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Research Paper

Pharmacovigilance Study of Adverse Drug Reaction in Diabetes Patient Receiving Antidiabetic Medication

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ABSTRACT

Diabetes mellitus is a chronic disease that requires long-term treatment with antidiabetic drugs. These medicines may cause adverse drug reactions (ADRs), which can affect patient safety and treatment outcomes. The present study was conducted to evaluate ADRs in diabetic patients receiving antidiabetic therapy.A total of 65 diabetic patients were included in the study. Data related to age, gender, prescribed drugs, type of ADR, and severity were collected and analyzed. The study showed that most patients belonged to the 21-40 years age group, and male patients were slightly higher in number than females. Hypoglycemia, nausea, sweating, diarrhea, dizziness, and increased urination were the most common ADRs reported. Metformin, glimepiride, insulin, and SGLT2 inhibitors were commonly associated with ADRs.Moderate ADRs were most frequently observed, followed by severe and mild reactions. Some severe ADRs required immediate medical attention.The study concludes that pharmacovigilance plays an important role in identifying and preventing ADRs in diabetic patients. Regular monitoring, patient counseling, and proper ADR reporting can improve patient safety and effective diabetes management.

INTRODUCTION

Pharmacovigilance : It can be defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems.[11] It plays role in identifying, assessing, understanding and preventing adverse effects or aany other drug – related problems with increasing use of Medicines Worldwide,monitoring their safety has become essential to protect public health. Pharmacovigilance word derived from two words “Pharmakon “(Greek Word for drug and “vigil are” (Latin word meaning to keep and watch). Pharmacovigilance literally Means “keep watch

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over drugs “It Ensures that Medicines used by patients are safe, Effective of good quality.According to WHO, Pharmacovigilance can be defined as the science and activities relating to the
detection, assessment, understanding and prevention of adverse effects or any other possible drug related problems.

Scope of Pharmacovigilance:

The pharmacovigilance aims to understand evaluate, identify and prevent adverse effect or other drug.

1] Adverse Event Reporting
2]Signal Detection
3]Risk Assessment
4]Post Marketing surveillance[11]

PharmacovigilanceHistory

:Pharmacovigilance started about 170 years ago, though it was not called Pharmacovigilance at that time.The thalidomide tragedy (1960s) led to the development of the modern global Pharmacovigilance system.

Pharmacovigilance focuses on monitoring the safety of medicines throughout their life cycle.In the 1980s, spontaneous reporting systems were recognized as important tools for detecting adverse drug reactions (ADRs).Many countries adopted post-marketing surveillance and used ADR reports for regulatory decisions, including drug withdrawal.Reporting of adverse drug reactions increased worldwide, reaching 200–300 reports per year per 10 million people.The European Commission made Pharmacovigilance a legal part of drug regulation.Pharmaceutical companies were required to report suspected adverse effects to regulatory authorities.Many countries made ADR reporting compulsory for healthcare professionals.Pharmacoepidemiology courses were introduced in universities to improve Pharmacovigilance knowledge.By the mid-2000s, efforts focused on:Intensifying ADR reporting.Monitoring specific drugs and adverse effects (skin, liver, eyes,etc.).Establish pharmacovigilance activities at regional, national, and international levels.Strengthen collaboration between pharmacists and physicians to improve ADR reporting.Encourage direct patient reporting of adverse drug reactions.

Use Prescription Event Monitoring (PEM) as an important pharmacovigilance tool.Implement Record Linkage Systems for better drug safety monitoring.Apply Case-Control Surveillance to identify drug-induced disorders.Enhance both the quality and quantity of ADR reports.Promote continuous monitoring to improve drug safety and patient care.

Diabetes:

Diabetes is a whole group of diseases in the body regulating blood sugar level. There is a lack of response to the insulin produced by the pancreas. Diabetes is a serious chronic disease that occurs either when the pancreas does not produce enough insulin or when the body cannot effectively use the insulin it produces. Diabetes is an important public health problem, affecting over 500 million people globally.[16]

Classified in three types which is:

1)Type 1 Diabetes: It caused by autoimmune -cells, leading to an absolute insulin deficiency.

2)Type-2 Diabetes: It is most common form characterized by insulin deficiency, closely linked to obesity and sedentary lifestyles.

3)Gestational Diabetes: Which found during pregnancy.

History of Diabetes: Diabetes mellitus comes from the Greek word diabetes ("to pass through") and the Latin word mellitus ("sweet like honey").Ancient descriptions: Diabetes was first described in ancient Egyptian records around 1500 BCE as a condition characterized by excessive

urination.Indian contribution: Ancient Indian physicians Sushruta and Charaka described Madhumeha ("honey urine"), noting that urine attracted ants due to

Drug Interaction :

1) Sulfonylureas + NSAIDs – Increased risk of hypoglycemia.
2) Metformin + Contrast Media – Risk of lactic acidosis.
3) SGLT2 Inhibitors + Diuretics – Dehydration and low blood pressure.
4) DPP-4 Inhibitors + ACE Inhibitors – Rare risk of angioedema.
5) Insulin + Beta Blockers – May mask hypoglycemia symptoms.
6) SGLT2 Inhibitors + Lithium – Reduced lithium levels.
7) Metformin + Cimetidine/Dolutegravil Increased metformin levels.
8) Aspirin + Beta Blockers + Alcohol – Increased or masked hypoglycemia.
9) Some Antibiotics, Antifungals & NSAIDs – May cause severe hypoglycemia.
10) Steroids & Oral Contraceptives – May increase blood glucose levels

Prevention :-

Maintain a healthy body weight.
Exercise regularly (at least 150 min/week).
Follow a balanced, healthy diet.
Avoid excess sugar, refined carbs, and processed foods.
Choose healthy unsaturated fats.
Avoid smoking and excessive alcohol intake.
Monitor blood sugar, blood pressure, and cholesterol regularly.
Get adequate sleep and manage stress.
Prevent high blood pressure and metabolic imbalance.
Follow a personalized diabetes care plan.

{2} AIM & OBJECTIVE:

Aim:

To evaluate adverse drug reactions (ADRs) associated with antidiabetic medications in diabetic patients through pharmacovigilance monitoring.

Objectives:

1)To identify and record ADRs in diabetic patients receiving antidiabetic therapy.
2)To assess the severity and pattern of ADRs caused by antidiabetic drugs.
3)To study the association between antidiabetic medications and common ADRs.
4)To analyze age-wise and gender-wise distribution of ADRs.
5)To compare the safety profiles of different antidiabetic drug classes.
6)To evaluate the incidence of mild, moderate, and severe ADRs.
7)To promote awareness of pharmacovigilance and ADR reporting.
8)To improve patient safety through continuous ADR monitoring.
9)To encourage early detection, prevention, and management of ADRs.

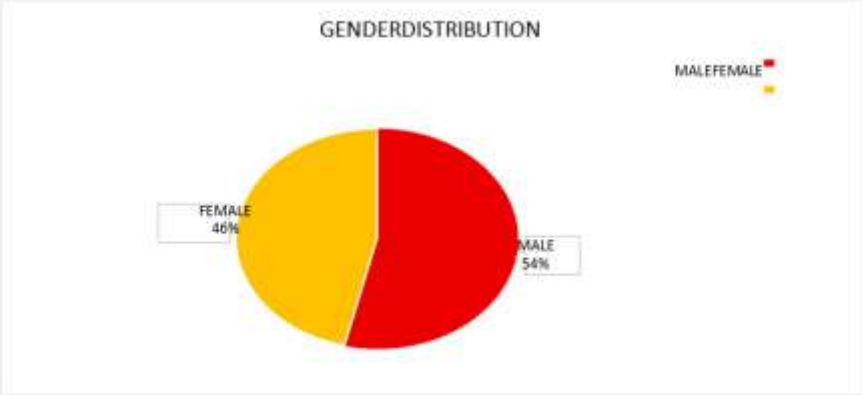
{3}METHODOLOGY: The age-wise distribution showed that the highest number of patients belonged to the 21–30 years age group (16 patients), followed by the 31–40 years group (13 patients). Moderate numbers were observed in the 41–50 and 51–60 years groups (8 patients each). Fewer patients were reported in the 0–10 years (4 patients), 61–70 years (2 patients), and 71–80 years (1 patient) age groups. Overall, young and middle-aged adults were the most affected and formed the major study popul

DATA COLLECTION :

Sr no	Patient name	Age	Drug	Dose	ADR	Severity
1	Pari Shrikant Tole	05	Insulin Aspart	0.3units	Hypoglycemia with seizures, Pale skin	Severe
2	Vinayak Ramesh Bhale	06	Human regular insulin	0.2units	Loss of subcutaneous fats	Mild
3	Anuj Ramesh More	08	Insulin	0.5units	Injectionsite reaction.	Mild
4	Shradhha Jadhav	10	Insulin	1.5units	Pain,Redness.	Mild
5	Rahul Mahajan	11	Insulin glargine	12units	Redness, lipohyperotropy	Mild
6	Kushi Rajesh Ugale	12	Insulin	1.5units	Rashes, Redness	Mild
7	Vishal Sanjay Sathe	13	insulin	1.5units	Shakinghands, Injection site reaction.	Mild
8	Tanuja Pankaj gore	14	Insulin	1.5units	Dizziness	Mild
9	Pooja Dalvi	14	Metformin HCl	500mg	Abdominal Pain,Dizziness	Moderat e
10	Ankush Kakade	16	Glimepiride	2mg	Hypoglycemia with dizziness	Severe

GENDER DISTRIBUTION :

The gender distribution of diabetic patients showed that 54% were males and 46% were females. Male patients were slightly higher in number, but both genders were almost equally represented in the study. The findings indicate that diabetes mellitus affects both males and females, with a slightly higher prevalence among males. This gender-wise distribution is important for understanding patient demographics and evaluating adverse drug reactions (ADRs) in diabetic patients.

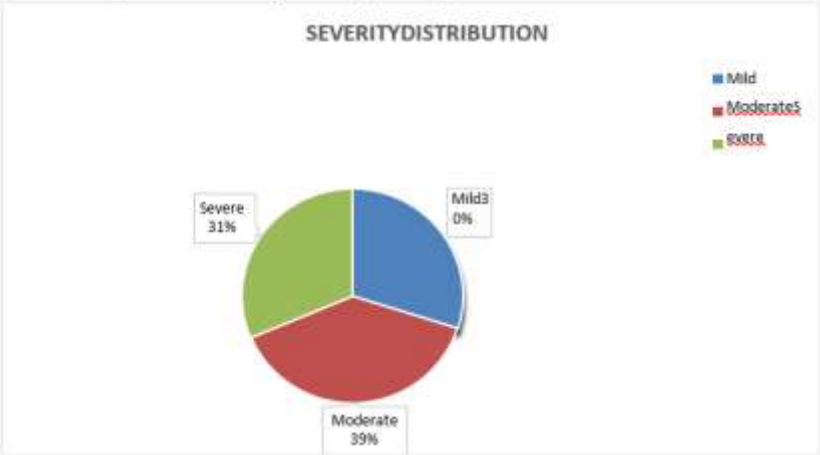


:Gender Distribution

SEVERITY DISTRIBUTION

The severity distribution of ADRs showed that moderate ADRs were the most common (26 patients), followed by severe ADRs (21 patients) and mild ADRs (20 patients). Mild reactions were less serious and manageable, while severe reactions required immediate medical attention. Overall, moderate ADRs were reported most frequently, indicating the need for proper

monitoring and treatment of patients experiencing ADRs



RESULT & DISSCUSSION :-

The present study was conducted on 65 diabetic patients receiving antidiabetic medications to evaluate adverse drug reactions (ADRs). The majority of patients belonged to the 21–30 years age group, and male patients (54%) were slightly higher in number than female patients (46%). Metformin, glimepiride, glibenclamide, insulin, and dapagliflozin were the most commonly prescribed antidiabetic drugs. Hypoglycemia was the most frequently reported ADR, followed by nausea, sweating, diarrhea, dizziness, itching, and increased urination. Severity assessment showed that moderate ADRs (39%) were more common than severe (31%) and mild (30%) ADRs. Several severe reactions, including hypoglycemia with seizures, pancreatitis, lactic acidosis, and severe infections, were also observed during the study.

DISSCUSION

The findings of the present study indicate that adverse drug reactions are common among diabetic patients receiving antidiabetic therapy. Hypoglycemia was the most frequently observed ADR and was mainly associated with insulin and sulfonylurea therapy. Gastrointestinal disturbances such as nausea, vomiting, and abdominal pain were commonly reported with metformin, while SGLT2 inhibitors were associated with urinary tract and genital infections. Most ADRs were moderate in severity and required proper medical supervision. These findings highlight the importance of pharmacovigilance, regular patient monitoring, and ADR reporting to improve drug safety and therapeutic outcomes in diabetic patients.

CONCLUSION

The present study concluded that adverse drug reactions (ADRs) are common in diabetic patients receiving antidiabetic medications. Hypoglycemia was the most frequently reported ADR, especially with insulin and sulfonylurea therapy. Gastrointestinal disturbances were commonly associated with metformin, while SGLT2 inhibitors caused urinary tract and genital infections. Most ADRs were moderate in severity, though some severe reactions such as hypoglycemia, pancreatitis, and lactic acidosis were also observed. The study highlights the importance of pharmacovigilance, regular monitoring, patient counseling, and ADR reporting to improve patient safety and effective diabetes management.

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