.69)	1 (0.69)	2 (1.39)	1 (0.65)	1 (0.65)	2 (1.31)
	31-40	36 (12.00)	7 (5.34)	6 (4.58)	13 (9.92)	6 (4.17)	4 (2.78)	10 (6.94)	7 (4.58)	5 (3.27)	12 (7.84)
	41-50	52 (17.33)	9 (6.87)	11 (8.40)	20 (15.27)	11 (7.64)	12 (8.33)	23 (15.97)	21 (13.73)	20 (13.07)	41 (26.80)
	51-60	74 (24.67)	18 (13.74)	18 (13.74)	36 (27.48)	12 (8.33)	20 (13.89)	32 (22.22)	22 (14.38)	19 (12.42)	41 (26.80)
	61-70	82 (27.33)	16 (12.21)	12 (9.16)	28 (21.37)	20 (13.89)	21 (14.58)	41 (28.47)	20 (13.07)	16 (10.46)	36 (23.53)
	>70	50 (16.67)	14 (10.7)	17 (12.98)	31 (23.66)	20 (13.89)	16 (11.11)	36 (25.00)	11 (7.19)	10 (6.54)	21 (13.73)
	Total	300 (100.00)	65 (49.62)	66 (50.38)	131 (43.67)	70 (48.61)	74 (51.39)	144 (48.00)	82 (53.59)	71 (46.41)	153 (51.00)
Gender	Male	218 (72.67)	49 (37.40)	40 (30.53)	89 (67.94)	49 (34.03)	53 (36.81)	102 (70.83)	44 (28.76)	48 (31.37)	92 (60.13)

	Female	82 (27.33)	20 (15.27)	22 (16.79)	42 (32.06)	20 (13.89)	22 (15.28)	42 (29.17)	30 (19.61)	31 (20.26)	61 (39.87)
Education	Literate	183 (61.00)	48 (36.64)	43 (32.82)	91 (75.83)	34 (23.61)	27 (18.75)	61 (61.62)	13 (8.50)	15 (9.80)	28 (60.87)
	Illiterate	117 (39.00)	19 (14.50)	10 (7.63)	29 (24.17)	22 (15.28)	20 (13.89)	42 (38.38)	8 (5.23)	10 (6.54)	18 (39.13)
Duration of Diabetes	<1 Year	28 (9.33)	5 (3.82)	6 (4.58)	11 (7.80)	5 (3.47)	6 (4.17)	15 (11.81)	6 (3.92)	7 (4.58)	13 (8.55)
	1-5 Years	76 (25.33)	14 (10.69)	15 (11.45)	29 (20.57)	13 (9.03)	16 (11.11)	27 (21.26)	16 (10.46)	15 (9.80)	31 (20.39)
	6-10 Years	94 (31.33)	22 (16.79)	26 (19.85)	48 (34.04)	26 (18.06)	22 (15.28)	39 (30.71)	24 (15.69)	28 (18.30)	52 (34.21)
	>10 Years	102 (34.00)	30 (22.90)	23 (17.56)	53 (37.59)	32 (22.22)	21 (14.58)	46 (36.22)	26 (16.99)	30 (19.61)	56 (36.84)

Figure 1: Diabetic complications



Out of 300 participants, 169 patients had diabetic complications, of which coronary artery disease was the highest in number 56 (46.67%) followed by chronic kidney disease 33 (27.50%) and diabetic foot was the lowest 14 (11.67%).

Table 10: Bivariate analysis to evaluate the factors influencing Practice, Knowledge, and Attitude

Of the three categories evaluated in the research study, the knowledge domain had eleven questions, while the attitude and practice domains each had seven questions. Participants received a score of '1' for each question they answered correctly, and a score of '0' for each incorrect response. After adding up each of these ratings, a total domain score for practice, attitude, and knowledge was determined separately.

The study team also sought to evaluate the demographic factors associated with good knowledge, attitude, and practice. For this reason, each domain—knowledge, attitude, and practice—was given a cut score of 60%. Participants who achieved a final score of > 6 in the knowledge domain were classified individually based on this cut-off, while those who achieved a final score of ≥ 4 were grouped separately in the practice and attitude domains. This segregated data was taken up for executing the bi-variate analysis separately for knowledge, attitude and practice. Table 10 lists the specifics of the individuals who have improved their knowledge, mindset, and practice. Bivariate analysis was done and it revealed that few demographic characteristics influenced knowledge, attitude and practice ($p< 0.05$) namely, age less than 50 years, Education-Literacy and duration of disease less than 5 years. With respective to practice domain separately males demonstrated better practice than females. Table 10 presents the specific outcomes of the bivariate analysis.

	KNOWLEDGE			ATTITUDE			PRACTICE		
Demographic Characteristic	**Odds Ratio**	**95% CI**	**P Value**	**Odds Ratio**	**95% CI**	**P Value**	**Odds Ratio**	**95% CI**	**P value**
Age									
Less than 50	0.5359	0.3281-0.8755	0.0127*	0.3746	0.2286-0.6140	0.0001*	0.652	0.4105-1.0357	0.0701
More than 50	1(Ref)			1(Ref)			1(Ref)		
Gender									
Male	0.6571	0.394-1.094	0.106	1.0658	0.6260-1.8148	0.8144	0.25	0.1250-0.4999	0.0001*
Female	1 (Ref)			1(Ref)			1(Ref)		
Education									
Literate	21.4198	11.695-39.2300	0.0001*	14.4431	7.7389-26.9553	< 0.0001*	18.2	8.6165-38.4425	< 0.0001*
Illiterate	1(Ref)			1(Ref)			1(Ref)		
Duration of Disease									
< 5 years	0.2884	0.1780-0.4675	0.0001*	0.3782	0.2348-0.6090	0.0001*	0.1837	0.1121-0.3011	< 0.0001*
≥ 5 years	1(Ref)			1(Ref)			1(Ref)		

* Statistically significant *p* value OR=Odds ratio, CI=Confidence interval

4.3 Drug Utilization Evaluation

DUE was conducted in all study participants for both control and interventional group. Monthly drug therapy costs and regimen distribution within the research population and usage pattern of most widely used multidrug ADD was analyzed. The prescribing trends of ADD within the study population was observed. Comparison of drugs prescribed in the subjects were analyzed using WHO Core prescribing indicator and ATC Code classification.

Table 11: Number of Medications and Socioeconomic Status of the study population

Sl. No	No. of Medications	No. of Subjects	Percentage	Socio-Economic Status	No. of Subjects	Percentage
1	One	18	6	Upper	27	9
2	Two	175	58.33	Upper Middle	48	16
3	Three	82	27.33	Lower Middle	121	40.33
4	Four	16	5.33	Upper lower	68	22.6
5	> Four	09	3.00	lower	36	12

Table 11 made it clear that, of the 300 participants in the study, 175 (58.33%) were taking two drugs, and 82 (27.33%) were taking three. It was shown that 121 (40.33%) of the participants belonged to the lower medium socioeconomic class, while 68 (22.6%) belonged to the upper lower class.

Table 12: Monthly drug therapy costs and regimen distribution within the research population

Sl. No	Cost of drug/month	No. of Subjects	Percentage	Regimen	No. of Subjects	Percentage
1	<100	67	22.33	Once Daily	122	40.66
2	100-200	144	48.00	Twice Daily	152	50.66
3	>200	89	29.66	Thrice Daily	26	8.66

Out of 300 patients, it was found that 67 (22.33%) spent less than 100 rupees a month on medication. In a similar vein, 89 patients (29.66%) had monthly drug costs exceeding 200 rupees, while 144 patients (48.00%) had monthly drug costs between 100 and 200 rupees. 152 (50.66 %) of the 300 study participants were taking diabetes meds twice a day, whereas 122 (40.66 %) were only taking them once. In contrast, only roughly 26 (8.6%) of the individuals used diabetic pills three times a day. Table 12 displays these findings.

Table 13: Usage patterns of the most widely used multidrug ADD regimens

Sl. No	Name of the drugs	Number of times prescribed	Percentage
Dual drug regimens			
1	Metformin+sulfonylureas	162	54.00
2	Metformin+thiazolidine diones	80	26.66
3	Metformin+alpha-glucosidase inhibitors	44	14.66
4	Metformin+DPP-4 inhibitors	37	12.33
5	Metformin+meglitinides	21	07.00
6	Sulfonylureas+thiazolidine diones	64	11.33
7	Sulfonylureas+alpha-glucosidase inhibitors	27	09.00
8	Metformin + regular insulin	132	44.00
	Total Dual drug regimens (n) = 567		
Triple drug regimens			
8	Metformin+sulfonylureas+ DPP-4 inhibitors	117	39.00
9	Metformin+thiazolidine diones+alpha-glucosidase inhibitors	48	16.00
10	Metformin + acarbose + premixed insulin	31	10.33
	Total Triple drug regimens (n) = 196		
Four drug regimens			
11	Metformin + voglibose + NPH insulin + regular insulin	18	06.00
12	Metformin + glimepiride + pioglitazone + voglibose	24	08.00
	Total Four drug regimens (n) = 42		

Of the 300 patients, the most often prescribed dual medication combination was 162 (54%) times metformin and sulfonylureas, followed by 132 (44%) times metformin and normal insulin. In triple therapy, metformin + sulfonylureas + DPP-4 inhibitors prescribed was 117 (39.00 %) followed by Metformin + thiazolidinediones + alpha-glucosidase inhibitors 48 (16.00 %). 18 (06.00 %) times Metformin + voglibose + NPH insulin + regular insulin prescribed was the highest four drug regimen.

Table 14: Use trends of the most popular multidrug ADD regimens in the Control and Interventional Groups

Sl. No	Name of the drugs	Control Group	Interventional Group	Number of times prescribed	Percentage
Dual drug regimens					
1	Metformin + sulfonylureas	78 (52.00)	84 (56.00)	162	54.00
2	Metformin + thiazolidinediones	42 (28.00)	38 (25.33)	80	26.66
3	Metformin + alpha-glucosidase inhibitors	21 (1400)	23 (15.33)	44	14.66
4	Metformin + DPP-4 inhibitors	19 (12.67)	18 (12.00)	37	12.33
5	Metformin + meglitinides	10 (6.67)	11 (7.33)	21	07.00
6	Sulfonylureas + thiazolidine diones	31 (20.67)	33 (22.00)	64	11.33
7	Sulfonylureas + alpha-glucosidase inhibitors	13 (8.67)	14 (9.33)	27	09.00
8	Metformin + regular insulin	64 (42.67)	68 (45.33)	132	44.00
	Total Dual drug regimens (n) = 567				

Triple drug regimens					
8	Metformin + sulfonylureas+ DPP-4 inhibitors	58 (38.67)	59 (39.33)	117	39.00
9	Metformin + thiazolidine diones+alpha-glucosidase inhibitors	25 (16.67)	23 (15.33)	48	16.00
10	Metformin + acarbose + premixed insulin	13 (8.67)	18 (12.00)	31	10.33
	Total Triple drug regimens (n) = 196				
Four drug regimens					
11	Metformin + voglibose + NPH insulin + regular insulin	8 (5.33)	10 (6.67)	18	06.00
12	Metformin + glimepiride + pioglitazone + voglibose	11 (7.33)	13 (8.67)	24	08.00
	Total Four drug regimens (n) = 42				

Table 15: Prescribing practices for oral hypoglycemic medications as a single medication regimen based on different pharmacological classes

Sl. No	ATC Code	Class of ADDs	Drugs (ATC Code)	Number of Patients	Percentage (%)
1	A10BA	Biguanides	Metformin A10BA02	162	54.00
2	A10BB	Sulfonylureas	Glimepiride A10BB12	78	26.00
			Glipizide A10BB07	64	21.33
			Glibenclamide A10BB01	47	15.66

			Gliclazide A10BB09	14	04.66
			Total	203	67.66
3	A10BF	α- Glucosidase inhibitors	Voglibose A10BF03	54	18.00
			Acarbose A10BF01	32	10.66
			Miglitol A10BF02	16	05.33
			Total	102	34.00
4	A10BG	Thiazolidinediones	Pioglitazone A10BG03	53	17.66
			Rosiglitazone A10BG02	27	09.00
			Total	80	26.66
5	A10BH	Dipeptidyl peptidase-4 (DPP-4) inhibitors	Vildagliptin A10BH02	41	13.66
			Linagliptin A10BH05	14	04.66
			Tenegliptin A10BH08	06	02.00
			Total	61	20.33
6	A10BJ	GLP-1 analog	Exenatide A10BJ01	06	02.00
7	A10A	Insulin A10AB	Regular insulin A10AB01	132	44.00
			NPH insulin A10AC	42	14.00
			premixed insulin A10AB30	31	10.33
			Total	205	68.33

Of the 300 patients, 205 (68.33%) received an insulin prescription; of all the medication groups, regular insulin had the greatest prescription rate. Sulfonylureas were prescribed to 203 individuals (67.66%), with glimepiride (78.00%) being the most often prescribed medication. It was noted that biguanides were prescribed to 162 (54.00%) of the patients. Among the patients prescribed α-glucosidase inhibitors (102, 34.00%) and DPP-4 inhibitors (61, 20.33%), vildagliptin was the most frequently prescribed medicine. Thiazolidinediones was prescribed in 80 (26.66 %) patients, while GLP-1 Analog was the least commonly prescribed drugs 06 (02.00 %). These results are shown in Table 15.

Table 16: Prescribing patterns for oral hypoglycemic medications as a single medication regimen depending on the different drug classes in the interventional and control groups

Sl. No	ATC Code	Class of ADDs	Drugs (ATC Code)	Control Group	Interventional Group	Number of Patients	Percentage (%)
1	A10BA	Biguanides	Metformin A10BA02	78 (52.00)	84 (56.00)	162	54.00
2	A10BB	Sulfonylureas	Glimepiride A10BB12	38 (25.33)	40 (26.67)	78	26.00
			Glipizide A10BB07	33 (22.00)	31 (20.67)	64	21.33
			Glibenclamide A10BB01	24 (16.00)	23 (15.33)	47	15.66
			Gliclazide A10BB09	7 (4.67)	7 (4.67)	14	04.66
			Total	102 (68.00)	101 (67.33)	203	67.66
3	A10BF	α- Glucosidase inhibitors	Voglibose A10BF03	28 (18.67)	26 (17.33)	54	18.00

			Acarbose A10BF01	16 (10.67)	16 (10.67)	32	10.66
			Miglitol A10BF02	9 (6.00)	7 (4.67)	16	05.33
			Total	53 (35.33)	49 (32.67)	102	34.00
4	A10BG	Thiazolidinediones	Pioglitazone A10BG03	26 (17.33)	27 (18.00)	53	17.66
			Rosiglitazone A10BG02	14 (9.33)	13 (8.67)	27	09.00
			Total	40 (26.67)	40 (26.67)	80	26.66
5	A10BH	Dipeptidyl peptidase-4 (DPP-4) inhibitors	Vildagliptin A10BH02	20 (13.33)	21 (14.00)	41	13.66
			Linagliptin A10BH05	8 (5.33)	6 (4.00)	14	04.66
			Tenegliptin A10BH08	3 (2.00)	3 (2.00)	06	02.00
			Total	31 (20.67)	30 (20.00)	61	20.33

6	A10BJ	GLP-1 analog	Exenatide A10BJ01	3 (2.00)	3 (2.00)	06	02.00
7	A10A A10AB	Insulin	Regular insulin A10AB01	62 (41.33)	70 (46.67)	132	44.00
			NPH insulin A10AC	20 (13.33)	22 (14.67)	42	14.00
			premixed insulin A10AB30	13 (8.67)	18 (12.00)	31	10.33
			Total	95 (63.33)	110 (73.33)	205	68.33

Table 17: WHO core prescribing indicators

SI. No	Core Indicators	Value
1	Average number of drugs prescribed per prescription	2.73
2	Percentage of drugs prescribed by generic name	480 (58.60 %)
3	Percentage of encounters with antibiotic prescribed	182 (22.22 %)
4	Percentage of encounters with injectable drug prescribed	245 (29.91 %)
5	Percentage of drugs prescribed from NLEM	673 (82.17 %)
6	Percentage of encounters with Fixed drug combination	805 (98.29 %)
Total number of drugs prescribed (n) = 819		

Adherence to WHO drug prescribing indicators is displayed in Table 17. In all, 819 medications were prescribed over 300 prescriptions. Next, it was discovered that 2.73 was the average amount of medications used per contact. The proportion of medications prescribed under generic names was 58.60%, whereas the proportion of injectable pharmaceuticals and antibiotics was found to be 22.22% and 29.91%, respectively. 82.17% of the medications that were prescribed came from the Essential Drug List. It was shown that 98.29% of the prescriptions under study had fixed dose combinations of several medications.

Table 18: Type of Co-morbid Conditions Among Study Subjects

Comorbid conditions	No. of Patients (%)			
	Control		Interventional	
	n = 150	%	n = 150	%
DM+Htn	12	8.00	14	9.33
DM + IHD	4	2.67	8	5.33
DM + MI	6	4.00	10	6.67
DM + CHF	5	3.33	7	4.67
DM+ CVD	9	6.00	9	6.00
DM + Hypothyroidism	2	1.33	1	0.67
DM+Retinopathy	11	7.33	10	6.67
DM+CKD	16	10.67	17	11.33
DM+Diabetic Foot	7	4.67	7	4.67
DM+Neuropathy	12	8.00	15	10.00
DM + Asthma	6	4.00	3	2.00
DM + COPD	5	3.33	3	2.00
DM + Seizures	4	2.67	2	1.33
DM + Anaemia	8	5.33	10	6.67
DM + Spondylitis	6	4.00	2	1.33
DM+Htn + CHF	3	2.00	6	4.00
DM +Htn + COPD	4	2.67	2	1.33
DM+Htn + Hypothyroidism	4	2.67	2	1.33
DM+Htn + Gout	2	1.33	2	1.33
DM + COPD+ Htn	3	2.00	2	1.33
DM + Asthma+ Htn	4	2.67	2	1.33
DM+Htn + IHD + LV Dysfunction	2	1.33	3	2.00
DM + Htn + COPD + Hypothyroidism	2	1.33	2	1.33
DM + Htn + arthritis + hypothyroidism	2	1.33	2	1.33
DM+ Htn + IHD + BPH	2	1.33	2	1.33
DM + others	9	6.00	7	4.67

HTN- Hypertension, DM – Diabetes mellitus, IHD – Ischemic Heart disease, MI – Myocardial Infarction, CHF – Congestive Heart failure, CVD – Cerebrovascular Diseases, CKD – Chronic Kidney Diseases, COPD – Chronic Obstructive Pulmonary Disease, LV Dysfunction – Left ventricular dysfunction, BPH – Benign prostatic hyperplasia**.**

Diabetes and Hypertension were most commonly observed co-morbidities, followed by hypothyroidism, COPD, and IHD. Comorbidities of admitted study subjects are depicted in Table 18.

4.4 Assessment of Drug Related Problems

A total of 321 DRPs were identified from 300 patients. The rate of occurrence of DRP was 1.07 per patient. Among the identified DRPs there were 131 DRPs from 150 subjects in the control group with DRP occurrence rate of 0.87, and 190 DRPs from 150 subjects in the interventional group with rate of occurrence of DRP of 1.26. The male constitutes for the highest number of DRP i.e 232 (72.27%) and female contributing to 89 (27.72%) of the total DRPs identified. The age group of 61-70 and >70 years were found to with maximum DRPs.

The identified DRPs were categorized as per PCNE classification version 9.1. Total problems related to treatment effectiveness were 176 (58.66 %), in which no effect of drug treatment, effect of drug treatment not optimal, untreated symptoms or indication were 31 (10.33%), 94 (31.33%) and 51(17.00%) respectively. Treatment safety like adverse drug events were 104 (34.67%) and other problems were unnecessary drug treatment 29 (9.67%) and unclear complaints 12 (4.00%). Of the 321 DRPs identified in the study subjects, the most common problem identified was treatment effectiveness followed by adverse drug reactions.

Of the 131 and 190 DRPs identified in the control group and interventional group respectively, treatment effectiveness and ADRs were most common DRP in both the groups. In the interventional group, effect of drug treatment not optimal, untreated indications (unnoticed indication, and new indication arising during hospital stay and delay) were the most common causes of DRPs followed by drug-drug interactions or combination of allopathy and herbal medications and no or incomplete drug treatment (Indication without drug), therapeutic drug duplication. There are few cases were no indication for drug and inappropriate drug prescribed. The similar pattern was observed in the control group also.

There are different dose selection causes seen in both the groups. Dosage regimen were more frequent, drug with higher dose and dosage regimen not frequent enough. The different causes of DRPs in control group and interventional groups are shown in Table 19.

Since there were no obvious causes for ADRs, they were grouped under Other Causes – No Obvious Cause. Some DRPs that were not classifiable in the problem list were included under Causes- Others. Drugs that were started for an indication but were continued to be used despite symptoms subsiding or normalization of laboratory/ biochemistry values were grouped under 'Continued use of Drug' under Other Causes.

Table 19: Pattern of Occurrence of Drug Related Problems

PCNE Code	**Characteristic (Detailed classification)**	**No of DRPs n(%)**		
		Control (n=150) (DRP=131)	Interventional (n=150) (DRP=190)	Total (n=300) (DRP=321)
The Problem				
P1: Treatment effectiveness There is a (potential) problem with the (lack of) effect of the pharmacotherapy				
P1.1	No effect of drug treatment	8 (6.11)	23 (12.11)	31 (9.66)
P1.2	Effect of drug treatment not optimal	46 (35.11)	48 (25.26)	94 (29.28)
P1.3	Untreated symptoms or indication	23 (17.56)	28 (14.74)	51 (15.89)
P2: Treatment safety Patient suffers, or could suffer, from an adverse drug event				
P2.1	Adverse drug event (possibly) occurring	35 (26.72)	69 (36.62)	104 (32.40)
P3 Other				
P3.1	Unnecessary drug treatment	14 (10.69)	15 (7.89)	29 (9.03)
P3.2	Unclear problem/complaint	5 (3.82)	7 (3.68)	12 (3.74)

The Cause				
C1. Drug selection The cause of the (potential) DRP is related to the selection of the drug (by patient or health professional)				
C1.1	Inappropriate drug according to guidelines/formulary	4 (3.05)	6 (3.16)	10 (3.12)
C1.2	No indication for drug	5 (3.82)	7 (3.68)	12 (3.74)
C1.3	Inappropriate combination of drugs, or drugs and herbal medications, or drugs and dietary supplements (Drug Interaction)	10 (7.63)	17 (8.95)	27 (8.41)
C1.4	Inappropriate duplication of therapeutic group or active Ingredient (Drug Duplication)	5 (3.82)	9 (4.74)	14 (4.36)
C1.5	No or incomplete drug treatment in spite of existing Indication (Indication without Drug)	6 (4.58)	10 (5.26)	16 (4.98)
C1.6	Too many different drugs/active ingredients prescribed for indication	3 (2.29)	5 (1.58)	8 (2.49)
C2. Drug form The cause of the DRP is related to the selection of the drug form				
C2.1	Inappropriate drug form/formulation (for this patient)	3 (2.29)	2 (1.05)	5 (1.56)

C3. Dose selection The cause of the DRP is related to the selection of the dose or dosage				
C3.1	Drug dose too low	4 (3.05)	8 (4.21)	12 (3.74)
C3.2	Drug dose too high	7 (5.34)	5 (2.63)	12 (3.74)
C3.3	Dosage regimen not frequent enough	7 (5.34)	8 (4.21)	15 (4.67)
C3.4	Dosage regimen too frequent	6 (4.58)	10 (5.26)	16 (4.98)
C3.5	Dose timing instructions wrong, unclear or missing	2 (1.53)	5 (2.63)	7 (2.18)
C4. Treatment duration The cause of the DRP is related to the duration of treatment				
C4.1	Duration of treatment too short	6 (4.58)	3 (1.57)	9 (2.80)
C4.2	Duration of treatment too long	7 (5.34)	12 (6.28)	19 (5.92)
C5. Dispensing The cause of the DRP is related to the logistics of the prescribing and dispensing process				
C5.1	Prescribed drug not available	4 (3.05)	5 (2.63)	9 (2.80)
C5.3	Wrong drug, strength or dosage advised (OTC)	1 (0.76)	2 (1.05)	3 (0.93)
C5.4	Wrong drug or strength dispensed	3 (2.29)	6 (3.16)	9 (2.80)
C6. Drug use process The cause of the DRP is related to the way the patient gets the drug administered by a health professional or other carer, despite proper dosage instructions (on label/list)				
C6.1	Inappropriate timing of administration or dosing intervals by a health professional	3 (2.29)	5 (2.63)	8 (2.49)
C6.2	Drug under-administered by a health professional	5 (3.82)	11 (5.79)	16 (4.98)

C6.3	Drug over-administered by a health professional	4 (3.05)	6 (3.16)	10 (3.12)
C6.4	Drug not administered at all by a health professional	4 (3.05)	4 (2.11)	8 (2.49)
C6.5	Wrong drug administered by a health professional	1 (0.76)	2 (1.05)	3 (0.93)
C6.6	Drug administered via wrong route by a health professional	1 (0.76)	3 (1.58)	4 (1.25)
C7. Patient related The cause of the DRP is related to the patient and his behaviour (intentional or nonintentional)				
C7.1	Patient intentionally uses/takes less drug than prescribed or does not take the drug at all for whatever reason	3 (2.29)	5 (2.63)	8 (2.49)
C7.2	Patient uses/takes more drug than prescribed	4 (3.05)	6 (3.16)	10 (3.12)
C7.4	Patient decides to use unnecessary drug	10 (7.63)	6 (3.16)	16 (4.98)
C7.6	Patient stores drug inappropriately	2 (1.53)	12 (6.32)	14 (4.36)
C9. Others				
C9.2	Continued use of drug	11(8.40)	10 (5.26)	21 (6.54)

Table 20: Drugs Implicated in Treatment Effectiveness Problems

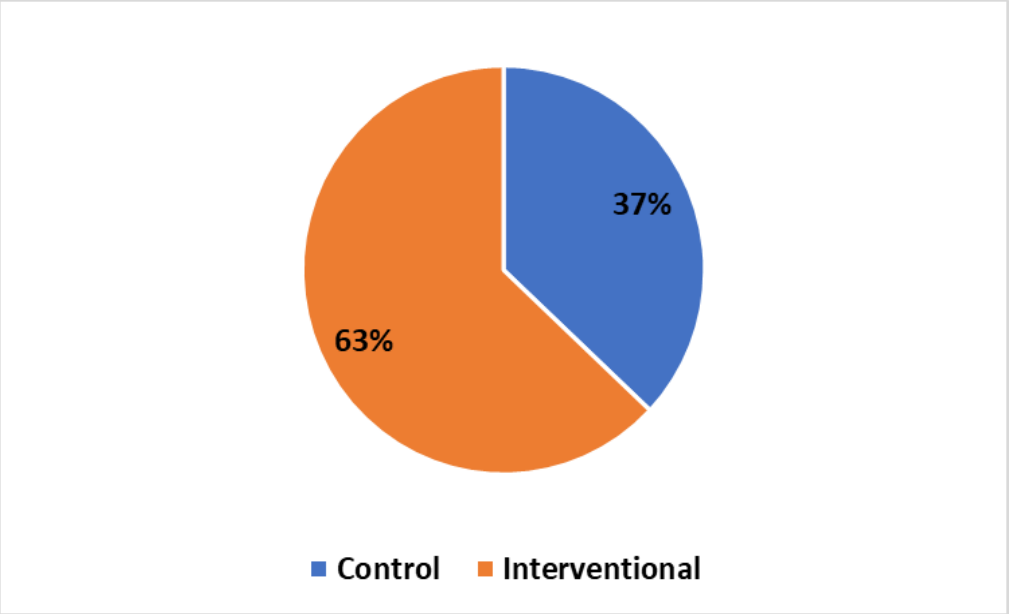
Description of Problem	Name of Drug	ATC Code	Number (%)		
			Control (n=77)	Interventional (n=99)	Total (n=176)
No effect of drug treatment	Metformin	A10BA02	1 (1.30)	4 (4.04)	5 (2.84)
	Regular Insulin	A10AB01	1 (1.30)	3 (3.03)	4 (2.27)
	Glimepiride	A10BB12	1 (1.30)	2 (2.02)	3 (1.70)
	Amlodipine	C08CA01	1 (1.30)	3 (3.03)	4 (2.27)
	Furosemide	C03CA01	1 (1.30)	3 (3.03)	4 (2.27)
	Spironolactone	C03DA01	1 (1.30)	2 (2.02)	3 (1.70)
	Telmisartan	C09CA07	1 (1.30)	3 (3.03)	4 (2.27)
	Piperacillin + Tazobactum	J01CR05	1 (1.30)	3 (3.03)	4 (2.27)
Effect of drug treatment not optimal	Pantoprazole	A02BC02	3 (3.90)	3 (3.03)	6 (3.41)
	Metformin	A10BA02	2 (2.60)	2 (2.02)	4 (2.27)
	Aspirin	B01AC06	2 (2.60)	2 (2.02)	4 (2.27)
	Metoprolol	C07AB02	2(2.60)	2 (2.02)	4 (2.27)
	Piperacillin + Tazobactum	J01CR05	4 (5.19)	4 (4.04)	8 (4.45)
	Isosorbide dinitrate	C01DA08	3 (3.90)	2 (2.02)	5 (2.84)
	Metronidazole	J01XD01	2 (2.60)	2 (2.02)	4 (2.27)
	amoxicillin and potassium clavulanate	J01CR02	3 (3.90)	2 (2.02)	5 (2.84)
	Ceftriaxone	J01DD04	3 (3.90)	3 (3.03)	6 (3.41)
	Regular Insulin	A10AB01	3 (3.90)	3 (3.03)	6 (3.41)
	Azithromycin	J01FA10	1 (1.30)	1 (1.01)	2 (1.14)

	Atorvastatin	C10AA05	2 (2.60)	2 (2.02)	4 (2.27)
	Phenytoin	N03AB02	0 (0.00)	1 (1.01)	1 (0.57)
	Clopidogrel	B01AC04	2 (2.60)	2 (2.02)	4 (2.27)
	Telmisartan	C09CA07	1 (1.30)	1 (1.01)	2 (1.14)
	Salbutamol	R03AC02	1 (1.30)	1 (1.01)	2 (1.14)
	Ambroxol	R05CB06	1 (1.30)	1 (1.01)	2 (1.14)
	Linezolid	J01XX08	1 (1.30)	1 (1.01)	2 (1.14)
	Mupirocin	D06AX09	0 (0.00)	1 (1.01)	1 (0.57)
	cephalexin	J01DB01	1 (1.30)	1 (1.01)	2 (1.14)
	clindamycin	J01FF01	1 (1.30)	1 (1.01)	2 (1.14)
	Doxycycline	A01AB22	1 (1.30)	1 (1.01)	2 (1.14)
	Ciprofloxacin	J01MA02	1 (1.30)	1 (1.01)	2 (1.14)
	Levofloxacin	J01MA12	1 (1.30)	1 (1.01)	2 (1.14)
	Metoprolol	C07AB02	1 (1.30)	1 (1.01)	2 (1.14)
	Cotrimoxazole	J01EE01	1 (1.30)	1 (1.01)	2 (1.14)
	Losartan	C09CA01	0 (0.00)	1 (1.01)	1 (0.57)
	Digoxin	C01AA05	1 (1.30)	1 (1.01)	2 (1.14)
	Meropenem	J01DH02	0 (0.00)	1 (1.01)	1 (0.57)
	Ondansetron	A04AA01	1 (1.30)	1 (1.01)	2 (1.14)
	Furosemide	C03CA01	1 (1.30)	1 (1.01)	2 (1.14)
Untreated symptoms or indication	Ferrous Sulphate	B03AA07	7 (9.09)	8 (8.08)	15 (8.52)
	Regular Insulin	A10AB01	4 (5.19)	5 (5.05)	9 (5.11)
	Metformin	A10BA02	4 (5.19)	5 (5.05)	9 (5.11)
	Calcium carbonate	A12AA04	4 (5.19)	5 (5.05)	9 (5.11)
	Amlodipine	C08CA01	2 (2.60)	3 (3.03)	5 (2.84)
	Telmisartan	C09CA07	2 (2.60)	2 (2.02)	4 (2.27)

Drug-Drug interactions in the study populations

A total of 27 drug-drug interactions were observed among 300 study participants. Out of which, 10 (37%) and 17 (63%) were observed in control group and interventional group respectively.

Figure 2: Drug-Drug interactions in the study populations



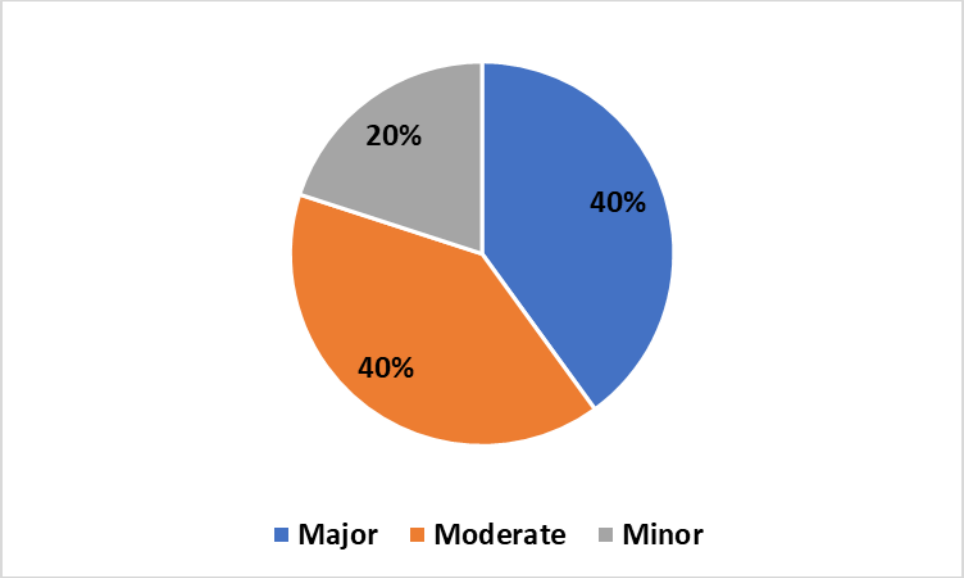
Drug-Drug interactions in the control group

Total of 10 drug-drug interactions were observed in control group. According to the severity of drug-drug interactions, major and moderate were predominantly high. 04 (40%) majorly drug interaction, 04 (40%) moderately severe drug interaction and 02 (20%) interaction of minor severity were found. The details of the drug-drug interactions were listed in Table no 21.

Table 21: Drug-Drug interactions in the control group

Drugs implicated	Severity	Mechanism	The outcome of the interactions
Aspirin + clopidogrel	Major	Aspirin, clopidogrel. Either increases toxicity of the other by pharmacodynamic synergism	Increases risk of bleeding
Heparin + aspirin	Major	aspirin, heparin. Either increases toxicity of the other by anticoagulation	Increases risk of bleeding
Metformin + aspirin	Major	synergistically inhibitory effects on cell viability	Hypoglycaemia
Glimepiride + aspirin	Major	aspirin increases effects of glimepiride by plasma protein binding competition	Risk of hypoglycaemia
Insulin + aspirin	Moderate	Unknown	Risk of hypoglycaemia
Insulin + furosemide	Moderate	Altered glucose Metabolism	Increased risk of hyperglycemia
Metoprolol + aspirin	Moderate	Decreased renal prostaglandin synthesis	Reduced diuretic effectiveness, hyperkalemia or possible nephrotoxicity
Metformin + Metoprolol	Moderate	Altered glucose metabolism and beta blockade	Hypoglycemia or hyperglycemia
Aspirin + Ranitidine	Minor	Reduces absorption of aspirin	Decreases aspirin plasma levels and decreases anti platelet effect of aspirin
Dobutamine + Metoprolol	Minor	Antagonism of dobutamine effects by beta adrenergic blockade	Decreased dobutamine efficacy

Figure 3: Classification of drug-drug interactions based on severity in control group



Drug-Drug interactions in the Interventional group

Total of 17 drug-drug interactions were seen in interventional group. According to the severity of drug-drug interactions, major and moderate were predominantly high. 06 (35%) majorly drug interaction, 08 (47%) moderately severe drug interaction and 03 (18%) interaction of minor severity were found. The details of the drug-drug interactions were listed in Table no 22.

Table 22: Drug-Drug interactions in the interventional group

Drugs implicated	**Severity**	**Mechanism**	**The outcome of the interactions**
Ramipril + Telmisartan	Major	Dual blockade of RAAS	**Increased risk of hypotension**
Digoxin + Furosemide	Major	Inhibition of Na-K-ATPase by Digoxin	Digitalis Toxicity
Digoxin + Spironolactone	Major	Inhibition of active tubular secretion of digoxin	Increased digoxin exposure
Heparin +	Major	aspirin, heparin. Either	Increases risk of

Aspirin		increases toxicity of the other by anticoagulation	bleeding
Spironolactone + Enalapril	Major	Pharmacodynamic synergism	Increased risk of hyperkalemia
Aspirin + Enalapril	Major	Inhibition of prostaglandin synthesis	Reduced hyponatremic and hypotensive effect of enalapril
Furosemide + Captopril	Moderate	Vasodilation and Relative intravascular volume depletion	Hypotension
Theophylline + Azithromycin	Moderate	Unknown	Increased serum theophylline concentration
Azithromycin + Phenytoin	Moderate	Unknown	Increased serum phenytoin levels
Ceftriaxone + Warfarin	Moderate	Unknown	Increased risk of bleeding
Pantoprazole + Warfarin	Moderate	Inhibition of CYP2C9 mediated warfarin metabolism by pantoprazole	Increased INR and Prothrombin time
Doxycycline + Iron	Moderate	Decreased tetracycline and Iron absorption	Decreased tetracycline and Iron effectiveness
Tramadol + Digoxin	Moderate	Unknown	Increased risk of digoxin toxicity
Tramadol + Warfarin	Moderate	Unknown	Increase in Prothrombin time and Increased risk of bleeding
Piperacillin + Gentamicin	Minor	Chemical inactivation of gentamicin	Decreased gentamicin efficacy
Aspirin + Ranitidine	Minor	Reduced absorption of aspirin	Decreased antiplatelet effect of aspirin

Figure 4: Classification of drug-drug interactions based on severity in interventional group

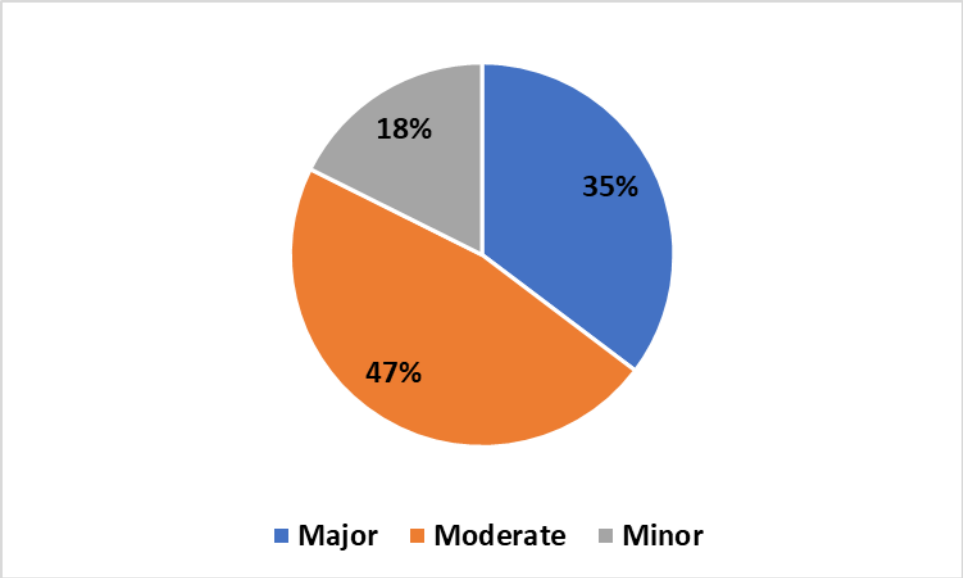
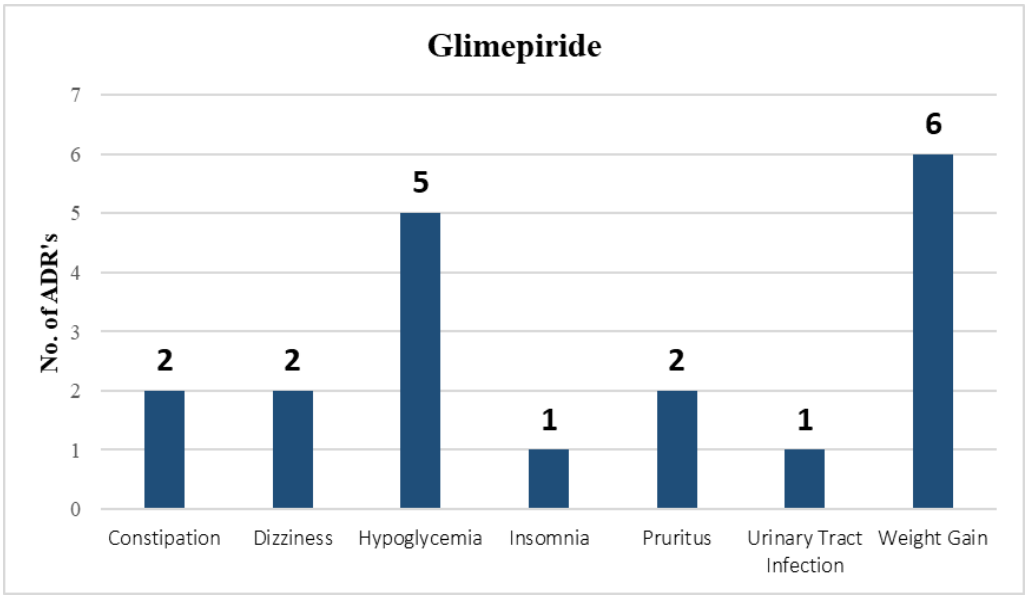


Table 23: Drugs Implicated ADRs in different groups

Sr. No.	Parameter		Total Number of Patients (300)	Number of ADRs (104)	Percentage of ADR
1	Study groups				
	Control		150	48	46.15
	Interventional		150	56	53.85
2	Gender groups				
	Control	Male	112	28	26.92
		Female	38	20	19.23
	Interventional	Male	106	29	27.88
		Female	44	27	25.96
3	Age Groups				
	Control	21-30	2	1	0.96
	Interventional		4	1	0.96
	Control	31-40	22	3	2.88
	Interventional		14	5	4.81
	Control	41-50	30	6	5.77
	Interventional		22	8	7.69
	Control	51-60	31	9	8.65
	Interventional		43	11	10.58
	Control	61-70	42	13	12.50
	Interventional		40	12	11.54
	Control	>70	23	16	15.38
	Interventional		27	19	18.27

Figure 5: Prevalence of ADR's in patients receiving Antidiabetic Drugs



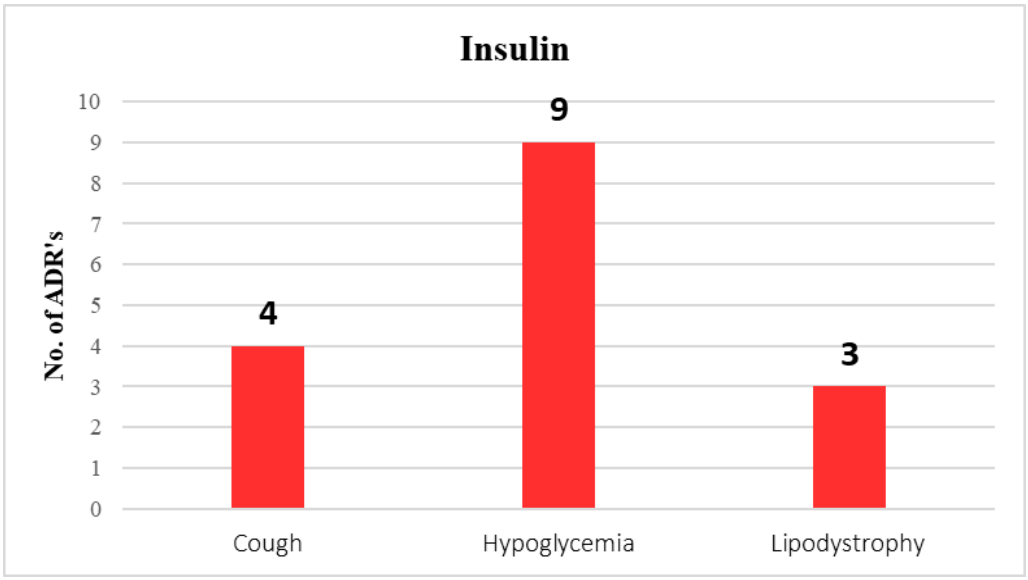
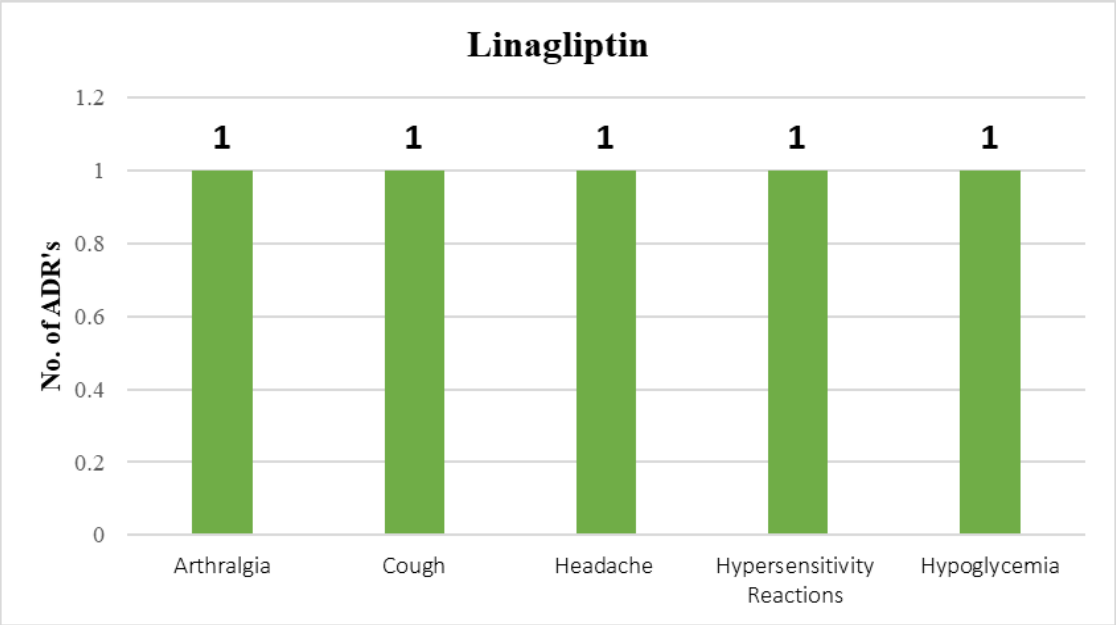


Figure 5: Prevalence of ADR's in patients receiving Antidiabetic Drugs (continued)



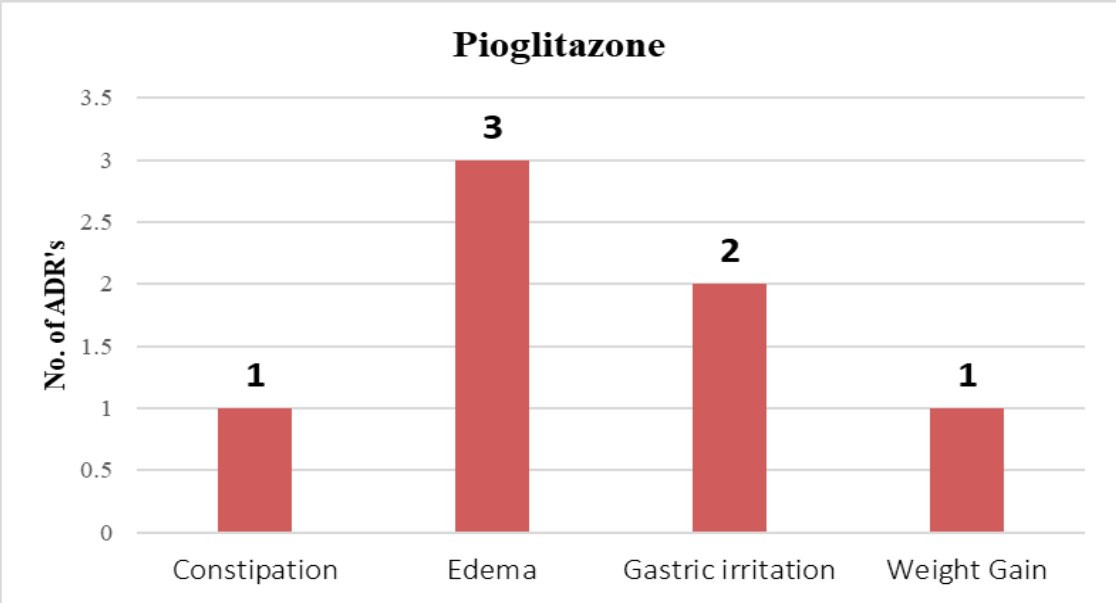
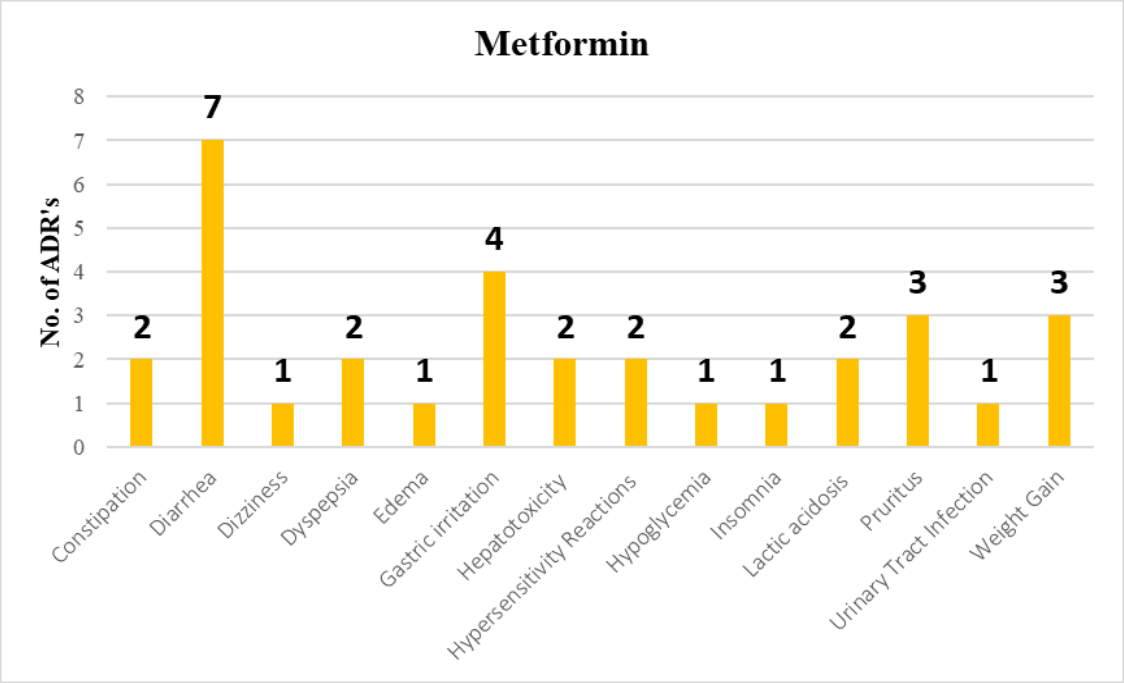


Figure 5: Prevalence of ADR's in patients receiving Antidiabetic Drugs (continued)



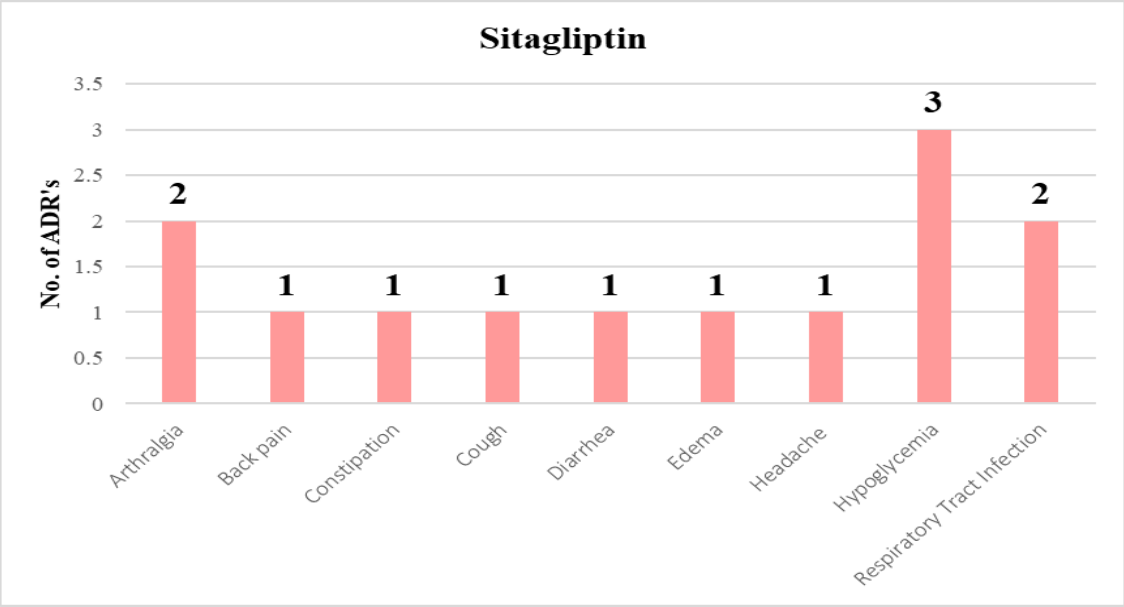
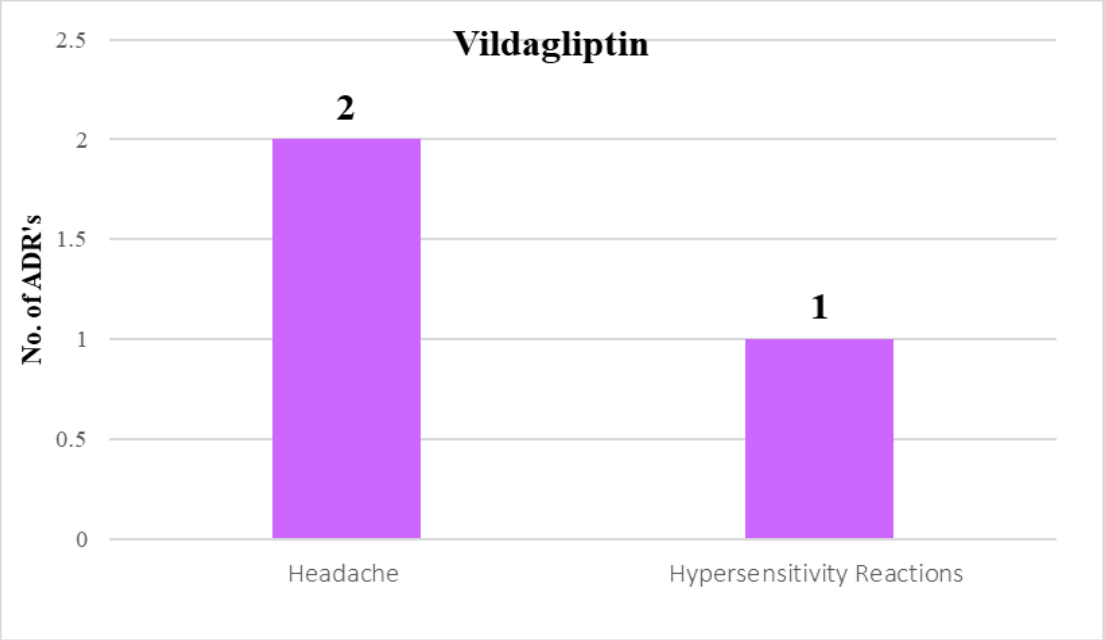


Figure 5: Prevalence of ADR's in patients receiving Antidiabetic Drugs (continued)



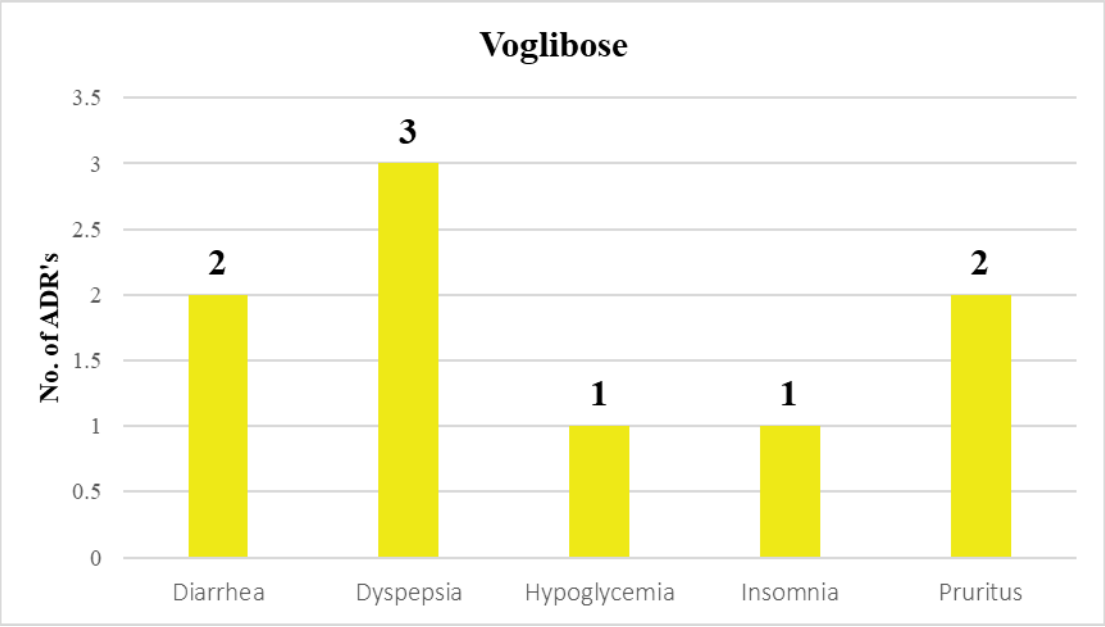


Table 24. Causality assessment of adverse drug reactions according to WHO-UMC

SR No	Categories	Control	Interventional	Number of ADRs (n=104)	% of ADRs
1	Certain	7 (6.73)	4 (3.85)	11	10.58
2	Probable	22 (21.15)	28 (26.92)	50	48.08
3	Possible	19 (18.27)	24 (23.08)	43	41.35
4	Unlikely	0 (0.00)	0 (0.00)	0	0.00
5	Conditional/unclassified	0 (0.00)	0 (0.00)	0	0.00
6	Unassessable/unclassifiable	0 (0.00)	0 (0.00)	0	0.00

Table 25. Causality assessment of adverse drug reactions according to Naranjo algorithm

SR No	Categories	Control	Interventional	Number of ADRs (n=104)	% of ADRs
1	Certain	5 (4.81)	4 (3.85)	9	8.65
2	Probable	20 (19.23)	35 (33.65)	55	52.88
3	Possible	18 (17.31)	22 (21.15)	40	38.46
4	Unlikely	0 (0.00)	0 (0.00)	0	0.00
5	Conditional/unclassified	0 (0.00)	0 (0.00)	0	0.00
6	Unassessable/unclassifiable	0 (0.00)	0 (0.00)	0	0.00

Table 26: WHO-UMC Causality Assessment of reported ADR's

Sr. No.	Suspected ADRs	No of ADRs	Control	Interventional	Certain (%)		Probable/Likely (%)		Possible (%)	
					Control	Interventional	Control	Interventional	Control	Interventional
1	Arthralgia	3	2	1	0 (0.00)	0 (0.00)	1 (33.33)	1 (33.33)	1 (33.33)	0 (0.00)
2	Back pain	1	0	1	0 (0.00)	0 (0.00)	0 (0.00)	1 (100)	0 (0.00)	0 (0.00)
3	Cough	6	2	4	0 (0.00)	0 (0.00)	1 (16.66)	2 (33.33)	1 (16.66)	2 (33.33)
4	Constipation	6	3	3	0 (0.00)	0 (0.00)	2 (33.33)	1 (16.66)	1 (16.66)	2 (33.33)
5	Diarrhoea	10	5	5	0 (0.00)	0 (0.00)	2 (20.00)	2 (20.00)	3 (30.00)	3 (30.00)
6	Dizziness	3	2	1	0 (0.00)	0 (0.00)	1 (33.33)	0 (0.00)	1 (33.33)	1 (33.33)
7	Dyspepsia	5	2	3	0 (0.00)	0 (0.00)	1 (20.00)	2 (40.00)	1 (20.00)	1 (20.00)
8	Edema	5	2	3	0 (0.00)	0 (0.00)	1 (20.00)	2 (40.00)	1 (20.00)	1 (20.00)
9	Gastric irritation	6	4	2	1 (16.66)	0 (0.00)	1 (16.66)	1 (16.66)	2 (33.33)	1 (16.66)
10	Headache	4	1	3	0 (0.00)	0 (0.00)	1 (25.00)	2 (50.00)	0 (00.00)	1 (25.00)
11	Hepatotoxicity	2	1	1	1 (50.00)	0 (0.00)	0 (0.00)	1 (50.00)	0 (0.00)	0 (0.00)

12	Hypoglycemia	20	9	11	2 (10.00)	4 (20.00)	3 (15.00)	5 (25.00)	4 (20.00)	2 (10.00)
13	Hypersensitivity Reactions	4	1	3	1 (25.00)	0 (0.00)	0 (00.00)	1 (25.00)	0 (00.00)	2 (50.00)
14	Insomnia	3	1	2	0 (0.00)	0 (0.00)	1 (33.33)	1 (33.33)	0 (00.00)	1 (33.33)
15	Lactic acidosis	2	2	0	1 (50.00)	0 (0.00)	1 (50.00)	0 (0.00)	0 (0.00)	0 (0.00)
16	Lipodystrophy	3	1	2	1 (33.33)	0 (0.00)	0 (00.00)	1 (33.33)	0 (0.00)	1 (33.33)
17	Pruritus	7	3	4	0 (0.00)	0 (0.00)	1 (14.29)	2 (28.57)	2 (28.57)	2 (28.57)
18	Respiratory Tract Infection	2	1	1	0 (0.00)	0 (0.00)	1 (50.00)	0 (0.00)	0 (00.00)	1 (50.00)
19	Urinary Tract Infection	2	1	1	0 (0.00)	0 (0.00)	1 (50.00)	1 (50.00)	0 (00.00)	0 (00.00)
20	Weight Gain	10	5	5	0 (00.00)	0 (00.00)	3 (30.00)	2 (20.00)	2 (20.00)	3 (30.00)
	Total	104	48	56	7 (6.73)	4 (3.85)	22 (21.15)	28 (26.92)	19 (18.27)	24 (23.08)

Table 27: Naranjo Causality Assessment of reported ADR's

Sr. No.	Suspected ADRs	No of ADRs	Control	Interventional	Certain (%)		Probable/Likely (%)		Possible (%)	
					Control	Interventional	Control	Interventional	Control	Interventional
1	Arthralgia	3	2	1	0 (0.00)	0 (0.00)	1 (33.33)	1 (33.33)	1 (33.33)	0 (0.00)
2	Back pain	1	0	1	0 (0.00)	0 (0.00)	0 (0.00)	1 (100)	0 (0.00)	0 (0.00)
3	Cough	6	2	4	0 (0.00)	0 (0.00)	1 (16.66)	2 (33.33)	1 (16.66)	2 (33.33)
4	Constipation	6	3	3	0 (0.00)	0 (0.00)	2 (33.33)	2 (33.33)	1 (16.66)	1 (16.66)
5	Diarrhoea	10	5	5	0 (0.00)	0 (0.00)	1 (10.00)	3 (30.00)	3 (30.00)	3 (30.00)
6	Dizziness	3	2	1	0 (0.00)	0 (0.00)	1 (33.33)	1 (33.33)	0 (0.00)	1 (33.33)
7	Dyspepsia	5	2	3	0 (0.00)	0 (0.00)	0 (0.00)	3 (60.00)	1 (20.00)	1 (20.00)
8	Edema	5	2	3	0 (0.00)	0 (0.00)	1 (20.00)	2 (40.00)	1 (20.00)	1 (20.00)
9	Gastric irritation	6	4	2	0 (0.00)	0 (0.00)	1 (16.66)	2 (13.33)	2 (33.33)	1 (16.66)
10	Headache	4	1	3	0 (0.00)	0 (0.00)	1 (25.00)	2 (50.00)	0 (00.00)	1 (25.00)
11	Hepatotoxicity	2	1	1	1 (50.00)	0 (0.00)	0 (0.00)	1 (50.00)	0 (0.00)	0 (0.00)
12	Hypoglycemia	20	9	11	1 (5.00)	4 (20.00)	3 (15.00)	6 (30.00)	4 (20.00)	2 (10.00)
13	Hypersensitivity Reactions	4	1	3	1 (25.00)	0 (0.00)	0 (00.00)	2 (50.00)	0 (00.00)	1 (25.00)

14	Insomnia	3	1	2	0 (0.00)	0 (0.00)	1 (33.33)	1 (33.33)	0 (00.00)	1 (33.33)
15	Lactic acidosis	2	2	0	1 (50.00)	0 (0.00)	1 (50.00)	0 (0.00)	0 (0.00)	0 (0.00)
16	Lipodystrophy	3	1	2	1 (33.33)	0 (0.00)	0 (00.00)	1 (33.33)	0 (0.00)	1 (33.33)
17	Pruritus	7	3	4	0 (0.00)	0 (0.00)	1 (14.29)	2 (28.57)	2 (28.57)	2 (28.57)
18	Respiratory Tract Infection	2	1	1	0 (0.00)	0 (0.00)	1 (50.00)	0 (0.00)	0 (00.00)	1 (50.00)
19	Urinary Tract Infection	2	1	1	0 (0.00)	0 (0.00)	1 (50.00)	1 (50.00)	0 (00.00)	0 (00.00)
20	Weight Gain	10	5	5	0 (00.00)	0 (00.00)	3 (30.00)	2 (20.00)	2 (20.00)	3 (30.00)
	Total	104	48	56	5 (4.80)	4 (3.85)	20 (19.23)	35 (33.65)	18 (17.31)	22 (21.15)

Table 28: Suspected ADRs Distribution based on Preventability assessment using Modified-Schumock and Thornton scale

SR No	Categories	Number of ADRs (n=104)	% of ADRs
1	Definitely preventable ADRs	64	61.53
2	Probably preventable ADRs	31	29.80
3	Non-preventable ADRs	09	8.65

Table 29: Suspected ADRs Distribution based on Severity assessment using Modified Hartwig and Siegel scale

SR No	Categories	Number of ADRs (n=104)	% of ADRs
1	Mild	22	21.15
2	Moderate	74	71.15
3	Severe	8	7.70

Table 30: Drugs Implicated Unnecessary drug treatment

SI. No	Description of Problem	Name of Drug	ATC Code	Number (%)		
				Control (n=19)	Interventional (n=22)	Total (n=29)
1.	Unnecessary drug treatment	Paracetamol	N02BE01	2 (10.53)	2 (9.09)	4 (9.76)
		Tramadol	N02AX02	2 (10.53)	2 (9.09)	4 (9.76)
		Ceftriaxone	J01DD63	1(5.26)	1(4.55)	2 (4.88)
		Ondansetron	A04AA01	1(5.26)	1(4.55)	2 (4.88)
		Azithromycin	J01FA10	2 (10.53)	3 (13.64)	5 (12.20)
		Cefixime	J01DD08	1(5.26)	1(4.55)	2 (4.88)
		Pantoprazole	A02BC02	1(5.26)	1(4.55)	2 (4.88)

		Metronidazole	J01XD01	1(5.26)	1(4.55)	2 (4.88)
		Terbutaline, combinations	R03CC53	1(5.26)	1(4.55)	2 (4.88)
		Bromhexine	R05CB02	1(5.26)	1(4.55)	2 (4.88)
		Omeprazole	A02BC01	1(5.26)	1(4.55)	2 (4.88)
2.	Unclear problem/complaint	Unable to Classify/Identify		3 (15.79)	4 (18.18)	7 (17.07)
		Data Missing/Comorbid Condition		2 (10.53)	3 (13.64)	5 (12.20)

Table 31: Clinical Pharmacist Interventions

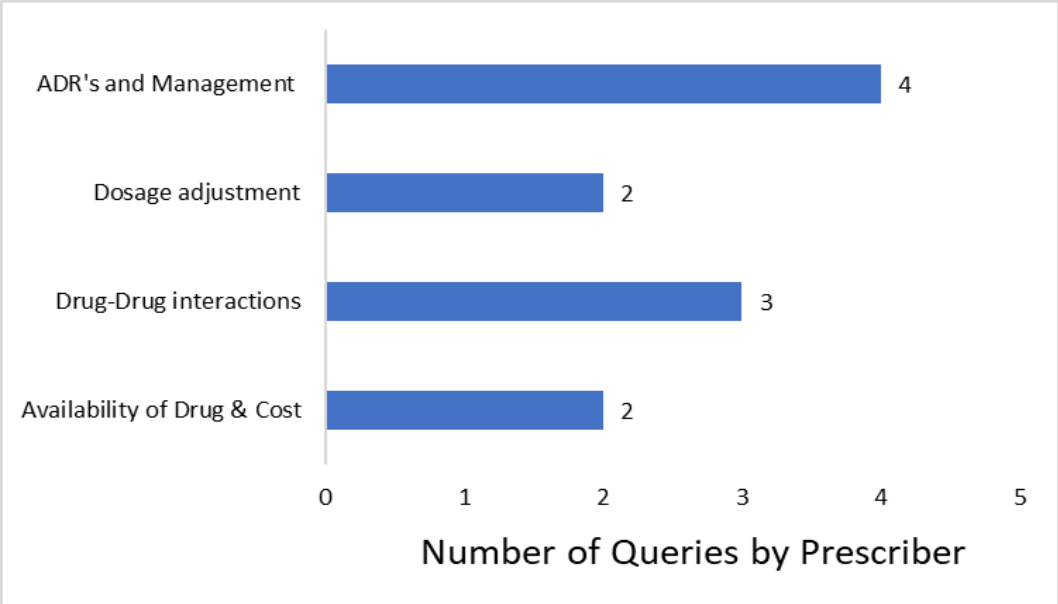
PCNE Code	**Characteristic (Detailed classification)**	**No of DRPs n(%)**		
		Control	Interventional	Total
The Planned Interventions				
I1. At prescriber level (102)				
I1.2	Prescriber asked for information	3 (2.94)	8 (7.84)	11 (10.78)
I1.3	Intervention proposed to prescriber	28 (27.45)	31 (30.39)	59 (57.84)
I1.4	Intervention discussed with prescriber	14 (13.73)	18 (17.65)	32 (31.37)
I2. At patient level (19)				
I2.1	Patient (drug) counselling	7 (36.84)	9 (47.37)	16 (84.21)
I2.4	Spoken to family member/caregiver	1 (5.26)	2 (10.53)	3 (15.79)

I3. At drug level (217)				
I3.1	Drug changed to …	10 (4.61)	12 (5.53)	22 (10.14)
I3.2	Dosage changed to …	18 (8.29)	32 (14.75)	50 (23.04)
I3.3	Formulation changed to …	4 (1.84)	6 (2.76)	10 (4.61)
I3.5	Drug paused or stopped	26 (11.98)	46 (21.20)	72 (33.18)
I3.6	Drug started	24 (11.06)	39 (17.97)	63 (29.03)
I4. Other intervention or activity (74)				
I4.1	Frequency Changed	12 (16.22)	16 (21.62)	28 (37.84)
I4.1	Laboratory Monitoring Requested	12 (16.22)	22 (29.73)	34 (45.95)
I4.1	Improved documentation	3 (4.05)	9 (12.16)	12 (16.22)

Out of 321 DRPs, majority of interventions were made at drug level 217 (52.67%) followed by prescriber level 102 (24.76%)] and other interventions 74 (17.96%). Of the total interventions made, 330 interventions were accepted and 82 interventions not accepted. Total acceptance of intervention proposals are shown in table 32.

Prescribers/Physician asked information pertaining to drug therapy to the clinical pharmacist to improve patient care. Among them, queries pertaining to ADR and Management (n=4) and Drug-Drug interactions (n=3). Number and category of queries asked by prescribers are shown in Fig 6.

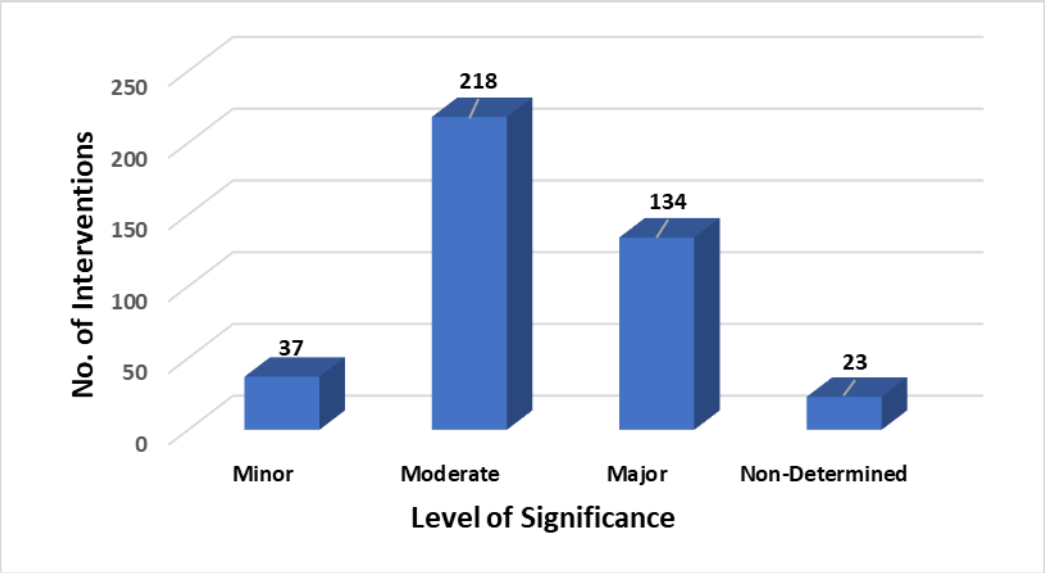
Figure 6: Information asked by Prescriber



Significance of Clinical Pharmacist Interventions

The significance of clinical pharmacist interventions were broadly classified as Minor, Moderate, Major and non-determined based on the ability of intervention to enhance effectiveness of therapy, reduce patient morbidity, reduce the drug related problems and reduce hospital stay. A total of 218 (52.91%) of interventions were found to have moderate significance, 134 (32.52%) to have major significance, and 37 (8.98%) to have minor significance. The significance of interventions is shown in Fig 7.

Fig 7: Significance of Clinical Pharmacist Interventions



Acceptance of the Intervention proposals

Among 412 interventions made, 330 interventions were accepted (80.10%). Intervention accepted and fully implemented constituted [231 (70.00%)] followed by partial implementation [72 (21.82%)]. The interventions not accepted were due to lack of feasibility [59 (71.95%)] and intervention not accepted 82 (19.90%). The details of the accepted intervention proposals have been depicted in table 32.

Table 32: Acceptance of the Intervention proposals

PCNE Code	**Characteristic (Detailed classification)**	**Total Interventions=412 n(%)**		
		Control	Interventional	Total
Acceptance of the Intervention proposals				
A1. Intervention accepted (by prescriber or patient) (330)				
A1.1	Intervention accepted and fully implemented	98 (29.70)	133 (40.30)	231(70.00)
A1.2	Intervention accepted, partially implemented	28 (8.48)	44 (13.33)	72 (21.82)
A1.3	Intervention accepted but not implemented	8 (2.42)	19 (5.76)	27 (8.18)

A2. Intervention not accepted (by prescriber or patient) (82)				
A2.1	Intervention not accepted: not feasible	40 (48.78)	19 (23.17)	59 (71.95)
A2.4	Intervention not accepted: unknown reason	18 (21.95)	5 (6.10)	23 (28.05)

Table 33: Outcome of Pharmacist Interventions

PCNE Code	**Characteristic (Detailed classification)**	**Total Interventions=412 n(%)**		
		Control	Interventional	Total
Status of the DRP				
O: Outcome of intervention				
O1. Solved (375)				
O1.1	Problem totally solved	181 (43.93)	194 (47.09)	375 (91.02)
O2. Partially Solved (30)				
O2.1	Problem partially solved	25 (6.07)	5 (1.21)	30 (7.28)
O3. Not solved (7)				
O3.2	Problem not solved, lack of cooperation of prescriber	4 (0.97)	1 (0.24)	5 (1.21)
O3.4	No need or possibility to solve problem	1 (0.24)	1 (0.24)	2 (0.49)

Among 412 accepted interventions, 375 interventions were Solved (91.02%) and 30 (7.28%) interventions were partially solved while not solved were 5 (1.21%) and no need to solve 2 (0.49%).

Time taken for Interventions by clinical pharmacists

The average time spent by pharmacist to review treatment chart, identify any problems in drug therapy, act on the problems as appropriate and document the intervention was 37 minutes (range: 5 to 180 minutes). Total time taken by clinical pharmacist to make 412 interventions was 15,244 minutes.

Drug Therapy Decision-Making According to Campagna's Model

Out of 330 interventions were accepted, the majority [178 (53.94%)] of the clinical pharmacist's intervention belonged to level-2 (corrective) decisions. Level 3 (consultative) and Levels 4 (proactive) accounted for [86 (26.06%)] and [49 (14.85%) respectively according to Campagna's decision-making model. The details of the drug therapy decision making parameters are depicted in table 34.

Table 34: Drug Therapy Decision-Making According to Campagna's Model

Level Decision Making	Control	Interventional	Total Number (%)
Level 1 (annotative)	8 (2.42)	9 (2.73)	17 (5.15)
Level 2 (corrective)	76 (23.03)	102 (30.91)	178 (53.94)
Level 3 (consultative)	24 (7.27)	62 (18.79)	86 (26.06)
Level 4 (proactive)	18 (5.45)	31 (9.39)	49 (14.85)

4.5 Assessment of Health-Related Quality of Life in study participants

The health-related quality of life of study participants were assessed by SF-36. The health-related quality of life was assessed at baseline, 6^{th} month, 12^{th} month and 24^{th} month in both control and interventional group.

Table 35: Assessment of Health-Related Quality of Life in study participants at baseline

SF-36 Domain	Baseline		
	Control Group (Mean Score)	**Interventional Group (Mean Score)**	**P value**
Vitality	47.2	46.1	**0.054**
Physical functioning	42.5	44.2	0.318
Bodily pain	41.7	40.1	0.009
General health perceptions	64.4	66.7	0.090
Physical role functioning	39.1	41.2	0.128
Emotional role functioning	31.7	33.1	0.010
Social role functioning	63.4	62.1	0.010
Mental health	58.1	56.9	0.030

Table 36: Assessment of Health-Related Quality of Life in study participants after 6 months

SF-36 Domain	Scores after 6 months		
	Control Group (Mean Score)	**Interventional Group (Mean Score)**	**P value**
Vitality	48.5	68.2	**<0.001***
Physical functioning	45.7	79.5	**<0.001***
Bodily pain	45.2	69.8	**<0.001***
General health perceptions	62.2	68.1	**<0.001***
Physical role functioning	42.1	71.4	**<0.001***
Emotional role functioning	30.2	70.4	**<0.001***
Social role functioning	60.6	90.1	**<0.001***
Mental health	54.7	72.7	**<0.001***

Table 37: Assessment of Health-Related Quality of Life in study participants after 12 months

SF-36 Domain	Scores after 12 months		
	Control Group (Mean Score)	**Interventional Group (Mean Score)**	**P value**
Vitality	46.2	69.1	**<0.001***
Physical functioning	43.4	78.1	**<0.001***
Bodily pain	44.9	67.2	**<0.001***
General health perceptions	64.6	72.4	**<0.001***
Physical role functioning	41.7	70.6	**<0.001***
Emotional role functioning	32.5	71.9	**<0.001***
Social role functioning	58.4	89.2	**<0.001***
Mental health	53.1	74.9	**<0.001***

Table 38: Assessment of Health-Related Quality of Life in study participants after 24 months

SF-36 Domain	Scores after 24 months		
	Control Group (Mean Score)	**Interventional Group (Mean Score)**	**P value**
Vitality	**42.3**	68.5	**<0.001***
Physical functioning	40.3	76.9	**<0.001***
Bodily pain	42.3	67.11	**<0.001***
General health perceptions	60.2	71.9	**<0.001***
Physical role functioning	40.8	69.4	**<0.001***
Emotional role functioning	31.9	72.1	**<0.001***
Social role functioning	57.8	90.2	**<0.001***
Mental health	51.1	73.8	**<0.001***

Table 39: Comparison of the control and intervention groups' HRQOL-SF scores

SF-36 Domain	Baseline Scores			Scores after 6 months			Scores after 12 months			Scores after 24 months		
	Control Group (Mean score)	Interventional group (Mean score)	P value	Control Group (Mean score)	Interventional group (Mean score)	P value	Control Group (Mean score)	Interventional group (Mean score)	P value	Control Group (Mean score)	Interventional group (Mean score)	P value
Vitality	47.2	46.1	0.054	48.5	68.2	<0.001*	46.2	69.1	<0.001*	42.3	68.5	<0.001*
Physical functioning	42.5	44.2	0.318	45.7	79.5	<0.001*	43.4	78.1	<0.001*	40.3	76.9	<0.001*
Bodily pain	41.7	40.1	0.009	45.2	69.8	<0.001*	44.9	67.2	<0.001*	42.3	67.11	<0.001*
General health perceptions	64.4	66.7	0.090	62.2	68.1	<0.001*	64.6	72.4	<0.001*	60.2	71.9	<0.001*
Physical role functioning	39.1	41.2	0.128	42.1	71.4	<0.001*	41.7	70.6	<0.001*	40.8	69.4	<0.001*
Emotional role functioning	31.7	33.1	0.010	30.2	70.4	<0.001*	32.5	71.9	<0.001*	31.9	72.1	<0.001*
Social role functioning	63.4	62.1	0.010	60.6	90.1	<0.001*	58.4	89.2	<0.001*	57.8	90.2	<0.001*
Mental health	58.1	56.9	0.030	54.7	72.7	<0.001*	53.1	74.9	<0.001*	51.1	73.8	<0.001*

SF Scores range from 0 – 100, Lower scores indicate more disability, higher scores indicate less disability, * p value <0.001 was significant.

Table 40: Multivariate linear regression study of HRQOL-related variables

Factors	β coefficient	Standard error	p-value
Age	-0.087	0.043	0.042
Gender (male)	2.155	0.623	<0.001
Marital status (married)	1.311	0.603	0.031
Education (primary)	1.321	0.679	0.052
Employment status (unemployed)	-1.931	0.753	0.011
Duration of diabetes	-0.463	0.152	0.002
HbA1c level	-1.269	0.238	<0.001
Interventional group	10.235	0.938	<0.001

p value <0.001 was significant.

4.6 Medication Adherence

Comparison of Medication Adherence Between Control and Interventional Group

Medication adherence was assessed utilizing MARS, a scale that classifies patients into categories of low and high medication adherence based on their cumulative scores. A cumulative score of 6 and above signifies high adherence, while a score below 6 is indicative of low adherence.

Table 41, presents the mean and standard deviations of the scores from patients in the control group over a span of 24 months. (Figure 8)

Table 41: Mean and SD of MARS scores of the control group

Control Group	Mean	Std. Deviation	N
0th month	4.31	2.18	150
6th month	4.67	2.06	138
24th month	4.28	1.93	128

Figure 8: Medication adherence in the control group

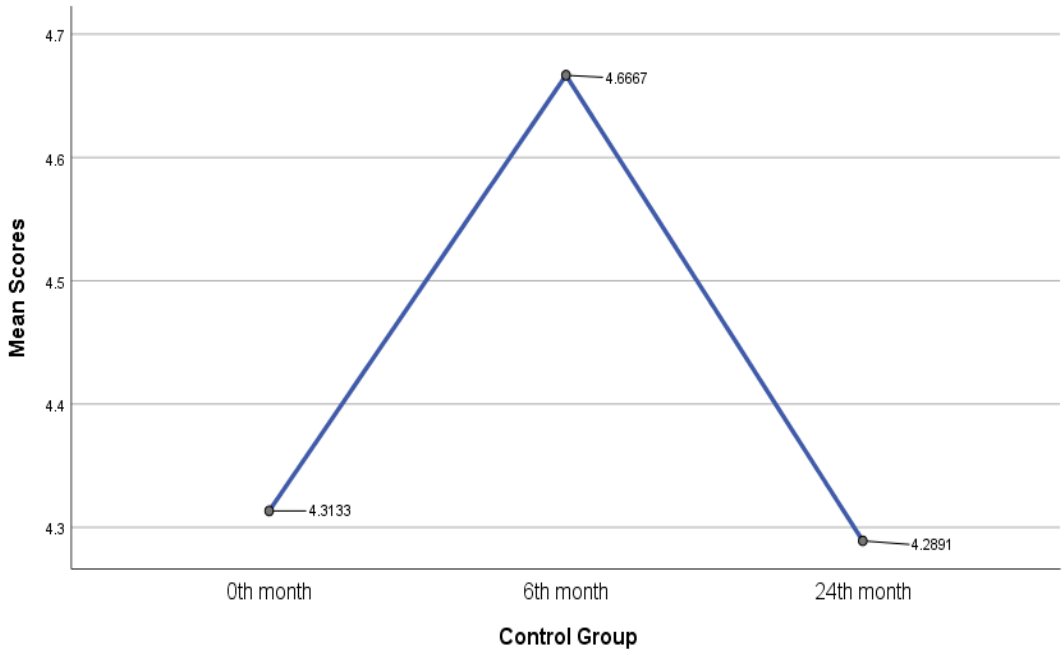
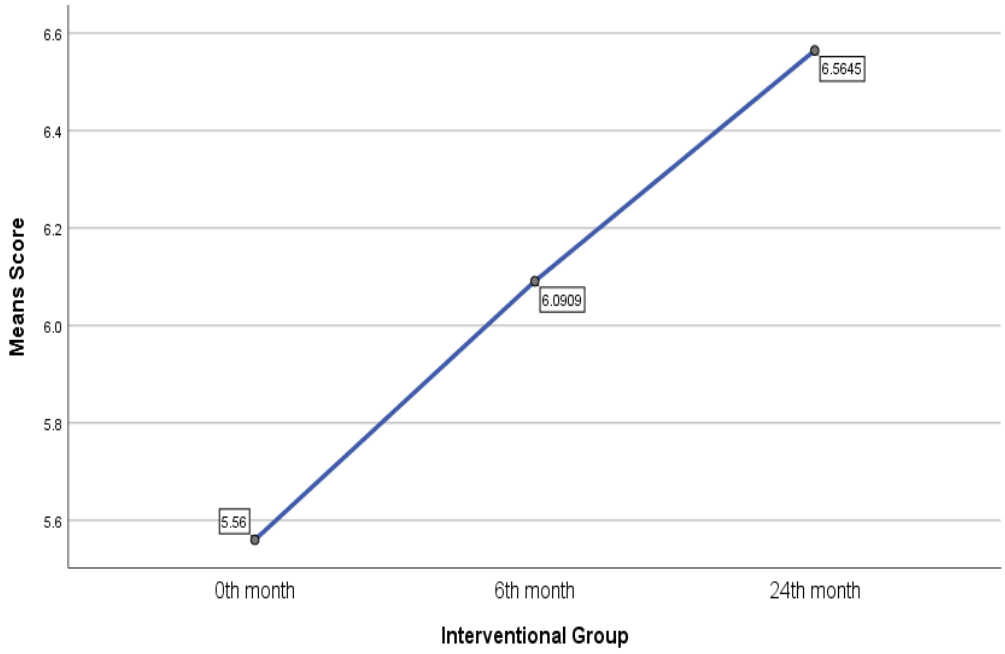


Table 42, displays the means and standard deviations of the scores derived from the individuals within the interventional group spanning a duration of 24 months. (Figure 9)

Table 42: Mean and SD of MARS scores of the interventional group

Interventional Group	Mean	SD	N
0^{th} month	5.56	1.48	150
6^{th} month	6.09	1.49	148
24^{th} month	6.56	1.47	124

Figure 9: Medication adherence in the interventional group



Variable levels of adherence were noted within the control group over a span of 2 years. The adherence to medication was observed to decrease in the levels even below those recorded at the initial 0^{th} month. In comparison, the interventional group exhibited a consistent rise in medication adherence over the course of 2 years.

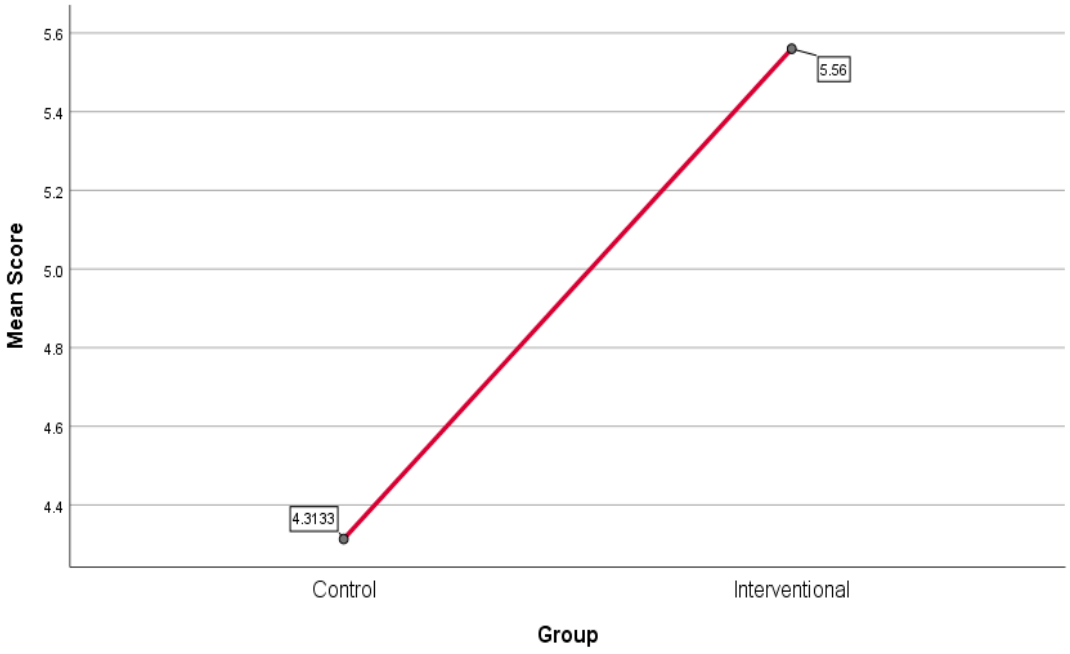
Medication Adherence between the Control and Interventional Group in 0th month

The mean and SD values of the control and interventional group at baseline are given in Table 43. (Figure 10)

Table 43: Group-wise mean and SD of MARS scores at 0th month

Group	Mean	SD	N
Control	4.31	2.18	150
Interventional	5.56	1.48	150

Figure 10: Comparison of Medication Adherence in 0th month



A One-Way ANOVA was performed to analyse the difference in medication adherence between the two groups. The effect of patient education on the medication adherence of diabetic patients was significant at the 0.05 level, F([1], [298]) = [33.36], p = [.000]. It was observed that the interventional group showed a higher adherence to their drug regimen than the control group. (Table 44)

Table 44: Summary of One-Way ANOVA of MARS scores in the 0th month

Source	Sum of Squares	df	Mean Square	F	Sig.
Between group	116.56	1	116.56	33.36	.000
Within group	1041.23	298	3.49		

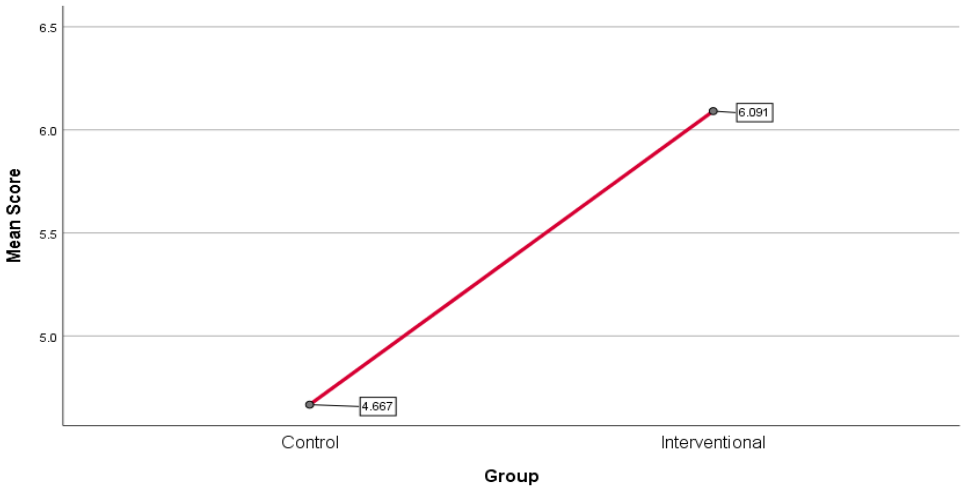
Medication Adherence between the Control and Interventional Group in 6th month

The mean and SD values of the control and interventional group in the 6th month are given in Table 45. (Figure 11)

Table 45: Group-wise mean and SD of MARS scores at 6th month

Group	Mean	SD	N
Control	4.67	2.06	138
Interventional	6.09	1.49	148

Figure 11: Comparison of medication adherence in the 6th month



A One-Way ANOVA revealed that the effect of patient education on the medication adherence of diabetic patients in 6th month was significant at the 0.05 level, F([1], [268]) = [41.79], p = [.000]. In the 6th month, the interventional group demonstrated notably greater medication adherence compared to the control group. (Table 46)

Table 46: Summary of One-Way ANOVA of MARS scores in the 6th month

Source	Sum of Squares	df	Mean Square	F	Sig.
Between-group	136.85	1	136.85	41.79	.000
Within group	877.57	284	3.27		

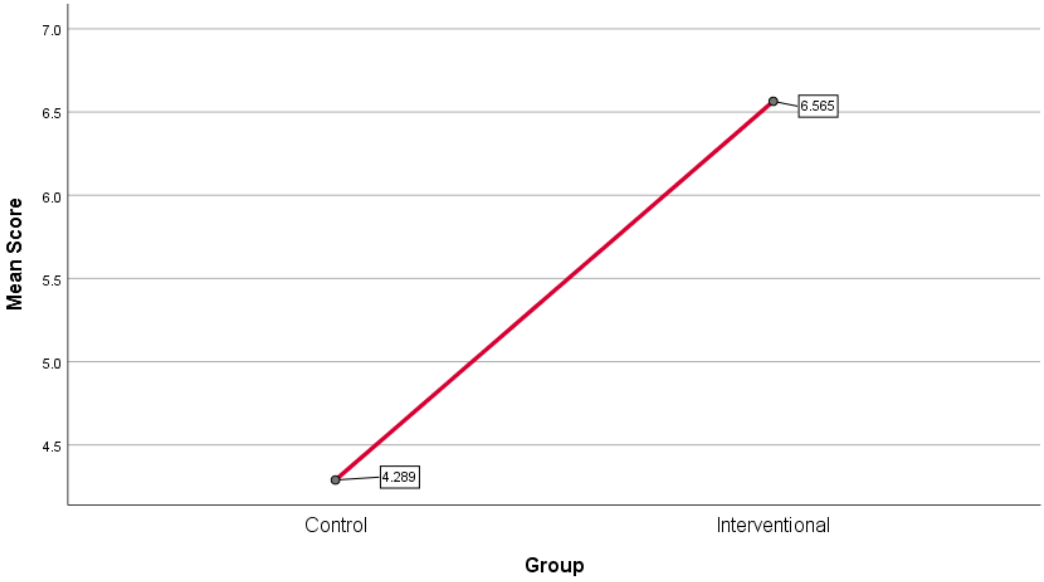
Medication Adherence between the Control and Interventional Group in 24th month

The mean and SD values of the control and interventional group in the 24th month are given in Table 47. (Figure 12)

Table 47: Group-wise mean and SD of MARS scores at 24th month

Group	Mean	SD	N
Control	4.29	1.93	128
Interventional	6.56	1.47	124

Figure 12: Comparison of medication adherence in the 24th month



A One-Way ANOVA revealed that the effect of patient education on the medication adherence of diabetic patients in 24th month was significant at the 0.05 level, F([1], [250]) = [109.75], p = [.000]. In the 24th month, the interventional group demonstrated notably greater medication adherence compared to the control group. (Table 48)

Table 48: Summary of One-Way ANOVA of MARS scores in the 24th month

Source	Sum of Squares	df	Mean Square	F	Sig.
Between-group	362.11	1	362.11	109.75	.000
Within group	742.78	250	2.97		

The interventional group exhibited a continuous increase in medication adherence, which can be attributed to the motivation stemming from noticeable health improvements resulting from consistent medication adherence since the beginning. This may have fostered a lasting commitment to adhering to drug regimens for chronic illnesses. In contrast, the control group experienced a decline in medication adherence over the span of two years, highlighting the importance of early patient education during the treatment process.

4.7 Patient Counselling

Impact of Patient Counselling by Clinical Pharmacist in Interventional Group

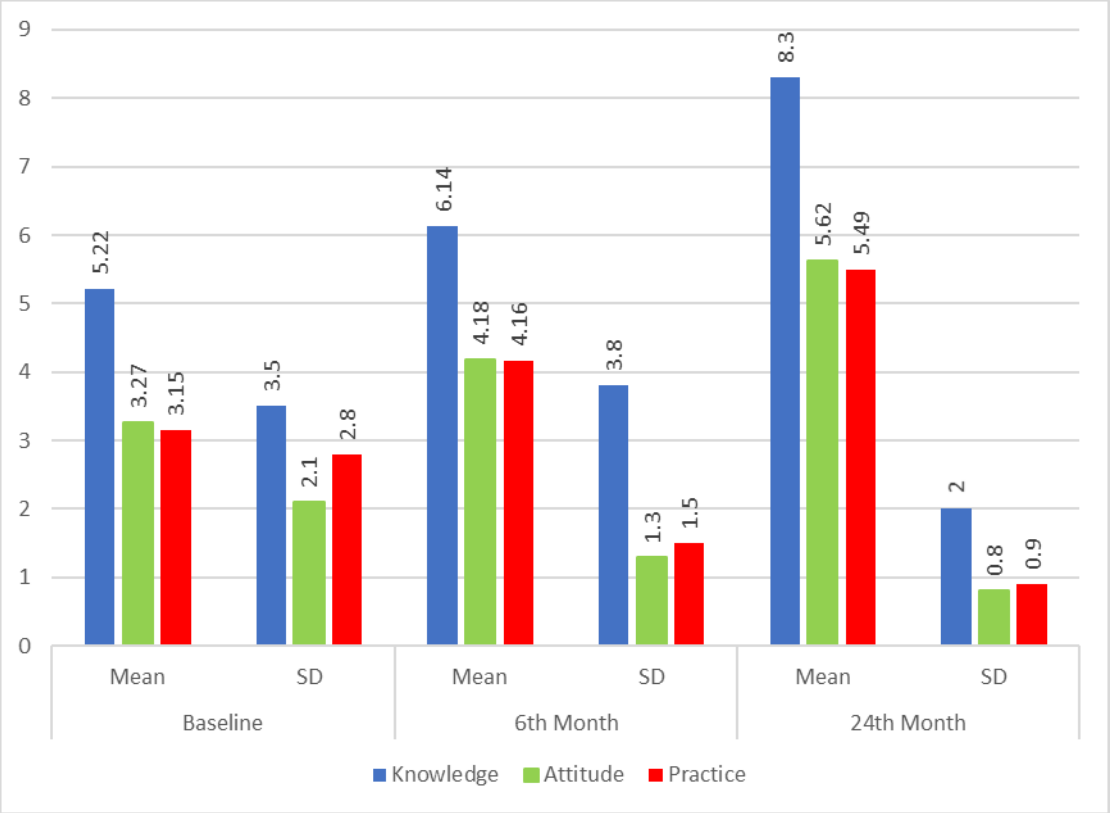
The patient education is provided to the interventional group to assess the influence of clinical pharmacist interventions in the study population at 6th month and 24th month. Patient counselling was done verbally and also printed patient information leaflets were provided. The patients were educated about disease, drugs and life style modifications. The patients were periodically followed up to assess their knowledge, attitude and practice towards diabetes and its treatment. The impact of interventional group KAP was depicted in the table 49.

Table 49: Knowledge, Attitude and Practice of Interventional Group over 24 Months

Variables	Baseline	6th Month	*p* value	6th Month	24th Month	*p* value
Knowledge	5.22±3.5	6.14±3.8	0.018	6.14±3.8	8.30±2.0	0.000
Attitude	3.27±2.1	4.18±1.3	0.000	4.18±1.3	5.62±0.8	0.000
Practice	3.15±2.8	4.16±1.5	0.000	4.16±1.5	5.49±0.9	0.000

Graph 1: Comparison of KAP in the Interventional Group across 24 Months.

Figure 13: Comparison of KAP in the Interventional Group across 24 Months



4.8 Assessment of Clinical Parameters

Clinical outcomes of the study participants were measured through the different clinical parameters in the control and interventional group at baseline and 24th month. Status of diabetic health of the patients was monitored through the different lab parameters like FBS, RBS, PPBS, HbA1c etc. The interventional group educated by clinical pharmacist showed better health outcome in almost all clinical parameters. These clinical parameters were measured at baseline and 24th month. The overall changes in the clinical parameters at different duration in both groups were depicted in the table 50.

Table 50: Comparison of clinical parameters in control and interventional group

Control Group				Interventional Group			p-value[c]	p-value[d]
Parameters	**Baseline**	**24th Month**	**p-value[a]**	**Baseline**	**24th Month**	**p-value[b]**		
FBS	155.59±11.1	154.48±9.0	0.366	156.62±8.1	137.98±4.3	0.000	0.364	0.000
RBS	249.81±5.4	250.33±5.9	0.441	250.59±5.7	230.46±6.0	0.000	0.229	0.000
PPBS	250.29±5.3	249.55±6.0	0.275	249.89±6.1	230.44±6.2	0.000	0.542	0.000
HbA1C	9.47±0.2	7.51±0.3	0.000	9.5±0.3	5.4±0.3	0.000	0.310	0.000
TC	300.75±12.4	280.07±11.6	0.000	298.67±12.5	211.17±6.5	0.000	0.150	0.000
TG	281.19±11.2	278.95±11.4	0.103	282.07±11.2	189.98±5.7	0.000	0.495	0.000
LDL	190.21±5.5	180.03±5.6	0.000	190.07±5.8	159.98±5.8	0.000	0.824	0.000
HDL	37.65±1.4	39.43±2.9	0.000	37.09±2.8	52.32±4.6	0.000	0.028	0.000
SBP	150.33±5.6	145.19±2.9	0.000	151.55±5.8	125.76±2.5	0.000	0.068	0.000
DBP	94.52±2.5	92.75±1.5	0.000	94.87±2.6	87.23±1.60	0.000	0.240	0.000

a: Baseline versus 24th month in the control group.
b: Baseline versus 24th month in the interventional group.
c: Baseline of control group vs baseline of interventional group.
d: 24th month of control group vs 24th month of interventional group.

5 DISCUSSION

5.1 KAP of study participants

The quality of care in diabetic mellitus patients was estimated using a KAP study. The study included 300 patients with age 18 years and above. Of the total population, 72.67% were male and 27.33% were female. The age group below 30 years accounted only for 2% of the entire population, the age group of 31–50 years was found to be 29.33% of the entire population, while the age group (50 years and above) consisted of 68.67% of the entire population. In a study performed by Jaiswal of the 100 patients, 61% were male and 39% were female and 46% fell within the age group of 41–60 years [126]. The results of this study were found to be consistence with previous studies and indicated that 94% of the patients were aware about high blood sugar levels and 90% were aware of monitoring it [127].

Our study was conducted to assess the KAP of patients suffering from type 2 DM in a tertiary care hospital. In the study, 56.33% of the subjects suffered from various complications, which include coronary artery disease (46%), CKD (27%), diabetic neuropathy (22%), diabetic retinopathy (17%), cerebrovascular disease (15%), and diabetic foot (11%).

According to a study conducted in Central India by Jaiswal, it was found that hypoglycemia and its manifestations were very common symptoms known by 85% of study participants. Other complications included vasculopathy (78%), neuropathy (68%), and retinopathy (68%).(127) In the Gana population, a study revealed that the most common diabetic complexiety in DM patients was a diabetic foot (51.5%), HTN (35.4%), neuropathy (29.2%), and nephropathy (5.4%) by Obirikorang *et al* [128]. Hypertension and type 2 DM are the most common comorbidities seen in both IHD

(40%) and CAD patients (38%) [129]. The study results demonstrated that 69.5% (*n* = 139) of the subjects were literate and 30.5% (*n* = 61) were found to be illiterate. (128)
A study conducted by Kant and Thapliyal revealed that out of 200 type 2 DM patients selected for the study, 22 patients were illiterate, 18 patients had completed primary level education, 24 patients had completed secondary/middle school education level, 26 subjects were graduates and only 10 patients were postgraduates [130].

The study results revealed that out of the total subjects, 82% (*n* = 164) were found to be non-alcoholic and only 18% (*n* = 36) of the subjects were found to be alcoholic. A study by Jaiswal showed that 16% of people decided to abstain from alcohol consumption. The study results demonstrated that out of the total subjects, only 22.5% (*n* = 45) of subjects consumed tobacco and 77.5% (*n* = 155) of the subjects did not consume tobacco [127].

A study by Jaiswal showed that smoking and tobacco were given up by 30% of the patients [127]. Another study by Shah *et al*. showed that only 7.14% of patients agreed that they should stop smoking and consuming alcohol to control DM [131].
Our study population was divided into three age categories; the 19–40 years of age group consisted of 20 subjects (10%). 73 subjects (36.5%) were grouped under the age group of 41–60 and 61 years and above containing 108 (54%) subjects. Among this age group, 41–60 had better knowledge as compared to the other two classes whereas better attitude and practice towards DM was observed in the age group 61 and above as compared to the other two groups.

Among the 300 subjects, 113 (57%) subjects were male and 60 (30%) subjects had a better attitude toward DM and 87 (43%) were female of which 47 (23.5%) had a better attitude towards DM. Our survey depicted that the male patients had better

knowledge and attitude toward DM than the female population, but female subjects had a good practice. Even though better knowledge and attitude toward DM were found in patients with a disease duration of 0–4 years, patients with a disease duration of 8 years and above had better practice.

The primary goal of our KAP study was to identify and document the levels of KAP s in a variety of type 2 diabetes patients. The knowledge of the participants was evaluated based on their understanding of DM, such as fundamental knowledge of DM, causes, complications, measuring BGLs, lifestyle changes, and so on. The research included 200 in-patients in total. We observed that majority of the participants were above the age of 30 years. Our study portrays the measure of participants with good knowledge at 31.5% (n = 63), with good attitude towards the disease at 24% (n = 47), and the ones exhibiting good practice were found to be at 13% (n = 107).

The study results demonstrated that there were minimal differences in KAPs irrespective of the differences in gender, education, and duration of the disease. Only four exceptions were observed within this study, the participants aged <50 years had better knowledge and attitude compared to patients more than 50 years of age (P < 0.01). Furthermore, literate participants were found to have statistically greater knowledge than the illiterate subjects and the difference was statistically significant. It was also noted that there was a statistical difference in the practice domain, the participants with a disease duration of more than 5 years were found to have better practice than the subjects with <5 years of duration of disease.

The outcomes of knowledge and demographics of the study sample suggested that the male participants (n = 89) exhibited more knowledge than female participants (n = 42). There was no significance (P = 0.10). The participants suffering from the

disease/condition for more than 5 years (*n* = 101) showcased more knowledge than participants suffering from the illness for <5 years (*n* = 40). The *P* value is significant for the knowledge of the duration of the disease (*P* < 0.0001). In our study, the literate subjects (*n* = 91) expressed more knowledge than illiterate subjects (*n* = 29) and there was found statistically significant (*P* = 0.0001). The participants belonging to the age group greater than 50 years (*n* = 95), had more knowledge than participants who were below the age of 50 years (*n* = 36). The outcomes were statistically significant (*P* < 0.01).

The outcomes of attitude and demographics of the study sample suggested that the male participants (*n* = 102) showed better attitudes toward the disease compared to female participants (*n* = 42) in the study. Our study exhibited that participants suffering from the condition for more than 5 years (*n* = 85) had a better attitude toward the disease compared to the participants suffering from the condition for <5 years (*n* = 42). The literate participants (*n* = 61) expressed a better attitude than the illiterate participants (*n* = 42). In our study, it was found that the participants belonging to the age group greater than 50 years (*n* = 109) had a better attitude toward the disease than participants who were below the age of 50 years (*n* = 35). The outcomes of practice and demographics of the study sample suggested that the male participants (*n* = 92) exhibited more practice than female participants (*n* = 62). The *P* value is not significant for the practice in gender distribution (*P* < 0.0001). In our study, the participants suffering from the disease for more than 5 years (*n* = 108) showcased better practice than patients suffering from the illness for <5 years (*n* = 44). The *P* value is not significant for the practice in the duration of the disease (*P* < 0.0001). In the study, the literate subjects (*n* = 28) expressed better practice compared to illiterate subjects in the study (*n* = 18). The participants in our study, belonging to

the age group greater than 50 years (*n* = 98) had better practice compared to the participants belonging to the age group lesser than 50 years (*n* = 55).

A study by Manju *et al*. revealed that the age of participants below 40 years had mean knowledge (58.87), and participants between the ages of 40–60 years had mean knowledge (56.65), and participants above or equal to the age of 60 years had mean knowledge (59.48) towards DM. The attitude was also high in patients in the age group (≥60 years). The age group <40 years showed better practice (65.03%). In the study, males showcased better knowledge (59.07%), as compared to females (57.36%), and also the attitude followed was slightly better in males (78.27%) than in females (76.66%). The practice exhibited by male participants were better (62.13%) when compared with female participants (57.65%). The participants with a degree or above qualification (72.58%) showed better knowledge compared to participants with primary qualifications (47.94%) [129].

A study by M. Niroomand showcased that the participants in the male category (62.44 ± 12.22) showed better knowledge than female participants (60.25 ± 12.45) and also have a better attitude towards the disease (49.95 ± 27.56) than female patients (44.04 ± 27.56). Female participants exhibited better practice (54.45 ± 18.4) than male participants (50.26 ± 17.53). In the study, the patients belonging to the category of >60 years of age, showed that these participants had better knowledge and attitude at (63.38 ± 12.45) and (49.38 ± 28.50) than the participants belonging to the age group of ≤60 years showed slightly better practice (53.21 ± 18.70) than patients in the age group of >60 years at (51.34 ± 17.42) [132].

In a study by P. K Rani *et al*. it was found that the participants between the age group of 26–35 years (*n* = 113) showed knowledge of (41.2%), the age group of 36–45 years (*n* = 161) showed knowledge of (52.6%) and the age group above 45 years (*n* = 186)

showed knowledge of (54.1%). Furthermore, female participants (*n* = 609) had better knowledge (51.7%) than male participants (*n* = 357) (47.0%). Participants with graduate and above education qualifications (*n* = 446) showed better knowledge (82.0%) than those with only primary education qualifications (*n* = 3) (9.4%) [133].

5.2 DUE of antidiabetic Drugs

Diabetes is a crucial health concern in India. The World Health Organization describes diabetes mellitus (DM) as a chronic metabolic disorder characterized by elevated blood glucose (or blood sugar) levels that, over time, adversely affect to the heart, blood vessels, eyes, kidneys, and nerves [134]. The World Health Organization defines drug usage as the promotion, distribution, prescription, and use of pharmaceuticals in a community while considering the social, medical, and financial consequences [135]. By 2030, there will likely be 80 million diabetes patients in India, up from 32 million in 2000, according to the WHO. The worrisome rise in diabetes prevalence in India calls for increased public awareness of the disease's causes and consequences [136].

After 300 diabetic participants were examined during the course of the study, it was shown that men were more likely than women to have diabetes (72.60% vs. 27.30%). A few studies by Lisha et al., Saiyad et al., Ramesh R et al., contradicted our findings, finding a high proportion of diabetes in female patients. A similar study by Vengurlekar S et al., Boccuzzi SJ et al., Johnson et al., Yurgin N et al., found that males had a higher prevalence of diabetes than females [137-139].

In this study, individuals aged 51–60 and 61–70 constitute a majority of diabetes patients (27.33% and 24.67%, respectively). Our results were in line with the observations made by Upadhyay et al. and Venkateswaramurthy et al. about a higher incidence of diabetes in the same age range. (138) Our research revealed that a greater

number of patients were overweight and obese. Boffetta et al. claimed that there was a direct correlation between Asian people's BMI and the prevalence of diabetes [136]. The majority of the patients in our study had DM for less than ten years. These results were similar to those of the Siddiq an et al. investigation [140].

Comparable to Pankaj CK et al., the current study indicated that the number of medications per prescription was higher—two per prescription [141]. In contrast to the findings of Ashutosh K et al., which suggested that the upper middle socioeconomic class was predominant, the greater number of the patients in this study were below middle socioeconomic class [134]. The cost of medication per month in our study was between 100 and 200 rupees, but it was less in Pankaj CK et al.'s investigation. Similar findings were found by Siddiq an et al. regarding the larger number of patients using diabetes drugs twice a day [140].

Our research indicates that insulin was typically given to hospitalized patients in the medicine ward, either as a monotherapy or in conjunction with oral antidiabetic drugs. The most typically given insulin preparation was regular insulin (44.00%), which was followed by NPH insulin mixtard (14.00%), a finding that was also observed in the study conducted by Gautam et al. [142]. For Type 2 Diabetes, metformin was the medication most frequently recommended (54.00%). In either a monotherapy or polytherapy setting, metformin was given after glimepiride (26.00%). Numerous other research conducted across the nation yielded similar results [142]. Patients admitted to inpatients wards with co morbidities often need insulin, because of its safer profile and quicker onset of action, which is why prescriptions for insulin, especially regular insulin, are becoming more common. This enhances the glycemic control of hospitalized patients and lowers the possibility of medication interactions [143].

Glimepiride has become a front-line treatment for SU due to its long t1/2, increased extra-pancreatic activity, decreased hyperinsulinemia, and decreased incidence of hypoglycemia. Because of significant postprandial hyperglycemia with controlled Fasting Plasma Glucose (FPG) in the majority of these follow-up encounters, an alpha-glucosidase inhibitor was used as an adjunct therapy as a dual medication regimen in 44 prescriptions with metformin. This was done in compliance with the 2016 International Diabetes Federation standards [144].

Out of 300 patients, only 102 prescriptions contained Voglibose 54 (18.00%), Acarbose 32 (10.66%), and Miglitol 16 (05.33%), which are comparable results to those reported in the study by Lahiry S et al. Compared to voglibose, it was against the data that supported the use of acarbose as a first-line adjuvant for lowering cardiovascular mortality in individuals with type 2 diabetes [144].

In total, 80 patients (17.66%) used thiazolidinediones as monotherapy; pioglitazone and rosiglitazone are used as add-on therapies by 53 patients (17.66%) and 27 patients (09.00%), respectively, according to identical findings by Pankaj CK et al. [141]. Metformin and thiazolidinedione prescriptions were prescribed together in 80 (26.66%) of the prescriptions. Despite the fact that pioglitazone and metformin together have been shown to reduce cardiovascular morbidity and insulin resistance, our analysis revealed that this class of medication is underutilized, possibly as a result of adverse effect concerns [141,144].

Among the 61 prescriptions (20.33%) containing DPP4 inhibitors were Vildagliptin 41 (13.66%), Linagliptin 14 (04.66%), and Tenegliptin 06 (02.00%). A study conducted by Pankaj CK et al. discovered a comparable outcome in relation to biguanides and sulfonylureas. Contrary to the findings of the current study, Truter I and Boccuzzi SJ et al.'s late 1990s investigations conducted in South Africa, the US,

and India reported that sulphonylureas were the most widely given antidiabetic drug [141]. In the trial, the GLP-1 analog Exenatide 06 (02.00%) is a less commonly used antidiabetic medication.

This analysis revealed that the majority of patients utilized a combination medication regimen of metformin plus sulfonylureas 162 (54.00%), which was also the case in the study by Lahiry S.et. al. [144]. Which was followed by Metformin + regular insulin (132; 44.00%) and Metformin + thiazolidinediones (80; 26.66%).

The most frequently prescribed three drug combinations were Metformin + Sulfonylureas + DPP4 inhibitors (117; 39.00%). The most frequently prescribed four drug regimens were 24 (08.00%) Metformin + glimepiride + pioglitazone + Voglibose, and 18 (06.00%) Metformin + voglibose + NPH insulin + normal insulin [139].

In our analysis, we discovered that the average number of prescriptions prescribed for antidiabetic medication was nearly half that of prescriptions written by Okoro RN et al. [145]. When data for WHO drug use indicators were analyzed, an average of 58.60% of prescriptions were written using the generic name. This was significantly more than Acharya et al.'s study [146]. In our analysis, the percentage of cases where antibiotics were administered was 22.22%. In our investigation, the percentage of prescriptions containing injections or injectable medications was 29.91%, exceeding the established standard value for the WHO (13.4-24.1%) [147] and less than the amount that Sahu G et al. [142]. Our analysis indicates that 82.17% of medications prescribed from NLEM, while a study by Hannan A et al. indicated that the percentage was 65.82% [148]. We found 98.29% of encounters with fixed drug combination.

The use of anti-diabetic medications in various age groups with differing disease durations has been documented in this study. The prescription patterns indicate that a broad range of antidiabetic medications, such as oral hypoglycemic medicines and various forms of insulin, were used by the research population. Given that diabetes is a chronic metabolic disease, research should be done on the cost of treatment, long-term effects, impact on co-existing illnesses, and adverse drug reactions that can occur from long-term use of diabetic drugs in order to improve quality of life.

5.3 Health Related Quality of Life

The findings of this study are consistent with other studies that looked at how interventions affected the HRQoL of diabetics. A meta-analysis by de Groot *et al* [149]. found that treatments centered on dietary modifications, physical activity, and self-management education improved the HRQoL of diabetics. Our study's findings also imply that a lifestyle modification-focused intervention can significantly enhance HRQoL.

Another study conducted by Rubin *et al*. [150]. investigated how a peer mentorship intervention affected the health-related quality of life (HRQoL) of diabetics. According to the study, the intervention greatly enhanced mental, physical, and vitality well-being. These results are in line with our study's findings, which also showed that the interventional group's physical functioning, vitality, and emotional role functioning all significantly improved.

The present study is distinctive, though, in that it focuses on how the intervention affects people with diabetes who are illiterate or who have had the disease for a longer period of time. According to the study's findings, lifestyle changes and interventions can enhance HRQoL in people with diabetes, including those with lower literacy levels and those who have had the disease for a longer period of time. This is an

important discovery because diabetic therapies frequently fail to take these populations into account.

Furthermore, our research contributes to the paucity of literature on the effects of therapies on the health-related quality of life (HRQoL) of diabetics in low- and middle-income nations. Our work offers valuable insights into the efficacy of interventions in low- and middle-income nations, as the majority of studies on this subject have been carried out in high-income countries. According to the findings, lifestyle modification-focused therapies can significantly raise the HRQoL of diabetics in these situations.

Overall, the results of this study are in line with earlier investigations into how interventions affect the HRQoL of people with diabetes. The study offers crucial insights into the efficacy of therapies in low- and middle-income countries, but it stands out for concentrating on people who are illiterate or have had diabetes for a longer period of time.

5.4 Adverse drug reactions

The current study has documented the occurrence and attempted to characterize likely adverse drug reactions (ADRs) associated with antidiabetic medicines in the diabetes outpatient and inpatient scenario in the Indian context. Insulin is not on this list of drugs, and pharmacovigilance profiling of anti-diabetic treatments is lacking in India, despite reports of ADR profiles of individual pharmaceuticals. Insulin-induced hypoglycemia was the most often reported adverse event in the majority of drug consumption studies [151]. The Schumock and Thornton criteria are used to assess the level of preventability of adverse drug reactions. These modified criteria have been used in numerous studies. It is separated into three categories: things that are definitely or totally preventable, things that are not preventable, and things in between

[152,153]. The University of Toronto's Naranjo and colleagues created the Naranjo Scale to determine whether an ADR is likely to be caused by a certain medicine or by other variables. Multiple studies have employed this tested technique. Ten questions on this scale can either be answered "Yes", "No" or "Do not know". For each response, a different point value (1, 0, + 1 or + 2) was given. Total scores can vary from 4 to +13; the reaction was considered certain if the score was 9 or higher, probable if it was between 5 and 8, conceivable if it was between 1 and 4, and questionable if it was 0. Of the observed ADRs, 26.92% in male and 19.23% in female belongs to control group and 27.88% in male and 25.96% in female were identified in interventional group. Age group belonging to >70 years were more prevalent to develop ADRs followed by age group 61-70. This is consistent with earlier findings, as demonstrated by a study by Mishra S. et al. [153], in which the total number of males in the study was 68 (56.7%), while females were 52(43.3%). The age group of 21 to 30 around 1.92% accounted for ADRs. Similarly, 7.69% of ADRs in 31-40 age group, 13.46% in 41-50 group, 51-60 age group accounted for 19.23% of ADRs, 61-70 had 24.03% of ADRs and age group of above 70 had 33.65% of ADRs. Similarly, Singh et al. found 11.8% of ADRs [154] in their study. (Name the author) ADR was found at 27.6% in one research [155]. In a study conducted by Saravanan K et al., the potential adverse drug reactions of drugs used in diabetes patients were observed in 35 patients (46.66%), with the majority of them being male (27 out of 35). Type A adverse drug reactions were identified during the phase of the study (Hypoglycemic, Diarrhea, Vomiting, Giddiness, Abdominal Distension) [156]. In our study the commonly observed ADRs were seen with hypoglycaemia i.e 20(19.23%) followed by 10 (9.61%) ADRs were weight gain and gastrointestinal system-related ADRs like diarrhea 10 (9.61%), constipation 6 (5.77%), gastric irritation 6 (5.77%) and 5 (4.80%) dyspepsia. A study

carried out in Italy found that 3,416 (2.3%) of the 1,48,289 gathered ADR reports were related to antidiabetic drugs [157]. Severe hypoglycemia (nearly 50% of significant ADR reports), primarily brought on by insulins or sulfonylureas, lactic acidosis from metformin, and pancreatitis from incretins were the most commonly reported serious ADRs. In that study, metabolic disorders were the most common ADRs for sulfonylureas and biguanides. The gastrointestinal system was the area most commonly impacted by alpha-glucosidase inhibitors, glucagon-like peptide-1 mimic, and dipeptidyl peptidase-4 (DPP-4) inhibitors [156-158]. In our study, frequency of ADRs among various anti-diabetic drugs revealed that the commonest ADR observed was hypoglycemia 19.23% and weight gain 9.61% caused by the drugs such as insulin, glimepiride, sitagliptin, metformin, voglibose, linagliptin. Cough accounted for 5.77% ADRs by the drugs insulin, sitagliptin, linagliptin. Lipodystrophies are characterized by an improper distribution of body fat, which can be inherited or acquired and can have either a generalized or a more focused (partial) distribution [158]. Investigations are still underway to identify the mechanism of hypoglycemia unawareness and defective insulin counterregulation. Recent investigations have proven the significance of hypoglycemia as a barrier to safe treatment. Previous episodes of severe hypoglycemia, hypoglycemia unawareness, impaired insulin counterregulation, and several coexisting illnesses such renal disease, malnutrition, coronary heart disease, and liver disease are all risk factors for severe hypoglycemia. In addition to self-monitoring of blood glucose (SMBG) via finger-stick testing, new minimally invasive continuous monitoring of glycemia shows promise in achieving improved control with increased safety [159]. According to the results it was observed that 48.07% were probable in which 22.15% in the control group and 26.92% in the intervention group. Total of 41.34% possible ADRs were significantly observed of which 18.26% in

control and 23.07% in intervention groups. ADRs were classified based on Naranjo algorithm, in which probable and possible were 55 (52.88%) and 40 (38.46%) respectively. The most effective treatment approaches for insulin-induced lipodystrophy are non-reuse of needles and rotation of injection sites with each injection. Injections of dexamethasone topically have been tried to treat insulin-induced lipoatrophy. Recognizing and effectively managing these problems are crucial. Irregular insulin absorption might result in variable glycemic levels and sudden episodes of hypoglycemia [159]. In a study by Tripathi CB et al., the severity evaluation revealed that the treatment group had 76% mild and 24% moderate responses, whereas the preventive group had 89% mild and 11% moderate reactions. ADR severity was much greater in the treatment group. With the exception of gastritis, nausea, and vomiting, the majority of ADRs fell into the nonpreventable group according to the Modified-Schumock and Thornton scale [160]. In our study, distribution of ADRs was done based on preventability assessment using Modified Schumock and Thornton scale of which 61.53% of ADRs were definitely preventable, 29.80% of ADRs were probably preventable and 8.65% of ADRs were non-preventable. The severity assessment using Modified Hartwig and Siegal scale where 21.15% accounted for mild ADRs, 71.15% for moderate ADRs and 7.70% for severe ADRs. This agrees with previous reports as shown in a study by Shareef et al. [161].

5.5 Drug related problems

Since PCNE classification was relatively new at the time of the study's inception and Strand et al. and Cipolle et al.'s classification systems had been extensively utilized in previous research, our study employed PCNE Version 9.1 to categorize drug-related problems. Furthermore, there is no consensus on the preferred method or framework for categorizing DRPs according to the population or the disease. Unlike the systems

of Strand et al. and Cipolle et al., we selected this categorization scheme since it included a large number of elements under which problems were categorized.

In our study, the rate of occurrence of DRP was 1.07 per patient. Among the identified DRPs there were 131 DRPs from 150 subjects in the control group with DRP occurrence rate of 0.87, and 190 DRPs from 150 subjects in the interventional group with rate of occurrence of DRP of 1.26. DRPs in patients with co-morbidities such as type 2 diabetes are becoming a major issue concerning quality of life of the patients [162]. A substantial increase in DRPs were observed, that can only be rectified by necessary clinical pharmacist interventions. Out of 300 diabetic patients in a tertiary care hospital, both control and interventional group were identified with DRPs. The age group of 61-70 and >70 years were found with maximum DRPs.

The total number of DRPs identified account for 321. Further, after identifying the DRPs, recommendations were provided by the clinical pharmacist to resolve a total of 412 DRPs, in which 330 (80.10%) recommendations were accepted. Out of the accepted recommendations, 231 (70.00%) were totally solved, 72 (21.82%) were partially solved and 27 (8.18%) were not solved. There were 82 non-accepted recommendations in which, 59 (71.95%) were not feasible and 23 (28.05%) were with unknown reasons.

In our study, maximum number of DRPs were found in patients aged between 60-70 years, which falls in line with the study conducted by Ramnath K et. al showed 83.4% prevalence of DRPs in geriatric patients [163]. According to our study, the prescriber acceptance rate was 80.09%, which is relatively comparable to a study conducted on Belgium 87.8% [164]. The study identified 218 diabetic male patients with DRPs (72.27%), which is in line with a study conducted by Berhane Hailu et. al. accounting

for 66.3% of diabetic male patients with DRPs. The male predominance of DRPs is observed in the study compared to female population [165].

Diabetic patients aged above 60 years of age are marked with a greater number of DRPs compared to diabetic patients below 50 years, that confirms the trend of increase of DRPs above 60 years of age. This may be due to contributing comorbidities, polypharmacy and characteristic pk-pd changes with age. This implies that a regular treatment chart review of aged population by the clinical pharmacist can potentially minimize the occurrence of DRPs [166]. The study conducted by Javedh Shareef et. al. imprinted drug use without indication as the major problem leading to DRPs which is contradictory to the present study that identifies treatment effectiveness (176) as the major problem [167]. The study contains 412 accepted DRP recommendations made by the clinical pharmacist which aligns with the study conducted by Muhammad Umair Khet Et. al that enlightens high acceptance of clinical pharmacist intervention by the prescriber that contributed to better understanding of DRPs and taking efforts in solving them [168].

As per the present study, drug selection (87 DRPs), dose selection (62), drug use process (49), patient related (48), treatment duration (20) are the major causes of DRPs. Whereas, a study conducted by Lotte stig et. al in diabetic patients, inappropriate use of drug by patients and insufficient drug monitoring were found as the major causes of DRPs [169].

In the present study, out of 412 Outcomes of interventions made, 375 (91.01%) Problems were totally solved, 30 (07.28%) partially solved and 7(1.69%) Problems were not solved, due to number of reasons including lack of cooperation of the prescriber. Therefore, the outcome of the interventions signifies the importance of clinical pharmacist role in the better management of DRPs and patient well-being.

The demolishment of DRPs in any therapy ensures effectiveness of the treatment and thereby, treatment optimization.

5.6 Patient Education/Counselling

The patient education plays a very significant role in managing diabetes mellitus. Overall, the patient counselling imparted by clinical pharmacist improved the health of the diabetic patients in the study population. The comparison of effectiveness of patient counselling on the level of knowledge, attitude and practice towards disease were assessed by using KAP Questionnaires. The interventional group displayed a significantly higher KAP compared to the control group which was similar to the studies conducted by Malathy, et al. [170] and Adepu et al. [171].

The benefit of the patient education in interventional group was clearly seen in their clinical parameters. The clinical parameters progressively improved from baseline (0 month), 6^{th} month to 24^{th} month upon patient counselling. This result was aligned with the study conducted by Hening, et al. [172]. The control of all these clinical parameters are very much essential to prevent the diabetic complications and to reduce the morbidity and mortality. Thus, patient education is pivotal in demonstrating better health outcomes in individuals living with diabetes.

5.7 Medication Adherence

The MARS scale was used to measure the medication adherence in both control and interventional group. Based on their cumulative scores, the scale divides patients into groups of high (≥6) and low medication adherence (<6). The medication adherence was assessed at different time periods i.e baseline (0^{th} month), 6^{th} month and 24^{th} month in both the groups. Our study results showed that, in the interventional group, the mean score of the medication adherence at baseline was 5.56±1.48 whereas it

progressively increased to 6.56±1.47 at 24th month. While in control group, the mean score of medication adherence at baseline was 4.31±2.18 which remained almost same at 24th month i.e. 4.28±1.93. The results were in accordance with the studies conducted by Mishra R *et al*. [173] and Darmada *et al*.[174].

Due to the patient education by clinical pharmacist and motivation brought by an observable health benefits from consistent medication adherence from the start, the interventional group showed a steady rise in medication adherence which created a long-lasting adherence towards medication regimens. However, the medication adherence in the control group remained unchanged over the span of two years showing the importance of clinical pharmacist mediated patient counselling.

6 SUMMARY

In our three-year study involving 300 type 2 diabetes patients in a tertiary care hospital, we uncovered significant insights. The majority were male (72%), and most were aged 50 and above (67%), experiencing complications such as coronary artery disease and chronic kidney disease. Our findings revealed high knowledge levels; 94% were aware about high blood sugar, and 90% understood how to monitor it. Notably, patients with 8+ years of disease duration demonstrated better practices, while those with 0–4 years displayed better knowledge and attitude. Males generally exhibited more knowledge and better attitudes, whereas females showcased good practices. Breaking down age groups, those aged 41–60 had better knowledge, while those 61 and above showed improved attitudes and practices. Overall, 31.5% displayed good knowledge, 24% good attitudes, and 13% good practices in managing type 2 diabetes. Despite minimal differences based on gender, education, and disease duration, exceptions included better knowledge and attitude in those aged <50 and improved practice in those with a disease duration of >5 years.

In our study on Drug Utilization Evaluation (DUE) of antidiabetic drugs on 300 individuals, males (72.60%) had higher diabetes prevalence than females (27.30%). Patients, aged 61-70 and 51-60, were often overweight with diabetic history of less than ten years. Prescriptions typically involved two medicines costing 100-200 rupees monthly. Insulin, especially regular insulin, was common in hospital settings. Common antidiabetic medications included metformin, glimepiride, and thiazolidinediones, with pioglitazone underused. Combination therapies like metformin + sulfonylureas were extensively. Drug utilization favored generic names (58.60%), with 22.22% involving antibiotics and 29.91% injectables. The study

highlights the need for exploring therapy cost, long-term consequences, and adverse reactions for a better quality of life in chronic diabetic medication.

This study underscores the positive impact of lifestyle modifications on the Health-Related Quality of Life (HRQOL) for individuals with diabetes. Results align with prior research on interventions, emphasizing improvements in physical functioning, vitality, and emotional well-being. Unique aspects include a focus on individuals with lower literacy and longer diabetes duration, highlighting their potential benefits from lifestyle interventions. The study contributes to understanding intervention effectiveness in low- and middle-income countries, emphasizing the importance of inclusive approaches for diverse demographics and socioeconomic settings.

In our study on adverse drug reactions (ADRs) caused by antidiabetic medications in India, we aimed to fill a gap in pharmacovigilance profiling, particularly lacking information on insulin-induced hypoglycemia. Utilizing criteria by Schumock and Thornton, along with the Naranjo Scale, we found higher ADR prevalence in males and the elderly (>70 years). Common ADRs included hypoglycemia, weight gain, and gastrointestinal issues. Categorizing ADRs based on WHO-UMC Causality and Naranjo algorithm revealed mostly probable and possible ADRs. The assessment of preventability indicated that 61.53% of ADRs are definitely preventable. In terms of severity, using the Modified Hartwig and Siegal scale, 71.15% were categorized as moderate ADRs. These findings contribute valuable insights into ADRs associated with antidiabetic medications in the Indian setting.

In our study on drug-related problems (DRPs) in diabetes patients, we utilized the PCNE Version 9.1 classification system. The overall rate of DRP occurrence was 1.07 per patient, with the interventional group having a higher rate of 1.26 compared to the control group's rate of 0.87. Among the identified 321 DRPs in patients aged 61-70

and >70 years, clinical pharmacist interventions led to recommendations for resolution. Out of 412 recommendations, 80.10% were accepted, with 70.00% totally solved. The study revealed a higher prevalence of DRPs in males (72.27%) and patients above 60 years, aligning with trends of comorbidities and polypharmacy. Major causes of DRPs included drug selection, dose selection, drug use process, patient-related factors, and treatment duration. The study demonstrated the efficacy of clinical pharmacist interventions, with 91.01% of outcomes resulting in total problem resolution, emphasizing the crucial role of pharmacists in managing DRPs and optimizing treatment.

We also found that clinical pharmacist-led counselling significantly improved the health of diabetic patients. Using KAP questionnaires, the interventional group exhibited higher levels of knowledge, attitude, and practice compared to the control group, consistent with findings in studies by Malathy et al. and Adepu et al. The positive impact of patient education was evident in the progressive improvement of clinical parameters from baseline (0 month) to 6th and 24th months in the interventional group, aligning with the results reported by Hening et al. These improvements in clinical parameters are crucial for preventing diabetic complications and reducing morbidity and mortality, underscoring the pivotal role of patient education in enhancing health outcomes for individuals with diabetes. In evaluating medication adherence using the MARS scale, our study observed notable differences between the interventional and control groups. In the interventional group, the mean medication adherence score increased from 5.56±1.48 at baseline to 6.56±1.47 at 24th month, reflecting a positive trend attributed to patient education by the clinical pharmacist and sustained motivation from observed health benefits. Conversely, the control group exhibited minimal change in medication adherence, with the mean score remaining almost the same from baseline (4.31±2.18) to 24th month (4.28±1.93).

7 CONCLUSION

In conclusion, our study involving 300 type 2 diabetes patients in a tertiary care hospital has yielded profound insights into various dimensions of diabetes management. The predominance of male participants, with a majority aged 50 and above, experiencing complications like coronary artery disease and chronic kidney disease, underlines the complexity of diabetes care in this population.

The study's emphasis on patient knowledge levels, drug utilization patterns, the impact of lifestyle modifications on Health-Related Quality of Life (HRQoL), adverse drug reactions (ADRs), drug-related problems (DRPs), patient education, and medication adherence has provided a comprehensive understanding of the challenges and opportunities in diabetes management.

Noteworthy findings include the positive influence of clinical pharmacist-led interventions across multiple domains. The study revealed the critical role of clinical pharmacists in addressing drug-related issues, with a high rate of problem resolution (91.01%) observed. The efficacy of patient education and counselling by clinical pharmacist was evident in the notable improvement in clinical parameters and medication adherence among the interventional group.

The study underscores the significance of tailored interventions by clinical pharmacist in optimizing diabetes care. The higher prevalence of DRPs in males and patients above 60 years, along with the successful resolution of the majority of identified problems, emphasizes the invaluable contribution of clinical pharmacists in managing the complexity of diabetes medication regimens.

The positive trends observed in medication adherence and improved knowledge, attitude, and practices among the interventional group highlight the transformative impact of clinical pharmacist-led interventions on patient outcomes. This reinforces

the crucial role of clinical pharmacists in enhancing patient education, promoting medication adherence, and addressing medication-related issues to achieve better health outcomes in individuals with diabetes.

Overall, the study advocates for the integration of clinical pharmacists into diabetes care teams, emphasizing their pivotal role in personalized interventions that consider the unique challenges faced by patients. The insights gleaned from this research contribute to the growing body of evidence supporting the indispensable role of clinical pharmacists in comprehensive diabetes management strategies, ultimately aiming for improved quality of life and better health outcomes for individuals living with diabetes.

7.1 Limitation of the Study

The number of subjects enrolled in the study was comparatively minimal. The study was restricted in the urban area of the Hubballi. The patients were unable to stay for a longer period of time in the counselling centre because of lack of awareness and interest in the counselling sessions. Patients with different comorbid conditions were also recruited in the study, which may had led to the poor health related quality of life of the patients.

7.2 Future Directions

The study can be conducted in multiple centres with large number of subjects. The pharmacoeconomic study can also be conducted to assess the economic burden of DM.

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Annexure I: PIS

Patient Information Sheet

Role of Clinical Pharmacist interventions in the management of Diabetes Mellitus: A Randomized controlled study

Introduction:

You have been invited to take part in a research study that aims to evaluate the benefits of pharmaceutical care in addition to usual care for patients with diabetes mellitus. This study is designed to assess whether pharmaceutical interventions provided by clinical pharmacists can lead to better quality of life and improved health outcomes for individuals living with diabetes mellitus.

Purpose of study:

The primary goal of this study is to investigate whether the involvement of clinical pharmacists in the management of diabetes mellitus can result in enhanced patient outcomes, including improved quality of life. By comparing the outcomes of patients who receive pharmaceutical care along with usual care to those who receive only usual care, we hope to determine the effectiveness of pharmacist interventions in diabetes management.

Why have you been chosen to take part in the study:

You have been chosen to take part in this study because you have been diagnosed with diabetes mellitus, aligning with the study's focus on evaluating the impact of clinical pharmacist interventions on the management of this condition. Your participation is essential to address the research question, and your willingness to contribute to advancing knowledge in diabetes care is greatly valued by the research team.

What does it mean to participate?

Your participation is entirely voluntary, to help you make your decision, please read this information sheet. You are free to discuss the content of this document with a member of your family. You may take much time as you like to consider whether take

or not to take part in the study. If you chose not to take part, your current and future care will not be affected. If you agree to take part you are free to withdraw from the study at any time without loss of benefits

Once you understand what is involved in the study and you wish to participate, you will be requested to sign the consent form. If you have a question or query at any time during the research study you should feel free to ask us and obtain answers to your questions. You are not giving any of your legal rights by volunteering for this research study or by signing this consent form.

To participate in the study means that you have given your consent to be a part of this study for a duration of one-two years during which the following will be required from you.

During the study:

During the study, your eligibility will be assessed, and if you meet the criteria, you will be randomly assigned to either the interventional or standard care group using the Sequentially Numbered Opaque Sealed Envelopes (SNOSE) method, ensuring a fair 50:50 chance of allocation. Participants in the interventional group will receive education and counselling sessions covering various aspects of diabetes management, including global and Indian scenarios, basic understanding of diabetes, prevention and control strategies, different antidiabetic medications, medication adherence improvement, and the role of clinical pharmacists in community awareness on diabetes. In contrast, participants in the standard care group will receive a checklist for noting the number of enrolled patients within a specified timeframe, followed by regular physician care. This study aims to assess the impact of these interventions on diabetes management outcomes.

Further contact after completion of baseline data collection:

After the hospital visit or follow-up we will ask you some question about your health, daily activity and lifestyle. Subsequently, we will also collect your routine information from the hospital record and your follow-up in OP.

Benefits from the study:

By patient counselling and education sessions, you may have a good amount of knowledge regarding diabetes, its cause, normal blood glucose levels, complication, and prevention. It improves the medication adherence and quality of life of participants. All the services to the patients in this study will not be charged for money and will be for free.

What are the risks in participating in the study:

By participating in this study, we don't expect that you will come across any dangerous event because of the study. The study doesn't have any potential intervention, the study involves clinical pharmacist education and counselling sessions, and other interventions if any will be made through our education modules.

Who has reviewed the study?

This study has been reviewed by the institutional ethics committee, which has responsibility for scrutinizing proposals for medical research on humans. The reviewing committee has raised no objection from the point of view of medical ethics.

Inquiries/ Questions:

If you have any research question, develop a research-related problem or note a change in your condition, you may contact any of the following Dr. AHM Viswanatha Swamy, Research Supervisor, HOD, Department of Pharmacy Practice, KLE College of Pharmacy, Hubballi-580031. Mob No 9448667355, Email ID-vmhiremath2004@gmail.com. If you wish to find out more about the IRB, contact the local institutional ethics committee of the academic affairs department, KLE Academy of Higher Education and research, Nehru Nagar, Belagavi - 590010.

"Thank you for taking to read this information sheet. If you wish to take part in this study, please sign and date the consent from given to you, you will be given a copy of the information sheet and your signed consent form."

Participant initials: _____

Annexure II: ICF

Role of Clinical Pharmacist interventions in the management of Diabetes Mellitus:

A Randomized controlled study

Participant Information Sheet

Version 1.0 Dated: April 2018

Study Site: The study will be conducted in the Vivekanand General Hospital, Hubli, 580031

Investigator's Name: Dr. Sanatkumar B Nyamagoud

Part-Time Ph.D Research Scholar

Department of Pharmacy Practice

KLE College of Pharmacy, Hubballi - 580031.

Mob No.: 7795641008, Email ID: dr.sanathnyamagoud@gmail.com

Introduction:

I am Dr. Sanatkumar B Nyamagoud, working for the Diabetes mellitus research. We are doing research on Role of Clinical Pharmacist interventions in the management of Diabetes mellitus Prevention and Care, which is a dangerous epidemic disease, threat to life is a major public health problem accounting for substantial morbidity and mortality in the country. I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them to me or, the study supervisor Dr.A.H.M.Viswanatha Swamy, Professor and Head, Department of Pharmacy Practice, KLE College of Pharmacy, Hubballi-580031.

At least 50% of diabetes mellitus patients are estimated to seek treatment, WHO recommendation on clinical pharmacy services and involvement of clinical pharmacist engaging ward round participation, medication error, medication adherence, identification of drug related problems, adverse drug reaction reporting and patient counselling has been translated into programmatic policy, strategy and intervention in low and middle-income countries. To ensure proper management in diabetes mellitus patients and their contacts and to reduce the complications of diabetes mellitus it is essential to collect complete information for all diabetes mellitus patients.

Purpose:

Our objectives are to assess the role of Clinical Pharmacist interventions in the management of diabetes Mellitus. To assess the impact of pharmaceutical care activities like patient education, improving medication adherence, identification and prevention of medication error, identification and prevention of drug related problems, adverse drug reaction reporting and patient counselling. To increases the compliance towards anti-diabetic drugs and to improve the overall health quality of life.

Research intervention:

This research study involves two groups 1) interventional group and 2) standard care group. For interventional group clinical pharmacist will provide patient counselling and education about diabetes and awareness includes distribution of diabetes mellitus information leaflets to diabetes patients, diabetes suspects as well as to any other patient who wish to know/need to know more about diabetes, Arrange and conduct group awareness activities. The patient counselling includes, a patient should be made aware that diabetes is a life-threatening disease and treatment is only effective if all prescribed drugs are taken regularly for the entire prescribed duration. Then clinical pharmacist has to be explaining what is diabetes and how it will effect, what are the normal ranges in different time interval and food intake, symptoms of diabetes, complication of diabetes, treatment of diabetes either from private or public sector. Information about taking some of the drugs or irregular taking of drugs is dangerous and makes the disease incurable, Motivation of the patient with respect to treatment requirements and expected duration of the treatment. Amount, frequency and duration of drugs, possible side-effects of drugs, Frequency and importance of blood glucose examinations,

examination and maintenance of HbA,C, importance of diet, patients who smoke should be motivated to make an informed decision to stop smoking. All cases should be informed personally about the harmful effects of smoking and alcohol consumption on health in general and the potential for poorer outcomes of health related quality of life. Give a copy of any DM information leaflet available. Telephonic interview and diabetes patient's home visit will be made whenever required. On the other, for standard care group only check list will be provided in which number of patients visits in certain period of time will be noted and followed with normal physician care. During which participants of both the groups will be monitored for study outcomes.

Participant Selection:

The target population for this study includes, patients diagnosed with diabetes mellitus from out and in-patient department of general medicine.

Voluntary participation:

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this and from this hospital will continue and nothing will change. You may change your mind later and stop participating even if you agreed earlier, even without giving any reason.

Study procedure:

Your eligibility for this study will be assessed. If you match eligibility criteria of the study, you will be allotted for one out of the two groups. Sequentially numbered, opaque, sealed envelopes (SNOSE) method will be used to allocate you in either of the group. By this method you will be having 50:50 chances in allocating in any of the two groups.

If you are in interventional group, education and patient counselling will be conducted which includes get introduced to Global and Indian DM scenario, understand basics of diabetes (DM), understand the principles and strategy of diabetes prevention and control, different antidiabetic medications including oral hypoglycaemic agents and insulin preparations, Understand how to improve medication adherence and health

related quality of life and Understand role of clinical pharmacist in generating community awareness on DM.

If you are in standard care group only checklist will be provided in which number of patients to be enrolled in certain period of time will be noted and followed with physician care.

Duration of the study:

The research takes place over one year to two year. During that time, it is necessary to enrol and monitor the diabetes patients.

Risk involved participating in the study:

By participating in this study, we don't expect that you will come across any dangerous event because of the study. Study don't have any potential intervention, study involves clinical pharmacist education and counselling sessions and other interventions if any will be made through our education modules.

Benefits involved participating in the study:

By the patient counselling and education sessions you may have good amount of knowledge regarding the diabetes, its cause, normal blood glucose levels, complication and prevention. It improves the medication adherence and quality of life of participants. All the services to the patients in this study will not be charged for money and will be for free.

Incentives:

Your participation in this study will not incur any expenditure and it is purely academic research, hence you will not be paid any incentive for participation in this study.

Confidentiality:

It is possible that if others in the community are aware that you are participating in this research, they may ask you questions. We will not be sharing the identity of those participating in the research with anyone. The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will not be identified by name and address of the patient, contact

number, E-mail address. Only the researchers will know what your number is and they will not misuse any of your details. It will not be shared with or given to anyone.

Sharing the Results:

The knowledge that we get from doing this research will be shared with you if you are interested before it is made widely available to the public. Confidential information will not be shared. There will be small meetings in the KLE academy of higher education and research, research committee and these will be announced. After these meetings, we will publish the results in scientific journal in order that other interested people may learn from our research.

Right to Refuse or Withdraw:

You are having rights to withdraw from the study at any time.

Whom to Contact:

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following Dr. A.H.M.Viswanatha Swamy, Research Supervisor, HOD, Department of Pharmacy Practice, KLE College of Pharmacy, Hubballi-580031. Mob No 9448667355, Email ID-vmhiremath2004@gmail.com.

This proposal has been reviewed and approved by local institutional ethics committee of Hubballi and Academic Affairs Department, KLE Academy of Higher Education and Research, Belagavi, 590010, which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact local institutional ethics committee of academic affairs department, KLE Academy of higher education and research, Nehru Nagar, Belagavi - 590010.

Certificate of consent:

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. 1 consent voluntarily to participate as a participant in this research and understand that I have the right to withdraw from the research at any time without in any way affecting my medical care.

Name of Participant _____

Signature of Participant _____

Date _____

(Day/month/year)

Impartial Witness (if participant is illiterate)

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness _____ and Thumb print of participant

Signature of witness_____

Date _____

(Day/month/year)

I have accurately read or witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print Name of Researcher _____

Signature of Researcher _____

Date _____

(Day/month/year)

A copy of this Informed Consent Form has been provided to participant _____ (initialled by the researcher/assistant).

ಮಧುಮೇಹದ ನಿರ್ವಹಣೆಯಲ್ಲಿ ವೈದ್ಯಕೀಯ ಔಷದಿ ತಜ್ಞರ ಪಾತ್ರ: ಎ ರಾಂಡಮೈಸ್ಡ್ ಅಧ್ಯಯನ

ಅಧ್ಯಯನದ ಭಾಗವಹಿಸುವ ಮಾಹಿತಿ ಹಾಳೆ

ಆವೃತಿ 1.0 ದಿನಾಂಕ ಎಪ್ರಿಲ್ 2019

ಅಧ್ಯಯನ ಸ್ಥಳ : ವಿವೇಕಾನಂದ ಜನರಲ್ ಆಸ್ಪತ್ರೆ, ದೇಶಪಾಂಡೆ ನಗರ ಹುಬ್ಬಳ್ಳಿ–31.

ಸಂಶೋಧಕರ ಹೆಸರು : ಡಾ.ಸನತಕುಮಾರ ಬಿ. ನ್ಯಾಮಗೌಡ, ಸಂಶೋಧನ ವಿದ್ವಾಂಸ,
ಫಾರ್ಮಸಿ ಪ್ರಾಕ್ಟೀಸ ವಿಭಾಗ,
ಕೆ.ಎಲ್.ಇ ಔಷಧ ವಿಜ್ಞಾನ ಮಹಾವಿಧ್ಯಾಲಯ ಹುಬ್ಬಳ್ಳಿ–31.
ಮೊಬೈಲ್ ಸಂಖ್ಯೆ: 7795641008
ಇ ಮೇಲ್: dr.sanathnyamagoud@gmail.com

ಪ್ರಸ್ತಾವನೆ:

ನಾನು ಡಾ.ಸನತಕುಮಾರ ಬಿ. ನ್ಯಾಮಗೌಡ, ಮಧುಮೇಹದ ನಿರ್ವಹಣೆಯಲ್ಲಿ ವೈದ್ಯಕೀಯ ಔಷದಿ ತಜ್ಞರ ಪಾತ್ರ: ಎ ರಾಂಡಮೈಸ್ಡ್ ಅಧ್ಯಯನ ಎಂಬ ವಿಷಯದ ಮೇಲೆ ಸಂಶೋಧನೆಯನ್ನು ಮಾಡುತ್ತಿದ್ದೇನೆ. ಮಧುಮೇಹವು ಸಾಂಕ್ರಮಿಕ ರೋಗವಾಗಿದ್ದು, ಇದು ದೇಶದ ಜನರ ಆರೋಗ್ಯವನ್ನು ಗಣನೀಯ ಪ್ರಮಾಣದಲ್ಲಿ ಕುಗ್ಗಿಸುವ ಮತ್ತು ಕ್ರಮೇಣ ಅವರ ಮರಣಕ್ಕೆ ಕಾರಣವಾಗುವಂತಹ ರೋಗವಾಗಿದೆ. ನಾನು ಮಧುಮೇಹವನ್ನು ತಡಗಟ್ಟುವಲ್ಲಿ ವೈದ್ಯಕೀಯ ಔಷದಿ ತಜ್ಞರ ಪಾತ್ರ ಬಗೆಗಿನ ಎಲ್ಲ ತರಹದ ಮಾಹಿತಿಯನ್ನು ಈ ಸಂಶೋಧನೆ ಮುಖಾಂತರ ತಿಳಿಸಲು ಮತ್ತು ಅಧ್ಯಯನದಲ್ಲಿ ಪಾಲ್ಗೋಳಲು ನಿಮ್ಮನು ಆಹ್ವಾನಿಸುತ್ತೇನೆ. ನೀವು ಸಂಶೋಧನೆಯಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳಲಿದ್ದಿರಾ ಇಲ್ಲವೋ ಎಂಬುದನ್ನು ನೀ ವೇ ನಿರ್ಧರಿಸಬಹದು. ನೀವು ನಿರ್ಧರಿಸುವ ಮೊದಲು, ನೀವು ಸಂಶೋಧನೆಯ ಬಗ್ಗೆ ಯಾರ ಹತ್ತಿರಾವಾದರೂ ಮಾತನಾಡಬಹುದು.

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ನಿಮಗೆ ಅರ್ಥವಾಗದ ಕೆಲುವು ಪದಗಳಿವೆ. ದಯವಿಟ್ಟು ಮಾಹಿತಿ ನೀಡುವ ಸಮಯದಲ್ಲಿ ನಿಮಗೆ ಅರ್ಥವಾಗದ ಪದಗಳ ಮತ್ತು ವಿಷಯಗಳ ಬಗ್ಗೆ ಕೇಳಲು ನಿಮಗೆ ಸಂಪೂರ್ಣ ಸ್ವಾತಂತ್ರ್ಯವಿದೆ ಮತ್ತು ಅದನ್ನು ಆದಷ್ಟು ಹೆಚ್ಚು ವಿವರಿಸಲು ಪ್ರಯತ್ನಸುತ್ತೇನೆ ಅಥವಾ ನೀವು ಕೆಲವೊಂದು ಪ್ರಶ್ನೆಗಳನ್ನು ನಂತರದಲ್ಲಿ ಕೇಳಲು ಬಯಸಿದ್ದಲ್ಲಿ ನಿಮ್ಮ ಪ್ರಶ್ನೆಗಳನ್ನು ನೇರವಾಗಿ ನನ್ನ ಬಳಿ ಕೇಳಬಹುದು ಅಥವಾ ಅಧ್ಯಯನ ಮೇಲ್ವಿಚಾರಕರಾದ ಡಾ.ಎ.ಎಚ್.ಎಂ.ವಿಶ್ವನಾಥಸ್ವಾಮಿ, ಫಾರ್ಮಸಿ ಪ್ರಾಕ್ಟೀಸ ವಿಭಾಗದ ಮುಖ್ಯಸ್ಥರು, ಕೆ.ಎಲ್.ಇ ಔಷಧ ವಿಜ್ಞಾನ ಮಹಾವಿಧ್ಯಾಲಯ ಹುಬ್ಬಳ್ಳಿ–೩೧. ರಲ್ಲಿ ಕೇಳಬಹುದು.

ಅಭಿವೃಧ್ಧಿಶೀಲ ಮತ್ತು ಅನಭಿವೃಧ್ಧಿ ದೇಶಗಳಲ್ಲಿ ವೈದ್ಯಕೀಯ ಔಷಧ ಸೇವೆಗಳನ್ನು ಮತ್ತು ವೈದ್ಯಕೀಯ ಔಷದಿ ತಜ್ಞರು ತಮ್ಮನು ತಾವು ಮಧುಮೇಹ ತಡೆಗಟ್ಟುವ ಕಾರ್ಯದಲ್ಲಿ ಅಂದರೇ ವಾರ್ಡ ಸುತ್ತಿನಲ್ಲಿ ಬಾಗವಹಿಸುವಿಕೆ, ಔಷದೀಯಲ್ಲಿನ ದೋಷ, ಔಷಧ ಸೇವಿಸುವಲ್ಲಿ ನಿಷ್ಠೆ, ಔಷಧ ಸಂಬಂದಿತ ಸಮಸ್ಯೆಗಳ ಗುರುತಿಸುವಿಕೆ, ವ್ಯತಿರಕ್ತ ಔಷಧ ಪ್ರತಿಕ್ರಿಯೆಗಳ ಬಗ್ಗೆ, ರೋಗಿಗಳ ಸಮಾಲೋಚನೆ ಎಂಬ ಮುತಾಂದ ಸೇವೆಗಳಲ್ಲಿ ವಿಶ್ವ ಆರೋಗ್ಯ ಸಂಸ್ಥೆ ಒಂದು ಕ್ರಮಬದ್ಧವಾದ ನೀತಿ ಮತ್ತು ತಂತ್ರ ಗಳನ್ನು ಜಾರಿಗೆ ತಂದಿದೆ. ಅದರಂತೆ ಡಯಾಬಿಟಸ ಮೆಲ್ಲಿಟಸ ರೋಗಿಗಳ ಬಗ್ಗೆ ಸರಿಯಾದ ಮಾಹಿತಿ ಸಂಗ್ರಹಿಣೆ ಮತ್ತು ರೋಗಿಗಳಲ್ಲಿ ರೋಗದ ಬಗ್ಗೆ ಸರಿಯಾದ ಮಾಹಿತಿ ಅದರ ನಿರ್ವಹಣೆಗೆ ಕೈಗೊಳಬೇಕಾದ ಕ್ರಮಬಧ್ಧವಾದ ಕ್ರಮಗಳಿಂದಾಗಿ ಗಂಭೀರ ಸಮಸ್ಯಯನ್ನು ತಡೆಗಟ್ಟಬಹುದಾಗಿದೆ.

ಉದ್ದೇಶ :

ಮಧುಮೇಹದ ನಿರ್ವಹಣೆಯಲ್ಲಿ ವೈದ್ಯಕೀಯ ಔಷದಿ ತಜ್ಞರ ಪಾತ್ರದ ಬಗ್ಗೆ ಮತ್ತು ಮಧುಮೇಹದ ತಡೆಗಟ್ಟುವ ಕ್ರಮಗಳ ನಿರ್ವಹಣೆ ನಮ್ಮ ಸಂಶೋಧನೆಯ

ಮೂಲ ಉದ್ದೇಶವಾಗಿದೆ. ಮಧುಮೇಹದ ತಡೆಗಟ್ಟುವಲ್ಲಿ ಔಷದೀ ಆರೈಕೆಯಲ್ಲಿ ರೋಗಿಗಳಿಗೆ ಶಿಕ್ಷಣ, ಸುಧಾರಿತ ಔಷಧ ಸೇವನೆ, ಔಷದೀಯಲ್ಲಿನ ದೋಷದ ಗುರುತಿಸುವಿಕೆ ಮತ್ತು ತೆಡೆಗಟ್ಟುವಿಕೆ, ಔಷಧ ಸಂಬಂದಿತ ಸಮಸ್ಯೆಗಳ ಗುರುತಿಸುವಿಕೆ, ವ್ಯತಿರಕ್ತ ಔಷಧ ಪ್ರತಿಕ್ರಿಯೆಗಳ ವಿವರಣೆ ಮತ್ತು ರೋಗಿಗಳ ಸಮಾಲೋಚನೆಗಳ ಬಗ್ಗೆ ವೈದ್ಯಕೀಯ ಔಷದಿ ತಜ್ಞರ ನಿರ್ವಹಿಸಬೇಕಾದ ಕ್ರಮಗಳ ಬಗೆಗಿನ ಮಾಹಿತಿ ಕಲೆ ಹಾಕುವುದು ಮತ್ತು ಮಧುಮೇಹದ ತೆಡೆಗಟ್ಟುವಲ್ಲಿ ಅನುಸರಿಸಬೇಕಾದ ಕ್ರಮಗಳ ಬಗ್ಗೆ ಶಿಸ್ತುಬದ್ಧವಾದ ನೀತಿ ಜಾರಿಗೆ ತರುವುದು. ಅದರ ಜೊತೆಗೆ ಜನರ ಒಟ್ಟಾರೆ ಆರೋಗ್ಯದಲ್ಲಿ ಗುಣಮಟ್ಟವನ್ನು ಕಾಪಾಡುಕೊಳ್ಳುವಂತೆ ಮತ್ತು ಹೆಚ್ಚಿಸುವಂತೆ ಕ್ರಮ ಕೈಗೊಳ್ಳುವುದು.

ಸಂಶೋಧನಾ ಹಸ್ತಕ್ಷೇಪ:

ಈ ಸಂಶೊಧನಾ ಅಧ್ಯಯನವು ಎರಡು ಗುಂಪುಗಳನ್ನು ಒಳಗೊಂಡಿದೆ:

೧) ಇಂಟರ್ವೆನ್ಷನಲ್ ಗ್ರುಪ್

೨) ಸ್ಟ್ಯಾಂಡರ್ಡ್ ಕೇರ್ ಗ್ರುಪ್

ಇಂಟರ್ವೆನ್ಷನಲ್ ಗ್ರುಪ್ ನಲ್ಲಿ ವೈದ್ಯಕೀಯ ಔಷದಿ ತಜ್ಞರು ಮಧುಮೇಹದ & ಅದರ ಜಾಗೃತಿ ಬಗ್ಗೆ ರೋಗಿಗಳ ಸಮಾಲೋಚನೆ ಮತ್ತು ಶಿಕ್ಷಣವನ್ನು ಒದಗಿಸುತ್ತಾರೆ. ಮಧುಮೇಹದ ರೋಗಿಗಳಿಗೆ, ರೋಗದ ಶಂಕಿತರಿಗೆ ಮತ್ತು ಮಧುಮೇಹದ ಬಗ್ಗೆ ತಿಳಿಯಲು ಬಯಸುವವರಿಗೆ ಮಾಹಿತಿ ಕರಪತ್ರಗಳನ್ನು ನೀಡಿ, ಗುಂಪು ಜಾಗೃತಿ ಚಟುವಟಿಕೆಗಳು ಮತ್ತು ರೋಗಿಯ ಸಮಾಲೋಚನೆ ಕಾರ್ಯಕ್ರಮ ಮಾಡುತ್ತಾರೆ.

ಮಧುಮೇಹವು ರೋಗಿಯ ಜೀವಕ್ಕೆ ಅಪಾಯಕಾರಿ ರೋಗ ಎಂದು ತಿಳಿದಿರಬೇಕು ಮತ್ತು ವೈಧ್ಯರು ಶಿಫಾರಸ್ಸು ಮಾಡಿದ ಔಷಧಿಗಳನ್ನು ನಿಯಮಿತವಾಗಿ ನಿಗದಿತ ಅವಧಿಯವರೆಗೆ ತೆಗೆದುಕೊಂಡರೆ ಮಾತ್ರ ಚಿಕಿತ್ಸೆ

ಪರಿಣಾಮಕಾರಿಯಾಗಿರುತ್ತದೆ. ವೈದ್ಯಕೀಯ ಔಷಧ ತಜ್ಞರು ಮಧುಮೇಹದ ರೋಗಿಗಳಿಗೆ ತಮ್ಮ ಆಹಾರ ಸೇವನೆ, ರಕ್ತದಲ್ಲಿನ ಸಕ್ಕರೆಯ ಅಂಶ, ಮಧುಮೇಹದ ಲಕ್ಷಣಗಳು ಮತ್ತು ತೊಂದರೆಗಳ ಬಗ್ಗೆ ವಿವರಿಸುತ್ತಾರೆ.

ಅನಿಯಮಿತ ಬೇಡವಾದ ಔಷಧೀಯ ಉಪಯೋಗವು ತುಂಬಾ ಅಪಾಯಕಾರಿಯಾಗ್ಗಿದ್ದು, ರೋಗವನ್ನು ಸಂಪೂರ್ಣ ಗುಣಪಡಿಸುದಿಲ್ಲ. ವೈದ್ಯಕೀಯ ಔಷಧ ತಜ್ಞರು, ರೋಗಿಯ ಚಿಕಿತ್ಸೆಗೆ ಸಂಬಂಧಿಸಿದ ಔಷಧಿಗಳನ್ನು ನಿಗದಿತ ಪ್ರಮಾಣ ಮತ್ತು ಅವಧಿಯಲ್ಲಿ ಅಡ್ಡಪರಿಣಾಮವಾಗದಂತೆ ತಡೆದು, ರಕ್ತದ ಗ್ಲುಕೋಸ್, HbA_1C ಪರೀಕ್ಷೆ ಮಾಡಿಸಿ ಮತ್ತು ಧೂಮಪಾನವನ್ನು ನಿಲ್ಲಿಸಲು ತಿಳುವಳಿಕೆ ನೀಡುತ್ತಾರೆ. ಅನಿವಾರ್ಯ ಸಮಯದಲ್ಲಿ ಟೆಲಿಫೋನಿಕ ಸಂದರ್ಶನ ಮತ್ತು ಮಧುಮೇಹ ರೋಗಿಗಳ ಮನೆಗೆ ಬೇಟಿ ನೀಡುತ್ತಾರೆ.

ಇನ್ನೊಂದೆಡೆ, ಸ್ಟ್ಯಾಂಡರ್ಡ್ ಕೇರ್ ಗ್ರುಪ್‌ನಲ್ಲಿ ಪರಿಶೀಲನಾ ಪಟ್ಟಿಯನ್ನು ಒದಗಿಸಲಾಗು ತ್ತದೆ. ಇದರಲ್ಲಿ ರೋಗಿಗಳ ನಿರ್ದಿಷ್ಟ ಸಮಯದಲ್ಲಿ ಬೇಟಿ ನೀಡುತ್ತಾರೆ. ಅಧ್ಯಯನದ ಫಲಿತಾಂಶಗಳಿಗಾಗಿ ಎರಡು ಗುಂಪುಗಳಲ್ಲಿ ಭಾಗವಸುವವರನ್ನು ಮೇಲ್ವಿಚಾರಣೆ ಮಾಡಲಾಗುತ್ತದೆ.

ಭಾಗವಹಿಸುವವರ ಆಯ್ಕೆ:

ಈ ಸಂಶೋಧನೆಯಲ್ಲಿ ಪಾಲ್ಗೋಳ್ಳುವ ರೋಗಿಗಳು ಮಧುಮೇಹ ರೋಗದಿಂದ ಬಲಳುತ್ತಿರಬೇಕು.

ಸ್ವಯಂಪ್ರೇರಿತ ಭಾಗವಹಿಸುವಿಕೆ:

ಈ ಸಂಶೋಧನೆಯಲ್ಲಿ ನಿಮ್ಮ ಭಾಗವಹಿಸುವಿಕೆ ಸಂಪೂರ್ಣವಾಗಿ ಸ್ವಯಂಪ್ರೇರಿತವಾಗಿರುತ್ತದೆ. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಬೇಕು ಅಥವಾ ಇಲ್ಲವೆಂಬುದು ನಿಮ್ಮ ಸ್ವಂತ ಆಯ್ಕೆಯಾಗಿರುತ್ತದೆ. ಒಂದು ವೇಳೆ ನೀವು ಭಾಗವಹಿಸಲು ನಿರ್ಧರಿಸಿದ್ದರೇ, ನಮ್ಮಿಂದ ಮತ್ತು ನಮ್ಮ ಆಸ್ಪತ್ರೆಯಿಂದ ಎಲ್ಲಾ

ರೀತಿಯ ಅಧ್ಯಯನದ ಸೇವೆಗಳು ಉಚಿತವಾಗಿ ಸ್ವೀಕರಿಸಬಹುದು ಮತ್ತು ಸೇವೆಗಳಲ್ಲಿ ಯಾವುದೆ ಬದಲಾವಣೆಯಾಗುವುದಿಲ್ಲ. ತದನಂತರ ಒಂದು ಕ್ಷಣ ನೀವು ನಿಮ್ಮ ಮನಸ್ಸುನ್ನ ಬದಲಾಯಿಸಿದೇ ಆಗಿದ್ದಲ್ಲಿ ನೀವು ಯಾವುದೇ ಕಾರಣವನ್ನು ನೀಡದೆ ಈ ಅಧ್ಯಯನದಿಂದ ಪಾಲ್ಗೋಳ್ಳುವುದನ್ನು ನಿಲ್ಲಿಸಬಹುದು.

ಅಧ್ಯಯನದ ವಿಧಾನ:

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ನಮ್ಮ ಅಧ್ಯಯನದ ಅರ್ಹತೆಯನ್ನು ಮೌಲ್ಯಮಾಪನ ಮಾಡಲಾಗುವುದು. ನೀವು ಅಧ್ಯಯನದ ಅರ್ಹತೆಯನ್ನು ಹೊಂದಿದ್ದರೇ ನಿಮ್ಮನ್ನು ಎರಡು ಗುಂಪುಗಳಲ್ಲಿ ಯಾವುದಾದರು ಒಂದಕ್ಕೆ ಸೇರಿಸಲಾಗುವುದು. ಅನುಕ್ರಮ ಸಂಖ್ಯೆಯ, ಅಪಾರದರ್ಶಕವಾದ ಮೊಹರಗೊಂಡ ಲಕೋಟೆಯ(SNOSE) ವಿಧಾನವನ್ನು ಬಳಸಿ ಗುಂಪುಗಳ ವಿಂಗಡಣೆಯನ್ನು ಮಾಡಲಾಗುತ್ತದೆ. ಈ ವಿಧಾನದಿಂದ ನೀವು ಎರಡು ಗುಂಪುಗಳಲ್ಲಿ ಯಾವುದಾದರೂ ಗುಂಪಿಗೆ ಹಂಚಿಕೆಯಾಗುವ ಅಂದರೇ ೫೦:೫೦ ಅವಕಾಶವನ್ನು ಹೊಂದಿರುವಿರಿ.

ನೀವು ಸ್ಟ್ಯಾಂಡರ್ಡ್ ಕೇರ್‌ಗ್ರುಪ್‌ನಲ್ಲಿದ್ದರೆ, ವಿದೇಶ ಮತ್ತು ಭಾರತದ ಮಧುಮೇಹದ ಕುರಿತು ಮಾಹಿತಿಯನ್ನು ತಿಳಿಸಲಾಗುತ್ತದೆ. ಮಧುಮೇಹದ ಮೂಲಭೂತ ಅಂಶಗಳನ್ನು ಅರ್ಥಮಾಡಿಸುವುದು, ಮಧುಮೇಹ ತಡೆಗಟ್ಟುವಲ್ಲಿ ಔಷದೀಯ ಶಿಕ್ಷಣ ಮತ್ತು ಸೇವನೆ, ಔಷದೀಯಲ್ಲಿನ ದೋಷ ಮತ್ತು ಸಮಸ್ಯೆಗಳ ಗುರುತಿಸುವಿಕೆ, ಆರೋಗ್ಯದ ಗುಣಮಟ್ಟ ಸುಧಾರಣೆ, ಮಧುಮೇಹದ ಔಷಧಿಗಳ ಬಗ್ಗೆ ಮತ್ತು ಇನ್ಸುಲಿನ ಸಿದ್ದತೆ, ಮಧುಮೇಹದ ಕುರಿತು ಸಮುದಾಯದಲ್ಲಿ ಜಾಗೃತಿ ಮೂಡಿಸುವಲಿ ್ಲಔಷಧಿ ತಜ್ಞರ ಪಾತ್ರವನ್ನು ತಿಳಿಸಲಾಗುತ್ತದೆ. ಒಂದು ವೇಳೆ ನೀವು ನಿಯಂತ್ರಣ ಗುಂಪಿನಲ್ಲಿದ್ದರೇ ಯಾವ ರೋಗಿಯು ಯಾವ ಸಮಯದಲ್ಲಿ ಸೇರ್ಪಡೆಯಾಗಿದ್ದಾರೆಂದು ತಿಳಿದುಕೊಳ್ಳಲಾಗುವುದು ಮತ್ತು ವೈಧ್ಯರ ಚಿಕಿತ್ಸೆಯ ಬಗ್ಗೆ ಗಮನಿಸಲಾಗುವುದು.

ಅಧ್ಯಯನದ ಅವಧಿ:

ಈ ಸಂಶೋಧನೆಯು ಒಂದರಿಂದ ಎರಡು ವರ್ಷದವರೆಗೆ ನಡೆಯುತ್ತದೆ. ಆ ಸಮಯದಲ್ಲಿ ಮಧುಮೇಹ ರೋಗಿಗಳನ್ನು ದಾಖಲಿಸುವುದು ಮತ್ತು ಮೇಲ್ವಿಚಾರಣೆ ಮಾಡಲಾಗುವುದು. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ನೀವು ಪಾಲ್ಗೊಳ್ಳುವ ಮೂಲಕ, ಅಧ್ಯಯನದ ಕಾರಣದಿಂದಾಗಿ ನೀವು ಯಾವುದೇ ಅಪಾಯಕಾರಿ ಘಟನೆಯನ್ನು ಎದುರಿಸುದಿಲ್ಲ.

ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸುವುದರಿಂದಾಗುವ ಪ್ರಯೋಜನಗಳು:

ರೋಗಿಯ ಸಮಾಲೋಚನೆ ಶಿಕ್ಷಣ ಮತ್ತು ತರಬೇತಿಯಿಂದ ನೀವು ಮಧುಮೇಹದ ಕಾರಣ, ರಕ್ತದಲ್ಲಿ ಸಕ್ಕರೆ ಪ್ರಮಾಣದ ದುಷ್ಪರಿಣಾಮಗಳು ಮತ್ತು ತಡೆಗಟ್ಟುವಿಕೆಯ ಕ್ರಮಗಳ ಬಗ್ಗೆ ಸಾಕಷ್ಟು ಜ್ಞಾನವನ್ನು ಹೊಂದಬಹದು. ಔಷಧಿಗಳನ್ನು ತೆಗೆದುಕೊಳ್ಳುವ ರೀತಿ ಮತ್ತು ಜೀವನದ ಗುಣಮಟ್ಟವನ್ನು ಹೇಗೆ ಸುಧಾರಿಸಕೊಳ್ಳಬೇಕೇಂದು ತಿಳಿಯುತ್ತದೆ. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳುವ ಎಲ್ಲಾ ರೋಗಿಗಳಿಗೆ ಯಾವುದೇ ರೀತಿಯ ಹಣ ಅಥವಾ ಶುಲ್ಕವನ್ನು ವಿದಿಸಲಾಗುವುದಿಲ್ಲ ಮತ್ತು ಎಲ್ಲಾ ಸೇವೆಗಳು ಉಚಿತವಾಗಿರುತ್ತವೆ.

ಪ್ರೋತ್ಸಾಹ:

ಈ ಅದ್ಯಯನದಲ್ಲಿ ನಿಮ್ಮ ಭಾಗವಹಿಸುವಿಕೆಯು ಯಾವುದೇ ಖರ್ಚಿಗೆ ಒಳಗಾಗುವುದಿಲ್ಲ ಮತ್ತು ಇದು ಕೇವಲ ಶೈಕ್ಷಣಿಕ ಸಂಶೋಧನೆಯಾದ್ದರಿಂದ ನಿಮಗೆ ಯಾವುದೇ ಪ್ರೋತ್ಸಾಹ ಧನವನ್ನು ನೀಡಲಾಗುವುದಿಲ್ಲ.

ಗೌಪ್ಯತೆ:

ಸಮುದಾಯದಲ್ಲಿ ಇತರರು ಈ ಸಂಶೋಧನೆಯಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳುತ್ತಿದಿರೆಂದು ತಿಳಿದಿದ್ದರೆ, ಅವರು ನಿಮಗೆ ಪ್ರಶ್ನೆಗಳನ್ನು ಕೇಳಬಹದು. ನಾವು–ನೀವು

ಯಾರೊಂದಿಗಾದರು ಸಂಶೋಧನೆಯಲ್ಲಿ ಭಾಗವಹಿಸುವವರ ಗುರುತನ್ನು ಹಂಚಿಕೊಳ್ಳುವುದಿಲ್ಲ. ಈ ಸಂಶೋಧನೆಯಿಂದ ನಾವು ಸಂಗ್ರಹಿಸಿದ ಮಾಹಿತಿಯು ಗೌಪ್ಯವಾಗಿರುತ್ತದೆ. ಸಂಶೋಧನೆಯ ಸಮಯದಲ್ಲಿ ಸಂಗ್ರಹಿಸಲ್ಪಡುವ ನಿಮ್ಮ ಮಾಹಿತಿ, ಹೆಸರು ಮತ್ತು ವಿಳಾಸ, ಮೊಬೈಲ್ ಸಂಖ್ಯೆ, ಇ–ಮೇಲ್ ವಿಳಾಸ ಗುರುತಿಸಲಾಗುವುದಿಲ್ಲ. ಸಂಶೊಧಕ ಮಾತ್ರ ನಿಮ್ಮ ಸಂಖ್ಯೆ ಏನೆಂದು ತಿಳಿದಿರುತ್ತಾರೆ ಮತ್ತು ಅವರು ನಿಮ್ಮ ಯಾವುದೇ ವಿವರಗಳನ್ನು ದುರುಪಯೋಗಪಡಿಸಿಕೊಳ್ಳುವುದಿಲ್ಲ ಮತ್ತು ಯಾರಿಗೂ ಹಂಚಲಾಗುದಿಲ್ಲ.

ಫಲಿತಾಂಶಗಳ ಹಂಚಿಕೆ:

ಸಾರ್ವಜನನಿಕರಿಗೆ ವ್ಯಾಪಕವಾಗಿ ಲಭ್ಯವಾಗುವ ಮೊದಲು ನಿಮಗೆ ಆಸಕ್ತಿ ಇದ್ದರೆ ಈ ಸಂಶೋಧನೆಯಿಂದ ನಾವು ಪಡೆಯುವ ಜ್ಞಾನವನ್ನು ನಿಮ್ಮೊಂದಿಗೆ ಹಂಚಿಕೊಳ್ಳಲಾಗುವುದು, ಗೌಪ್ಯ ಮಾಹಿತಿಯನ್ನು ಯಾರೊಂದಿಗೂ ಹಂಚಿಕೊಳ್ಳಲಾಗುವುದಿಲ್ಲ. ಕೆ.ಎಲ್.ಇಯ ಅಕಾಡಮಿಯ ಉನ್ನತ ಶಿಕ್ಷಣ ಮತ್ತು ಸಂಶೋಧನೆ, ಬೆಳಗಾವಿಯ ಸಂಶೋಧನಾ ಸಮಿತಿಯಲ್ಲಿ ಸಭೆಗಳನ್ನು ನಡೆಸಲಾಗುವುದು ಮತ್ತು ಆ ಸಭೆಯಲ್ಲಿ ಈ ಸಂಶೋಧನೆಯ ಜ್ಞಾನವನ್ನು ಘೋಷಿಸಲಾಗುವುದು. ಈ ಸಭೆಗಳ ತದನಂತರ, ಇತರೇ ಆಸಕ್ತಿ ಜನರು ನಮ್ಮ ಸಂಶೋಧನೆಯಿಂದ ಕಲಿಯಬಹುದಾದ ಸಾಧ್ಯತೆಗಾಗಿ ನಾವು ಈ ಫಲಿತಾಂಶಗಳನ್ನು ವೈಜ್ಞಾನಿಕ ನಿಯತಕಾಲಿಕದಲ್ಲಿ ಪ್ರಕಟಿಸುತ್ತೇವೆ.

ನಿರಾಕರಿಸುವ ಮತ್ತು ಹಿಂತೆಗೆದುಕೊಳ್ಳುವ ಹಕ್ಕು:

ನೀವು ಯಾವ ಸಮಯದಲ್ಲಾದರೂ ಅಧ್ಯಯನದಿಂದ ಹಿಂಪಡೆಯಲು ಹಕ್ಕುಗಳಿವೆ.

ಯಾರಿಗೆ ಸಂಪರ್ಕಿಸಬೇಕು:

ನೀವು ಯಾವುದೇ ರೀತಿಯ ಪ್ರಶ್ನೆಗಳನ್ನು ಹೊಂದಿದ್ದರೆ ನೀವು ಈಗ ಅಥವಾ ನಂತರ ಅಂದರೇ ಅಧ್ಯಯನ ಪ್ರಾರಂಭವಾದ ನಂತರ ಕೂಡ ಕೇಳಬಹುದು. ನೀವು ಕೆಲವೊಂದು ಪ್ರಶ್ನೆಗಳನ್ನು ನಂತರದಲ್ಲಿ ಕೇಳಲು ಬಯಸಿದ್ದಲ್ಲಿ ನಿಮ್ಮ ಪ್ರಶ್ನೆಗಳನ್ನು ನೇರವಾಗಿ ನನ್ನ ಬಳಿ ಕೇಳಬಹುದು ಅಥವಾ ಅಧ್ಯಯನದ ಸಂಶೋಧನಾ ಮೇಲ್ವಿಚಾರಕರಾದ ಡಾ.ಎ.ಎಚ್.ಎಂ.ವಿಶ್ವನಾಥಸ್ವಾಮಿ, ಫಾರ್ಮಸಿ ಪ್ರಾಕ್ಟೀಸ ವಿಭಾಗದ ಮುಖ್ಯಸ್ಥರು, ಕೆ.ಎಲ್.ಇ ಔಷಧ ವಿಜ್ಞಾನ ಮಹಾವಿಧ್ಯಾಲಯ ಹುಬ್ಬಳ್ಳಿ–೫೧. ರಲ್ಲಿ ಕೇಳಬಹುದು. ಮೊಬೈಲ್ ಸಂಖ್ಯೆ –9448667355. ಇ ಮೇಲ್– (vmhiremath2004@gmail.com).

ಈ ಪ್ರಸ್ತಾವನೆಯನ್ನು ಶೈಕ್ಷಣಿಕ ವ್ಯವಹಾರಗಳ ವಿಭಾಗ, ಕೆ. ಎಲ್. ಇ. ಶೈಕ್ಷಣಿಕ, ಉನ್ನತ ಶಿಕ್ಷಣ ಮತ್ತು ಸಂಶೋಧನೆ ಬೆಳಗಾವಿ–೧೦ ಮತ್ತು ಇವರ ಹುಬ್ಬಳ್ಳಿಯ ಅಂಗಸಂಸ್ಥೆಯಲ್ಲಿ ಕೂಡಾ ಪರಿಶೀಲಿಸಲಾಗಿದೆ ಮತ್ತು ಅನುಮೋದಿಸಲಾಗಿದೆ. ಇದು ಸಂಶೋಧನೆಯಲ್ಲಿ ಪಾಲ್ಗೋಳ್ಳುವವರಿಗೆ ಹಾನಿಯಾಗದಂತೆ ರಕ್ಷಿಸಿಸುತ್ತದೆ.ಆಯ್ಆರ್‌ಬಿ ಬಗ್ಗೆ ನೀವು ಇನ್ನಷ್ಟು ಹೆಚ್ಚಿನ ಮಾಹಿತಿ ತಿಳಿದುಕೊಳ್ಳಲು ಬಯಸಿದರೆ, ಶೈಕ್ಷಣಿಕ ವ್ಯವಹಾರಗಳ ವಿಭಾಗ, ಕೆ. ಎಲ್. ಇ. ಶೈಕ್ಷಣಿಕ, ಉನ್ನತ ಶಿಕ್ಷಣ ಮತ್ತು ಸಂಶೋಧನೆ ಬೆಳಗಾವಿ–೧೦ ಸಂಪರ್ಕಿಸಿರಿ.

ಸಮ್ಮತಿಯ ಪ್ರಮಾಣ ಪತ್ರ:

ನಾನು ಮೇಲ್ಕಂಡ ಮಾಹಿತಿಯನ್ನು ಓದಿದ್ದೇನೆ ಮತ್ತು ಅದನ್ನು ಬೇರೆಯವರಿಂದ ಇದರ ಬಗ್ಗೆ ತಿಳಿದುಕೊಂಡಿದ್ದೇನೆ. ಅದರ ಬಗ್ಗೆ ಪ್ರಶ್ನೆಗಳನ್ನು ಕೇಳಲು ನಾನು ಅವಕಾಶ ಹೊಂದಿದ್ದೇನೆ ಮತ್ತು ನಾನು ಕೇಳಿದ ಎಲ್ಲಾ ಪ್ರಶ್ನೆಗಳಿಗೆ ನನಗೆ ತೃಪ್ತಿಯಾಗುವಂತೆ ಮಾಹಿತಿ ನೀಡಲಾಗಿದೆ. ಈ ಸಂಶೋಧನೆಯಲ್ಲಿ ಭಾಗವಹಿಸಲು ನಾನು ಸ್ವಯಂ ಪ್ರೇರಣೆಯಿಂದ ಸಮ್ಮತಿಸುತ್ತೇನೆ ಮತ್ತು ನನ್ನ ವೈದ್ಯಕೀಯ ಆರೈಕೆಗೆ ಯಾವುದೇ ತೊಂದರೆಯಾದರೆ ನಾನು ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ಈ ಸಂಶೋಧನೆಯಿಂದ ಹಿಂತೆಗೆದುಕೊಳ್ಳುವ ಹಕ್ಕನ್ನು ಹೊಂದಿದ್ದೇನೆ.

ಭಾಗವಹಿಸುವವರ ಹೆಸರು : _____

ಭಾಗವಹಿಸುವವರ ಸಹಿ : _____

ದಿನಾಂಕ : _____

(ದಿನ / ತಿಂಗಳು / ವರ್ಷ)

ನಿಷ್ಪಕ್ಷಪಾತ ವಿಟ್ನೆಸ್ (ಭಾಗವಹಿಸುವವರು ಅನಕ್ಷರಸ್ಥರಾಗಿದ್ದರೆ)

ಸಂಭಾವ್ಯ ಪಾಲ್ಗೊಳ್ಳುವವರಿಗೆ ಸಮ್ಮತಿಯ ರೂಪವನ್ನು ನಿಖರವಾದ ಓದುವೆಂದು ನಾನು ಸಾಕ್ಷಿಯಾಗಿದ್ದೇನೆ ಮತ್ತು ಪ್ರಶ್ನೆಗಳನ್ನು ಕೇಳಲು ವ್ಯಕ್ತಿಗೆ ಅವಕಾಶವಿದೆ. ವ್ಯಕ್ತಿಯು ಮುಕ್ತವಾಗಿ ಒಪ್ಪಿಗೆ ನೀಡಿದ್ದಾನೆ ಎಂದು ನಾನು ದೃಢೀಕರಿಸುತ್ತೇನೆ.

ಸಾಕ್ಷಿಯ ಸಹಿ _____ ಮತ್ತು ಭಾಗವಹಿಸುವವರ ತಮ್ ಮುದ್ರಣ -

ಸಾಕ್ಷಾಧಾರದ ಹೆಸರು _____

ದಿನಾಂಕ _____

(ದಿನ / ತಿಂಗಳು / ವರ್ಷ)

ಸಂಭಾವ್ಯ ಪಾಲ್ಗೊಳ್ಳುವವರಿಗೆ ಸಮ್ಮತಿ ರೂಪದ ನಿಖರವಾದ ಓದುವಿಕೆಯನ್ನು ನಾನು ನಿಖರವಾಗಿ ಓದಿದ್ದೇನೆ ಅಥವಾ ಸಾಕ್ಷಿಯಾಗಿದ್ದೇನೆ ಮತ್ತು ಒಬ್ಬ ವ್ಯಕ್ತಿಗೆ ಪ್ರಶ್ನೆಗಳನ್ನು ಕೇಳಲು ಅವಕಾಶವಿದೆ. ವ್ಯಕ್ತಿಯು ಮುಕ್ತವಾಗಿ ಒಪ್ಪಿಗೆ ನೀಡಿದ್ದಾನೆ ಎಂದು ನಾನು ದೃಢೀಕರಿಸುತ್ತೇನೆ.

ಸಂಶೋಧಕರ ಹೆಸರು_____

ಸಂಶೋಧಕರ ಸಹಿ _____

ದಿನಾಂಕ _____

(ದಿನ / ತಿಂಗಳು / ವರ್ಷ)

ಭಾಗವಹಿಸುವವರುಗೆ ಈ ತಿಳುವಳಿಕೆಯ ಸಮ್ಮತಿಯ ಫಾರ್ಮ್ನ ಒಂದು ಪ್ರತಿಯನ್ನು ಒದಗಿಸಲಾಗಿದೆ (ಸಂಶೋಧಕರು / ಸಹಾಯಕರಿಂದ ಪ್ರಾರಂಭಿಸಲಾಗಿದೆ)

Annexure III: Patient Data Collection Form

K. L. E. COLLEGE OF PHARMACY, HUBBALLI.

DEPARTMENT OF PHARMACY PRACTICE

3rd Floor, Vivekanand General Hospital, Deshpandenagar,
HUBBALLI-580029. Ph. 0836-2254245 E-mail: Kleclinpharmdic@gmail.com

PATIENT DATA COLLECTION FORM

Patient Name/Initials:				I.P. No:	Ward/unit:
Age:	Sex:	Height:	Weight:	D.O.A:	D.O.D:
Consulting Physician:				Social History	
Present Complaints:				Smoking:	Alcoholic:
				Past Medical History:	
Previous ADR's if any:				Past Medication History:	

LABORATORY INVESTIGATIONS

Date																	
Temp.																	
B.P																	
P.R																	
Res.Rate																	
Blood Sugar(mg%) F.B.S																	
P.B.S																	
R.B.S																	

	COMPLETE BLOOD COUNT						ELECTROLYTES					
1	RBC						19	Na^+(133-146mEq/L)				
2	WBC						20	K^+(2.8-5.2mEq/L)				
3	Haemoglobin(13.0-17.0gm%)						21	Ca^{+2}(8.5-11mg/dL)				
4	Platelets count (1.5-4.5lacks/cumm)						22	PO_4^{-2}(2.5-4.5mg/dL)				
5	ESR(mm/hr) 0-10						23	Cl^-(8.5-11mg/dL)				
6	Polymorphs(40-60)							RENAL FUNCTION TESTS				
7	Lymphocytes(20-45%)						24	Urea/BUN(10-15mg/dL)				
8	Basophills(0-1%)						25	Uric acid(2.5-7.0mg/dL)				
9	Esinophils(1-6%)						26	Sr.Creatinine(0.9-1.4mg/dL)				
10	Monocytes(1-4%)							LIVER FUNCTION TESTS & ENZYMES				
11	PCV(40-54%)						27	SGOT/AST(<40μL)				
12	MCV(80-100fL)						28	ALT(<40μL)				
13	MCH(26-34pg/cell)						29	Albumin(3.5-5.5gm/dL)				
14	MCHC(32-36g/dL)						30	Globulin(1.8 3.6gm/dL)				
	THYROID MARKERS						31	Bilirubin Total(0.2-1.0mg/dL)				
15	T3(0.6-2.0ng/ml)						32	Acid phospatase ACP(0-9U/L)				
16	T4(5-12μg/ml)						33	CPK Total(15-125U/L)				
17	TSH(0.3-6.0μU/ml)						34	CPK M B(0-26U/L)				
18							35	LHD(200-400U/L)				

LIPID PROFILE						URINE EXAMINATION					
36	Cholesterol(150-250mg/dl)					45	Colour				
37	HDL(30-70mg/dl)					46	Bile Salt				
38	VLDL(15-45mg/dl)					47	Bile Pigment				
39	Triglycercles(65-170mg/dl)					48	Albumin				
						49	Pus Cells				
40	LDL(90-136mg/dl)					50	Sugar				
41	CHL/HDL ratio(4.0-6.7)					51	WBC(≤5/hpf)				
42	CSF Sugar(50-80mg/dl)					52	RBC(≤3/hpf)				
43	CSF Protein(15-45mg/dl)					53	Casts(0-4/ipf)				
44	CSF Chloride(120-130mg/dl)					54	Epithelial Cells(≤3/hpf)				
OTHERS											
55						60					
56						61					
57						62					
58						63					
59						64					

Other Investigations:

Diagnosis:

Drug Interactions:

S.NO	INTERACTING DRUGS	Severity of interaction			Effect	Clinical Management
	Drug-Drug & Drug-Food/Lifestyle	Major	Moderate	Minor		

PROGRESS NOTE:

S.NO	Prescribed Drugs		Dose	Indication	Dates of Treatment	Cost/unit	Total cost
	T.name (ROA & Frequency)	G. Name					
1.							
2.							
3.							
4.							
5.							
6.							
7.							
8.							
9.							
10.							
11.							
12.							
13.							
14.							
15.							
16.							
17.							
18.							
19.							
20.							
21.							

SUSPECTED ADVERSE DRUG REACTIONS :

Sl. No.	Suspected Drug	Drug started	Drug Stopped	Date of onset of Reaction	Description of suspected reaction

DISCHARGE MEDICATION :

No.	Drugs		Dose & days
	Brand name	Generic name	

PATIENT COUNSELLING FOR:

A. DISEASE:

B. MEDICATION:

C. LIFESTYLE:

Sign & date of Student ***Signature of staff*** ***Signature of HOD***

Annexure IV: Patient Counselling Documentation Form

KLE COLLEGE OF PHARMACY
DEPARTMENT OF PHARMACY PRACTICE
3rd Floor, Vivekanand General Hospital Deshpandenagar,
HUBBALLI-580029. Ph. : 0836-2254245
E-mail : kleclinpharmdic@gmail.com

PATIENT COUNSELLING DOCUMENTATION FORM

Date : ..... Time : .....

Type of Patient : ☐ In-patient : ☐ Out patient :
IP-Number : OP-Number :
Unit : Dept. :

Age: Sex: M/F Allergies:

Current medical problem:

Current medication :

Disease counselled :

Counselling steps followed :

- ☐ Case sheet reviewed
- ☐ Self introduction done
- ☐ Purpose of counselling told
- ☐ Initial drug related information obtained
- ☐ Patient was warned about taking other medication including OTC's herbal drugs etc.
- ☐ Actual counselling done
- ☐ Patient's understanding towards therapy was ascertained
- ☐ Counselling points summarized

Points covered during counselling session :

- ☐ Name and purpose of medication
- ☐ Dosage regimen
- ☐ Advice on missed dose
- ☐ Potential side effects
- ☐ Significant interactions (Drug-drug, drug-food, drug-disease)
- ☐ Precautions to be taken
- ☐ Storage recommendations
- ☐ Benefits of completing the course
- ☐ Life style modification

Any major barriers involved: ☐ Yes ☐ No

If Yes,
- ☐ Patient based
- ☐ Provider based
- ☐ System based

Quote specific barrier (if any) :

Time taken for counselling :
- ☐ Less than 10 min
- ☐ 10 to 20 min
- ☐ More than 20 min

Counselling provided to :
- ☐ Patient
- ☐ Patient's representative

If patient's representative, give reason :

- ☐ Patient is unconscious
- ☐ Language problem
- ☐ Hearing problem
- ☐ Pediatric patient
- ☐ Others (Please specify)

Counselling aids used :

- ☐ Pictograms
- ☐ Dummy inhaler device
- ☐ Spacer
- ☐ None
- ☐ Others (Please specify)

Counselling material provided :

- ☐ Patient information leaflets
- ☐ Pamphlets
- ☐ Product information leaflets
- ☐ None
- ☐ Others (Please specify)

Understanding of the patient ascertained : ☐ **Yes** ☐ **No**

Name of counselling Clinical Pharmacist : **Name of patient:**

Signature : **Patient Signature :**

Date : **Signature of Staff :**

FOR THE USE OF PATIENT COUNSELLING ASSESSMENT PANEL
PATIENT COUNSELLING QUALITY ASSURANCE FORM

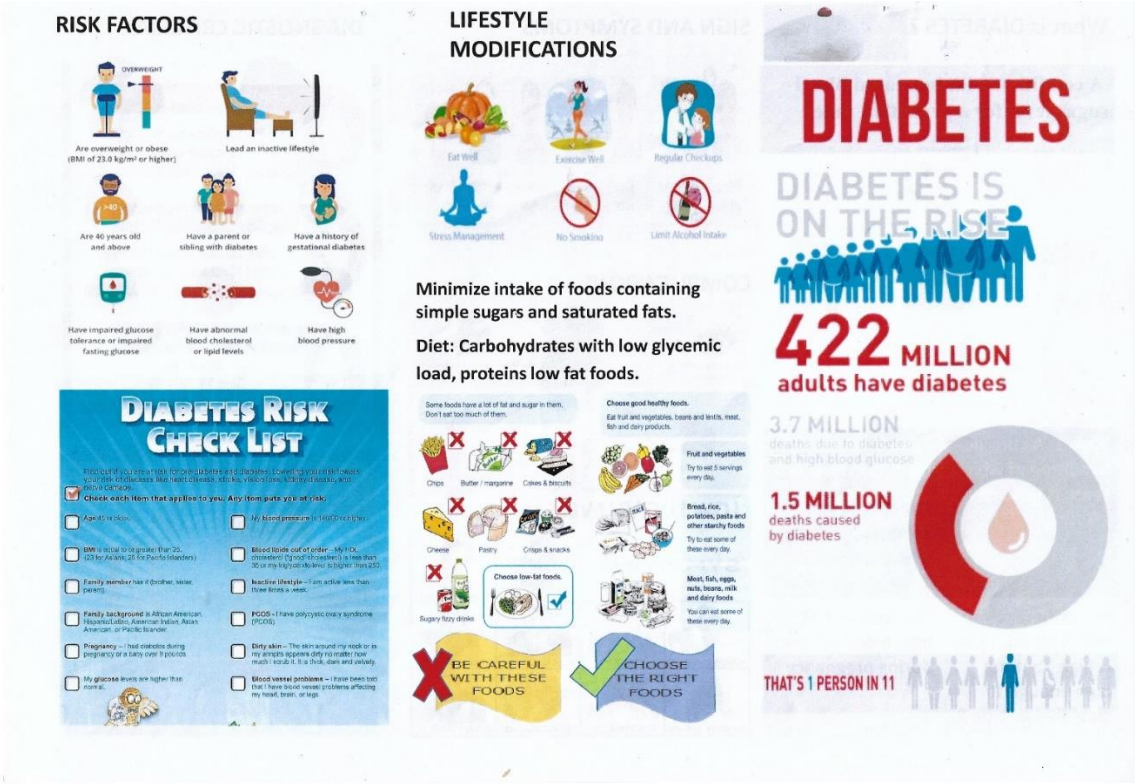
1. Whether counselling steps were followed ?
   ☐ YES ☐ NO
2. Whether counselling points were covered during counselling session?
   ☐ YES ☐ NO
3. Whether counselling aids were used ?
   ☐ YES ☐ NO
4. Whether counselling materials were provided?
   ☐ YES ☐ NO
5. Whether the barriers were rightly overcome (if any) ?
   ☐ YES ☐ NO
6. Was the understanding of patient ascertained?
   ☐ YES ☐ NO
7. Was the time taken for counselling appropriate?
   ☐ YES ☐ NO
8. Was the process of patient counselling properly documented ?
   ☐ YES ☐ NO

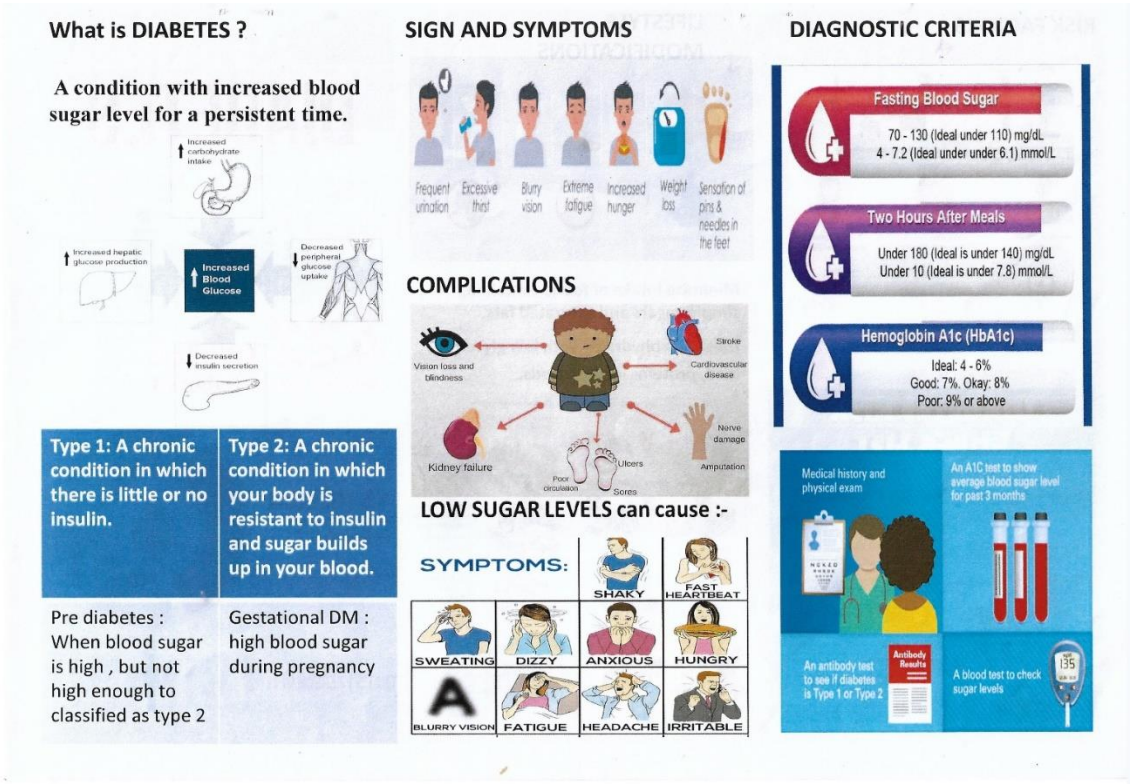
GRADE : **A** (Excellent), **B** (Good), **C** (Can improve), **D** (Should improve)

Note :	A=7-8 points	B=5-6 points	C=3-4 points	&	D=<3

REMARKS :

Annexure V: PIL





DIABETIC KETOACIDOSIS (DKA)

It is a serious condition that can result from untreated/ undiagnosed diabetes. It can lead to diabetic coma or even death.

DIABETES IN PREGNANCY

LIFESTYLE CHANGES


DRINK CINNAMON TEA

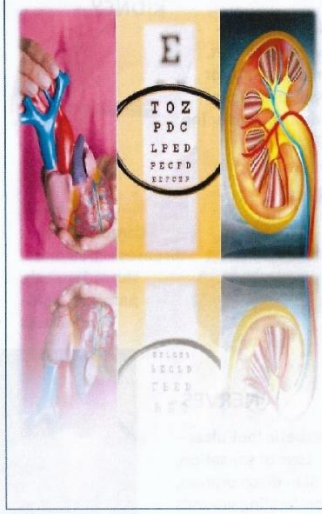

EAT THE RIGHT CARBOHYDRATES

OPT FOR A SUGAR-FREE DIET

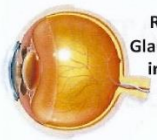

SLEEP WELL


EAT A HEALTHY BREAKFAST

COMPLICATIONS OF DIABETES



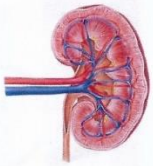
EYE -



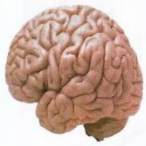
Retinopathy, Cataract & Glaucoma – Floating spots in vision, Blurred vision, Blocked vision

KIDNEY –

Nephropathy – Swelling of feet, ankles, hands or eyes, protein in urine, & worsening BP



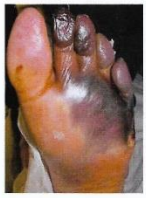
BRAIN -



Stroke & Cerebrovascular diseases – weakness, slurred speech, paralysis, light-headedness

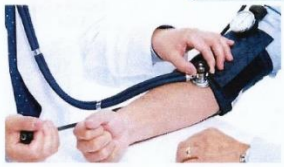
NERVES -

Diabetic foot ulcer – Loss of sensation, Skin discoloration, Non-healing wounds

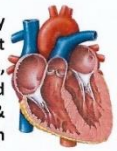


DIABETIC FOOT CARE

DOS	DON'TS
Regularly moisturize your feet. Regular foot exams to prevent complications	Never use heating pads , hot water bottles or electric blankets . Don't put your feet in hot water – test with your hand first.
Keep shaking your legs for adequate flow of blood . Maintain healthy blood sugar level to avoid cell damage.	Don't wear tight, elastic or thick, bulky socks. Don't let your feet get wet during snow/ rain. Don't walk barefoot, even at home.



Hypertension & Coronary artery disease – Chest pain, burning, numbness, chest tightness, blurred vision, sweating, fatigue & confusion



DIABETES & your HEART

ABCs of Diabetes

A for the A1C test.
It shows your last 3 months blood sugar levels. High levels can harm your heart & blood vessels, kidneys feet & eyes.

B for Blood Pressure
High BP makes your heart work more. It can cause heart attack, stroke & kidney disease.

C for Cholesterol.
Bad cholesterol can build up & clog your blood vessels. It can cause heart attack or stroke.

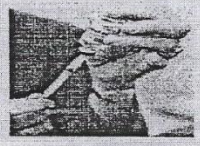
Tips to reduce your risk for heart disease.

ಕೆ.ಎಲ್.ಇ ವಿಶ್ವವಿದ್ಯಾಲಯದ ವಿಜ್ಞಾನ ಮಹಾವಿದ್ಯಾಲಯ
ಫಾರ್ಮಸಿ ಪ್ರ್ಯಾಕ್ಟೀಸ್ ವಿಭಾಗ
ವಿವೇಕಾನಂದ ಜನರಲ್ ಆಸ್ಪತ್ರೆ ದೇಶಪಾಂಡೆ ನಗರ, ಹುಬ್ಬಳ್ಳಿ.

ಹೆಚ್ಚಿನ ರಕ್ತದ ಗ್ಲೂಕೋಸ್ (ಸಕ್ಕರೆ) ಹೈಪರಗ್ಲ್ಯಾಸೀಮಿಯಾ	ಕಡಿಮೆ ರಕ್ತದ ಗ್ಲೂಕೋಸ್ (ಸಕ್ಕರೆ) ಹೈಪೋಗ್ಲ್ಯಾಸೀಮಿಯಾ
ಬಾಯಾರಿಕೆ ಹೆಚ್ಚಾಗುವಿಕೆ ಮತ್ತು ಪದೇ ಪದೇ ಮೂತ್ರವಿಸರ್ಜನೆ.	ಬೇವರುವಿಕೆ,ಶೀತ ತೇವ ಚರ್ಮ
ದೌರ್ಬಲ್ಯ	ಮಂದ ದೃಷ್ಟಿ
ವಾಕರಿಕೆ ಮತ್ತು ವಾಂತಿ	ಆಳವಾದ ಉಸಿರಾಟ
ರಕ್ತದ ಸಕ್ಕರೆ ಅಂಶ ಹೆಚ್ಚಾಗುವುದು.	ರಕ್ತದ ಸಕ್ಕರೆ ಅಂಶ ಕಡಿಮೆಯಾಗುವುದು.
ನೋವು	ತೀಲೆನೋವು
	ದುರ್ಬಲ ಮತ್ತು ತಲೆತಿರುಗುವಿಕೆ.
ನಿಯಂತ್ರಿಸಲು ಏನು ಮಾಡುವುದು ?	
ನಿಮ್ಮ ವೈದ್ಯರನ್ನು ಭೇಟಿಮಾಡಿ ಮತ್ತು ಅವರ ಸಲಹೆಗಳನ್ನು ಪಾಲಿಸಿ	ಶುದ್ಧ ಗ್ಲೂಕೋಸ್‌ನ್ನು ತೆಗೆದುಕೊಳ್ಳಿ. ಉದಾ: ಗ್ಲೂಕಾನ್-ಡಿ
ಪ್ರತಿ ನಿತ್ಯ ನಿಮ್ಮ ರಕ್ತದ ಗ್ಲೂಕೋಸ್ ಪರಿಶೀಲಿಸಿ.	ಹಣ್ಣು/ ಸ್ಯಾಂಡವೀಚ್/ಬಿಸ್ಕತ್ತ ಗಳನ್ನು ಸೇವಿಸಿ.
ಸಾಮಾನ್ಯ ಇನ್ಸುಲಿನ/ ಔಷಧಗಳನ್ನು ಮುಂದುವರಿಸಿ.	ರಕ್ತದ ಗ್ಲೂಕೋಸ್ ಮಟ್ಟವನ್ನು ಖಚಿತಪಡಿಸಿಕೊಳ್ಳಿ ಮತ್ತು ಹತ್ತು ನಿಮಿಷದ ನಂತರ ಅದರ ಸುಧಾರಣೆಯ ಬಗ್ಗೆ ಖಚಿತಪಡಿಸಿಕೊಳ್ಳಿ.
ಆಹಾರ ಯೋಜನೆಯನ್ನು ಮುಂದುವರಿಸಿ.	15 ನಿಮಿಷದ ನಂತರ ಸುಧಾರಣೆಯಾಗದಿದ್ದರೇ ನಿಮ್ಮ ವೈದ್ಯರಿಗೆ ಕರೆಮಾಡಿ.

ಮಧುಮೇಹ ಒಂದು ರೋಗ, ಇದನ್ನು ವಾಸಿಮಾಡಲು ಸಾಧ್ಯವಿಲ್ಲ ಆದರೆ ಇದನ್ನು ನಿಯಂತ್ರಿಸಬಹುದು. ಪ್ರಮುಖವಾಗಿ ಮೊದಲೆ ಹೇಳಿದ್ದಲ್ಲಿ ಇದರ ಗುಣಲಕ್ಷಣಗಳ ಬಗ್ಗೆ ತಿಳಿದುಕೊಂಡರೇ ಚಿಕಿತ್ಸೆ ಫಲಕಾರಿಯಾಗಬಹುದು.

ಮಧುಮೇಹದ ಬಗ್ಗೆ ಸಂಪೂರ್ಣ ಮಾಹಿತಿ



ಮಧುಮೇಹ ಎಂದರೇನು?

ಮಧುಮೇಹ ಎಂದರೇ ನಿಮ್ಮ ದೇಹದ ಒಂದು ಸ್ಥಿತಿ, ಇದರಲ್ಲಿ ಆಹಾರದಲ್ಲಿನ ಗ್ಲೂಕೋಸ್(ಸಕ್ಕರೆ) ಅಂದ ಬದಲಾವಣೆ ಆಗದೇ ಇರುತ್ತವೆ. ಸಾಮಾನ್ಯವಾಗಿ ನಮ್ಮ ದೇಹವು ಇನ್ಸುಲಿನ ಎಂಬ ಹಾರ್ಮೋನನ್ನು ಉತ್ಪಾದಿಸುತ್ತದೆ. ಈ ಹಾರ್ಮೋನ ರಕ್ತದಲ್ಲಿನ ಗ್ಲೂಕೋಸ್(ಸಕ್ಕರೆ)ಯನ್ನು ದೇಹದ ಇತರೇ ಜೀವಕೋಶಗಳಿಗೆ ಶಕ್ತಿಯಾಗಿ ಉಪಯೋಗಿಸುತ್ತದೆ.

ಸಾಮಾನ್ಯವಾಗಿ ಮಧುಮೇಹ ರೋಗಿಗಳಲ್ಲಿ ಇನ್ಸುಲಿನ ಕಡಿಮೆ ಪ್ರಮಾಣದಲ್ಲಿ (ಇನ್ಸುಲಿನ ಅವಲಂಬಿತ ಮಧುಮೇಹ) ಅಥವಾ ಇನ್ಸುಲಿನ ಉತ್ಪಾದನೆ ಆಗುವುದಿಲ್ಲ. ಇನ್ನೂ ಕೆಲವು ಕಾರಣಗಳಿಗೆ ಇನ್ಸುಲಿನ ಕೆಲಸವೇ ಮಾಡುವುದಿಲ್ಲ (ಇನ್ಸುಲಿನ ಅವಲಂಬಿತ ಅಲ್ಲದ ಮಧುಮೇಹ). ಎಲ್ಲ ಮಧುಮೇಹ ರೋಗಿಗಳ ಗುರಿ ಅವರವರ ರಕ್ತದ ಗ್ಲೂಕೋಸ್(ಸಕ್ಕರೆ) ಅಂಶವನ್ನು ಸಾಮಾನ್ಯ ಶ್ರೇಣಿ ಮತ್ತು ಸುರಕ್ಷತಾ ಮಟ್ಟದಲ್ಲಿ ಇಡಬೇಕು.

ಮಧುಮೇಹದ ಮುಖ್ಯ ಗುಣಲಕ್ಷಣಗಳು:-

- ಪದೇ ಪದೇ ಮೂತ್ರವಿಸರ್ಜನೆ
- ಸುಸ್ತು /ಶಕ್ತಿಯ ನಷ್ಟ
- ಪದೇ ಪದೇ ಬಾಯಾರಿಕೆ
- ಮಂದ ದೃಷ್ಟಿ
- ವಿಪರೀತ ಹಸಿವು
- ಕಾಲಿನ ಪಾದ ಮರಗಟ್ಟುವಿಕೆ(ಜುಮ್ಮಹಿಡಿಯುವದು)
- ತ್ವರಿತ ತೂಕ ನಷ್ಟ
- ಚರ್ಮದ ಸೋಂಕು ಮತ್ತು ಯಾತನೆಯಿಂದ ಗುಣವಾಗಲು ಬಹಳ ಸಮಯ ತೆಗೆದುಕೊಳ್ಳಬಹುದು.

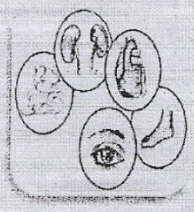
ಅಪಾಯದ ಅಂಶಗಳು :–

- 40 ವರ್ಷದ ಮೇಲ್ಪಟ್ಟಿನ ವಯಸ್ಸು
- ನಿಯಮಿತ ವ್ಯಾಯಮದ ಕೊರತೆ ಮತ್ತು ಆರೋಗ್ಯಯುತವಾದ ಜೀವನ ಶೈಲಿ
- ಆನುವಂಶಿಯತೆ/ಕುಟುಂಬದ ವಂಶಸ್ಥರಲ್ಲಿ ಮಧುಮೇಹ ರೋಗ ಇರುವಿಕೆಯ ಬಗ್ಗೆ ತಿಳಿದುಕೊಳ್ಳುವುದು.
- ಅತಿಯಾದ ಕೊಬ್ಬಿನ ಮಟ್ಟ
- ಅತಿಯಾದ ತೂಕ
- ಅಧಿಕ ರಕ್ತದೊತ್ತಡ/ತೀವ್ರ ರಕ್ತದೊತ್ತಡ.

ತೊಂದರೆಗಳು/ತೊಡಕಗಳು:

ಅತೀಯಾದ ಮಧುಮೇಹ ಮತ್ತು ಅನಿಯಂತ್ರಣದಿಂದ ರಕ್ತನಾಳ ಮತ್ತು ನರಗಳ ಮೇಲೆ ಹಾನಿಯುಂಟಾಗುವ ತೊಂದರೆಗಳು:

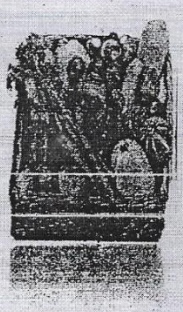
- ದೃಷ್ಟಿದೋಷ
- ಪಾದಗಳಲ್ಲಿ
- ಪಿತ್ತಜನಕಾಂಗ ಮತ್ತು ಮೂತ್ರಪಿಂಡ
- ರೋಗದೊಂದಿಗೆ ಹೋರಾಡುವ ಸಾಮರ್ಥ್ಯ
- ಹೃದಯ ಮತ್ತು ರಕ್ತದ ಹರಿವು



ಮಧುಮೇಹ ತಡೆಗಟ್ಟುವ ವಿಧಾನಗಳು:–

ಸಕ್ಕರೆ ಅಂಶವನ್ನು ಸಮಾನ್ಯ ಶ್ರೇಣಿ ಮತ್ತು ಸುರಕ್ಷತಾ ಮಟ್ಟದಲ್ಲಿ ಇಡಲು ನಿಮ್ಮ ಜೀವನದಲ್ಲಿ ಬದಲಾವಣೆಗಳನ್ನು ಕೈಗೊಳ್ಳಬೇಕು. ಅಂದರೇ ನಿಯಮಿತ ಸಮತೋಲನ ಆಹಾರ ಸೇವನೆ, ವ್ಯಾಯಮ ಮತ್ತು ಔಷಧಗಳನ್ನು ಸರಿಯಾದ ಪ್ರಮಾಣದಲ್ಲಿ ಸೇವಿಸುವುದರಿಂದ ನಿಮ್ಮ ದೇಹದ ರಕ್ತದ ಸಕ್ಕರೆ ಅಂತವನ್ನು ತಡೆಗಟ್ಟಬಹುದಾಗಿದೆ.

1. ಆಹಾರಕ್ರಮ(ಡಯಟ): ಮಧುಮೇಹವನ್ನು ತಡೆಗಟ್ಟುವಲ್ಲಿ ಸರಿಯಾದ ಆಹಾರ ಕ್ರಮ ಒಂದು ಮಹತ್ವದ ಅಂಶವಾಗಿದೆ. ಅದರಲ್ಲಿ ಇನ್ಸುಲಿನ ಅವಲಂಬಿತ ಅಲ್ಲದ ರೋಗಿಗಳಲ್ಲಿ ಇದು ಪ್ರಮುಖ ಪಾತ್ರ ವಹಿಸುತ್ತವೆ. ಆಹಾರದ ಕ್ರಮದ ಸರಿಯಾದ ಯೋಜನೆಗಳ ಬಗ್ಗೆ ಅಥವಾ ಔಷಧಗಳನ್ನು (ಇನ್ಸುಲಿನ ಅಥವಾ ಮಾತ್ರೆಗಳ) ಬಗ್ಗೆ ತಿಳಿಯಲೊಳ್ಳು ಔಷಧತಜ್ಞ (ಫಾರ್ಮಸಿಸ್ಟ) ಅಥವಾ ವೈದ್ಯರೊಡನೆ ಚರ್ಚಿಸಿ ಮತ್ತು ಅವರ ಸಲಹೆಗಳನ್ನು ಕಟ್ಟುನಿಟ್ಟಾಗಿ ಪಾಲಿಸಿ.

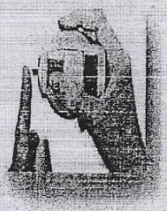


2. ವ್ಯಾಯಮ: ವೇಗದಾದ ನಡಿಗೆ, ಓಟ, ಸೈಕಲ್ ಚಲಾಯಿಸುವುದದು, ಕುಣಿತ, ಈಜು ಇವುಗಳನ್ನು ಕಡಿಮೆ ಎಂದರೇ ಒಂದು ವಾರಕ್ಕೆ ಮೂರು ಸಲವಾದರೂ ಮಾಡಬೇಕು. ಇವುಗಳಿಂದ ದೈಹಿಕವಾಗಿ ಸದೃಢವಾಗುವುದರ ಜೊತೆಗೆ ಮಧುಮೇಹ ರೋಗವನ್ನು ನಿಯಂತ್ರಸಬಹುದಾಗಿದೆ. ಅದರಂತೆ ದೇಹದಲ್ಲಿ ಇನ್ಸುಲಿನ ಉತ್ಪಾದನೆ ಪ್ರಮಾಣ ಅಧಿಕವಾಗುತ್ತವೆ.

ಒಂದು ದೇಳೆ ವ್ಯಾಯಮದಲ್ಲಿ ಬದಲಾವಣೆ ಮಾಡುವುದಾದರೆ ಮೊದಲು ನಿಮ್ಮ ವೈದ್ಯರೊಡನೆ ಚರ್ಚಿಸಿ ಬದಲಾವಣೆ ಮಾಡಿಕೊಳ್ಳಬೇಕು.

ವೈಯಕ್ತಿಕ ಕಾಳಜಿ/ಸ್ವಕಾಳಜಿ ಅಂಶಗಳು/ಸಲಹೆಗಳು:

1. ರಕ್ತದ ಗ್ಲೂಕೋಸ್ (ಸಕ್ಕರೆ) ಪ್ರಮಾಣದ ಬಗ್ಗೆ ಸ್ವಯಂವಾಗಿ ನಿಗಾಯಿಡುವುದು : ಬೇರೆ ಬೇರೆ ರೀತಿಯಾದ ಅಥವಾ ಸರಿಯಾದಲ್ಲದ ಆಹಾರ ಕ್ರಮ , ವ್ಯಾಯಾಮದಿಂದ ದೇಹದಲ್ಲಿ ಅಯಾಸ, ಆನಾರೋಗ್ಯ ಕಾಣಿಸಿಕೊಂಡರೆ ಮೊದಲು ವೈದ್ಯ ಅಥವಾ ಔಷಧತಜ್ಞ (ಫಾರ್ಮಸಿಸ್ಟ) ರೊಡನೆ ಸಮಾಲೋಚಿಸಿ ಅದರ ಪರಿಹಾರ ಕಂಡುಕೊಳ್ಳಬಹುದು.



2. ಗಾಯಗಳು ಮತ್ತು ಸೋಂಕುಗಳಾಗದಂತೆ ಎಚ್ಚರವಹಿಸಬೇಕು. ಸಾಮಾನ್ಯವಾಗಿ ಮಧುಮೇಹವಿರುವ ವ್ಯಕ್ತಿಗಳಲ್ಲಿ ಗಾಯ ಮತ್ತು ಸೋಂಕು ಕಾಣಿಸಿಕೊಂಡರೆ ಅವುಗಳನ್ನು ಗುಣಪಡಿಸಲು ಬಹಳ ಸಮಯ ಒಡಿಯುತ್ತದೆ. ಆದ್ದರಿಂದ ಗಾಯಿಗಳು ಮತ್ತು ಸೋಂಕುಗಳಾಗದಂತೆ ಎಚ್ಚರವಹಿಸಬೇಕು.
3. ಸಂಪೂರ್ಣವಾದ ವೈದ್ಯಕೀಯ ತಪಾಸಣೆ–

ಸಂಪೂರ್ಣವಾದ ವೈದ್ಯಕೀಯ ತಪಾಸಣೆಯನ್ನು ಕನಿಷ್ಠ ಒಂದು ವರ್ಷಕ್ಕೆ ಒಮ್ಮೆಯಾದರು ಪರೀಕ್ಷಿಸಬೇಕು ಅದರಲ್ಲಿ ಕಣ್ಣು ಮತ್ತು ಕಾಲಿನ ಪಾದದ ಬಗೆಗೆ ಎಚ್ಚರದಿಂದಿರಬೇಕು ಅಥವಾ ಪರೀಕ್ಷಿಸಬೇಕು.

4. ಧೂಮಪಾನ ನಿಷೇಧ
5. ನಿಯಮಿತ ಆಹಾರ ಸೇವನೆಯಿಂದ ಕಡಿಮೆ ರಕ್ತದ ಗ್ಲೂಕೋಸ್ (ಸಕ್ಕರೆ)ಯನ್ನು ತಪ್ಪಿಸಬಹುದು.

ಅಧಿಕ ರಕ್ತದ ಗ್ಲೂಕೋಸ್ (ಸಕ್ಕರೆ) ವಿರುದ್ಧ ಕಡಿಮೆ ರಕ್ತದ ಗ್ಲೂಕೋಸ್

ಅಧಿಕ ರಕ್ತದ ಗ್ಲೂಕೋಸ್ (ಸಕ್ಕರೆ) ಮತ್ತು ಕಡಿಮೆ ರಕ್ತದ ಗ್ಲೂಕೋಸ್ ಜೀವಕ್ಕೆ ಗಂಭೀರವಾದ ಹಾನಿಯನ್ನುಂಟು ಮಾಡುತ್ತವೆ. ಅದಕ್ಕಾಗಿ ನೀವು ರಕ್ತದ ಗ್ಲೂಕೋಸ್ (ಸಕ್ಕರೆ) ಮಟ್ಟದ ಎಚ್ಚರಿಕೆ ಅಂಶಗಳು ಮತ್ತು ಅದರ ನಿವಾರಣೆ ಕ್ರಮಗಳ ಬಗ್ಗೆ ತಿಳಿದುಕೊಳ್ಳುವುದು ಅತ್ಯವಶ್ಯಕವಾಗಿದೆ.

Annexure VI: KAP Questionnaires

Knowledge based questionnaires:

Sr. No.	Questionnaires	Answer
1	Have you ever heard of Diabetes?	Yes/ No
2	Is obesity the major cause of diabetes?	Yes/ No
3	Do you know how to measure Diabetes?	Yes/ No
4	Do you know what is Glucose Tolerance Test?	Yes/ No
5	Is lifestyle modification required for a diabetic patient?	Yes/ No
6	Do you know that exercise can help you manage your diabetes?	Yes/ No
7	Can high blood pressure worsen the disease?	Yes/ No
8	Is Fibre rich diet good for Diabetes?	Yes/ No
9	Can medicines alone be used for the treatment of diabetes?	Yes/ No
10	Does diabetes have the potential to harm the body's other organs?	Yes/ No
11	Have you ever participated in a diabetes awareness program?	Yes/ No

Attitude based questionnaires:

Sr. No.	Questionnaires	Answer
1	Do you prefer to exercise every day?	Yes/ No
2	Do you prefer to monitor Fasting Blood Sugar (FBS) and Post Prandial Blood Sugar (PPBS) levels every month?	Yes/ No
3	Do you think taking two doses will help your diabetes get under control faster?	Yes/ No
4	Do you prefer to take medications regularly?	Yes/ No
5	Do you believe that regular check-ups with your doctor are required?	Yes/ No
6	Do you believe that long-term treatments will inevitably lead to organ failures?	Yes/ No
7	Do you prefer to take HbA1c (Glycated hemoglobin) test once in every 3 months?	Yes/ No

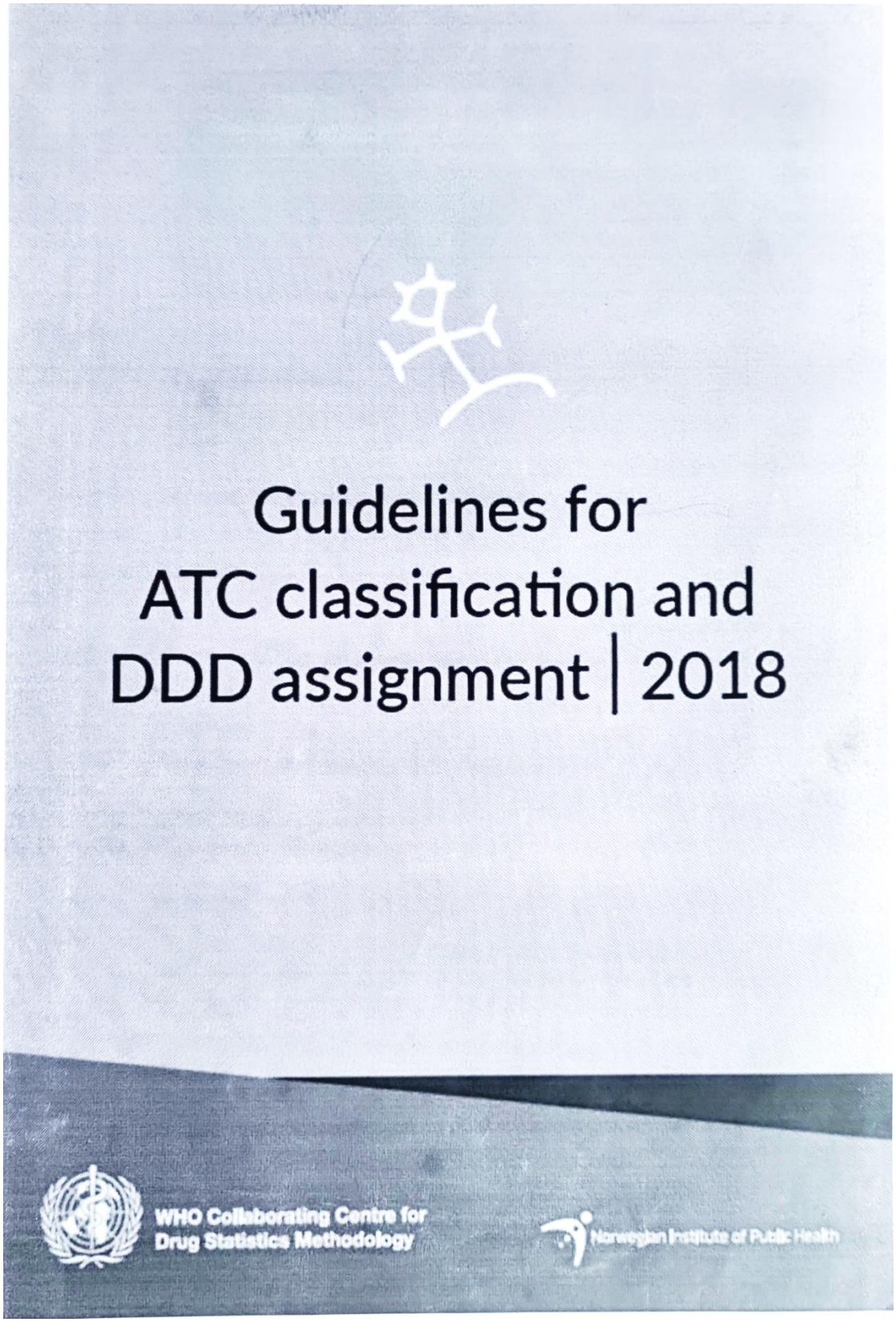
Practice based questionnaires:

Sr. No.	Questionnaires	Answer
1	Do you exercise for 30-60 minutes every day?	Yes/ No
2	Do you monitor Blood Glucose Level every month?	Yes/ No
3	Do you always eat small and frequent meals?	Yes/ No
4	Do you exclude rice from meals?	Yes/ No
5	Do you take medications regularly?	Yes/ No
6	Do you get your HbA1c test done every 3 months?	Yes/ No
7	Do you have habit of Alcohol consumption?	Yes/ No

Annexure VII: WHO Core prescribing indicators

Sr. No.	Core Indicators
1	Average number of drugs prescribed per prescription
2	Percentage of drugs prescribed by generic name
3	Percentage of encounters with antibiotic prescribed
4	Percentage of encounters with injectable drug prescribed
5	Percentage of drugs prescribed from NLEM (National List of Essential Medicines)
6	Percentage of encounters with Fixed drug combination

Annexure VIII: ATC Classification



It has been considered most appropriate to assign fixed DDDs based on the average use of the different combinations without considering and comparing the strengths of the various components. One UD is the fixed DDD for products dosed as 1 tablet daily whereas two UD is the fixed DDD for products dosed as 2 tablets daily. The assigned DDDs cannot always be compared with the DDDs assigned for plain preparations.

See list of DDDs for combined products, www.whocc.no.

A10BF ***Alpha glucosidase inhibitors***

A10BG ***Thiazolidinediones***

The DDD for troglitazone is based on combination therapy. The DDDs for rosiglitazone and pioglitazone are based on monotherapy.

A10BH ***Dipeptidyl peptidase 4 (DPP-4) inhibitors***

A10BJ ***Glucagon-like peptide-1 (GLP-1) analogues***

A10BK ***Sodium-glucose co-transporter 2 (SGLT2) inhibitors***

Inhibitors of SGLT1 and SGLT2, e.g. sotagliflozin, are also classified here.

A10BX ***Other blood glucose lowering drugs, excl. insulins***

Low strength tablets (e.g. 0.8 mg) of bromocriptine are classified in G02CB01.

Nateglinide in combination with thioctic acid is classified in A10BX03.

A10X OTHER DRUGS USED IN DIABETES

A10XA ***Aldose reductase inhibitors***

A11 **VITAMINS**

Vitamins constitute a comprehensive group of therapeutic and prophylactic preparations. Before classifying any product it is important to be familiar with the main subdivision of the group.

It may be necessary to consider whether a product is a vitamin preparation with iron or an iron preparation with vitamins, a mineral preparation with vitamins or a vitamin preparation with minerals, or if the product should be regarded as a tonic etc. As an aid to such considerations, guidelines are given at each sublevel.

Vitamin B_{12} is classified in B03 - *Antianemic preparations*.

A10 **DRUGS USED IN DIABETES**

A10A INSULINS AND ANALOGUES

This group comprises both human - and animal insulins.

Insulin preparations are classified at 4 different 4th levels, according to onset and duration of action. Each 4th level is differentiated in 5th levels according to origin of insulin.

Products consisting of, e.g. beef and pork insulin, are classified as combinations (30-levels) at each 4th level according to onset and duration of action.

The DDD for insulins is 40 units.

A10AB ***Insulins and analogues for injection, fast-acting***

A10AC ***Insulins and analogues for injection, intermediate-acting***

A10AD ***Insulins and analogues for injection, intermediate- or long-acting combined with fast-acting***

Combinations of fast acting insulins with intermediate-acting or long-acting insulins are classified in the 5th levels here.

A10AE ***Insulins and analogues for injection, long-acting***

A10AF ***Insulins and analogues for inhalation***

A10B BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS

Fixed combinations of blood glucose lowering drugs and lipid modifying agentes are classified here.

A10BA ***Biguanides***

A10BB ***Sulfonylureas***

The DDD for micronized glibenclamide is lower compared to non-micronized formulations, due to higher bioavailability.

The DDD for gliclazide is based on the modified release formulation.

A10BC ***Sulfonamides (heterocyclic)***

A10BD ***Combinations of oral blood glucose lowering drugs***

Combinations with thioctic acid are allowed in A10BD05.

Annexure IX: Classification for Drug related problems

Classification for Drug related problems

V9.1

This classification can freely be used in Pharmaceutical Care Research and practice, as long as the PCNE association is informed of its use and results of validations. The classification is available both as a Word document and a PDF document.

Contact: drp@pcne.org

This classification should be referred to as 'The PCNE Classification V 9.1'

With some adaptations, this version is backwards compatible with version 8.

PCNE Classification for Drug-Related Problems V9.1 - Page 2

Introduction

During the working conference of the Pharmaceutical Care Network Europe in January 1999, a classification scheme was constructed for drug related problems (DRPs). The classification is part of a total set of instruments. The set consists of the classification scheme, reporting forms and cases for training or validation. The classification system is validated and adapted regularly. The current version is V9.1, which has been developed after a validation round and an expert workshop in February 2020. It is backwards compatible with V8 (with some adaptations), but not with versions before V8 because a number of major sections have been revised.
The classification is for use in research into the nature, prevalence, and incidence of DRPs and also as a process indicator in experimental studies of Pharmaceutical Care outcomes. It is also meant to help health care professionals to document DRP-information in the pharmaceutical care process. Throughout the classification the word 'drug' is used, where others might use the term 'medicine'.
The hierarchical classification is based upon similar work in the field, but it differs from existing systems because it separates the problems from the causes. Quality experts will recognise that most of the causes are often named 'Medication Errors' by others.
The following official PCNE-DRP definition is the basis for the classification:

A Drug-Related Problem is an event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes.

The basic classification now has 3 primary domains for problems, 9 primary domains for causes and 5 primary domains for Planned Interventions, 3 primary domains for level of acceptance (of interventions) and 4 primary domains for the Status of the problem.
However, on a more detailed level there are 7 grouped sub domains for problems, 43 grouped sub domains for causes and 17 grouped sub domains for interventions, and 10 subdomains for intervention acceptance. Those sub-domains can be seen as explanatory for the principal domains.
In 2003 a scale has been added to indicate if or to what extend the problem has been solved, containing 4 primary domains and 7 sub domains.

J. W. Foppe van Mil, Nejc Horvat, Tommy Westerlund, Ina Richling
Zuidlaren, May 2020

PCNE Classification for Drug-Related Problems V9.1 - Page 3

The basic classification

	Code V9.1	Primary domains
Problems (also potential)	**P1**	**Treatment effectiveness** There is a (potential) problem with the (lack of) effect of the pharmacotherapy
	P2	**Treatment safety** Patient suffers, or could suffer, from an adverse drug event
	P3	**Other**
Causes (including possible causes for potential problems)	**C1**	**Drug selection** The cause of the DRP can be related to the selection of the drug
	C2	**Drug form** The cause of the DRP is related to the selection of the drug form
	C3	**Dose selection** The cause of the DRP can be related to the selection of the dosage schedule
	C4	**Treatment duration** The cause of the DRP is related to the duration of treatment
	C5	**Dispensing** The cause of the DRP can be related to the logistics of the prescribing and dispensing process
	C6	**Drug use process** The cause of the DRP is related to the way the patient gets the drug administered by a health professional or carer, in spite of proper instructions (on the label)
	C7	**Patient related** The cause of the DRP can be related to the patient and his behaviour (intentional or non-intentional)
	C8	**Patient transfer related** The cause of the DRP can be related to the transfer of patients between primary, secondary and tertiary care, or transfer within one care institution.
	C9	**Other**
Planned Interventions	**I0**	**No intervention**
	I1	**At prescriber level**
	I2	**At patient level**
	I3	**At drug level**
	I4	**Other**
Intervention Acceptance	**A1**	**Intervention accepted**
	A2	**Intervention not accepted**
	A3	**Other**
Status of the DRP	**O0**	**Problem status unknown**
	O1	**Problem solved**
	O2	**Problem partially solved**
	O3	**Problem not solved**

PCNE Classification for Drug-Related Problems V9.1 - Page 4

The Problems

Primary Domain	Code V9.1	Problem
1.Treatment effectiveness There is a (potential) problem with the (lack of) effect of the pharmacotherapy.	**P1.1** **P1.2** **P1.3**	No effect of drug treatment despite correct use Effect of drug treatment not optimal Untreated symptoms or indication
2. Treatment safety Patient suffers, or could suffer, from an adverse drug event. *N.B. If there is no specific cause, skip Causes coding.*	**P2.1**	Adverse drug event (possibly) occurring
3. Other	**P3.1**	Unnecessary drug-treatment
	P3.2	*Unclear problem/complaint. Further clarification necessary (please use as escape only)*

❑	Potential Problem
❑	Manifest Problem

PCNE Classification for Drug-Related Problems V9.1 - Page 5

The Causes (including possible causes for potential problems)

[N.B. One problem can have more causes]

	Primary Domain	Code V9.1	Cause
Prescribing & drug selection	**1. Drug selection** The cause of the (potential) DRP is related to the selection of the drug (by patient or health professional)	**C1.1**	Inappropriate drug according to guidelines/formulary
		C1.2	No indication for drug
		C1.3	Inappropriate combination of drugs, or drugs and herbal medications, or drugs and dietary supplements
		C1.4	Inappropriate duplication of therapeutic group or active ingredient
		C1.5	No or incomplete drug treatment in spite of existing indication
		C1.6	Too many different drugs/active ingredients prescribed for indication
	2. Drug form The cause of the DRP is related to the selection of the drug form	**C2.1**	Inappropriate drug form/formulation (for this patient)
	3. Dose selection The cause of the DRP is related to the selection of the dose or dosage	**C3.1**	Drug dose too low
		C3.2	Drug dose of a single active ingredient too high
		C3.3	Dosage regimen not frequent enough
		C3.4	Dosage regimen too frequent
		C3.5	Dose timing instructions wrong, unclear or missing
	4. Treatment duration The cause of the DRP is related to the duration of treatment	**C4.1**	Duration of treatment too short
		C4.2	Duration of treatment too long
Disp	**5. Dispensing** The cause of the DRP is related to the logistics of the prescribing and dispensing process	**C5.1**	Prescribed drug not available
		C5.2	Necessary information not provided or incorrect advice provided
		C5.3	Wrong drug, strength or dosage advised (OTC)
		C5.4	Wrong drug or strength dispensed
Use	**6. Drug use process** The cause of the DRP is related to the way the patient gets the drug administered ***by a health professional or other carer***, despite proper dosage instructions (on label/list)	**C6.1**	Inappropriate timing of administration or dosing intervals by a health professional
		C6.2	Drug under-administered by a health professional
		C6.3	Drug over-administered by a health professional
		C6.4	Drug not administered at all by a health professional
		C6.5	Wrong drug administered by a health professional
		C6.6	Drug administered via wrong route by a health professional
	7. Patient related The cause of the DRP is related to the patient and his behaviour (intentional or non-intentional)	**C7.1**	Patient intentionally uses/takes less drug than prescribed or does not take the drug at all for whatever reason
		C7.2	Patient uses/takes more drug than prescribed
		C7.3	Patient abuses drug (unregulated overuse)
		C7.4	Patient decides to use unnecessary drug
		C7.5	Patient takes food that interacts
		C7.6	Patient stores drug inappropriately
		C7.7	Inappropriate timing or dosing intervals
		C7.8	Patient unintentionally administers/uses the drug in a wrong way

PCNE Classification for Drug-Related Problems V9.1 - Page 6

		C7.9	Patient physically unable to use drug/form as directed
		C7.10	Patient unable to understand instructions properly
Seamless	**8. Patient transfer related** The cause of the DRP can be related to the transfer of patients between primary, secondary and tertiary care, or transfer within one care institution.	**C8.1**	Medication reconciliation problem
	9. Other	**C9.1**	No or inappropriate outcome monitoring (incl. TDM)
		C9.2	Other cause; specify
		C9.3	No obvious cause

The Planned Interventions

N.B. One problem can lead to more interventions

Primary Domain	Code V9.1	Intervention
No intervention	**I0.1**	No Intervention
1. At prescriber level	**I1.1**	Prescriber informed only
	I1.2	Prescriber asked for information
	I1.3	Intervention proposed to prescriber
	I1.4	Intervention discussed with prescriber
2. At patient level	**I2.1**	Patient (drug) counselling
	I2.2	Written information provided (only)
	I2.3	Patient referred to prescriber
	I2.4	Spoken to family member/caregiver
3. At drug level	**I3.1**	Drug changed to …
	I3.2	Dosage changed to …
	I3.3	Formulation changed to …
	I3.4	Instructions for use changed to …
	I3.5	Drug paused or stopped
	I3.6	Drug started
4. Other intervention or activity	**I4.1**	Other intervention (specify)
	I4.2	Side effect reported to authorities

PCNE Classification for Drug-Related Problems V9.1 - Page 7

Acceptance of the Intervention proposals

N.B. One status of acceptance per intervention proposal

Primary domain	Code 9.1	Implementation
1. Intervention accepted (by prescriber or patient)	**A1.1**	Intervention accepted and fully implemented
	A1.2	Intervention accepted, partially implemented
	A1.3	Intervention accepted but not implemented
	A1.4	Intervention accepted, implementation unknown
2. Intervention not accepted (by prescriber or patient)	**A2.1**	Intervention not accepted: not feasible
	A2.2	Intervention not accepted: no agreement
	A2.3	Intervention not accepted: other reason (specify)
	A2.4	Intervention not accepted: unknown reason
3. Other (no information on acceptance)	**A3.1**	Intervention proposed, acceptance unknown
	A3.2	Intervention not proposed

Status of the DRP

N.B. This domain depicts the outcome of the intervention. One problem (or the combination of interventions) can only lead to one level of solving the problem

Primary Domain	Code V9.1	Outcome of intervention
0. Not known	**O0.1**	Problem status unknown
1. Solved	**O1.1**	Problem totally solved
2. Partially solved	**O2.1**	Problem partially solved
3. Not solved	**O3.1**	Problem not solved, lack of cooperation of patient
	O3.2	Problem not solved, lack of cooperation of prescriber
	O3.3	Problem not solved, intervention not effective
	O3.4	No need or possibility to solve problem

Annexure X: Drug Interaction Documentation Form

KLE

KLE COLLEGE OF PHARMACY

DEPARTMENT OF PHARMACY PRACTICE

3rd Floor, Vivekanand General Hospital Deshpandenagar,
HUBBALLI-580029. Ph. : 0836-2254245

E-mail : kleclinpharmdic@gmail.com

DRUG INTERACTION DOCUMENTATION FORM

Date : ..... Unit : ..... Dept. : ..... IP Number : .....

Patient Details :

Age : ..... Sex : ☐ Male ☐ Female PMHx :

Allergies :

Diagnosis :

Drugs involved :

Brief description of Drug interaction :

Case narrative :

Suggestions made :

Significance of Drug interaction : ☐ Minor
☐ Moderate
☐ Major

Reference consulted : ☐ Med Line ☐ DI Files ☐ Other (Specify)
☐ Micromedex ☐ IDIS ☐ Texts :

Name of Clinical Pharmacist : Name of Staff incharge :

Signature : Date : Signature : Date :

Interaction Note :

Annexure XI: Pharmacist Intervention Documentation Form

KLE COLLEGE OF PHARMACY
DEPARTMENT OF PHARMACY PRACTICE
3rd Floor, Vivekanand General Hospital Deshpandenagar,
HUBBALLI-580029. Ph. : 0836-2254245
E-mail : kleclinpharmdic@gmail.com

PHARMACIST INTERVENTION DOCUMENTATION FORM

Date : ..... **Unit :** **IP Number :** .....

Patient Details :

Age : **Sex :** ☐ **Male** ☐ **Female** **PMHx :**

Diagnosis :

Drug(s) Involved :

Date of drug prescribed :

Day of problem Identified :

DRP Identified :

- ☐ Untreated Indication
- ☐ Drug use without indication
- ☐ Subtherapeutic dose
- ☐ Overdose
- ☐ ADR
- ☐ Drug Interaction
- ☐ Improper drug selection
- ☐ Alternative dosage forms
- ☐ Others (Please specify)

Specific background information collected? ☐ Yes ☐ No

Reason for Intervention :

Problem indentified discussed with concerned Physician : ☐ Yes ☐ No

Suggestions made:

Suggestion made at appropriate time : ☐ Yes ☐ No

Accepted : ☐ Yes ☐ No

If no, give reason (s) : Changed : ☐ Yes ☐ No

Significance of intervention :

- ☐ Minor.
- ☐ Moderate
- ☐ Major

Reference Consulted : ☐ Medline : ☐ DI Files : ☐ Others :
☐ IDIS : ☐ Texts :
☐ Micromedex : ☐ Personal Knowledge :

Follow up :

Name of the Pharmacist : **Signature :**

Pharmacist (Staff) in-charge : **Signature :**

Minor : Problems requiring small adjustments and optimization to therapy, which are not expected to significantly alter hospital stay, resource utilixation of clinical outcome.

Moderate : Problems requiring adjustments, which are expected to enhance effectiveness of drug therapy producing minor reductions in patient morabidity of treatment costs.

Major : Problems requiring intervention expected to prevent or address very serious drug related problems with a minimum f estimated effect on reducing hospital stay by no less than 24 hours.

Annexure XII: Suspected ADR Notification Form

KLE
ACADEMY OF HIGHER EDUCATION AND RESEARCH
EMPOWERING PROFESSIONALS Deemed-to-be-University

KLE COLLEGE OF PHARMACY, HUBBALLI

DEPARTMENT OF PHARMACY PRACTICE

3RD Floor, Vivekanand General Hospital, Deshpandenagar,HUBBALLI-580029. Ph. 0836-2254245

E-mail: Kleclinpharmdic@gmail.com

NOTIFICATION OF A SUSPECTED ADVERSE DRUG REACTION FORM

Patient Name : ..... Age : ..... Sex : .....

I.P. /O.P. No. : ..... Dept. : ..... Unit : .....

Suspected drug(s) : .....

Date of Suspected drug(s) started : .....

Date of onset of reaction : .....

Brief description of reaction : .....

.....

Name of the Reporting Doctor/PG's/Clinical Pharmacist/Others.....

Signature : ..... Date : .....

Please return this form the department of Clinical Pharmacy so that a Clinical Pharmacist can investigate and document the suspected adverse drug reaction as soon as possible.

Annexure XIII: Suspected ADR Reporting Form

KLE COLLEGE OF PHARMACY
DEPARTMENT OF PHARMACY PRACTICE
3rd Floor, Vivekanand General Hospital Deshpandenagar,
HUBBALLI-580029. Ph. : 0836-2254245
E-mail : kleclinpharmdic@gmail.com

SUSPECTED ADVERSE DRUG REACTION REPORTING & ASSESSMENT FORM

Section A : Details of Patient :

Patient name : _____ Sex : ☐ M ☐ F Pregnant ☐ No. ☐ Yes ☐ Unknown

Weight (if known) : ____ kg Age _____ D.O.A. : D.O.D. :

Previous ADRs (from past medication history)

Section B : Details of Suspected Drug :

Brand Name of Drug /Generic	Route / Frequency	Dose	Date Started	Date Stopped	Prescribed for	Manufacturer and Batch No./Lot	Exp. Date

Section B : Details of Suspected Drug :

Date of reaction/event started : Date of Recovery :

Reaction Abated after Drug Stopped or Dose Reduced					Reaction reappeared after Re-introduction				
Yes	No	Unknown	NA	Reduced Dose	Yes	No	Unknown	NA	Reduced Dose

Description of Event :

Test/ Laboratory abnormality relevant to event (Mention Dates) :

Seriousness of event :
Death : (/ /)
Life theatening :
Hospitalization-initial or prolonged
Disability :
Congenital anomaly :
Required intervention to prevent permanent imparirment / damage :
Other : (Specify)

Section D: Details of Concomitant medications :

All Drug Therapies Prior to ADR	Dosage	Route	Date Started	Date Stopped	Reason for Use

Section E : Details of Reporter :

Details of the Reporter :
Name : _____
Occupation :
Date of Report :
Signature :
Mobile :

Annexure XIV: Causality Assessment Scale

Casualty Assessment : [Naranjo Scale]

[Definite:>= 9 or greater, probable for a score of 5-8, possible for 1-4 and doubtful if the score is O]

Question	Yes	No	Don't Know/NA	Score
1. Are there previous conclusioe reports on this reaction?	+1	0	0	
2. Did the adverse event appear after the suspected drug was administered?	+2	-1	0	
3. Did the adverse reaction improve when the drug was discontinued or a specific antagonist was administered?	+1	0	0	
4. Did the adverse event reappear when the drug was re-administered?	+2	-1	0	
5. Are there alternative causes (other than the drug) that could on their own have caused the reaction?	-1	+2	0	
6. Did the reaction reappear when a placebo was given?	-1	+1	0	
7. Was the drug detected in blood (or other fluids) in concentrations known to be toxic?	+1	0	0	
8. Was the reaction more severe when the dose was increased or less severe when the dose was decreased?	+1	0	0	
9. Did the patient have a similar reaction to the same or similar drugs in anu previous exposure?	+1	0	0	
10. Was the adverse event confirmed by any objective evidence?	+1	0	0	
			Total	

Report: ☐ **Definite** ☐ **Probable** ☐ **Possible** ☐ **Doubtful**

✓ **Hartwig's Severity Assessment Scale: [Mild= level 1 and 2, moderate= level 3 and 4, severe= 5, 6 and 7.]**

Hartwig's Severity Assessment Scale	Level	Description
	1	An ADR occurred but required no change in treatment with the suspected drug.
	2	The ADR required that treatment with the suspected drug be held, discontinued, or otherwise changed. No antidote or other treatment requirement was required. No increase in length of stay(LOS)
	3	The ADR required that treatment with the suspected drug be held, discontinued, or otherwise changed. AND/OR An Antidote or other treatment was required. No increase in length of stay (LOS)
	4	Any level 3 ADR which increases length of stay by at least 1 day. OR The ADR was the reason for the admission
	5	Any level 4 ADR which requires intensive medical care
	6	The adverse reaction caused permanent harm to the patient
	7	The adverse reaction either directly or indirectly led to the death of the patient

Report : ☐ Mild ☐ Moderate ☐ Severe

Intervention performed :

☐ Drug stopped ☐ Drug replaced ☐ Supplement added ☐ No change

Conclusion :

Annexure XV: Schmuck and Thornton scale

Sr. no.	Schmuck and Thornton Criteria	Yes	No
Definitely preventable ADEs			
1.	Was there a history of allergy or previous reaction to the drug?		
2.	Was the drug involved inappropriate for the patient's clinical condition?		
3.	Was the dose, route, or frequency of administration inappropriate for patient's age, weight or disease state?		
4.	Was toxic serum drug concentration or lab monitoring test documented?		
5.	Was there a known treatment for ADEs?		
Probably preventable ADEs			
6.	Was therapeutic drug monitoring or other necessary lab test not performed?		
7.	Was the drug interaction involved in ADEs?		
8.	Was poor compliance involved in ADE?		
9.	Were preventative measures not prescribed or administered to the patient?		
Non-preventable ADEs or ADRs			
10.	If all the above criteria not fulfilled.		

On the basis of Schmuck and Thornton criteria, ADEs are,

Definitely preventable ADEs ☐ Probably preventable ADEs ☐

Non-preventable ADEs / adverse drug reaction (ADRs) ☐

Annexure XVI: WHO-UMC Causality assessment scale

the UPPSALA MONITORING CENTRE

The use of the WHO-UMC system for standardised case causality assessment

Why causality assessment?

An inherent problem in pharmacovigilance is that most case reports concern *suspected* adverse drug reactions. Adverse reactions are rarely specific for the drug, diagnostic tests are usually absent and a rechallenge is rarely ethically justified. In practice few adverse reactions are 'certain' or 'unlikely'; most are somewhere in between these extremes, i.e. 'possible' or 'probable'. In an attempt to solve this problem many systems have been developed for a structured and harmonised assessment of causality [1]. None of these systems, however, have been shown to produce a precise and reliable quantitative estimation of relationship likelihood. Nevertheless, causality assessment has become a common routine procedure in pharmacovigilance. The advances and limitations of causality assessment are reviewed in *Table 1* [2].

Table 1. Advances and limitations of standardised case causality assessment

What causality assessment can do	What causality assessment cannot do
Decrease disagreement between assessors	Give accurate quantitative measurement of relationship likelihood
Classify relationship likelihood	Distinguish valid from invalid cases
Mark individual case reports	Prove the connection between drug and event
Improvement of scientific evaluation; educational	Quantify the contribution of a drug to the development of an adverse event
	Change uncertainty into certainty

The WHO-UMC causality assessment system

The WHO-UMC system has been developed in consultation with the National Centres participating in the Programme for International Drug Monitoring and is meant as a practical tool for the assessment of case reports. It is basically a combined assessment taking into account the clinical-pharmacological aspects of the case history and the quality of the documentation of the observation. Since pharmacovigilance is particularly concerned with the detection of unknown and unexpected adverse reactions, other criteria such as previous knowledge and statistical chance play a less prominent role in the system. It is recognised that the semantics of the definitions are critical and that individual judgements may therefore differ. There are other algorithms that are either very complex or too specific for general use. This method gives guidance to the general arguments which should be used to select one category over another.

The various causality categories are listed in *Table 2*. The original descriptions and an explanation are presented under 'Definitions' [3]. In *Table 2* the assessment criteria of the various categories are shown in a point-wise way, as has been developed for practical training during the UMC Training Courses.

Table 2. WHO-UMC Causality Categories

Causality term	*Assessment criteria**
Certain	• Event or laboratory test abnormality, with plausible time relationship to drug intake • Cannot be explained by disease or other drugs • Response to withdrawal plausible (pharmacologically, pathologically) • Event definitive pharmacologically or phenomenologically (i.e. an objective and specific medical disorder or a recognised pharmacological phenomenon) • Rechallenge satisfactory, if necessary
Probable / Likely	• Event or laboratory test abnormality, with reasonable time relationship to drug intake • Unlikely to be attributed to disease or other drugs • Response to withdrawal clinically reasonable • Rechallenge not required
Possible	• Event or laboratory test abnormality, with reasonable time relationship to drug intake • Could also be explained by disease or other drugs • Information on drug withdrawal may be lacking or unclear
Unlikely	• Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible) • Disease or other drugs provide plausible explanations
Conditional / Unclassified	• Event or laboratory test abnormality • More data for proper assessment needed, or • Additional data under examination
Unassessable / Unclassifiable	• Report suggesting an adverse reaction • Cannot be judged because information is insufficient or contradictory • Data cannot be supplemented or verified

* All points should be reasonably complied with

The use of the WHO-UMC system

To illustrate how the system works, we suggest to first make a comparison of the criteria and wording of 'Probable' and Certain'. First of all there is one more criterion in the category 'Certain', the fourth: 'Event definitive pharmacologically or phenomenologically', i.e. an objective and specific medical disorder or a recognised pharmacological phenomenon (for instance 'grey baby syndrome' and chloramphenicol, or anaphylaxis immediately after the administration of a drug that had been given previously). This means that any other event is automatically excluded and can never qualify for 'Certain' (even in the case of a positive rechallenge observation). For 'Certain', rechallenge information with a satisfactory outcome is requested (i.e. what has happened when the drug was first stopped and later on resumed), unless the evidence in the report is already convincing without a re-exposure. For 'Probable', on the other hand, a rechallenge is not required. To qualify as 'Certain' the interval between the start of the drug and the onset of the event must be 'plausible'; this means that there is in sufficient detail a positive argument in support of the view that the drug is causally involved, pharmacologically or pathologically. For 'Probable' the time relationship should be 'reasonable'; this is a more neutral term covering everything that is not unreasonable. Also, with regard to the second criterion, 'alternative causes', the wording is different in 'Probable'. For 'Certain' the occurrence of the event cannot be explained by any disease the patient is known to

have or any other drug taken. For 'Probable', on the other hand, the event is 'unlikely' to be attributable to another cause. Also the dechallenge situations (i.e. what happened after stopping) are different. In a 'Certain' case report, the course of events constitutes a positive argument in favour of holding the suspected drug responsible, in pharmacological or pathological respects, whereas in a 'Probable' case it is sufficient if it is 'clinically reasonable' (i.e. not unreasonable).

The essential distinctions between 'Probable' and 'Possible' are that in the latter case there may be another equally likely explanation for the event and/or there is no information or uncertainty with regard to what has happened after stopping.

The criteria that may render the connection 'Unlikely' are firstly the time relationship is improbable (with the knowledge at the time), and/or another explanation is more likely. The term 'Unclassified / Conditional' is of a preliminary nature and is appropriate when, for a proper assessment, there is more data needed and such data are being sought, or are already under examination. Finally when the information in a report is incomplete or contradictory and cannot be complemented or verified, the verdict is 'Unclassifiable'.

Since by far the most frequent categories in case reports are 'Possible' and 'Probable', the usual approach to using the system is to choose one of these categories (depending on the impression of the assessor) and to test if the various criteria fit with the content of the case report. If the report seems stronger one can go one step 'higher' (e.g. from 'Possible' to 'Probable'), if the evidence seems weaker one should try a 'lower' category. To see if that category is the right one or if it does again not seem to fit, the next adjacent term is tried.

For drug-drug interactions the WHO-UMC system can be used by assessing the actor drug, which influences the kinetics or dynamics of the other drug (which has usually been taken over a longer period), in the medical context of the patient.

How does it work?

How the WHO-UMC causality assessment system can be used will be illustrated with the aid of a few real-life case reports. These will be made available on the UMC website in the near future.

1. Meyboom RHB, Royer RJ. Causality Classification in Pharmacovigilance Centres in the European Community. Pharmacoepidemiology and Drug Safety 1992; 1:87-97.

2. Meyboom RHB. Causal or Casual? The Role of Causality Assessment in Pharmacovigilance. Drug Safety 17(6): 374-389, 1997.

3. Edwards IR, Biriell C. Harmonisation in Pharmacovigilance. Drug Safety 10(2): 93-102, 1994.

Annexure XVII: SF-36

SF-36 Questionnaire

Patient's Name: _____ Date:

INSTRUCTIONS: Please answer every question. Some questions may look like others, but each one is different. Please take the time to read and answer each question carefully by circling the number that best represents your response.

1. In general, would you say your health is?

Excellent (1)	Very Good (2)	Good (3)	Fair (4)	Poor (5)

2. <u>Compared to one year ago</u>, how would you rate your health in general <u>now</u>?

Much better now than one year ago (1)	Somewhat better now than one year ago (2)	About the same as one year ago (3)	Somewhat worse now than one year ago (4)	Much worse now than one year ago (5)

3. The following questions are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much: (circle one number on each line)

	Yes, Limited A Lot	Yes, Limited A Little	No, Not Limited At All
A. **Vigorous activities**, such as running, lifting heavy objects participating in strenuous sports	1	2	3
B. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3
C. Lifting or carrying groceries	1	2	3
D. Climbing **several** flights of stairs	1	2	3
E. Climbing **one** flight of stairs	1	2	3
F. Bending, kneeling, or stooping	1	2	3
G. Walking **more than a mile**	1	2	3
H. Walking **several hundred yards**	1	2	3
I. Walking **one hundred yards**	1	2	3
J. Bathing or dressing yourself	1	2	3

4. During the <u>past 4 weeks</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health?</u> (Circle one number on each line)

	All the time	**Most** of the time	**Some** of the time	A **little** of the time	**None** of the time
A. Cut down on the **amount of time** you spend on work or other activities	1	2	3	4	5
B. **Accomplished less** than you would like	1	2	3	4	5
C. Were limited in the **kind** of work or other activities	1	2	3	4	5
D. Had **difficulty** performing the work or other activities (for example, it took extra effort)	1	2	3	4	5

5. During the <u>past 4 weeks</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of any emotional problems</u> (such as feeling depressed or anxious)? (Circle one number on each line)

	All the time	**Most** of the time	**Some** of the time	**A little** of the time	**None** of the time
A. Cut down on the **amount of time** you spend on work or other activities	1	2	3	4	5
B. **Accomplished less** than you would like	1	2	3	4	5
C. Did work or activities **less carefully than usual**	1	2	3	4	5

6. During the <u>past 4 weeks</u>, to what extent has your <u>physical health or emotional problems</u> interfered with your social activities with family, friends, neighbours, or groups? (Circle one)

Not at all (1)	Slightly (2)	Moderately (3)	Quite a bit (4)	Extremely (5)

7. How much <u>bodily</u> pain have you had during the <u>past 4 weeks</u>? (Circle one)

None (1)	Very Mild (2)	Mild (3)	Moderate (4)	Severe (5)	Very Severe (6)

8. During the <u>past 4 weeks</u>, how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)? (Circle one)

Not at all (1)	Slightly (2)	Moderately (3)	Quite a bit (4)	Extremely (5)

9. These questions are about how you feel and how things have been with you <u>during the past 4 weeks</u>. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the <u>past 4 weeks</u>… (Circle one number on each line)

	All the time	**Most** of the time	**Some** of the time	**A little** of the time	**None** of the time
A. did you feel full of life?	1	2	3	4	5
B. have you been very nervous?	1	2	3	4	5
C. have you felt so down in the dumps nothing could cheer you up?	1	2	3	4	5
D. have you felt calm and peaceful?	1	2	3	4	5

E. did you have a lot of energy?	1	2	3	4	5
F. have you felt downhearted and depressed?	1	2	3	4	5
G. did you feel worn out?	1	2	3	4	5
H. have you been happy?	1	2	3	4	5
I. did you feel tired?	1	2	3	4	5

10. During the <u>past 4 weeks</u>, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting friends, relatives, etc.)?

All of the Time (1)	Most of the Time (2)	Some of the Time (3)	A Little of the Time (4)	None of the Time (5)

11. How TRUE or FALSE is each of the following statements for you? (Circle one number on each line)

	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
A. I seem to get sick a little easier than other people	1	2	3	4	5
B. I am as healthy as anybody I know	1	2	3	4	5
C. I expect my health to get worse	1	2	3	4	5
D. My health is excellent	1	2	3	4	5

Annexure XVIII: Medication Adherence Rating Scale

SI. No.	Questions	Answer
1	Do you ever forget to take your medication?	Yes / No
2	Are you careless at times about taking your medication?	Yes / No
3	When you feel better, do you sometimes stop taking your medication?	Yes / No
4	Sometimes if you feel worse when you take the medication, do you stop taking it?	Yes / No
5	I take my medication only when I am sick	Yes / No
6	It is unnatural for my mind and body to be controlled by medication	Yes / No
7	My thoughts are clearer on medication	Yes / No
8	By staying on medication, I can prevent getting sick.	Yes / No
9	I feel weird, like a 'zombie' on medication	Yes / No
10	Medication makes me feel tired and sluggish	Yes / No

Annexure XIX: Ethical Clearance Letter

KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH
(Formerly known as KLE University)
(Deemed-to-be-University established u/s 3 of the UGC Act, 1956)
Accredited 'A' Grade by NAAC (2nd Cycle) Placed in Category 'A' by MHRD (GoI)
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☎: 0831-2444444 FAX: 0831-2493777 Web: http://www.kledeemeduniversity.edu.in E-mail: info@kledeemeduniversity.edu.in

Ref.No.KAHER/EC/19-20/29061900 4 28th June 2019

To,
Dr. Sanatkumar B Nyamagoud
Part-Time Ph.D. Research Scholar,
2018-19 Batch, Faculty of Pharmacy,
KAHER, Belagavi.

Dear Research Scholar

The KAHER Ethics Committee on Human Subjects for Ph.D. Research Project met on 14th **May 2019** to consider your application for approval of the research project **"Role of clinical pharmacist interventions in the management of diabetes mellitus: A Randomized controlled study."**

As there are no ethical issues involved in your proposed research project, the committee has provided approval for this research project.

You are requested to report to Ethical Committee of the following:

1. Any deviation from or change of the protocol.
2. Any changes in study documents.

(Dr. Anita Dalal)
Member-Secretary
Ethical Committee (Human) for Ph. D. Research
KAHER, Belagavi.

(Dr. B.C. Kotintot)
Chairman
Ethical Committee (Human) for Ph. D. Research
KAHER, Belagavi.

CC to: - The Director Research Foundation, KAHER, Belagavi.
- The Director Academic Affairs, KAHER, Belagavi.
- The Registrar, KAHER, Belagavi.
- Special Officer to Hon. Vice Chancellor, KAHER, Belagavi.

KLE

COLLEGE OF PHARMACY-HUBBALLI

A constituent unit of

KLE Academy of Higher Education and Research

(Deemed-to-be-University)

Accredited 'A' Grade by NAAC (2nd Cycle) Placed in Category 'A' by MHRD (GoI)

Recognised by Government of Karnataka

Approved by Pharmacy Council of India (PCI) & All India Council for Technical Education (AICTE), New Delhi

(Re-accredited by NBA, AICTE, New Delhi)

Institutional Ethics Committee

Date: 16-04-2019

To,

Principal Investigator/s: Dr. Sanatkumar B Nyamagoud

Guide/Co-guide/Co-investigators: Prof. / Dr. A.H.M. Vishwanathaswamy

The institutional ethics committee meeting was held on 23/03/2019. The committee reviewed and discussed your application to conduct the clinical research proposal/project entitled "Role of Clinical Pharmacist interventions in the management of Diabetes Mellitus: A Randomized controlled study." . (KLECOPH/IEC/PhD/2018-19/01. dated: 23/03/2019)

Decision of Committee:

- Approved : ☑
- Provisionally Approved : ☐
- Pending : ☐
- Not Approved : ☐

Member Secretary

Dr. A.H.M. Vishwanathaswamy

KLES COLLEGE OF PHARMACY HUBBALLI 580031

Chairperson

Dr. V.G. Kamakandi

Principal

KLES College of Pharmacy

(A constituent unit of KLE Academy of Higher Education & Research)

Vidyanagar, HUBBALLI - 580 031

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Annexure XX: Publications

Original Article

Access this article online
Quick Response Code:

Website: https://journals.lww.com/blde
DOI: 10.4103/bjhs.bjhs_141_22

Assessment of knowledge, attitude, and practices in patients with Diabetes mellitus in a tertiary care hospital

Sanatkumar B. Nyamagoud*, Agadi Hiremath Viswanatha Swamy, Bharati Kangrali[1]

Abstract:

BACKGROUND: Over half of the population in India is at risk of having diabetes mellitus (DM) at some time in their lives, making the disease a significant public health concern. Knowledge, attitudes, and practices in DM patients in tertiary care hospitals need to be assessed to understand knowledge, attitude, and practice (KAP) in the study population and also to build a relationship with patient demographics to improve the level of treatment and management of DM.

AIM AND OBJECTIVE: The study aimed to assess the knowledge, attitude, and practices of patients with DM in a study population.

MATERIALS AND METHODS: It was a prospective randomized controlled study where the participants were randomized into two groups, i.e., the interventional or study group and control group. The study was conducted for 3 years in Vivekanand General Hospital, Hubballi. A total of 300 subjects ($n = 300$), i.e., interventional ($n = 150$) and the control group ($n = 150$) with the age of 18 years and above and were diagnosed with DM were assessed with a self-designed questionnaire to collect data and subjected to statistical tests such as an Independent Student's *t*-test and Bivariate analysis.

RESULTS: The study analysis depicted that the majority of the study participants had a better KAP in all demographic domains. The assessment of literate subjects showed better KAP results. It was also noted that subjects with a disease duration of more than 5 years had better knowledge (72.51%), attitude (75.69%), and practice (64.06%), contrary to the subjects with a disease duration <5 years with poor knowledge (27.48%), attitude (24.3%), and practice (35.95%). The bivariate test results demonstrated that there is a significant difference ($P < 0.05$) in the domains of age, education, and duration of disease with respect to knowledge, attitude, and practice.

CONCLUSION: The analysis revealed that the study participants had inadequate knowledge, lack of attitude, and inadequate practices. Thus, effective health education interventions are necessary to address the disease, its management, associated complications, and lifestyle modifications.

Keywords:

Attitude, diabetes mellitus, knowledge, lifestyle modifications, practice, self-designed questionnaires

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Address for correspondence:
Sanatkumar B. Nyamagoud, Department of Pharmacy Practice, KLE College of Pharmacy, Hubballi - 580 031, A Constituent Unit of KLE Academy of Higher Education and Research, Belagavi, Karnataka, India.
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Published: 19-07-2023

Diabetes mellitus (DM) is a group of endocrine metabolic diseases characterized by hyperglycemia and abnormalities in carbohydrate, lipid, and protein metabolism. It has the potential to cause persistent microvascular, macrovascular, and neuropathic problems.[1]

India is the diabetic capital of the world, with an estimated 72.96 million cases of diabetes in the adult population. The prevalence in urban areas ranges between 10.9% and 14.2%, on the other hand, the prevalence in rural areas ranges from 3% to 7.8% among the population aged 20 years and above with a much higher prevalence among individuals aged over 50 years (as per INDIAB study).[2,3]

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The use of Insulin for the treatment of type 1 DM and the critical management of type 2 DM is very essential. Despite this, many people fail to adhere to the prescription pattern. Management and treatment of DM require the use of oral hypoglycemic agents and injectable insulin therapy along with certain lifestyle modifications.

DM has reached potentially epidemic proportions in India. Diabetes and its possible consequences cause huge morbidity and mortality, posing significant health-care expenses for both families and society.[2]

The death rates worldwide due to DM are relatively high. This creates the need for a carefully planned and discreetly carried out study to precisely analyze the knowledge, attitude, and practice (KAP) levels in the population concerning DM an absolute necessity.[4] The present study was designed to identify and interpret the demographic and geographic distribution of diabetes mellitus and also to understand the awareness of the population toward antidiabetes campaigns. The study may be used to provide a baseline for identifying educational needs and developing methods for promoting positive attitudes and healthy behaviors among diabetics. Diabetics must be informed about certain current monitoring techniques and encouraged to practice them.[5-8]

Providing regular information about the disease, medication, and lifestyle modification will certainly provide consequent improvement in a KAP study which will lead to better control of the disease.[9-13] Patient education improves the effectiveness of treatment and better management of prevailing health problems.[14]

In most KAP surveys, data are collected orally by an interviewer using a structured, standardized questionnaire. These data can then be analyzed statistically or qualitatively depending on the study's aims and methodology. A KAP survey might be structured to collect data about diabetes, but it can also include questions on general health behaviors and attitudes. A KAP survey collects information on respondents' understanding of diabetes. KAP surveys can reveal knowledge gaps, cultural views, or behavioral patterns that can help people understand and act toward DM, as well as pose challenges or create barriers.[15] They can recognize information, i.e. widely known and attitudes that are widely held. They can, to some extent, discover factors that influence behavior that most people are unaware of, as well as reasons for people's attitudes and how and why they engage in specific health behaviors.[9] KAP is measured using a self-designed 25-item KAP survey form that contains 11 knowledge questions, 7 attitude questions, and 7 practice questions.

Materials and Methods

Participants and data collection

It is a prospective randomized controlled study in which the subjects were randomized into two groups, i.e., interventional or study group and control group. The study was conducted for 3 years at Vivekanand General Hospital, Hubballi. The study included patients of age above 18 years and diagnosed with DM (both type 1 and type 2) in outpatient and inpatient wards of the general medicine department with or without comorbid conditions. At the start of the study, each participant was informed about the research objectives for filling out the questionnaire and the survey's confidentiality, and each gave informed consent. All participants were told that their identities would be kept confidential and that the findings would only be used for study purposes. A total of 300 diabetic patients participated in the study. Student participants meeting the study criteria filled out the data collection form which had demographic information, socio-economic status, and mobile phone-related information. Research work was executed in accordance with the ethical principles of "The Declaration of Helsinki" after obtaining prior voluntary consent from the study participants. Wherever required, the study team aided participants in filling out the data collection form.

Ethical clearance

Ethical clearance was obtained from Institutional Ethical Committee from KLE Academy of Higher Education and Research Belagavi (Reference number: KAHER/EC/19-20/290619004).

Questionnaire

After conducting an extensive literature review, a self-made questionnaire was developed using the most current information from reputable sources such as the World Health Organization, Centers for Disease Control and Prevention, and Indian Ministry of Health and Family Welfare. The questionnaire consisted of two sections: the first segment focused on participant demographics, while the second assessed KAP related to diabetes. The KAP section included 11 knowledge questions, 7 attitude questions, and 7 practice questions. The majority of the knowledge questions pertained to the participant's comprehension of clinical signs and symptoms, risk factors, severity, prevention, control, and management, and were answered with a simple yes/no response format, where yes received one point and no received zero points. The attitude and practice questions provided specific answer choices related to blood glucose level monitoring, exercise, medication adherence, meal, and follow-up. The KAP questionnaire underwent independent review and validation by three physicians, and only minor grammatical changes were suggested.

During the study, a total of 300 diabetic patients, both out-and in-patients with various comorbidities, were interviewed. The participants' demographic data, medical history, laboratory results, progress charts, and prescribed medication were collected and recorded using a suitable data collection form. The KAP questionnaire, consisting of 25 questions, was administered to the participants, and the results were analyzed using MS-Excel 2020 and SPSS 160. The findings were presented using descriptive statistics, such as mean, percentage, tables, graphs, and pie charts. A multivariate analysis was conducted to determine the significance and relationships among the variables.

Statistical analysis

The participants' data were imported directly into Excel spreadsheets and carefully examined for any errors or incomplete entries. We obtained responses from all 300 subjects without any errors, and the data were then coded to calculate final KAP scores. Statistical analysis was performed using SPSS Version 16.0, and demographic variables were subjected to bivariate analysis to identify potential determinants for good KAP among the study participants. A *P* value of 0.05 was used to describe statistical significance.

Results

Distribution of demographic characteristics

Of 300 participants, 218 were male (72.60%) and 82 were female (27.30%). The age group distribution of 61–70 years was the largest, with 82 (27.33%) participants, followed by the age group of 21–30 years, which had the fewest participants at 6 (02.00%). A participant's BMI distribution of 85 (28.33%), 108 (36.00%), and 33 (11.00%), respectively, revealed obese, overweight, and underweight. Majority of the participants, 174 (58%) and 187 (62.33%), were linked to alcohol and smoking. There were 91 (30.33%) and 51 (17.00%) participants who did not smoke or drink alcohol, respectively. One hundred and eighty-three of the participants had literate (61%) while 117 were illiterate (39%). To determine the socioeconomic class of the individuals, Kuppuswamy's scale was used. The majority of participants, 121 (40.33%), belonged to the lower middle class, while the least number, 27 (9.00%) from the upper class. The majority of study subjects (102, 34.00%) had diabetes for more than 10 years, whereas just 28 (9.33%) of the patients had the disease for less than a year. The complete breakdown of the categorical demographics of the study participants, expressed as a percentage, is provided in Table 1.

Out of 300 subjects, 131 (43.67%) patients had better knowledge, 144 (48.00%) had a better attitude, and 153 (51.00%) had better practice. The majority of the patients in the study population were over 60 years old. Out of 218 males, 89 (68.46%) patients had better knowledge, 102 (75.56%) had a better attitude and 36 (60.00%) had better practice. Out of 183 literate patients, 91 (75.83%), 61 (61.62%), and 28 (60.87%) patients had better KAP, respectively. Of the patients with diabetes, more than 10 years were 102, of which 53 (37.59%) patients had better knowledge, 46 (36.22) patients had a better attitude, and 56 (36.84%) patients had better practice.

Out of 300 participants, 169 patients had diabetic complications, of which coronary artery disease was the highest number 56 (46.67%) followed by chronic kidney disease 33 (27.50%), and diabetic foot was the lowest 14 (11.67%) as depicted in Figure 1.

Knowledge

The study result depicted that, out of 300 subject's majority of the subjects heard of diabetes and also knew that obesity is the major cause. Only 18 (6.00%) subjects were aware of the glucose tolerance test and only 38 (12.67%) subjects ever participated in a diabetes awareness program as shown in Table 2 and Figure 2.

Attitude

The study illustrated that, out of 300 subject's majority of the subjects, i.e., 82.67% (n = 248) had a positive attitude toward taking the medications regularly. Whereas, 16.33% of subjects believe that regular check-ups with their doctor are required. The remaining results regarding the assessment of attitude in patients with DM in a tertiary care hospital are mentioned in Table 3 and Figure 3.

Practice

The study results demonstrated that out of 300 subjects, 61.00% (n = 183) had good practice of taking medications regularly. There was the least practice of 23.67% (n = 71) HbA1c testing and monitoring blood glucose levels monthly in 49.33% (n = 148) of respondents. The results regarding the practice are detailed in Table 4 and Figure 4.

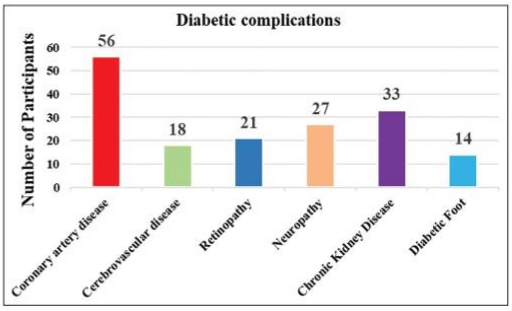

Figure 1: Distribution of subjects based on diabetic complications

Table 1: Demographics of the study participants

Demographics	Category	Control group	Interventional group	Total, *n* (%)
Age	21-30	2	4	6 (2.00)
	31-40	22	14	36 (12.00)
	41-50	30	22	52 (17.33)
	51-60	31	43	74 (24.67)
	61-70	42	40	82 (27.33)
	>70	23	27	50 (16.67)
Gender	Male	112	106	218 (72.67)
	Female	38	44	82 (27.33)
BMI	Under weight	20	13	33 (11.00)
	Normal weight	33	41	74 (24.67)
	Over weight	59	49	108 (36.00)
	Obese	38	47	85 (28.33)
Socioeconomic status	Upper	16	11	27 (9.00)
	Upper middle	22	26	48 (16.00)
	Lower middle	60	61	121 (40.33)
	Upper lower	30	38	68 (22.67)
	Lower	22	14	36 (12.00)
Duration of diabetes (years)	<1	16	12	28 (9.33)
	1-5	35	41	76 (25.33)
	6-10	42	52	94 (31.33)
	>10	57	45	102 (34.00)
Marital status	Married	128	133	261 (87.00)
	Unmarried	12	09	21 (7.00)
	Widowed	10	08	18 (6.00)
Literacy status	Literate	93	90	183 (61.00)
	Illiterate	57	60	117 (39.00)
Occupation	Employed	90	83	173 (57.67)
	Unemployed	60	67	127 (42.33)
Smoking	Nonsmoker	42	49	91 (30.33)
	Smoker	92	82	174 (58.00)
	Recently quit	16	19	35 (11.67)
Alcohol	Alcoholic	97	90	187 (62.33)
	Nonalcoholic	26	25	51 (17.00)
	Recently quit	27	35	62 (20.67)
Diabetic complications	Coronary artery disease	20	36	56 (46.67)
	Cerebrovascular disease	9	9	18 (15.00)
	Retinopathy	11	10	21 (17.50)
	Neuropathy	12	15	27 (22.50)
	Chronic kidney disease	16	17	33 (27.50)
	Diabetic foot	7	7	14 (11.67)

BMI=Body mass index

Out of the three domains assessed within the research study, the knowledge domain consisted of 11 questions, attitude, and practice domain consisted of 7 questions each. For each question, a score of '1' was given if the participant gave the correct answer, and a score of '0' was given if the participant gave the wrong answer. All these scores were added at the end and a total domain score was calculated independently for KAP.

The study team also aimed at assessing the demographic determinants which predicted good KAP. For this purpose, a cut off of 60% score was set for each domain, i.e., KAP. Based on this cut off, participants with a final score of ≥6 were grouped separately in the knowledge domain and participants with a final score of ≥4 were grouped separately in the attitude and practice domains, respectively. These segregated data were taken up for executing the bi-variate analysis separately for KAP. Details of the participants with better KAP are represented in Table 5. Bivariate analysis was done and it revealed that a few demographic characteristics influenced KAP ($P < 0.05$) namely, age <50 years, education-literate, and duration of disease <5 years. With respective to practice domain separately males demonstrated better practice than females. The detailed results of the bivariate analysis are represented in Table 6.

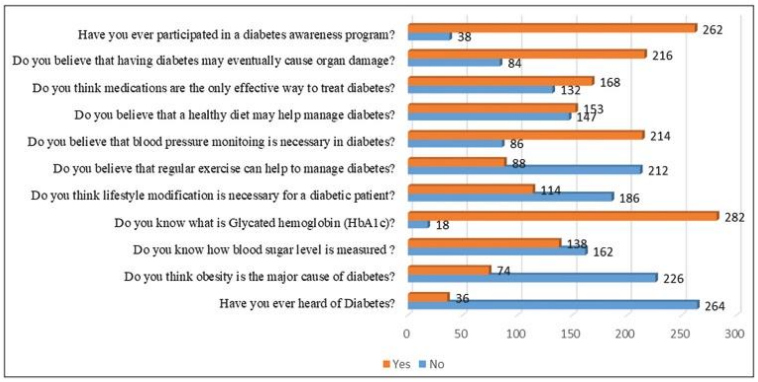

Figure 2: Knowledge based patient response on diabetes mellitus

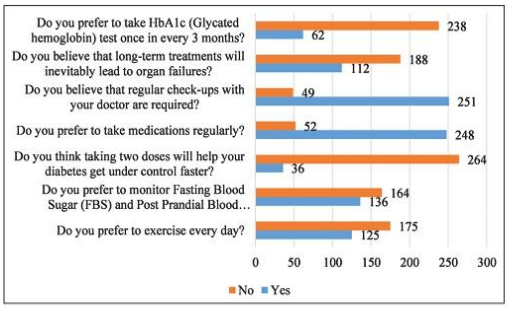

Figure 3: Attitude-based patient response on diabetes mellitus

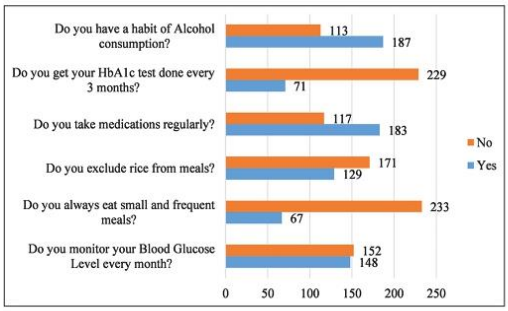

Figure 4: Practice-based patient response on diabetes mellitus

Discussion

The quality of care in diabetic mellitus patients was estimated using a KAP study. The study included 300 patients with age 18 years and above. Of the total population, 72% were male and 27% were female. The age group below 30 years accounted only for 2% of the entire population, the age group of 31–50 years was found to be 29% of the entire population, while the age group (50 years and above) consisted of 67% of the entire population.

Table 2: Responses for knowledge-based questionnaires

Questionnaires	Yes, *n* (%)	No, *n* (%)
Have you ever heard of diabetes?	264 (88.00)	36 (12.00)
Is obesity the major cause of diabetes?	226 (75.33)	74 (24.67)
Do you know how to measure diabetes?	162 (54.00)	138 (46.00)
Do you know what is glucose tolerance test?	18 (6.00)	282 (94.00)
Is lifestyle modification required for a diabetic patient?	186 (62.00)	114 (38.00)
Do you know that exercise can help you manage your diabetes?	212 (70.67)	88 (29.33)
Can high blood pressure worsen the disease?	86 (28.67)	214 (71.33)
Is fiber-rich diet good for diabetes?	147 (49.00)	153 (51.00)
Can medicines alone be used for the treatment of diabetes?	132 (44.00)	168 (56.00)
Does diabetes have the potential to harm the body's other organs?	84 (28.00)	216 (72.00)
Have you ever participated in a diabetes awareness program?	38 (12.67)	262 (87.33)

In a study performed by Jaiswal of the 100 patients, 61% were male and 39% were female and 46% fell within the age group of 41–60 years.[16,17] The results of this study were found to be consistence with previous studies and indicated that 94% of the patients were aware about high blood sugar levels and 90% were aware of monitoring it.[17]

Our study was conducted to assess the KAP of patients suffering from type 2 DM in a tertiary care hospital. In the study that was carried out over 3 years, 56.33% of the subjects suffered from various complications, which include coronary artery disease (46%), CKD (27%), diabetic neuropathy (22%), diabetic retinopathy (17%), cerebrovascular disease (15%), and diabetic foot (11%).

According to a study conducted in Central India by Jaiswal, it was found that hypoglycemia and its

manifestations were very common symptoms known by 85% of study participants. Other complications included vasculopathy (78%), neuropathy (68%), and retinopathy (68%).[17] In the Gana population, a study revealed that the most common diabetic complication in DM patients was a diabetic foot (51.5%), HTN (35.4%), neuropathy (29.2%), and nephropathy (5.4%) by Obirikorang *et al*.[18] Hypertension and type 2 DM are the most common comorbidities seen in both IHD (40%) and CAD patients (38%). The study results demonstrated that 69.5% (n = 139) of the subjects were literate and 30.5% (n = 61) were found to be illiterate.[18]

Table 3: Responses for attitude based questionnaires

Questionnaires	Yes, *n* (%)	No, *n* (%)
Do you prefer to exercise every day?	125 (41.67)	175 (58.33)
Do you prefer to monitor FBS and PPBS levels every month?	136 (45.33)	164 (54.67)
Do you think taking two doses will help your diabetes get under control faster?	36 (12.00)	264 (88.00)
Do you prefer to take medications regularly?	248 (82.67)	52 (17.33)
Do you believe that regular check-ups with your doctor are required?	251 (83.67)	49 (16.33)
Do you believe that long-term treatments will inevitably lead to organ failures?	112 (37.33)	188 (62.67)
Do you prefer to take HbA1c test once in every 3 months?	62 (20.67)	238 (79.33)

FBS=Fasting blood sugar, PPBS=Postprandial blood sugar, HbA1c=Glycated hemoglobin

Table 4: Responses for practice based questionnaires

Questionnaires	Yes, *n* (%)	No, *n* (%)
Do you exercise for 30-60 min every day?	128 (42.67)	172 (57.33)
Do you monitor your blood glucose level every month?	148 (49.33)	152 (50.67)
Do you always eat small and frequent meals?	67 (22.33)	233 (77.67)
Do you exclude rice from meals?	129 (43.00)	171 (57.00)
Do you take medications regularly?	183 (61.00)	117 (39.00)
Do you get your HbA1c test done every 3 months?	71 (23.67)	229 (76.33)
Do you have a habit of alcohol consumption?	187 (62.33)	113 (37.67)

HbA1c=Glycated hemoglobin

A study conducted by Kant and Thapliyal revealed that out of 200 type 2 DM patients selected for the study, 22 patients were illiterate, 18 patients had completed primary level education, 24 patients had completed secondary/middle school education level, 26 subjects were graduates and only 10 patients were postgraduates.[19]

The study results revealed that out of the total subjects, 82% (n = 164) were found to be non-alcoholic and only 18% (n = 36) of the subjects were found to be alcoholic. A study by Jaiswal showed that 16% of people gave up alcohol. The study results demonstrated that out of the total subjects, only 22.5% (n = 45) of subjects consumed tobacco and 77.5% (n = 155) of the subjects did not consume tobacco.[17]

A study by Jaiswal showed that smoking and tobacco were given up by 30% of the patients.[17] Another study by Shah *et al*. showed that only 7.14% of patients agreed that they should stop smoking and consuming alcohol to control DM.[20]

Table 5: Demographics of the study population and prevalence of better knowledge, attitude, and practice within the study population

Demographic details	Total, *n* (%)	Participants with better knowledge (≥ 6), *n* (%)	Participants with better attitude (≥ 4), *n* (%)	Participants with better practice (≥ 4), *n* (%)
Age				
21-30	6 (2.00)	3 (2.29)	2 (1.39)	2 (1.31)
31-40	36 (12.00)	13 (9.92)	10 (6.94)	12 (7.84)
41-50	52 (17.33)	20 (15.27)	23 (15.97)	41 (26.80)
51-60	74 (24.67)	36 (27.48)	32 (22.22)	41 (26.80)
61-70	82 (27.33)	28 (21.37)	41 (28.47)	36 (23.53)
>70	50 (16.67)	31 (23.66)	36 (25.00)	21 (13.73)
Total	300 (100.00)	131 (43.67)	144 (48.00)	153 (51.00)
Gender				
Male	218 (72.67)	89 (67.94)	102 (70.83)	92 (60.13)
Female	82 (27.33)	42 (32.06)	42 (29.17)	61 (39.87)
Education				
Literate	183 (61.00)	91 (75.83)	61 (61.62)	28 (60.87)
Illiterate	117 (39.00)	29 (24.17)	42 (38.38)	18 (39.13)
Duration of diabetes (years)				
<1	28 (9.33)	11 (7.80)	15 (11.81)	13 (8.55)
1-5	76 (25.33)	29 (20.57)	27 (21.26)	31 (20.39)
6-10	94 (31.33)	48 (34.04)	39 (30.71)	52 (34.21)
>10	102 (34.00)	53 (37.59)	46 (36.22)	56 (36.84)

Table 6: Bi-variate analysis for assessing the determinants affecting the knowledge, attitude, and practice

Demographic characteristic	Knowledge			Attitude			Practice		
	OR	95% CI	*P*	OR	95% CI	*P*	OR	95% CI	*P*
Age									
<50	0.5359	0.3281-0.8755	0.0127*	0.3746	0.2286-0.6140	0.0001*	0.652	0.4105-1.0357	0.0701
>50	1 (reference)			1 (reference)			1 (reference)		
Gender									
Male	0.6571	0.394-1.094	0.106	1.0658	0.6260-1.8148	0.8144	0.25	0.1250-0.4999	0.0001*
Female	1 (reference)			1 (reference)			1 (reference)		
Education									
Literate	21.4198	11.695-39.2300	0.0001*	14.4431	7.7389-26.9553	<0.0001*	18.2	8.6165-38.4425	<0.0001*
Illiterate	1 (reference)			1 (reference)			1 (reference)		
Duration of disease (years)									
<5	0.2884	0.1780-0.4675	0.0001*	0.3782	0.2348-0.6090	0.0001*	0.1837	0.1121-0.3011	<0.0001*
≥5	1 (reference)			1 (reference)			1 (reference)		

*Statistically significant *P* value. OR=Odds ratio, CI=Confidence interval

Our study population was divided into three age categories; the 19–40 years of age group consisted of 20 subjects (10%). 73 subjects (36.5%) were grouped under the age group of 41–60 and 61 years and above containing 108 (54%) subjects. Among this age group, 41–60 had better knowledge as compared to the other two groups whereas better attitude and practice towards DM was observed in the age group 61 and above as compared to the other two groups.

Among the 300 subjects, 113 (57%) subjects were male and 60 (30%) subjects had a better attitude toward DM and 87 (43%) were female of 47 (23.5%) had a better attitude. Our survey depicted that the male patients had better knowledge and attitude toward DM than the female population, but female subjects had a good practice. Even though better knowledge and attitude toward DM were found in patients with a disease duration of 0–4 years, patients with a disease duration of 8 years and above had better practice.

The primary goal of our KAP study was to identify and document the levels of KAP s in a variety of type 2 diabetes patients. The knowledge of the participants was evaluated based on their understanding of DM, such as fundamental knowledge of DM, causes, complications, measuring BGLs, lifestyle changes, and so on. The research included 200 in-patients in total. We observed that majority of the participants were above the age of 30 years. Our study portrays the measure of participants with good knowledge at 31.5% (n = 63), with good attitude towards the disease at 24% (n = 47), and the ones exhibiting good practice were found to be at 13% (n = 107).

The study results demonstrated that there were minimal differences in KAPs irrespective of the differences in gender, education, and duration of disease. The detailed study results of the independent sample *t*-test are given in Table 6. Only four exceptions were observed within this study, the participants aged <50 years had better knowledge and attitude compared to patients more than 50 years of age ($P < 0.01$). Furthermore, literate participants were found to have statistically greater knowledge than the illiterate subjects and the difference was statistically significant. It was also noted that there was a statistical difference in the practice domain, the participants with a disease duration of more than 5 years were found to have better practice than the subjects with <5 years of duration of disease.

The outcomes of knowledge and demographics of the study sample suggested that the male participants (n = 89) exhibited more knowledge than female participants (n = 42). There was no significance (P = 0.10). The participants suffering from the disease/condition for more than 5 years (n = 101) showcased more knowledge than participants suffering from the disease for <5 years (n = 40). The P value is significant for the knowledge of the duration of the disease ($P < 0.0001$). In our study, the literate subjects (n = 91) expressed more knowledge than illiterate subjects (n = 29) and there was found statistically significant (P = 0.0001). The participants belonging to the age group of more than 50 years (n = 95), had more knowledge than participants who were below the age of 50 years (n = 36). The results were statistically significant ($P < 0.01$).

The outcomes of attitude and demographics of the study sample suggested that the male participants (n = 102) showed better attitudes toward the disease compared to female participants (n = 42) in the study. Our study exhibited that participants suffering from the condition for more than 5 years (n = 85) had a better attitude toward the disease compared to the participants suffering from the condition for <5 years (n = 42). The literate participants (n = 61) expressed a better attitude than the illiterate participants (n = 42). In our study, it was found

that the participants belonging to the age group of more than 50 years (n = 109) had a better attitude toward the disease than participants who were below the age of 50 years (n = 35).

The outcomes of practice and demographics of the study sample suggested that the male participants (n = 92) exhibited more practice than female participants (n = 62). The P value is not significant for the practice in gender distribution (P < 0.0001). In our study, the participants suffering from the disease for more than 5 years (n = 108) showcased better practice than patients suffering from the disease for <5 years (n = 44). The P value is not significant for the practice in the duration of the disease (P < 0.0001). In the study, the literate subjects (n = 28) expressed better practice compared to illiterate subjects in the study (n = 18). The participants in our study, belonging to the age group of more than 50 years (n = 98) had better practice compared to the participants belonging to the age group of fewer than 50 years (n = 55).

A study by Manju *et al*. revealed that the age of participants below 40 years had knowledge (58.87), and participants between the ages of 40–60 years had knowledge (56.65), and participants above or equal to the age of 60 years had knowledge (59.48). The attitude was also high in patients in the age group of (≥60 years). The age group of <40 years showed better practice (65.03). In the study, males showcased better knowledge (59.07), as compared to females (57.36), and also the attitude followed was slightly better in males (78.27) than in females (76.66). The practice exhibited by male participants was better (62.13) than by female participants (57.65). The participants with a degree or above qualification (72.58) showed better knowledge compared to participants with primary qualifications (47.94).[21]

A study by M. Niroomand showcased that the participants in the male category (62.44 ± 12.22) showed better knowledge than female participants (60.25 ± 12.45) and also have a better attitude toward the disease (49.95 ± 27.56) than female patients at (44.04 ± 27.56). Female participants exhibited better practice (54.45 ± 18.4) than male participants (50.26 ± 17.53). In the study, the patients belonging to the category of >60 years of age, showed that these participants had better knowledge and attitude at (63.38 ± 12.45) and (49.38 ± 28.50) than the participants belonging to the age group of ≤60 years showed slightly better practice (53.21 ± 18.70) than patients in the age group of >60 years at (51.34 ± 17.42).[22]

In a study by P. K Rani *et al*. it was found that the participants between the age group of 26–35 years (n = 113) showed knowledge of (41.2%), the age group of 36–45 years (n = 161) showed knowledge of (52.6%) and the age group above 45 years (n = 186) showed knowledge of (54.1%). Furthermore, female participants (n = 609) had better knowledge (51.7%) than male participants (n = 357) (47.0%). Participants with graduate and above education qualifications (n = 446) showed better knowledge (82.0%) than those with only primary education qualifications (n = 3) (9.4%).[5]

Conclusion

The prospective observational study undergone at an Indian tertiary care hospital concludes low knowledge, a negative attitude, and good behavior among the population. The majority of them had knowledge of diabetes but had no insight into its measurements and what normal blood glucose levels were. Many individuals were unaware of its risk factors such as obesity, lack of exercise, and so on. A lot of diabetic patients were not on proper diets and had no understanding of the daily diet plan. This implies effective health education interventions about diabetes, its treatments, and lifestyle modifications are required to improve diabetes KAPs, specifically involving lifestyle modifications and dietary management, to slow the progression of diabetes and prevent other complications associated with it. Additional research in the area conducted from time to time is necessary to verify, compare and record the results of the previous KAP studies on DM with the recent studies for any improvement or deterioration in the KAPs in the patients suffering from DM. The study can be conducted in larger populations for a longer duration among the general public and various departments such as gynecology, pediatric, and psychiatric for investigating more precise pharmacoeconomic data.

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Conflicts of interest
There are no conflicts of interest.

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Original Article

Drug Utilization Evaluation of Antidiabetic Drugs in a Tertiary Care Teaching Hospital: Analysis from a Randomized Controlled Study

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ABSTRACT

Background: Diabetes Mellitus (DM) is a chronic metabolic condition characterized by high blood glucose levels and changes in carbohydrate, lipid and protein metabolism due to insulin secretion, action, or both.[1] Diabetes affects 537 million persons worldwide in 2021 and its management and selection of antidiabetic drugs is a major health concern. **Objectives:** The study was aimed to evaluate the prescription pattern of antidiabetic drugs in a tertiary care hospital in Hubballi, Karnataka. **Materials and Methods:** It was a Prospective randomized controlled study where the participants were randomized into two groups i.e., the interventional or study group and control group. **Results:** Of the 300 diabetic patients, 150 were included in the control group and another 150 in the observational group in which 218 (72.6%) were males and 82 (27.3%) were females. Males were higher than females. The maximum number of patients were in the age group of 61-70 years, followed by 51-60 years. 175 (58.33%) subjects were taking two medications followed by 82 (27.33%) were receiving three medications. 152 (50.66%) were receiving diabetic medications two times in a day followed 122 (40.66%) were taking once in a day. Out of 300 Patients, 205 (68.33%) patients were prescribed insulin, of which regular insulin was the highest. **Conclusion:** It was found that metformin and insulin use is greater with higher use among middle-age patients. Regular insulin was the most often used insulin.

Keywords: Antidiabetic drugs, Diabetes mellitus, Drug utilization evaluation, Randomized controlled study, Tertiary care hospital.

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INTRODUCTION

Diabetes Mellitus (DM) is a chronic metabolic condition characterized by high blood glucose levels and changes in carbohydrate, lipid, and protein metabolism due to reduced insulin secretion, action, or both.[1] It is the most common endocrine illness that is widely regarded as the most serious public health issue and concern to human health, impacting people in both developed and developing countries. This chronic illness can have a consequence on almost every system in the human body, resulting in long-term macro and microvascular complications.[2]

Global prevalence of DM is expected to increase by 5.4% and in India alone around 57.2 million population are expected to be diabetic by year 2025.[3] Over the time DM may leads to serious health complications of heart,blood vessels, eyes, kidneys and nerves thus emphasizing the need of diagnosis, treatment, management and prevention. World Health Organization (WHO) has been putting efforts globally to prevent risk and provide equitable, comprehensive and affordable care to ensure quality treatment.[4] Several standardised guidelines have been proposed by American Diabetes Association and Indian Council of Medical Research for effective care and managment Diabetes. Diabetes management either by insulin[5] or non-insulin[6] therapies have seriously associated comorbidities namely hypoglycemia, weight gain etc. necessitating the need for safer long term treatment modalities.[7] Additional burden of polypharmacy and physicians incompetency to distinguish appropriate and inappropriate has been leading to adverse health outcomes in DM patients.[8] Considering the chronic nature of diabetes management and long-term treatment regimen, there is need to asscess the class of antidiabetic drugs, their utilization, prescription pattern, drug regimens and adherence to WHO prescribing core indicators. Therefore the proposed study emphasizes on evaluation of utilization of Antidiabetic medications in DM patients.

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MATERIALS AND METHODS

Study designed was a Prospective randomized controlled study where the participants were randomized into two groups i.e., the interventional or study group and control group. The study was conducted at a Vivekananda General Hospital, Hubballi, Karnataka. The target population for the study included patients diagnosed with DM. Population with DM, aged above 18 years who visited the general medicine ward outpatient and inpatient department during the study period were enrolled into the study. A total of 300 subjects divided into two groups of 150 each were considered for study. Data obtained from this study were grouped and analysed by tables using Statistical Package for Social Sciences (SPSS) version 21.0.

The data collected were analyzed using modified WHO prescribing core indicators core and WHO ATC Code as mentioned. The prescribing indicators that were measured included 1. Average number of drugs per encounter = Total number of drugs prescribed / total number of encounters 2. Percentage of drugs prescribed by generic name = (Number of drugs prescribed by generic name / Total number of drugs prescribed) x100 3. Percentage of encounter with antibiotics prescribed = (Number of patients encounters with antibiotics / Total number of drugs prescribed) x100 4. Percentage of encounters with injectable drug prescribed = (Number of patients encounters with injections / Total number of drugs prescribed) x100 5. Percentage of drugs prescribed from NLEM = Number of drugs prescribed from NLEM/ Total number of drugs prescribed) x 100.[7]

Randomization

Computer generated simple randomization was employed, while SNOSE method was used to allot participants randomly to the study group or control group. The randomization numbers under concealment and were known after recruiting the patient to the study by filling patient details on closed envelope. SNOSE method - Sequentially Numbered, Opaque, Sealed Envelopes (SNOSE) was used for concealment.

Study procedure

Once patients satisfied the eligibility criteria and consent was taken, patients were subjected for randomization to either study or control group. Sources of data were patient Data Collection Forms, Patient's Case records during Hospital stay, Medication Charts and Lab reports.

Ethical Considerations

Ethical approval was obtained from the Institutional Ethical Committee of KLE Academy of Higher Education and Research. All the patients were randomized after the written informed consent. Reference number: KAHER/EC/19-20/290619004.

RESULTS

Of the 300 diabetic patients, 150 were included in the control group and another 150 in the observational group. The 300 patients with DM who were on oral hypoglycemic agents, insulin only or in combination with oral hypoglycemic agents were enrolled in the study, out of which 218 (72.67%) were males, and 82 (27.33%) were females. Males were higher than females. Among the study population, the maximum number of patients were in the age group of 61-70 years, followed by 51-60 years. Demographic details of enrolled patients are presented in Table 1.

Out of 300 subjects, 108 (36.00%) of subjects were found to be overweight, followed by 85 (28.33%) belonging to the obese class. Similarly, 102 (34.00%) subjects were shown to have diabetes duration of >10 years, and 28 (9.33%) were recently diagnosed subjects with less than one year of duration.

It was evident from Table 2 that, out of 300 study population, 175 (58.33%) subjects were taking two medications followed by 82 (27.33%) were receiving three medications. 121 (40.33%) of the subjects were found to be in Lower Middle socio-economic class, followed by 68 (22.67%) of subjects belonging to upper lower class.

It was revealed that out of 300 patients, 67 (22.33%) had total medicine expenditure each month of less than 100 rupees. Similarly, the total cost of medicine per month for 144 (48.00%) patients was between 100 and 200 rupees, whereas the total cost of drug per month for 89 (29.66%) patients was more than 200 rupees. Out of 300 study subjects, 152 (50.66%) were receiving diabetic medications two times in a day followed by 122 (40.66%) were taking once in a day. Whereas only about 26 (8.66%) subjects were taking diabetic medications three times a day. These results are shown in Table 3.

Of the 300 patients, 162 (54.00%) times Metformin and Sulfonylureas dual drug regimen was highest prescribed followed by 132 (44.00%) times metformin+regular insulin. In triple therapy, metformin+sulfonylureas+DPP4 inhibitors prescribed was 117 (39.00%) followed by Metformin+thiazolidine diones+alphaglucosidase inhibitors 48 (16.00%). The highest four drug regimen, Metformin+Voglibose+NPH insulin+Regular insulin was prescribed 18 (6.00%) times. These results are shown in Table 4.

Out of 300 Patients, 205 (68.33%) patients were prescribed with insulin, of which regular insulin was the highest. 203 (67.66%) patients were prescribed sulfonylureas, of which Glimepiride 78 (26.00%) was the most commonly prescribed drug. It was observed that 162 (54.00%) patients were prescribed with biguanides. α-Glucosidase Inhibitors in 102 (34.00%) patients and DPP-4 Inhibitors were prescribed in 61 (20.33%) patients of which vildagliptin was the most commonly prescribed drug. Thiazolidinediones class of drugs were prescribed in 80 (26.66%)

Table 1: Clinical Characteristics of the Study Population.

Variables	Sub variables	No. of Subjects	Percentage
Gender	Male	218	72.67
	Female	82	27.33
Age Distribution	21-30	06	02.00
	31-40	36	12.00
	41-50	52	17.33
	51-60	74	24.67
	61-70	82	27.33
	>70	50	16.67
BMI (kg/m^2)	Underweight (< 18.5)	33	11.00
	Normal Weight (18.5-24.9)	74	24.66
	Overweight (25-30)	108	36.00
	Obese (> 30)	85	28.33
Duration of Diabetes	<1 Year	28	09.33
	1-5 Years	76	25.33
	6-10 Years	94	31.33
	>10 Years	102	34.00

Table 2: Number of Medications and Socio-economic Status of the study population.

Sl. Noo	No. of Medications	No. of Subjects	Percentage	Socio-Economic Status	No. of Subjects	Percentage
1	One	18	06.00	Upper	27	09.00
2	Two	175	58.33	Upper Middle	48	16.00
3	Three	82	27.33	Lower Middle	121	40.33
4	Four	16	5.33	Upper lower	68	22.67
5	> Four	09	3.00	Lower	36	12.00

Table 3: Cost therapy of medication per month and distribution of regimen in the study population.

Sl. No	Cost of drug/ month	No. of Subjects	Percentage	Regimen	No. of Subjects	Percentage
1	<100	67	22.33	Once Daily	122	40.66
2	100-200	144	48.00	Twice Daily	152	50.66
3	>200	89	29.66	Thrice Daily	26	8.66

patients, while GLP-1 analog 06 (02.00%), was the least prescribed drug. These results are shown in Table 5.

Table 6 demonstrates adherence to WHO drug prescribing indicators. The total number of drugs prescribed in 300 prescriptions were 819. The average number of drugs per encounter was found to be 2.73. The percentage of drugs prescribed in generic name was 58.60% and the percentage of antibiotics and injectable drugs were found to be 22.22% and 29.91% respectively. The percentage of drugs prescribed from Essential drug list was 82.17%. Fixed dose combinations of various drugs in the prescriptions studied was found to be 98.29%.

DISCUSSION

In India, Diabetes is a serious health issue. DM is defined by the World Health Organization as a chronic, metabolic condition marked by increased blood glucose (or blood sugar) levels that lead to significant damage to the heart, blood vessels, eyes, kidneys, and nerves over time.[9] Drug use is defined by the WHO as the marketing, distribution, prescription, and use of pharmaceuticals in a society, taking into account the medical, social, and economic repercussions.[10] According to the WHO, India had 32 million diabetes patients in 2000, which is expected to rise to 80 million by 2030. Diabetes is becoming more prevalent in India at an alarming rate, necessitating more public knowledge regarding the causes of diabetes and its repercussions.[11]

Table 4: Utilization pattern of most commonly encountered multidrug ADD regimens.

Sl. No	Name of the drugs	Number of times prescribed	Percentage
Dual drug regimens			
1	Metformin+sulfonylureas	162	54.00
2	Metformin+thiazolidine diones	80	26.66
3	Metformin+alphaglucosidase inhibitors	44	14.66
4	Metformin+DPP4 inhibitors	37	12.33
5	Metformin+meglitinides	21	07.00
6	Sulfonylureas+thiazolidine diones	64	11.33
7	Sulfonylureas+alphaglucosidase inhibitors	27	09.00
8	Metformin + regular insulin	132	44.00
	Total Dual drug regimens (n) = 567		
Triple drug regimens			
8	Metformin+sulfonyl ureas+ DPP4 inhibitors	117	39.00
9	Metformin+thiazolidine diones+alphaglucosidase inhibitors	48	16.00
10	Metformin + acarbose + premixed insulin	31	10.33
	Total Triple drug regimens (n) = 196		
Four drug regimens			
11	Metformin + voglibose + NPH insulin + regular insulin	18	06.00
12	Metformin + glimepiride + pioglitazone + voglibose	24	08.00
	Total Four drug regimens (n) = 42		

During the course of the study, 300 diabetic individuals were analysed, and it was discovered that males had a higher prevalence of diabetes than females (Males 72.60%; Females 27.30%). A similar study by Vengurlekar S *et al.*, Boccuzzi SJ *et al.*, Johnson *et al.*, Yurgin N *et al.*, found that males had a higher prevalence of diabetes than females, while a few studies by Lisha *et al.*, Saiyad *et al.*, Ramesh R *et al.*, contradicted our findings, which found a high proportion of diabetes in female patients.[12-14]

The majority of diabetes patients (27.33% and 24.67%) in this study are in the 61-70 and 51-60 year old age group respectively. Upadhyay *et al.* and Venkateswaramurthy *et al.* observed a greater incidence of diabetes in the same age range, which is consistent with our findings.[13] According to the findings of our research, we found that more patients were obese and overweight. According to Boffetta *et al.*, there is a clear link between BMI and diabetes prevalence in Asian people.[11] Maximum patients in our research had a DM history less than ten years. These findings were comparable to the study conducted by Siddiq *et al.*[2]

Two medicines per prescription were found to be greater in the current investigation, comparable to Pankaj CK *et al.*[5] The majority of the patients in this study were from the lower middle socioeconomic class, which contrasts with Ashutosh K *et al.* findings, which indicated that the upper middle socioeconomic class was dominant.[9] Our study's cost of medicine per month was between 100 and 200 rupees, which was lower in Pankaj CK *et al*'s study. The patients receiving diabetic medications two times in a day were higher which was similar by Siddiq *et al.*[2]

According to our findings, Patients hospitalized to the medicine ward were usually provided insulin, either as monotherapy or in combination with oral antidiabetic medications. Regular insulin was the most often administered insulin preparation (44.00%), followed by NPH insulin mixtard (14.00%) which was a similar outcome in the Mahmood *et al.* and Gautam *et al.* study.[15] Metformin was the most commonly prescribed medicine for T2DM is metformin (54.00%). Metformin was administered as monotherapy or as part of a polytherapy followed by glimepiride (26.00%). Similar outcomes were found in a number of other studies done around the country.[15] The increasing prevalence of insulin prescriptions, particularly regular insulin, is related to the fact that patients admitted to indoor wards with co morbidities frequently require insulin because of its safety profile and speedier start of action. This also decreases the risk of medication interactions and improves the hospitalized patients' glycemic control.[6]

Because of its lengthy $t_{1/2}$, higher extrapancreatic activity, reduced hyperinsulinemia, and lower incidence of hypoglycemia, glimepiride has emerged as a front-liner among the SU. An alpha-glucosidase inhibitor was employed as an adjunct therapy

Table 5: Prescribing pattern of oral hypoglycemic drug as single drug regimen based on various classes of drugs.

Sl. No	ATC Code	Class of ADDs	Drugs (ATC Code)	Number of Patients	Percentage (%)
1	A10BA	Biguanides	Metformin A10BA02	162	54.00
2	A10BB	Sulfonylureas	Glimepiride A10BB12	78	26.00
			Glipizide A10BB07	64	21.33
			Glibenclamide A10BB01	47	15.66
			Gliclazide A10BB09	14	04.66
			Total	203	67.66
3	A10BF	α- Glucosidase inhibitors	Voglibose A10BF03	54	18.00
			Acarbose A10BF01	32	10.66
			Miglitol A10BF02	16	05.33
			Total	102	34.00
4	A10BG	Thiazolidinediones	Pioglitazone A10BG03	53	17.66
			Rosiglitazone A10BG02	27	09.00
			Total	80	26.66
5	A10BH	Dipeptidyl peptidase-4 (DPP-4) inhibitors	Vildagliptin A10BH02	41	13.66
			Linagliptin A10BH05	14	04.66
			Tenegliptin A10BH08	06	02.00
			Total	61	20.33
6	A10BJ	GLP-1 analog	Exenatide A10BJ01	06	02.00
7	A10A	Insulin A10AB	Regular insulin A10AB01	132	44.00
			NPH insulin A10AC	42	14.00
			premixed insulin A10AB30	31	10.33
			Total	205	68.33

Table 6: WHO core prescribing indicators.

Sl. No	Core Indicators	Value
1	Average number of drugs prescribed per prescription.	2.73
2	Percentage of drugs prescribed by generic name.	480 (58.60%)
3	Percentage of encounters with antibiotic prescribed.	182 (22.22%)
4	Percentage of encounters with injectable drug prescribed.	245 (29.91%)
5	Percentage of drugs prescribed from NLEM (National List of Essential Medicines).	673 (82.17%)
6	Percentage of encounters with Fixed drug combination.	805 (98.29%)
Total number of drugs prescribed (n) = 819		

as a dual medication regime in 44 prescriptions with metformin because of considerable postprandial hyperglycemia with managed Fasting Plasma Glucose (FPG) in majority of these follow-up encounters, this was done in accordance with the 2016 standards of the International Diabetes Federation.[4]

Only 102 prescriptions out of 300 patients contained Voglibose 54 (18.00%), Acarbose 32 (10.66%) and Miglitol 16 (05.33%) where similar results found in the study by Lahiry S *et al.* It was against the evidence supporting the use of acarbose as a first-line adjuvant for lowering cardiovascular mortality in T2DM patients when compared to voglibose.[4]

Overall, thiazolidinediones are used as monotherapy by 80 (17.66%) of patients, with pioglitazone and rosiglitazone being used as add-on therapy by 53 (17.66%) and 27(09.00%) of patients, respectively and similar result by Pankaj CK *et al.*[5] In 80 (26.66%) of the prescriptions, metformin and thiazolidinediones were prescribed together. It's possible that pioglitazone was dispensed from the hospital pharmacy. Although the combination of metformin and pioglitazone has been demonstrated to improve insulin resistance and cardiovascular morbidity, it was found to be an underused class in our analysis, perhaps because of concerns about side effects.[4,5]

DPP4 inhibitors accounted in 61 prescriptions (20.33%) where Vildagliptin 41 (13.66%), Linagliptin 14 (04.66%) and Tenegliptin 06 (02.00%). A research by Pankaj CK *et al.* found a similar effect when it came to biguanides and sulfonylureas. Sulphonylureas were described as the most often prescribed antidiabetic medication in late 1990s studies in South Africa, the United States, and India by Truter I and Boccuzzi SJ *et al.*, which contradicts the current study.[5] The GLP-1 analog Exenatide 06 (02.00%) is less used anti-diabetic drug in the study.

This study showed that metformin + sulfonylureas 162 (54.00%) dual drug regime was the commonly used in most of the patients and which was similar in the study conducted by Lahiry S.[4] It is followed by Metformin + regular insulin 132 (44.00%) and Metformin+thiazolidine diones 80 (26.66%).

Among three drug combination Metformin+sulfonyl ureas+ DPP4 inhibitors 117 (39.00%) were most frequently prescribed fixed dose combination. In four drug regime most widely used is Metformin + glimepiride + pioglitazone + Voglibose which accounts for 24 (08.00%) and Metformin + voglibose + NPH insulin + regular insulin is 18 (06.00%).[14]

We found out that the average number of drugs prescribed per prescription for treatment with antidiabetic drugs was almost half the average number of drugs per prescription found out by Okoro RN *et al.*[16] Data was analysed for WHO drug utilization indicators in which we saw a trend of using generic name for prescribing which stood at 58.60%. This was way higher than the study done by Acharya, *et al.*[17] The percentage of encounters with antibiotics prescribed is at 22.22% in our study. The percentage of prescriptions with injections/injectable drugs in our study was 29.91%, which is higher than the derived standard value for WHO (13.4-24.1%)[18] and lower than the value reported by Sahu G *et al.*[15] Hannan A *et al.* study showed the percentage of drugs prescribed from NLEM was 65.82% whereas our study shows the percentage of drugs prescribed from NLEM at 82.17%.[19] We saw 98.29% of encounters with fixed drug combination.

This study has reported the antidiabetic drug usage pattern in different age groups with varying disease durations. The prescription patterns suggest the usage of wide class of antidiabetic drugs including different types of Insulin's and oral hypoglycaemic agents in the study population. Since the DM is a chronic metabolic disorder, therapy cost, long term consequences, effect on comorbid conditions, and adverse drug reactions arising out of chronic diabetic medications are to be explored for better quality of life.

CONCLUSION

Diabetes should be managed properly to enhance the patient's quality of life. The majority of the prescriptions in the research were reasonable, but there is still room for improvement. More than 90% of patients were diagnosed with type 2 diabetes. Oral hypoglycemic medications were administered often, indicating greater glycemia at the time of diagnosis. Based on the results of the randomization study on prescription patterns, which included 300 patients, it was found that metformin and insulin use is greater in men, with higher use among middle-age patients.

Regular insulin was the most often used insulin because it was less expensive than insulin analogues. Insulin preparations aid in the reduction of insulin resistance, resulting in improved glycemic control. Dose and duration, as well as interactions with

other drugs, should all be considered while prescribing rationally. Patients and physicians should work together to achieve the goal of glucose levels and live a happier, healthier life.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

DM: Diabetes Mellitus; **ADA**: American Diabetes Association; **ICMR:** Indian Council of Medical Research; **WHO:** World Health Organization; **SPSS:** Statistical Package for social sciences; **SNOSE:** Sequentially numbered opaque sealed envelopes; **FPG:** Fasting Plasma glucose; **NLEM:** National List of Essential Medicines.

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Original Article

Assessment of Health-Related Quality of Life and Associated Factors among Type 2 Diabetes Mellitus Patients Attending a Tertiary Care Hospital

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ABSTRACT

Background: Type 2 diabetes mellitus is a chronic disease that can affect the quality of life of individuals. Health-Related Quality of Life (HRQOL) is an important outcome measure in assessing the impact of diabetes on individuals' lives. This study aimed to assess the HRQOL of individuals with type 2 diabetes in India using the SF-36 questionnaire, identify factors associated with HRQOL, and evaluate the overall QOL of this population. **Materials and Methods:** In this study, 300 individuals with type 2 diabetes mellitus were recruited from tertiary care hospitals in India. The Health-Related Quality of Life (HRQOL) assessment was conducted using the SF-36 questionnaire, which evaluates eight domains of QOL. A structured questionnaire was used to collect demographic and clinical data. Multiple linear regression was employed to identify factors that are associated with HRQOL. **Results:** The mean age of participants was 56.5 years, and 53% were male. The mean scores for all eight domains of the SF-36 questionnaire were lower in individuals with type 2 diabetes compared to the general population in India. The most affected were physical functioning, role-physical, bodily pain, and vitality domains. Multiple linear regression analysis revealed that age, gender, education, duration of diabetes, and comorbidities were significantly associated with HRQOL. **Conclusion:** Individuals with type 2 diabetes mellitus in India have lower HRQOL than the general population. The physical health domains of the SF-36 questionnaire were the most affected. Age, gender, education, duration of diabetes, and comorbidities were identified as important factors associated with HRQOL. This study highlights the need for interventions to improve the QOL of individuals with type 2 diabetes mellitus in India.

Keywords: Diabetes Mellitus, Quality of life, Type 2 DM, Factors, Clinical Pharmacy, Clinical Pharmacist.

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INTRODUCTION

Diabetes has emerged as a significant clinical and public health issue worldwide. The International Diabetes Federation (IDF) estimates that around 537 million people aged 20-79 years have diabetes, and this figure is expected to rise to 643 million by 2030 and 783 million by 2045, making it the world's most significant chronic non-communicable health issue.

India, in particular, has a high prevalence of diabetes, with an estimated 77 million adults aged 18 years or older living with type 2 diabetes and over 25 million adults being prediabetic, putting them at a higher risk of developing diabetes in the future. India is often called the "Diabetes Capital of the World," accounting for approximately 17% of the global diabetes population.[1]

Diabetes mellitus is a chronic disease that leads to microvascular and macrovascular complications due to uncontrolled glycemic levels, ultimately affecting an individual's Quality of Life (QOL).[2] Quality of life is crucial to health outcomes and is increasingly considered when assessing medical interventions and health policy.[3-5] QOL has become increasingly recognized as a crucial aspect of diabetes management in recent years. Understanding the causes of low QOL experienced by individuals with diabetes may aid doctors in providing better treatment. All health interventions aim to improve Health-Related Quality of Life (HRQOL), which is a significant health outcome.[6]

The SF-36 questionnaire is a widely used general HRQOL assessment for comparisons and descriptions across various health conditions.[7] However, there is a dearth of research on the

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HRQOL of individuals with type 2 diabetes in India. Therefore, the current study aims to characterize the HRQOL of individuals with type 2 diabetes as measured by the SF-36 questionnaire and identify factors associated with the HRQOL of individuals with type 2 diabetes mellitus in India.

MATERIALS AND METHODS

Study Design

The study design used in this research was a prospective randomized controlled study. This study employed a randomized controlled trial design wherein participants were allocated randomly to either the intervention or control group, and the study outcomes of interest were compared between the two groups. This study design is beneficial for assessing the impact of an intervention or treatment on a specific outcome in a population of interest. This study evaluated the impact of a medication adherence intervention on HRQoL in patients with DM using a randomized controlled study design.

Study Site

The study was conducted at Vivekanand General Hospital in Deshpande Nagar, Hubballi. Vivekanand General Hospital is a 350-bedded tertiary care hospital equipped with modern facilities and amenities to provide quality healthcare services to patients. The hospital caters to a large population from northern Karnataka, India. It has a dedicated department of general medicine for diagnosing and managing various medical conditions, including diabetes mellitus. The hospital is staffed with qualified and experienced medical professionals, including physicians, nurses, and paramedical staff, to provide round-the-clock patient care and support. The hospital has state-of-the-art diagnostic and therapeutic facilities, including a fully equipped laboratory, radiology and imaging services, and a pharmacy, making it an ideal site for conducting research studies.

Study Population

The target population for this study included patients diagnosed with diabetes mellitus. Inclusion criteria were patients above 18 years, diagnosed with diabetes mellitus (both type 1 and type 2) in outpatient and inpatient wards of the general medicine department, patients willing to participate in the study, and diabetes with or without co-morbid conditions. Exclusion criteria were non-diabetic patients, patients who are less than 18 years, patients who are extremely ill, and patients with mental incompetence.

Ethical consideration

The Institutional Ethical Committee from KLE Academy of Higher Education and Research Belagavi approved the study protocol, and the reference number for the approval was KAHER/EC/19-20/290619004. Before the study, the researchers explained its purpose and procedures to the participants, and their written consent was obtained.

Sample size

To determine the sample size for the study, a pilot study was conducted on 10 patients, divided into two groups with five participants in each group. The standard deviation of medication adherence in Group A (interventional) and Group B (control) was 1.02 and 1.55, respectively. The total standard deviation was calculated as S=S1+S2^2.

The sample size of the study was determined using the following formula:

$$n = 2S^2(Z1-\alpha/2 + Z1-\beta)^2 / d^2$$

Where,

n = sample size S = total standard deviation Z1-α/2 = 1.96 at 5% α-error Z1-β = 1.68 at 95% power of test d = 0.25 (minimum detectable difference).

Based on the calculation, the final sample size was determined to be n=150 in each group (i.e., interventional and control group), for a total sample size of 300 patients.

This sample size was selected to ensure that the study had sufficient power to detect a clinically significant difference in health-related quality of life between the two groups. The sample size also ensured that the study results would be statistically significant, with a p-value of less than 0.05.

Randomization

To minimize selection bias and ensure that the study groups were comparable, the participants were randomly assigned to the interventional and control groups using computer-generated simple randomization by Sequentially Numbered, Opaque, Sealed Envelopes (SNOSE) approach. The randomization process was performed by an independent researcher who was not involved in the recruitment or data collection process. The envelopes were opened only after the participant had provided written informed consent and met all the inclusion criteria.

Study Procedure

The study was conducted at Vivekanand General Hospital in Deshpande Nagar, Hubballi, between August 2019 and January 2020. The participants were recruited from the outpatient and inpatient wards of the Department of General Medicine and divided into control and interventional groups. The inclusion criteria were patients aged 18 years and above with a confirmed diagnosis of diabetes mellitus (both type 1 and type 2) with or without comorbidities such as cerebrovascular diseases, coronary artery diseases, neuropathy, and nephropathy. Participants who were willing to take part in the study and were receiving anti-diabetic medications were included. Patients under 18 years,

pregnant women, and patients with mental incompetencies were excluded (Figure 1).

After obtaining written informed consent, the participants were randomly assigned to either the interventional or control group. The control group received standard care and treatment for diabetes as per the hospital protocol. The interventional group received standard care and treatment for diabetes and an additional intervention consisting of counselling sessions, medication adherence education, and lifestyle modification advice. The counselling sessions were conducted by a trained healthcare professional and focused on the participants' disease conditions, medications, lifestyle modifications, complications, medication adherence, adverse drug reactions, typical side effects, and drug use.

Data was collected using a structured SF-36 questionnaire, adopted with prior permission from Burholt *et al.*[8] The questionnaire was broadly categorized into eight domains with thirty-six questions, as shown in Table 1. The SF-36 questionnaire is a widely used instrument for assessing HRQoL and has been validated in various populations, including patients with diabetes mellitus. The responses were collected from both the control and interventional groups and scored. The highest score depicts a more favourable, and the lowest score represents an unfavourable health state.

Follow-up assessments were scheduled for the interventional group six months after the initial assessment. During the follow-up visits, the participants were counselled again on their disease condition, medications, lifestyle modifications, complications, medication adherence, adverse drug reactions, common side effects, and drug use. The data collected for HRQoL was undifferentiated between outpatient and inpatient subjects.

Statistical Analysis

Data were analyzed using the Statistical Package for Social Sciences (SPSS) software version 26.0. Descriptive statistics were used to summarize the demographic and clinical characteristics of the participants. For comparisons between the interventional and control groups, the independent-sample t-test was used for continuous variables, while the chi-square test was used for categorical variables. A p-value of <0.05 was considered statistically significant. Multivariate regression analysis was performed to determine the factors associated with HRQoL.

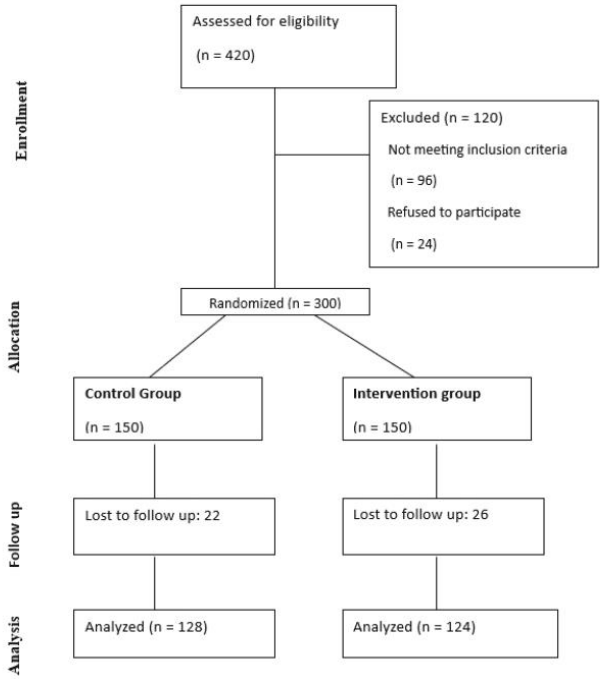

Figure 1: Consort Diagram.

Table 1: Socio-demographic characteristics of the participants.

Sl. No.	Demographics	Category	Control Group	Interventional Group	Total Number	Percentage
1	Age	21-30	2	4	6	2.00
		31-40	22	14	36	12.00
		41-50	30	22	52	17.33
		51-60	31	43	74	24.67
		61-70	42	40	82	27.33
		>70	23	27	50	16.67
2	Gender	Male	112	106	218	72.67
		Female	38	44	82	27.33
3	Body Mass Index (BMI)	Under Weight	20	13	33	11.00
		Normal Weight	33	41	74	24.67
		Over Weight	59	49	108	36.00
		Obese	38	47	85	28.33
4	Socio-economic Status	Upper	16	11	27	9.00
		Upper Middle	22	26	48	16.00
		Lower Middle	60	61	121	40.33
		Upper lower	30	38	68	22.67
		Lower	22	14	36	12.00
5	Duration of Diabetes	<1 Year	16	12	28	9.33
		1-5 Years	35	41	76	25.33
		6-10 Years	42	52	94	31.33
		>10 Years	57	45	102	34.00
6	Marital Status	Married	128	133	261	87.00
		Unmarried	12	09	21	7.00
		Widowed	10	08	18	6.00
7	Literacy Status	Literate	93	90	183	61.00
		Illiterate	57	60	117	39.00
8	Occupation	Employed	90	83	173	57.67
		Unemployed	60	67	127	42.33
9	Smoking	Non-smoker	42	49	91	30.33
		Smoker	92	82	174	58.00
		Recently quit	16	19	35	11.67
10	Alcohol	Alcoholic	97	90	187	62.33
		Non-Alcoholic	26	25	51	17.00
		Recently quit	27	35	62	20.67

RESULTS

This study aimed to assess the effect of an intervention on the Health-Related Quality of Life (HRQOL) of individuals with diabetes while considering various demographic, clinical, and lifestyle factors that could potentially impact HRQOL. The participants were stratified based on age, gender, Body Mass Index (BMI), socioeconomic status, duration of diabetes, marital status, literacy status, occupation, smoking, and alcohol use, as detailed in Table 1.

A total of 300 participants were included in the study, with 150 in the control group and 150 in the interventional group. The majority of the participants were male (72.67%), between 51-70 years old (52%), overweight or obese (64.33%), lower-middle class (40.33%), and married (87%). A significant proportion of

participants had diabetes for over ten years (34%), and 39% were illiterate.

The study results indicated that the intervention significantly impacted most domains of HRQOL (Table 2). After six months of intervention, the interventional group showed significant improvements in vitality (68.2 vs 48.5, $p<0.001$), physical functioning (79.5 vs 45.7, $p<0.001$), bodily pain (69.8 vs. 45.2, $p<0.001$), general health perceptions (68.1 vs. 62.2, $p<0.001$), physical role functioning (71.4 vs. 42.1, $p<0.001$), emotional role functioning (70.4 vs. 30.2, $p<0.001$), social role functioning (90.1 vs. 60.6, $p<0.001$), and mental health (72.7 vs. 54.7, $p<0.001$). However, no significant improvement was observed in the vitality domain (46.1 vs. 47.2, $p=0.054$).

The multiple linear regression analysis conducted in this study aimed to identify factors associated with HRQOL in patients with diabetes (Table 3). The results showed significant associations between HRQOL and various factors included in the model. The R-squared value of 0.675 indicates that the model explains approximately 67.5% of the variance in the HRQOL score.

Age, gender, and duration of diabetes were found to have significant effects on HRQOL. Age had a negative coefficient, suggesting that the HRQOL score decreases as age increases. Gender also had a significant effect, with females having a lower HRQOL score than males. Finally, the duration of diabetes had a negative effect, implying that as the duration of diabetes increases, the HRQOL score decreases.

Comorbidities, such as neuropathy, nephropathy, and coronary artery disease, were significant predictors of HRQOL. Participants with neuropathy and nephropathy had lower HRQOL scores, while those with coronary artery disease had a higher HRQOL score.

Medication adherence positively affected HRQOL, with participants who adhered to their medications having higher HRQOL scores. Similarly, the intervention group had a higher HRQOL score than the control group, indicating the positive impact of the intervention on HRQOL.

Table 2: Analysis of HRQOL-SF Scores between control and intervention group.

SF-36 Domain	Baseline Scores			Scores after 6 months		
	Control Group (Mean score)	Interventional group (Mean score)	*p* value	Control Group (Mean score)	Interventional group (Mean score)	*p* value
Vitality	47.2	46.1	0.054	48.5	68.2	<0.001*
Physical functioning	42.5	44.2	0.318	45.7	79.5	<0.001*
Bodily pain	41.7	40.1	0.009	45.2	69.8	<0.001*
General health perceptions	64.4	66.7	0.090	62.2	68.1	<0.001*
Physical role functioning	39.1	41.2	0.128	42.1	71.4	<0.001*
Emotional role functioning	31.7	33.1	0.010	30.2	70.4	<0.001*
Social role functioning	63.4	62.1	0.010	60.6	90.1	<0.001*
Mental health	58.1	56.9	0.030	54.7	72.7	<0.001*

SF Scores range from 0 – 100, Lower scores indicate more disability, higher scores indicate less disability, * *p* value <0.001 was significant

Table 3: Multivariate linear regression analysis of factors associated with HRQOL.

Factors	β coefficient	Standard error	*p*-value
Age	-0.087	0.043	0.042
Gender (Male)	2.155	0.623	<0.001
Marital status (Married)	1.311	0.603	0.031
Education (Primary)	1.321	0.679	0.052
Employment status (Unemployed)	-1.931	0.753	0.011
Duration of diabetes	-0.463	0.152	0.002
HbA_{1c} level	-1.269	0.238	<0.001
Interventional group	10.235	0.938	<0.001

p value <0.001 was significant.

DISCUSSION

This study's results align with previous research that has examined the effects of interventions on the HRQOL of people with diabetes. A meta-analysis by de Groot *et al.*[9] reported that interventions focused on self-management education, physical activity, and dietary changes positively affected the HRQOL of individuals with diabetes. The results of our study also suggest that an intervention that targets lifestyle modifications can lead to significant improvements in HRQOL.

Another study conducted by Rubin *et al.*[10] examined the impact of a peer mentoring intervention on the HRQOL of individuals with diabetes. The study found that the intervention significantly improved physical functioning, vitality, and emotional well-being. These findings are consistent with the results of our study, which also found significant improvements in physical functioning, vitality, and emotional role functioning in the interventional group.

However, the current study is unique in its focus on the impact of the intervention on individuals with diabetes who are illiterate or have been living with diabetes for a longer duration. The study's findings suggest that even individuals with lower literacy levels and those living with diabetes for longer can benefit from lifestyle interventions to improve HRQOL. This finding is significant as these subgroups are often overlooked in interventions targeting individuals with diabetes.

In addition, our study adds to the limited research on the impact of interventions on the HRQOL of individuals with diabetes in low- and middle-income countries. Most studies on this topic have been conducted in high-income countries, and our study provides important insights into the effectiveness of interventions in low- and middle-income countries. The findings suggest that interventions aimed at lifestyle modifications can effectively improve the HRQOL of individuals with diabetes in these settings.

Overall, the current study's findings are consistent with previous research on the impact of interventions on the HRQOL of individuals with diabetes. However, the study is unique in its focus on individuals who are illiterate or have been living with diabetes for a longer duration and provides essential insights into the effectiveness of interventions in low- and middle-income countries.

CONCLUSION

In conclusion, this study demonstrates that a structured diabetes education program can significantly improve the HRQOL of individuals with diabetes. The intervention effectively improved all domains of the SF-36 questionnaire, particularly in physical and emotional well-being domains. The findings highlight the importance of incorporating diabetes education programs in routine diabetes care to improve the overall health outcomes of individuals with diabetes. Further studies are needed to assess the long-term impact of such interventions on HRQOL and other clinical outcomes in individuals with diabetes.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

HRQOL: Health-Related Quality of Life; **IDF:** International Diabetes Federation; **QOL:** Quality of Life; **SNOSE:** Sequentially Numbered Opaque Sealed Envelopes; **SPSS:** Statistical Package for Social Sciences; **BMI:** Body Mass Index

SUMMARY

The study summarises about type 2 diabetes mellitus in India. It emphasizes that type 2 diabetes is a chronic condition that can influence an individual's quality of life. The study aimed to assess Health-Related Quality of Life (HRQOL) using the SF-36 questionnaire among 300 individuals with type 2 diabetes in India. The results indicated that individuals with diabetes had lower HRQOL scores, particularly in physical health domains like physical functioning, role-physical, bodily pain, and vitality. The study identified factors such as age, gender, education, duration of diabetes, and comorbidities as significant contributors to HRQOL. It concludes by emphasizing the need for interventions to improve the quality of life for individuals with type 2 diabetes in India.

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RESEARCH ARTICLE

Prevalence of adverse drug reactions in diabetic patients receiving antidiabetic medications at tertiary care hospital

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ABSTRACT:
Background: Diabetes mellitus is a chronic metabolic condition defined by elevated blood glucose levels caused by abnormalities in insulin secretion, insulin action, or both. Anti-diabetic drug pharmacovigilance can be extremely useful in identifying and resolving the adverse drug reactions (ADRs) and safeguarding patients from needless injury. **Objective:** The objective of the study was to determine the prevalence of various adverse events caused by the use of anti-diabetic medications in patients treated at tertiary care hospital. **Method:** It was a randomized controlled study where the participants were randomized into two groups i.e., interventional or study group and control group. All suspected ADRs were collected, analysed and confirmed by the physician-in-charge and were assessed for causality using WHO-UMC Causality Categories, Naranjo's causality assessment scale, preventability using Modified-Schumock and Thornton scale, severity using Modified Hartwig and Siegel scale by the Causality Assessment Committee (CAC). **Results:** The study included a total of 300 subjects among which 218 were male (72.67%) and 82 were female (27.33%). A total of 300 patients, 104 ADRs were identified, in which 46.15% were observed in the control group and 53.85% in the interventional group. Females were more prevalent to the ADRs. The majority of ADRs were seen in age group of >70 in which 15.38% were observed in the control group and 18.27% in the interventional group. The Highest observed ADR of 20 (19.23%) was Hypoglycemia in which 9(8.65) were observed in the control group and 11(10.57) in the interventional group followed by weight gain i.e, 10 (9.61%) in which 5(4.80%) were observed in the control group and 5(4.80%) in the interventional group. **Conclusion:** ADR relating to antidiabetic therapy utilizing oral antidiabetics and insulin was found to be prevalent. The doctors and clinical pharmacists are therefore needed to identify and report the appropriate signals generated to the nearest ADR monitoring centre or Pharmacovigilance Programme of India for the benefit of the patients.

KEYWORDS: Clinical pharmacist, Adverse drug reaction, Antidiabetic drugs, Randomized controlled study, Causality assessment scale.

INTRODUCTION:

Diabetes is a chronic metabolic condition defined by elevated blood glucose levels caused by abnormalities in insulin secretion, insulin action, or both. Diabetes complications, whether acute or chronic, are associated with long-term microvascular and macrovascular alterations such as organ damage, organ failure, and multi-organ dysfunction[1]. The prevalence of diabetes mellitus (DM) is increasing at a rapid speed globally and has reached epidemic proportions in many countries.

Worldwide, 415 million people have been diagnosed with diabetes and the number is expected to reach beyond 642 million by 2040. In India, more than 65.1 million people have been diagnosed with diabetes and the calculations suggest that 89 million people will be inflicted by 2030. Notably about 56 percent of afflicted population will be from urban regions[2].

For Type 2 diabetes, an oral antidiabetic medication (OAD) is the first line of treatment. However, because type 2 diabetes is progressive accompanied with long-term treatment typically involving a combination of two or more oral medications. The ideal usage of OADs is frequently constrained by safety and tolerability. According to World Health Organization an adverse drug reaction (ADR) is characterized as a noxious,

unexpected, and unwanted outcome that happens as a result of dose commonly used in humans for diagnosis, prevention, and treatment of disease or change of physiological function. ADRs are generally caused by a variety of circumstances, including polypharmacy, medication interactions, and the complexity of diseases[3–9]. However, drugs used to treat diabetes are evidenced to have many ADRs. Most of them are well documented (e.g., hypoglycaemia associated with insulin or sulfonylureas), but despite this knowledge, ADRs in patients taking anti-diabetic treatment do occur, and in many cases, these ADRs are severe and life-threatening[10]. Anti-diabetic drug pharmacovigilance can be extremely useful in identifying ADRs and inform doctors about the likelihood and specifics of such events, safeguarding patients from needless injury[11]. The Pharmacovigilance Programme of India (PvPI) is taking steps to encourage spontaneous ADR reporting while pharmacovigilance operations in India are still in their infancy[12–15]. However, there are not many reports on the ADR profile of antidiabetic medications specifically that are available in India. Therefore, the purpose of this study was to determine the prevalence of various adverse events caused by the use of anti-diabetics in patients treated at tertiary care hospital.

METHODOLOGY:

The study was conducted at Vivekanand General Hospital, Deshpande Nagar, Hubballi. The target population for this study included patients diagnosed with diabetes mellitus. It was a randomized controlled study where 300 the participants were randomized into two groups i.e., interventional (150) and control group (150). The study was carried out for a period of 2 years. Informed consent form (ICF) in english and in other patient-preferred local languages like Kannada were obtained from eligible patients. The study included the patients of age above 18 years and who were diagnosed with DM in out and in-patient general medicine department with co-morbid conditions such as cerebrovascular diseases, coronary artery diseases, neuropathy and nephropathy and willing to participate in the study. The study excluded non-diabetic patients and pregnant women. Patients with extreme illness and mental incompetence were also excluded from this study. The suspected adverse drug reaction reporting form version 1.4 released by the Indian Pharmacopeia Commission, PvPI, were used as materials and data sources[3]. ADR reporting form collects all pertinent data on patient information and adverse effects such as, suspected adverse reaction, suspected medication(s), and reporter information etc. All suspected adverse drug reactions were collected, analysed, and confirmed by the doctor and inhouse medical officer-in-charge and were assessed by the Causality Assessment Committee (CAC) for causality using WHO-UMC Causality Categories[16], Naranjo's causality assessment scale, preventability using Modified-Schumock and Thornton scale[17], and severity using Modified Hartwig and Siegel scale[18].

Ethical approval: Ethical clearance for this study was obtained from Institutional Ethical Committee from KLE Academy of Higher Education and Research Belagavi. Reference number: KAHER/EC/19-20/290619004.

RESULTS:

In the study, 208 (72.67%) participants were male and the rest 82 (27.33%) participants were female. The highest percentage of population belonged to the geriatric's category. Of the observed patients, 108 (36.00%) were overweight and 85 (28.33%) patients were obese. The socioeconomic status of participants varying from lower middle and upper lower were 121 (40.33%) and 68 (22.67%), respectively.

Duration of diabetes i.e., >10 years, was highest i.e., 102 (34.00%) followed by 94 (31.33%) falling in category of 6 to 10 years. Married and unmarried patients contributed to 261 (87.00%) and 21 (7.00%), respectively.

The majority of participants, or 183 (61.00%), were literate, while 117 (39.00%) were illiterate, with the latter group contributing insignificantly. Of the total participants, 174 (58.00%) engaged in smoking, and 187 (62.33%) were alcohol addicts. The demographic representation of study participants have been depicted in Table No. 1

A total of 104 ADR's were observed both in control (46.15%) and interventional (53.85%) groups. Of the observed ADRs in control and interventional group, 26.92% were male and 19.23% were female participants.

Belongs to control group and 27.88% in male and 25.96% in female were identified in interventional group. Age group belonging to >70 years were more prevalent to develop ADRs followed by 61-70. The lowest ADRs were identified in 21-30 accounting for 1(0.96%) in control and 1(0.96%) in the interventional group. Total ADR occurrence on basis of age and gender were shown in Table No. 2.

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Table 1: Demographics of the study participants

Sl. No.	Demographics	Category	Control Group	Interventional Group	Total Number	Percentage
1	Age	21-30	2	4	6	2.00
		31-40	22	14	36	12.00
		41-50	30	22	52	17.33
		51-60	31	43	74	24.67
		61-70	42	40	82	27.33
		>70	23	27	50	16.67
2	Gender	Male	112	106	218	72.67
		Female	38	44	82	27.33
3	Body Mass Index (BMI)	Under Weight	20	13	33	11.00
		Normal Weight	33	41	74	24.67
		Over Weight	59	49	108	36.00
		Obese	38	47	85	28.33
4	Socioeconomic Status	Upper	16	11	27	9.00
		Upper Middle	22	26	48	16.00
		Lower Middle	60	61	121	40.33
		Upper lower	30	38	68	22.67
		Lower	22	14	36	12.00
5	Duration of Diabetes	<1 Year	16	12	28	9.33
		1-5 Years	35	41	76	25.33
		6-10 Years	42	52	94	31.33
		>10 Years	57	45	102	34.00
6	Marital Status	Married	128	133	261	87.00
		Unmarried	12	09	21	7.00
		Widowed	10	08	18	6.00
7	Literacy Status	Literate	93	90	183	61.00
		Illiterate	57	60	117	39.00
8	Occupation	Employed	90	83	173	57.67
		Unemployed	60	67	127	42.33
9	Smoking	Non-smoker	42	49	91	30.33
		Smoker	92	82	174	58.00
		Recently quit	16	19	35	11.67
10	Alcohol	Alcoholic	97	90	187	62.33
		Non-Alcoholic	26	25	51	17.00
		Recently quit	27	35	62	20.67
11	Diabetic complications	Coronary artery disease	20	36	56	46.67
		Cerebrovascular disease	9	9	18	15.00
		Retinopathy	11	10	21	17.50
		Neuropathy	12	15	27	22.50
		Chronic Kidney Disease	16	17	33	27.50
		Diabetic Foot	7	7	14	11.67

Table 2: ADR occurrence: Age and Gender-wise

Sr. No.	Parameter		Total Number of Patients (300)	Number of ADRs (104)	Percentage of ADR
1	**Study groups**				
	Control		150	48	46.15
	Interventional		150	56	53.85
2	**Gender group**				
	Control	Male	112	28	26.92
		Female	38	20	19.23
	Interventional	Male	106	29	27.88
		Female	44	27	25.96
3	**Age Group**				
	Control	21-30	2	1	0.96
	Interventional		4	1	0.96
	Control	31-40	22	3	2.88
	Interventional		14	5	4.81
	Control	41-50	30	6	5.77
	Interventional		22	8	7.69
	Control	51-60	31	9	8.65
	Interventional		43	11	10.58
	Control	61-70	42	13	12.50
	Interventional		40	12	11.54
	Control	>70	23	16	15.38
	Interventional		27	19	18.27

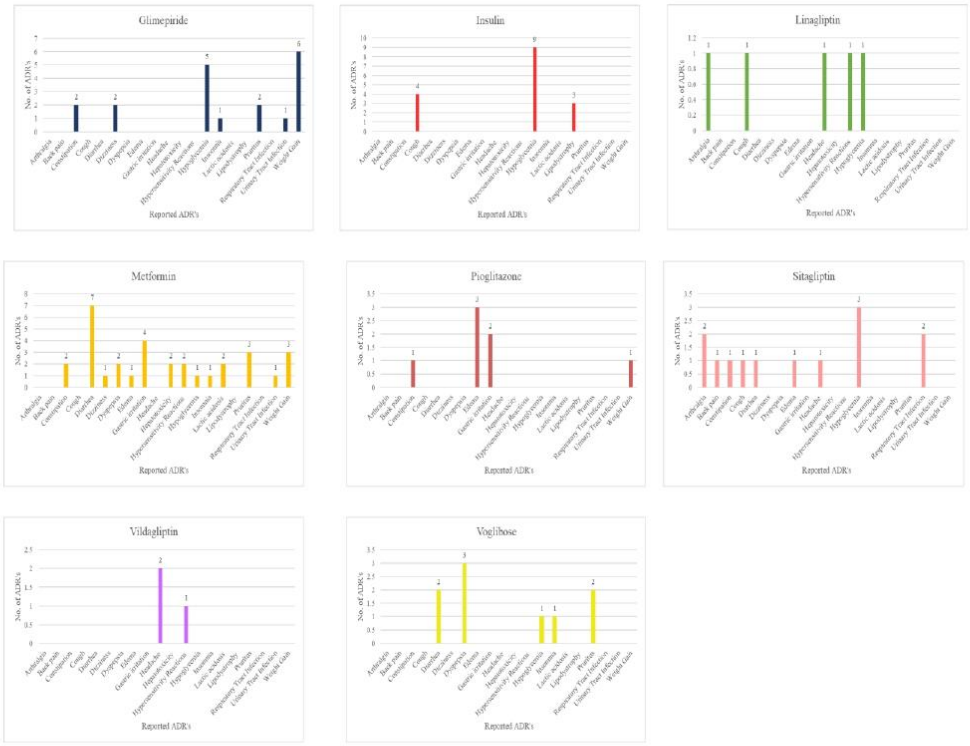

Figure 1: Prevalence of ADR's in patients receiving Antidiabetic Drugs

Table 3: WHO-UMC Causality Assessment of reported ADR's.

Sr. No.	Suspected ADRs	No of ADRs	Control	Interventional	Certain (%)		Probable/Likely (%)		Possible (%)	
					Control	Interventional	Control	Interventional	Control	Interventional
1	Arthralgia	3	2	1	0 (0.00)	0 (0.00)	1 (33.33)	1 (33.33)	1 (33.33)	0 (0.00)
2	Back pain	1	0	1	0 (0.00)	0 (0.00)	0 (0.00)	1 (100)	0 (0.00)	0 (0.00)
3	Cough	6	2	4	0 (0.00)	0 (0.00)	1 (16.66)	2 (33.33)	1 (16.66)	2 (33.33)
4	Constipation	6	3	3	0 (0.00)	0 (0.00)	2 (33.33)	1 (16.66)	1 (16.66)	2 (33.33)
5	Diarrhoea	10	5	5	0 (0.00)	0 (0.00)	2 (20.00)	2 (20.00)	3 (30.00)	3 (30.00)
6	Dizziness	3	2	1	0 (0.00)	0 (0.00)	1 (33.33)	0 (0.00)	1 (33.33)	1 (33.33)
7	Dyspepsia	5	2	3	0 (0.00)	0 (0.00)	1 (20.00)	2 (40.00)	1 (20.00)	1 (20.00)
8	Edema	5	2	3	0 (0.00)	0 (0.00)	1 (20.00)	2 (40.00)	1 (20.00)	1 (20.00)
9	Gastric irritation	6	4	2	1 (16.66)	0 (0.00)	1 (16.66)	1 (16.66)	2 (33.33)	1 (16.66)
10	Headache	4	1	3	0 (0.00)	0 (0.00)	1 (25.00)	2 (50.00)	0 (00.00)	1 (25.00)
11	Hepatotoxicity	2	1	1	1 (50.00)	0 (0.00)	0 (0.00)	1 (50.00)	0 (0.00)	0 (0.00)
12	Hypoglycemia	20	9	11	2 (10.00)	4 (20.00)	3 (15.00)	5 (25.00)	4 (20.00)	2 (10.00)
13	Hypersensitivity Reactions	4	1	3	1 (25.00)	0 (0.00)	0 (00.00)	1 (25.00)	0 (00.00)	2 (50.00)
14	Insomnia	3	1	2	0 (0.00)	0 (0.00)	1 (33.33)	1 (33.33)	0 (00.00)	1 (33.33)
15	Lactic acidosis	2	2	0	1 (50.00)	0 (0.00)	1 (50.00)	0 (0.00)	0 (0.00)	0 (0.00)
16	Lipodystrophy	3	1	2	1 (33.33)	0 (0.00)	0 (00.00)	1 (33.33)	0 (0.00)	1 (33.33)
17	Pruritus	7	3	4	0 (0.00)	0 (0.00)	1 (14.29)	2 (28.57)	2 (28.57)	2 (28.57)
18	Respiratory Tract Infection	2	1	1	0 (0.00)	0 (0.00)	1 (50.00)	0 (0.00)	0 (00.00)	1 (50.00)
19	Urinary Tract Infection	2	1	1	0 (0.00)	0 (0.00)	1 (50.00)	1 (50.00)	0 (00.00)	0 (00.00)
20	Weight Gain	10	5	5	0 (00.00)	0 (00.00)	3 (30.00)	2 (20.00)	2 (20.00)	3 (30.00)
	Total	104	48	56	7 (6.73)	4 (3.85)	22(21.15)	28 (26.92)	19 (18.27)	24 (23.08)

Out of 104 ADRs, 20(19.23%) ADRs were seen with hypoglycaemia followed by10 (9.61%) ADRs were weight gain and gastrointestinal system-related ADRs like diarrhoea 10 (9.61%), constipation 6 (5.77%), gastric irritation 6 (5.77%) and 5 (4.80%) dyspepsia. The total no. of ADRs and its causality assessment by WHO UMC Causality and Naranjo is depicted in Table No. 3 and Table No. 6 respectively. Suspected ADRs Distribution based on Preventability assessment using Modified-Schumock and Thornton scale is shown in Table No. 4. Suspected ADRs Distribution based on Severity assessment using Modified Hartwig and Siegel scale is shown in Table No. 5.

Table 4: Suspected ADRs Distribution based on Preventability assessment using Modified-Schumock and Thornton scale

SR No	Categories	Number of ADRs (n=104)	% of ADRs
1	Definitely preventable ADRs	64	61.53
2	Probably preventable ADRs	31	29.80
3	Non-preventable ADRs	09	8.65

Table 5: Suspected ADRs Distribution based on Severity assessment using Modified Hartwig and Siegel scale

SR No	Categories	Number of ADRs (n=104)	% of ADRs
1	Mild	22	21.15
2	Moderate	74	71.15
3	Severe	8	7.70

Table 6: Causality assessment of adverse drug reactions according to Naranjo algorithm

SR No	Categories	Control	Interventional	Number of ADRs (n=104)	% of ADRs
1	Certain	5 (4.81)	4 (3.85)	9	8.65
2	Probable	20 (19.23)	35 (33.65)	55	52.88
3	Possible	18 (17.31)	22 (21.15)	40	38.46
4	Unlikely	0 (0.00)	0 (0.00)	0 (0.00)	0.00
5	Conditional/unclassified	0 (0.00)	0 (0.00)	0 (0.00)	0.00
6	Unassessable/unclassifiable	0 (0.00)	0 (0.00)	0 (0.00)	0.00

DISCUSSION:

In the diabetes outpatient and inpatient setting in the Indian context, the current study has documented the incidence and sought to characterise probable ADRs caused by antidiabetic medications. Contrary to reports of ADR profiles of specific medications, India lacks pharmacovigilance profiling of antidiabetic medicines in general, and insulin is not included in this list. The most often reported adverse event in the majority of medication consumption studies is insulin-induced hypoglycemia[3]. For determining how preventable ADRs are, the Schumock and Thornton criteria were developed. Several researches have employed these criteria in its modified version. It is divided into three categories: things that can be absolutely or probably prevented, and those that can't be prevented[19,20].The University of Toronto's Naranjo and colleagues created the Naranjo Scale to determine whether an ADR is likely to be caused by a certain medicine or by other variables. Multiple studies have employed this tested technique. Ten questions on this scale can either be answered "Yes", "No" or "Do not know". For each response, a different point value (1, 0, + 1 or + 2) is given. Total scores can vary from 4 to +13; the reaction is deemed certain if the score is 9 or higher, probable if it is between 5 and 8, conceivable if it is between 1 and 4, and questionable if it is 0. Of the observed ADRs, 26.92% in male and 19.23% in female belongs to control group and 27.88% in male and 25.96% in female were identified in interventional group. Age group belonging to >70 years were more prevalent to develop ADRs followed by 61-70. This is consistent with earlier findings, as demonstrated by a study by Mishra S. et al.[20], in which the total number of males in the study was 68 (56.7%), while females were 52(43.3%). The age group of 21 to 30 around 1.92% accounted for ADRs. Similarly, 7.69% of ADRs in 31-40 age group, 13.46% in 41-50 group, 51-60 age group accounted for 19.23% of ADRs, 61-70 had 24.03% of ADRs and age group of above 70 had 33.65% of ADRs. Similarly, Singh et al. found 11.8% of ADR(2) in their investigation. ADR was found at 27.6% in one research[21].Table 3 listed out frequency of different Adverse Drug Reactions (ADR) among different class of Anti-Diabetic Drugs. In a study conducted by Saravanan K et al., the potential adverse drug reactions of drugs used in diabetes patients were observed in 35 patients (46.66%), with the majority of them being male (27 out of 35). Type A adverse drug reactions were identified during the phase of the study (Hypoglycemic, Diarrhea, Vomiting, Giddiness, Abdominal Distension)[22]. In our study the commonly observed ADRs were seen with hypoglycaemia i.e 20(19.23%) followed by 10 (9.61%) ADRs were weight gain and gastrointestinal system-related ADRs like diarrhoea 10 (9.61%), constipation 6 (5.77%), gastric irritation 6 (5.77%) and 5 (4.80%) dyspepsia. A study carried out in Italy found that 3416 (2.3%) of the 148,289 ADR reports that were gathered were related to antidiabetic drugs[23]. Severe hypoglycemia (nearly 50% of significant ADR reports), primarily brought on by insulins or sulfonylureas, lactic acidosis from metformin, and pancreatitis from incretins were the most commonly reported serious ADRs. In that study, metabolic disorders were the most common ADRs for sulfonylureas and biguanides. The gastrointestinal system was the area most commonly impacted by alpha-

glucosidase inhibitors, glucagon-like peptide-1 mimic, and dipeptidyl peptidase-4 (DPP-4) inhibitors[22-24]. In our study, frequency of ADRs among various anti-diabetic drugs revealed that the commonest ADR observed was hypoglycemia 19.23% and weight gain 9.61% caused by the drugs such as insulin, glimepiride, sitagliptin, metformin, voglibose, linagliptin. Cough accounted for 5.77% ADRs by the drugs insulin, sitagliptin, linagliptin. Lipodystrophies are characterised by an improper distribution of body fat, which can be inherited or acquired and can have either a generalised or a more focused (partial) distribution[24]. Investigations are still underway to identify the mechanism of hypoglycemia unawareness and defective insulin counterregulation. Recent investigations have proven the significance of hypoglycemia as a barrier to safe treatment. Previous episodes of severe hypoglycemia, hypoglycemia unawareness, impaired insulin counterregulation, and several coexisting illnesses such renal disease, malnutrition, coronary heart disease, and liver disease are all risk factors for severe hypoglycemia. In addition to self-monitoring of blood glucose (SMBG) via finger-stick testing, new minimally invasive continuous monitoring of glycemia shows promise in achieving improved control with increased safety[25]. In table 3, ADRs were grouped based on WHO-UMC Causality assessment which is the standard scale for analyzing the certainty of an adverse drug reaction. According to the results it was observed that 48.07% were probable in which 22.15% in the control group and 26.92% in the intervention group. Total of 41.34% possible ADRs were significantly observed of which 18.26% in control and 23.07% in intervention groups. In table 6, ADRs were classified based on Naranjo algorithm, in which probable and possible were 55 (52.88%) and 40 (38.46%) respectively. The most effective treatment approaches for insulin-induced lipodystrophy are non-reuse of needles and rotation of injection sites with each injection. Injections of dexamethasone topically have been tried to treat insulin-induced lipoatrophy. Recognizing and effectively managing these problems are crucial. Irregular insulin absorption might result in variable glycaemic levels and sudden episodes of hypoglycemia[25]. In a study by Tripathi CB et al., the severity evaluation revealed that the treatment group had 76% mild and 24% moderate responses, whereas the preventive group had 89% mild and 11% moderate reactions. ADR severity was much greater in the treatment group. With the exception of gastritis, nausea, and vomiting, the majority of ADRs fell into the nonpreventable group according to the Modified-Schumock and Thornton scale[26]. In our study, distribution of ADRs was done based on preventability assessment using Modified Schumock and Thornton scale in table 4. 61.53% of ADRs were definitely preventable, 29.80% of ADRs were probably preventable and 8.65% of ADRs were non-preventable. Table 5 listed out the severity assessment using Modified Hartwig and Siegal scale where 21.15% accounted for mild ADRs, 71.15% for moderate ADRs and 7.70% for severe ADRs. This agrees with previous reports as shown in a study by Shareef et al[27].

CONCLUSION:

Adverse drug reactions due to oral antidiabetic agents and insulin is a very common problem. Although they are unlikely to be life-threatening, they can still make many patients feel uncomfortable in different ways. Hypoglycemia is the most common adverse effects which was reported by oral antidiabetics and insulin. Gastrointestinal adverse effects like constipation, diarrhoea and dyspepsia were second highest mostly related to DPP4 inhibitors. There were few reports of arthralgia, back pain by Sitagliptin (DPP4 inhibitors). The adverse effects should be considered very cautiously while treating and prescribing to patients with relevant co morbid conditions. Since anti-diabetic medications are typically taken for life, the risk and harmful effects resulting from patients' concurrent co-morbidities shouldn't be disregarded while prescribing. The doctors and clinical pharmacists need to notify and report these ADRs to nearer ADR monitoring centre in order to identify the appropriate signal generation for the benefit of the society. More information on prescribed medications and their adverse effects will help to lower the incidence of ADR and guarantee patient safety.

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Annexure XXI: Certificates of Oral and Poster Presentations

BLDEA's
SSM College of Pharmacy &
Research Centre, Vijayapur, Karnataka.

NAAC
Accredited With Grade "B"

Best e-presentation award

to

Dr. Sanatkumar Nyamagoud

Asst. Prof. Dept. of Pharmacy Practice
KLE College of Pharmacy Hubballi.

for having won **SECOND PLACE** in an e-paper presentation entitled

" Clinical Pharmacist led intervention towards management of type 2 diabetes Mellitus -A prospective, randomized controlled study" in AICTE Sponsored National Conference (ONLINE) on "Recent Developments In Pharmacology" on 13th November, 2021. Organised by **Dept. of Pharmacology,**

BLDEA's SSM College of Pharmacy and Research Centre, Vijayapur-586103. Karnataka.

AICTE RDP 2021

Dr. Shivakumar Hugar, Coordinator
Dr. V P Patil, Co-Coordinator
Dr. Nanjappaiah H M, Scientific Committee In-charge
Dr. R B Kotnal, Convener

CliMed Research Solutions
WYHF INDIA
ISMTM-2021

CERTIFICATE
OF APPRECIATION

THIS CERTIFICATE IS AWARDED TO

Dr. Sanatkumar B Nyamagoud

has participated/Presented Oral/Poster entitled

Impact of clinical pharmacist-led diabetes management clinic on health Outcomes -A prospective, randomized controlled study

and won **CC01** in the International Symposium on Medication Therapy Management-2021 (ISMTM) held on 12 - 14 November, 2021, jointly organized by **Sultan Ul Uloom College of Pharmacy & CliMed Research Solutions** in collaboration with Indian Pharmaceutical Association, World Youth Heart Federation -India, Association of Community Pharmacists of India, and International Federation for Medical Therapy Management.

Dr. Ajit Singh, CEO & Co-Founder, CliMed Research Solution, Gurgaon, India
Dr Anupama Koneru, Principal, Sultan Ul Uloom College of Pharmacy, Hyderabad
Dr. TV Narayana, President, Indian Pharmaceutical Association (IPA)
Dr. Anantha Nagappa Naik, President, Association of Community Pharmacists of India (ACPI)
Dr. Priyansh Shah, President, World Youth Heart Federation (WYHF)

॥ jai sri gurudev ॥

Sri Adichunchanagiri College of Pharmacy

ADICHUNCHANAGIRI UNIVERSITY

CERTIFICATE

This certificate is presented to Dr./Ms./Mr./Mrs./

Dr. Sanatkumar B Nyamagoud

for the valuable participation in the **E-Poster Competition** held on 23rd August 2021 during the 'One Day National Conference on **PATIENT SAFETY'** organized by Department of Pharmacy Practice, Sri Adichunchanagiri College of Pharmacy, Adichunchanagiri University in association with IPA (Karnataka State Branch), AIMS, AH&RC, ACN.

Dr. Rajesh Venkataraman
Professor & Head
Department of Pharmacy Practice
SACCP, ACU

Dr. Ramesh B
Dean of Pharmacy & Principal
SACCP, ACU

NITTE (Deemed to be University)

ISPOR Improving healthcare decisions

2nd International Virtual Conference on Advances in Health Economics and Outcomes Research

Theme: Broadening the economic view and approach towards patient safety

CERTIFICATE

This is to certify that **Dr. Sanatkumar Nyamagoud**

Participated in **E -Poster Presentation** for the topic entitled **Drug Utilization Evaluation of Antidiabetic Drugs in a Tertiary Care Teaching Hospital: A Randomized Controlled Study** in the **2nd International Virtual Conference on Advances in Health Economics and Outcomes Research** jointly organized by **ISPOR Nitte (Deemed to be University) Student Chapter** and **Dept. of Pharmacy Practice, NGSM Institute of Pharmaceutical Sciences,** Mangaluru, Karnataka, India on 21st and 22nd October 2021.

Prof. (Dr.) Satheesh Kumar Bhandary
Vice Chancellor
Nitte (Deemed to be University)

Prof. (Dr.) C. S. Shastry
Organizing Chairman

Dr. Uday Venkat Mateti
Convener

Dr. Juno J. Joel
Organizing Secretary