RESEARCH PAPER

ADVERSE DRUG REACTIONS AND SAFETY PROFILE OF ANTIDIABETIC DRUGS IN TYPE 2 DIABETES PATIENTS

Dr. Razwan Ashraf1, Dr. Athar Parvaiz2, Qamar Sajad3, Hashmat Ullah Khan4*, Dr. Rafaqat Malik5, Dr. Sania Attique6, Ali Mukhtar Mahgoub7

1General Physician, Aziz Bhatti Shaheed Teaching Hospital, Gujrat, Pakistan
2Senior Registrar, Department of Medicine, Sahara Medical College, Narowal
3Assistant Professor, Medicine/Endocrinology, Fatima Memorial Hospital, Lahore
4*Assistant Professor, Department of Medicine, Lady Reading Hospital, Peshawar (Corresponding Author). Email: dr_hashmatkhan134@yahoo.com
5Assistant Professor, Frontier Medical College, Abbottabad
6PGR 1st Year (General Medicine), Medical Unit 2, Jinnah Hospital, Lahore
7Consultant of Internal Medicine, Department of Internal Medicine, Prince Mohammed bin Abdulaziz Hospital, Riyadh, Saudi Arabia

ABSTRACT

Background: Type 2 diabetes mellitus (T2DM) is a chronic metabolic condition and is characterized by a need for lifelong medical treatment with medications to control blood sugar and prevent complications. Continuous use of antidiabetic medications is frequently associated with adverse drug reactions (ADRs), which may negatively affect patient compliance, therapeutic outcomes, and overall safety.

Objective: To assess the adverse drug effects and safety profile of antidiabetic drugs in patients with Type 2 DM receiving antidiabetic therapy at a tertiary care hospital.

Methods: The study was a cross-sectional observational study conducted at the Aziz Bhatti Shaheed Teaching Hospital in Gujrat, Pakistan, from January 2025 to January 2026. Non-probability consecutive sampling was used, and 100 diagnosed T2DM patients taking oral antidiabetic drug and/or insulin therapy were enrolled. Structured interviews and medical record reviews were used for demographic data, treatment patterns, laboratory parameters, and adverse drug reactions. The causality and severity for ADRs were determined by the Naranjo Probability Scale and Modified Hartwig and Siegel Severity Scale, respectively. Data analysis was carried out by SPSS 26.0 software.

Results: Among 100 participants, 46.0% experienced at least one adverse drug reaction during therapy. The most frequent ADRs were gastrointestinal, such as nausea, diarrhea, and abdominal discomfort, especially in those taking metformin. Sulfonylureas and insulin therapy were the greatest risk factors for hypoglycemia. The majority of ADRs were either mild (60.9%) or moderate (30.4%), with severe reactions making up 8.7% of cases. The frequency of ADR was significantly associated with combination therapy, advanced age, obesity, long duration of diabetes, and high HbA1c level ($p < 0.05$).

Conclusion: Adverse drug reactions are a frequent problem in Type 2 diabetes mellitus patients on antidiabetic treatment. To enhance the safety of medicines and therapeutic compliance in diabetic populations, regular pharmacovigilance monitoring, individualized treatment, and counseling of patients are required.

Keywords: Type 2 diabetes mellitus, adverse drug reactions, antidiabetic drugs, pharmacovigilance, hypoglycemia, drug safety.

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Introduction

Diabetes mellitus type 2 (T2DM) is one of the most prevalent chronic metabolic disorders worldwide and a major public health challenge due to its fast-growing prevalence, severity of the long-term complications, and significant economic impact on health care systems[1]. It is a disease of insulin resistance, progressive pancreatic β-cell dysfunction, impaired glucose metabolism, and chronic hyperglycaemia[2]. Recent international estimates predict that the number of people with diabetes will continue to grow globally as a result of increasing prevalence of sedentary lifestyle, obesity, urbanization, unhealthy diets, and ageing of the population[3]. The rapid lifestyle changes and inadequate healthcare facilities are driving the burden of T2DM in developing countries, especially South Asia. In diabetic patients, long-term hyperglycemia leads to the occurrence of severe microvascular and macrovascular complications such as nephropathy, neuropathy, retinopathy, ischemic heart diseases, stroke, and peripheral vascular

diseases, which in turn leads to increased morbidity and mortality rates[4].

Long-term pharmacologic therapy for optimal glycemic control and prevention of diabetes related complications is the key to effective management of Type 2 diabetes mellitus[5]. At present, there are several classes of drugs that are available to treat T2DM, including biguanides, sulfonylureas, thiazolidinediones, DPP-4 inhibitors, SGLT-2 inhibitors, GLP-1 receptor agonists, and insulin preparations. Of these agents, metformin is the most widely used first-line oral anti-diabetic drug due to its effectiveness, low cost, and heart-friendly profile. Yet, combination therapy or insulin use is eventually required by many patients because of the progressive decline of pancreatic β-cell function and the uncontrolled glycemic state[6].

Diabetic drugs (antidiabetic drugs) are essential in reducing diabetic complications and prolonging patient survival; however, the extended and general application of the drugs is often accompanied by adverse drug reactions (ADRs)[7]. Adverse drug reactions are an unwanted and harmful effect of a drug that is used at therapeutic doses to prevent, diagnose, or treat a disease. Side effects of antidiabetic agents include mild gastrointestinal upset to serious life-threatening events, including profound hypoglycemia, lactic acidosis, hepatic dysfunction, electrolyte imbalance, cardiovascular instability, pancreatitis, and hypersensitivity reactions[8]. The most frequent side effects of metformin are gastrointestinal side effects such as nausea, abdominal pain, diarrhea, and bloating; sulfonylureas and insulin are strongly linked to episodes of hypoglycemia and weight gain. Other newer classes of antidiabetic drugs like SGLT2 inhibitors have also been associated with urinary tract infections, genital fungal infections, dehydration, and diabetic ketoacidosis[9].

Adverse drug reactions can have a profound impact on patient adherence, therapeutic outcomes, quality of life, and health care expenses[10]. There is a strong correlation between frequent or severe ADRs and poor medication compliance, inadequate glycemic control, hospital admissions, and risk of diabetes-related complications[11]. Elderly diabetic patients are at high risk of ADRs due to alterations in drug metabolism, age-related physiological changes, multiple comorbidities, impaired renal function, and polypharmacy. Moreover, many diabetic patients are on multiple other drugs for hypertension, dyslipidaemia, cardiovascular diseases, and renal problems, which can lead to drug-drug interactions and medication-related toxicity[12].

Pharmacovigilance systems are critical to detecting, assessing, and preventing adverse drug effects for chronic treatments. For the diabetic population, continuous monitoring of ADRs is particularly crucial as the antidiabetic drugs are generally taken for life and their doses may need to be changed or multiple drugs may be needed[13]. Several international studies have shown significant differences in the prevalence and nature of ADRs among diabetics depending on different demographic, treatment, genetic susceptibility, and healthcare practices. Although the application of antidiabetic drugs is growing in Pakistan, local information about their safety profile and adverse drug reaction pattern is still scarce. The underreporting of ADRs, lack of pharmacovigilance, irrational prescribing patterns, and patient ignorance further complicate medication safety monitoring in developing healthcare systems[14,15].

It is important to understand the frequency, severity, and prediction of adverse drug reactions of antidiabetic drugs to optimize treatment strategies, counselling of patients, medication adherence, and to prevent preventable complications. Early identification and management of ADRs can significantly reduce the burden on the health system and positively influence therapeutic outcomes in the diabetic population[16].

Therefore, the present study was conducted to evaluate the adverse drug reactions and safety profile of antidiabetic drugs among patients with Type 2 diabetes mellitus receiving treatment at a tertiary care hospital. The objective of the study was to determine the most frequently occurring ADRs, their severity, causality, and factors that contribute to the risk of ADRs in diabetic patients receiving pharmacological therapy[17].

Materials and Methods

The cross-sectional observational study was conducted at Aziz Bhatti Shaheed Teaching Hospital,

Gujrat, Pakistan, from January 2025 to January 2026. The study aimed to assess the prevalence, type, severity, and safety profile of adverse drug reactions due to antidiabetic drugs amongst patients with Type 2 diabetes mellitus.

The study was conducted using a non-probability consecutive sampling technique, which included a total of 100 patients with Type 2 diabetes mellitus. Patients of both sexes, aged ≥ 30 years, with Type 2 diabetes mellitus (T2DM) and taking at least one antidiabetes drug for at least three months were included. Patients who were on oral antidiabetic drugs (OADs), insulin therapy, or combination therapy were recruited.

Patients who had Type 1 diabetes mellitus, gestational diabetes, acute diabetic emergencies, severe hepatic failure, end-stage renal disease, malignancy, severe psychiatric illness, incomplete medical records, or who were unwilling to provide informed consent were excluded from the study. Patients who were treated with an antidiabetic drug for less than 3 months were also excluded to allow sufficient drug exposure for evaluation of adverse drug reactions.

Informed consent was obtained, and demographic and clinical data were gathered from a structured data collection form. Recorded variables were: Age, gender, body mass index, duration of diabetes, family history of diabetes, comorbid conditions, smoking, type of antidiabetic drug used, duration of drug therapy, number of drugs taken, and history of adverse drug reaction. Laboratory parameters such as fasting blood glucose, random blood glucose, HbA1c, serum creatinine, liver function tests, and lipid profile were retrieved from hospital records if available.

Adverse drug effects were detected by direct patient interviews, physical examination, physician notes, and patient medical records. The patients were asked in particular about the presence of nausea, vomiting, abdominal pain, gastrointestinal transit disorders, bloating, dizziness, sweating, tremors, palpitations, hypoglycemic episodes, weight gain, skin rash, itching, urinary disorder, genital infections, fatigue, and hospitalization due to drug use. Hypoglycemia was considered a hypoglycemic symptom with a confirmed blood glucose level less than 70 mg/dL or symptoms resolving after ingesting glucose.

The suspected adverse drug reactions were categorized based on the antidiabetic drug used, clinical presentation, the affected organ system, and the treatment outcome. The Naranjo Adverse Drug Reaction Probability Scale was used to determine the causality of each adverse drug reaction, and these were classified as definite, probable, possible, and doubtful. To assess the severity of adverse drug reactions, the Modified Hartwig and Siegel Severity Assessment Scale was used, which has been categorized into mild, moderate, and severe.

Antidiabetic medications evaluated in this study were metformin, sulfonylureas, insulin, dipeptidyl peptidase-4 inhibitors, sodium-glucose cotransporter-2 inhibitors, and combination therapy. Monotherapy was considered the use of one antidiabetic drug, and combination therapy was the use of two or more antidiabetic drugs. Patients were also evaluated for potential risk factors for ADRs such as advanced age, duration of diabetes, glycaemic control, polypharmacy, renal impairment, and presence of comorbid diseases.

Data entered and analyzed by SPSS version 26.0. Numerical variables like age, duration of diabetes, body mass index, fasting blood glucose, and HbA1c were presented as mean ± standard deviation. Qualitative variables (gender, drug class, type of adverse drug reaction, severity category, and causality assessment) were expressed as numbers and percentages. The frequency of adverse drug reactions (ADR) in various treatment groups was compared by using the chi-square test. An independent sample t-test was used to compare continuous variables when applicable. Statistically significant results were defined as p-values < 0.05.

The present study was approved by the institutional ethical review committee of Aziz Bhatti Shaheed Teaching Hospital, Gujrat, Pakistan. All participants gave written informed consent. Confidentiality of patients was maintained throughout the study, and all the data collected were for research purposes only.

Results

The present study included 100 patients with Type 2 diabetes mellitus who were on antidiabetic therapy. The average age of study subjects was 55.9 ± 11.4

years. The age group 51-60 years had the maximum number of patients (38.0%), followed by the age group 41-50 years (24.0%). The male population accounted for 58.0%, and the female population accounted for 42.0% of all the patients enrolled in the study. There was an overweight or obese status in most patients, and a high percentage of patients had diabetes for more than five years. Comorbidities most commonly found in diabetic patients were hypertension and dyslipidemia. Combination antidiabetic therapy was more frequently used than monotherapy, indicative of a relatively late stage of the disease and poor glycemic control in a large fraction of the patients. Demographic and clinical characteristics are provided in detail in Table 1.

Table 1: Demographic and Clinical Characteristics of Study Participants (n=100)

Variables	Frequency (n)	Percentage (%)
Age Group (Years)		
30–40 years	12	12.0
41–50 years	24	24.0
51–60 years	38	38.0
61–70 years	20	20.0
>70 years	6	6.0
Gender Distribution		
Male	58	58.0
Female	42	42.0
Duration of Diabetes		
<5 years	31	31.0
5–10 years	44	44.0
>10 years	25	25.0
Body Mass Index		
Normal weight	21	21.0
Overweight	47	47.0
Obese	32	32.0
Comorbidities		
Hypertension	61	61.0
Dyslipidemia	39	39.0
Ischemic heart disease	17	17.0
Chronic kidney disease	11	11.0
Treatment Pattern		
Monotherapy	36	36.0
Combination therapy	64	64.0

Prescribed antidiabetic drugs were analysed and revealed that metformin was the most widely used drug as monotherapy or in combination drug therapy. The most common combination of drugs used among those in this study was metformin and sulfonylureas. Prolonged duration of the disease and poor glycemic control were more associated with insulin therapy. There was a lower use of newer antidiabetic medications, including DPP-4 inhibitors and SGLT2 inhibitors. A total of 46 patients had at least one adverse drug reaction during the study period, and the prevalence of ADRs was 46.0% overall. Gastrointestinal adverse effects were the most frequent group of ADRs, especially in patients receiving metformin, while hypoglycemic events were primarily related to sulfonylurea and insulin treatment. UTI and fungal infections of the genitalia were mostly seen in the SGLT2 inhibitor group. Table 2 lists the distribution of antidiabetic drugs and associated ADRs.

Table 2: Distribution of Antidiabetic Therapy and Associated Adverse Drug Reactions

Drug Regimen / ADR Pattern	Frequency (n)	Percentage (%)
Antidiabetic Therapy		
Metformin alone	24	24.0
Sulfonylurea alone	7	7.0
Insulin alone	5	5.0
Metformin + Sulfonylurea	31	31.0
Metformin + Insulin	12	12.0
Metformin + DPP-4 inhibitor	8	8.0
Metformin + SGLT2 inhibitor	6	6.0
Triple therapy	7	7.0
Adverse Drug Reactions Observed		
Nausea	14	14.0
Diarrhea	11	11.0
Abdominal discomfort	9	9.0
Hypoglycemia	13	13.0
Dizziness	8	8.0
Generalized weakness	7	7.0
Weight gain	6	6.0

Urinary tract infection	5	5.0
Genital fungal infection	3	3.0
Skin rash/allergy	4	4.0
Pedal edema	3	3.0
Elevated liver enzymes	2	2.0

Adverse drug reactions were further analysed and found that most of the ADRs were mild and were either self-reliquilated or as a result of dose adjustment. A moderate adverse reaction occurred in a small proportion of the people and needed symptom treatment and/or a change in treatment, but severe reactions that needed hospitalisation were rare. The most clinically significant adverse event seen during the study was severe hypoglycemia. The causality assessment was done using the Naranjo Adverse Drug Reaction Probability Scale, which revealed that most of the adverse drug reactions were probable, followed by possible and definite reactions. The severity and casualty assessment results are summarised in Table 3.

Table 3: Severity and Causality Assessment of Adverse Drug Reactions

Variables	Frequency (n)	Percentage (%)
Severity of ADRs		
Mild	28	60.9
Moderate	14	30.4
Severe	4	8.7
Causality Assessment		
Definite	9	19.6
Probable	27	58.7
Possible	10	21.7
Doubtful	0	0.0

Elderly patients, patients with longer duration of diabetes (more than 10 years), obese patients, and combination antidiabetic therapy groups had significantly more adverse drug reactions compared with other groups in the comparative analysis. Yet, elevated glycemic status, indicated by higher HbA1c, was also significantly related to a higher rate of ADRs. Patients with ADRs had significantly higher levels of fasting blood glucose, random blood glucose, serum creatinine, and liver enzymes than patients who did not have an ADR. The relation between clinical variables, laboratory parameters, and incidence of adverse drug reactions is given in Table 4.

Table 4: Association of Clinical and Laboratory Variables with Adverse Drug Reactions

Variables	ADR Present	ADR Absent	p-value
Age >60 years	18 (39.1%)	8 (14.8%)	0.011
Diabetes duration >10 years	17 (37.0%)	8 (14.8%)	0.018
Combination therapy	35 (76.1%)	29 (53.7%)	0.024
Obesity	21 (45.7%)	11 (20.4%)	0.015
HbA1c >8%	29 (63.0%)	19 (35.2%)	0.009
Fasting blood glucose (mg/dL)	182.4 ± 42.8	151.7 ± 36.5	0.004
Random blood glucose (mg/dL)	254.9 ± 51.2	216.3 ± 44.6	0.006
Serum creatinine (mg/dL)	1.3 ± 0.4	1.0 ± 0.3	0.019
ALT (U/L)	39.5 ± 11.7	32.8 ± 9.2	0.031

Overall, the present study demonstrated that adverse drug reactions are common among patients with Type 2 diabetes mellitus receiving long-term antidiabetic therapy. The most common ADRs reported with treatment were gastrointestinal and hypoglycemia. The results also showed that the risk of adverse drug reactions was significantly associated with advanced age, longer duration of diabetes, obesity, poor glycemic control, and the use of multiple antidiabetic drugs. Most ADRs were mild to moderate, but severe events, including marked hypoglycemia, were clinically significant due to lack of adherence to therapy, patient safety, and risk of hospitalization.

Discussion

The present study aimed to assess the adverse drug reactions and safety profile of Antidiabetic Drugs in patients with Type 2 Diabetes mellitus on treatment in a tertiary care hospital in Pakistan. The results showed that in diabetic patients receiving long-term pharmacological treatment, ADRs are very common, with an overall prevalence of 46.0%. The findings emphasize the need for continuous pharmacovigilance surveillance, as well as personalized therapeutic care, for diabetic patients[2].

The demographic data of the present study showed that the majority of the patients were of middle age group

and elderly age groups, with the highest being the 51-60 age group[3]. There was also a higher proportion of males to females participating in the study. Demographic characteristics seen in this regional and international evaluation of diabetes prevalence and drug safety profiles are comparable to those reported in earlier studies. Age is known to be a significant risk factor for drug-related adverse effects due to several other factors, including decreasing renal function, changing liver metabolism, having multiple underlying health conditions, and the use of multiple medications[4].

Metformin was found to be the most commonly used antidiabetic drug (mono or in combination)[5]. The results are in line with existing international diabetes guidelines, which prioritize metformin most of all due to its effectiveness, affordability, and, as a result, beneficial cardiovascular profile as a first-line pharmacological treatment in Type 2 diabetes mellitus[6]. In the present study, gastrointestinal adverse effects such as nausea, diarrhea, and abdominal discomfort were the most frequently reported ADRs, especially in the group taking metformin[7]. The same results have been reported in other pharmacovigilance studies, but in the past, metformin-induced gastrointestinal intolerance was the most frequent drug-related adverse event and a major reason for non-compliance and stopping treatment with metformin. This could be related to changes in the way the gut processes glucose, changes in how much serotonin is produced by the gut, and changes in gut microbiota[8].

Hypoglycemia was the second most frequently observed adverse drug reaction and was mainly associated with sulfonylurea and insulin therapy[9]. Severe hypoglycemic episodes are one of the most clinically important complications of diabetes therapy due to the possibility of causing hospitalisation, cardiovascular instability, neurological impairment, falls, and death. In the current study, hypoglycemia was more common in elderly patients, patients with longer duration of disease, and in patients who received combination antidiabetic therapy[10]. These results are similar to previous studies showing that the use of insulin-based therapies or a combination of glucose-lowering medications was associated with a greater risk of hypoglycemia. Hypoglycemic events in diabetic populations may also be exacerbated by poor dietary compliance, renal impairment, and irregular intake of medication[11].

The study also revealed that combination therapy significantly increased the rate of ADRs compared to monotherapy. Patients with uncontrolled diabetes frequently need combination therapy as a result of the progressive pancreatic β-cell dysfunction and insulin resistance[12]. Multidrug therapy, however, significantly contributes to drug-drug interactions, cumulative toxicity, overlapping pharmacodynamics, and medication adherence. The increased incidence of ADRs in patients with poor glycemic control and high HbA1c levels also indicated that disease severity and treatment intensification may be risk factor for ADRs[13].

UTI and genital fungal infection were seen to be more common among patients taking SGLT2 inhibitors[14]. This is biologically plausible as it is known that SGLT2 inhibitors induce glucosuria, which can lead to an environment in the urinary tract and genital area that is conducive to microbial growth. The overall incidence of these infections was relatively low, but these adverse effects are clinically significant as they could have a poor impact on patient comfort and treatment compliance compared with gastrointestinal or hypoglycemic complications[15].

The severity assessment showed that most of the drug adverse reactions were mild or moderate and were either self-limited or corrected by either dose reduction and/or supportive therapy[16]. There were not many severe ADRs to hospital, suggesting that the overall safety profile of currently prescribed antidiabetic drugs is not bad when properly monitored. However, even minor ADRs may have a profound effect on adherence to and effectiveness of drug treatment if left undetected and uncontrolled. The causality assessment results showed that the majority of the reactions were classified as probable on the Naranjo Probability Scale, indicating that there existed a very good correlation between the drug under consideration and adverse reaction[17].

The current study highlights the need for the good implementation of a pharmacovigilance system and patient counseling in the healthcare setting for diabetes[18]. Adverse drug reactions (ADRs) can be reported and recognised early, and this can

significantly contribute to therapeutic decision making, prevent avoidable complications, and improve overall treatment outcomes. To prevent drug-related morbidity among diabetic patients, healthcare professionals should give extensive counseling on the possible side effects, adherence to drug therapy, dietary precautions, and early signs of symptoms[19].

The present study has some limitations. To date, the study was performed in a single tertiary care center and had a relatively small sample size, potentially limiting the generalizability of the results to larger populations[13]. Further, the cross-sectional nature of the study prevented evaluation of delayed adverse reactions. More multicenter longitudinal trials with a greater number of patients are suggested to further assess long-term safety outcomes and the influence of pharmacogenetics in the context of antidiabetic therapy[18-20].

Conclusion

Adverse drug reactions are common in patients with Type 2 diabetes mellitus who are receiving antidiabetic therapy, and gastrointestinal disturbances and hypoglycemia are the most common adverse effects. Gastrointestinal intolerance was highly associated with metformin, while hypoglycemic episodes were more highly associated with sulfonylureas and insulin therapy. The use of combination antidiabetic therapy, obesity, poor glycemic control, adverse drug reaction, and advanced age were all significant risk factors for adverse drug reactions. While most of the adverse drug reactions (ADRs) were of mild to moderate intensity, severe reactions (including hospitalizations) were also detected, underscoring the need for ongoing pharmacovigilance and therapeutic monitoring. To enhance medication safety, adherence to medication, and glycemic outcomes for diabetic patients, early identification of ADRs, individual treatment strategies, dose optimization, and appropriate patient counseling are necessary. The results of the current study justify the efforts to improve the adverse drug reaction reporting systems and to encourage the rational use of medicines in diabetic care to minimize drug-related morbidity and improve patient safety.

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