

ASSESSMENT OF DRUG UTILIZATION PATTERN AND ADVERSE DRUG REACTIONS IN DIABETIC PATIENTS AT A TERTIARY CARE HOSPITAL

¹Muhammad Riaz, ²Noor Ul Eman, ³Wafa Majeed, ⁴Muhammad Alamgir, ⁵Muhammad Asif Shahzad, ⁶Irfan Ul Haq, ⁷Hafiz Muhammad Faisal, ⁸Muhammad Hamza, ⁹Muhammad Zubair Khan, ¹⁰Talha Ijaz, ¹¹Mudassar Ahmed, ¹²Shoyab Ali, ¹³Iqra Khalid, ¹⁴Muhammad Suleman Shahbaz, ¹⁵Zuaha Noor, ¹⁶Syeda Mashal Fatima, ¹⁷Ussama Hafeez, ¹⁸Akif Saeed, CH, ¹⁹Samreena Shaukat, ²⁰Muhammad Ateeb

¹Department of Pharmacology, Faculty of Pharmaceutical Sciences, Government College University Faisalabad (GCUF), Faisalabad, Pakistan

²Faculty of Pharmaceutical Sciences, Government College University Faisalabad (GCUF), Faisalabad, Pakistan

³Department of Pharmacy, Faculty of Health and Pharmaceutical Sciences, University of Agriculture Faisalabad, Faisalabad, Pakistan

⁵Faculty of Pharmacy, Bahauddin Zakariya University, Multan, Pakistan

⁶Faculty of Pharmacy, Bahauddin Zakariya University, Multan, Pakistan

⁷Faculty of Pharmaceutical Sciences, Government College University Faisalabad (GCUF), Faisalabad, Pakistan

⁸Department of Pharmaceutics, Government College University Faisalabad (GCUF), Faisalabad, Pakistan

⁹Faculty of Pharmaceutical Sciences, The University of Faisalabad, Faisalabad, Pakistan

¹⁰Faculty of Pharmaceutical Sciences, Government College University Faisalabad (GCUF), Faisalabad, Pakistan

¹¹Faculty of Pharmaceutical Sciences, Government College University Faisalabad (GCUF), Faisalabad, Pakistan

¹²Akhtar Saeed College of Pharmaceutical Sciences, Bahria Town, Lahore, Pakistan

¹³Faculty of Pharmaceutical Sciences, Government College University Faisalabad (GCUF), Faisalabad, Pakistan

¹⁴Islam College of Pharmacy, Sialkot, Pakistan

¹⁵Faculty of Pharmaceutical Sciences, Government College University Faisalabad (GCUF), Faisalabad, Pakistan

¹⁶Institute of Microbiology, Faculty of Life Sciences, Government College University Faisalabad, Faisalabad, Pakistan

¹⁷Institute of Microbiology, Faculty of Life Sciences, Government College University Faisalabad, Faisalabad, Pakistan

¹⁸Health Service Academy, Islamabad

¹⁸Director, Medical Services and Research, Hope Family Clinic & Rehab, Faisalabad, Pakistan

¹⁹Department of Eastern Medicine, Government College University Faisalabad Pakistan

²⁰Department of Public Health, Faculty of Medicine and Allied Health Sciences, The University of Faisalabad, Faisalabad 38000, Pakistan.

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ABSTRACT

Diabetes Mellitus is a long-term chronic metabolic disorder where pharmacotherapy is a requirement to treat the underlying condition and includes comorbidities which creates polypharmacy with an increased potential for adverse drug reactions (ADRs). The objective of this study was to evaluate drug use and determine the occurrence of ADRs among diabetic patients treated at a tertiary care. A prospective, observational study was done with diabetic patients being treated in outpatient and inpatient settings. Patient demographics, clinical characteristics, medications prescribed, and medications associated with the ADRs, were collected and analyzed. Based on the type of antidiabetic medications used and how frequently they were prescribed, drug utilization was assessed. ADRs were evaluated for causality, severity, and outcome. According to the results, the most commonly prescribed drugs included the oral hypoglycemic agents (OHA) such as metformin followed by insulin and combination therapies. Many patients were prescribed multiple medications (polypharmacy) due to co-existing conditions (e.g., hypertension and dyslipidemia). Many of the ADRs associated with the use of these medications occurred: the three most often reported ADRs were hypoglycemia, gastrointestinal disturbances, and dizziness. Most of the reported ADRs were classified as mild-to-moderate in severity and were effectively managed without any major complications. The results of this study indicate that healthcare providers should use rational prescribing and will benefit from ongoing monitoring of their patients as well as enabling pharmacovigilance opportunities to improve treatment outcomes in diabetic patients while ensuring their patients are safe from drug-related issues.

Keywords: Diabetes mellitus, Drug utilization pattern, Adverse drug reactions, Pharmacovigilance, Polypharmacy, Antidiabetic drugs, Metformin, Insulin therapy, Rational prescribing, Tertiary care hospital

Introduction

Diabetes mellitus is a chronic metabolic disease marked by an ongoing high blood sugar level and results from either having a problem with insulin or in how the body uses insulin. Diabetes is one of the fastest growing non-communicable diseases in the world; due to its rapid increase in cases, it is now viewed as a significant public health concern because of its long-term health implications and the increased prevalence of diabetes mellitus. Diabetes can occur in individuals of all ages; however the incidence of diabetes is more common in adults due to a sedentary lifestyle, obesity, poor nutrition, genetic predisposition and an ageing population. If blood sugar levels remain uncontrolled for prolonged periods of time, serious complications can develop (microvascular and macrovascular), including retinopathy, nephropathy, neuropathy, ischemic heart disease and stroke. These complications result in a decreased quality of life. To manage diabetes, a variety of methods, such as lifestyle changes, dietary control, physical activity and medications must be used. There are numerous types of medications available for managing diabetes which include: biguanides, sulphonylureas, DPP4 inhibitors, SGLT2 inhibitors, GLP1 receptor agonist and insulin

therapy. The choice of medication will vary based upon the patient, the patient's other medical conditions, as well as the patient's goals of therapy. Due to the long-term nature of diabetes, ongoing monitoring and appropriate use of medications is necessary in order to achieve good control of blood glucose levels and avoid any complications. (American Diabetes Association et al., 2024)

Pharmacotherapy also has an important role in pharmacoepidemiological drug use research, permitting investigation of the prescribing, dispensing, and utilization patterns (or consumption of medication or drugs). Drug utilization research assists in determining whether medication or drugs have been dispensed in accordance with universally accepted standards for their use (i.e., are they being used for the right reason, at the right dose, with the right frequency, for the right duration, in the right place?) by providing insights into how the use of specific medications aligns with established evidence-based treatment recommendations. In people with diabetes, drug utilization studies play an especially important role because they often require multiple medications to treat not only glycemic control but also concurrent conditions (i.e., comorbidities) such as hypertension and/or

dyslipidaemia, as well as cardiovascular disease. This can result in polypharmacy, or the excessive use of multiple medications, which in turn may lead to an increased risk of drug-drug interactions, unwanted side effects (i.e., adverse drug reactions), and/or failure to adhere to prescribed medications and/or therapeutic failure. Drug utilization studies can also be used to identify common prescribing patterns for drugs, determine the frequency with which specific drug combinations are prescribed, and identify instances where medications are prescribed contrary to an evidence-based guideline. Drug utilization studies can also assist with evaluating the rationality of prescribing practices for patients with diabetes in contributing to the improvement of quality of healthcare. Additionally, within tertiary care hospitals, where most patients will present with complex, severe, or chronic disease conditions, drug utilization studies are extremely useful in developing and optimising therapeutic regimens and therapies for patients with diabetes. Furthermore, the results obtained from drug utilization studies will assist healthcare providers in making decision-making and improving outcomes for patients with diabetes, while also reducing unnecessary burden caused by medication and ancillary costs associated with providing medication to patients with diabetes. (Kumar et al., 2023)

An ADR is an unwanted/ undesirable reaction to a drug that develops when the therapeutic doses used to treat/protect alleviate / prevent a condition (as stated in paragraph). ADRs are an important topic in clinical practice because they are often the cause of: 1) additional harm to patients (e.g., morbidity); 2) death (e.g., mortality); 3) longer times spent in hospitals/hospital admissions; 4) increased costs to the healthcare system (e.g., healthcare expenditures); 5) when using drugs for long periods of time and/or using many different medications simultaneously; 6) will have effects on patient adherence, and 7) the degree of glycemia control for that patient will be adversely impacted. Compared to many patients, diabetic patients are at an increased risk to experience ADRs as a result of: 1) being older (physiologic changes); 2) the presence of comorbid conditions with other diseases they may have; and 3) taking multiple medications for

an extended period of time. The two most frequently reported ADRs with antidiabetic medications are: 1) hypoglycemia and 2) gastrointestinal side effects (nausea, diarrhea, etc.); however, both can also contribute to weight gain and be associated with other side effects, such as dizziness, lactic acidosis (rare in patients taking metformin), and allergies/hypersensitivity. When administered properly, the adverse effect of insulin therapy can cause hypoglycemia if not monitored closely. Depending on the frequency and/or severity of the adverse effects/reactions caused by ADRs will have negative impacts on patients' ability to adhere to treatment, delayed glycemic control or difficulty obtaining 'good/glycemic' control, and/or the development of complications. Therefore, when considering ways to improve patient safety and positive patient outcomes, identifying, reporting, and/or treating ADRs as early as possible are critical; also, healthcare providers will be able to utilize an improved monitoring process to identify high-risk medications and/or at-risk populations to assist in creating more individualized patient-specific therapies and prescribing habits. (Edwards & Aronson, 2000)

Pharmacovigilance means detecting, assessing, understanding, and preventing adverse effects or other drug-related problems. It is a major contributor to patient safety and optimizing drug benefit-risk ratio. This area of pharmacovigilance is particularly important for chronic conditions (like diabetes mellitus), requiring patients to receive multiple drugs as part of their long-term pharmacotherapy. Many adverse drug reactions are not identified in clinical trials, as the samples used are limited in number and/or duration of time; they become apparent only after they have been widely used in the real world. For this reason, post-marketing monitoring is important to discover rare and long-term adverse effects. Due to having a diverse patient population, secondary/tertiary care hospitals are also excellent locations to perform pharmacovigilance functions because they are usually well-equipped with advanced diagnostic capabilities and employ healthcare providers skilled in caring for patients. Information gained from data collected in these hospitals can be used to recognize patterns of adverse drug reactions, recognize risk factors for adverse drug reactions and establish drug safety

profiles. Such information will assist regulatory agencies and practitioners improve prescriptions, update treatment guidelines, and enhance the safe use of drugs in clinical practice. Strengthening pharmacovigilance systems lead to improved healthcare quality and better patient outcomes. (Montastruc et al., 2021)

To provide evidence about how medications are actually being used in practice and how they might improve the care that patients receive, assessments of drug utilisation and adverse drug reactions (ADRs) are critical for rationally delivering medications to patients with diabetes and can enhance the quality of health care provided. Drug utilisation studies provide useful information on how drugs are prescribed and used in the real world and can identify irrational prescribing practices, drug overuse and underutilisation, and deviations from established treatment guidelines. At the same time, assessment of ADRs provides valuable insight into the safety and tolerability of antidiabetic therapies. This is especially important in tertiary care hospitals where patients typically present with multiple co-existing diseases and complex drug therapy regimens. Data from studies evaluating drug utilisation and ADRs can assist practitioners in optimising patient care by improving treatment strategies, decreasing medication-related issues, and enhancing patient adherence to medication regimens. Data from these studies also provide support for the development of evidence-based policy and improve pharmacovigilance systems in healthcare organisations. By bringing together assessments of drug utilisation and ADRs, we can ultimately provide safer, more effective, and more rational uses of medications in patients with diabetes to improve the clinical outcome for diabetic patients and improve their quality of life. (International Diabetes Federation et al., 2024)

Diabetes is a chronic metabolic disease with increasing prevalence

Diabetes mellitus is a chronic metabolic disorder marked by elevated blood sugar levels resulting from insufficient insulin secretion, insufficient insulin action, or both. It is one of the world's fastest-growing non-communicable diseases and poses significant public health challenges that have arisen from its increasing prevalence due to a lack of physical activity; poor dietary habits;

obesity; genetic predisposition; and an aging population. If left untreated, diabetes will lead to damaging microvascular and macrovascular complications (e.g., nephropathy; neuropathy; retinopathy; cardiovascular issues; and strokes) that negatively impact quality of life and increase mortality risk. Successful management of diabetes requires an integrated approach consisting of lifestyle changes, dietary modifications, exercise, and long-term pharmacotherapy. Antidiabetic medications that are commonly prescribed include metformin, sulfonylureas, insulins, DPP-4 inhibitors, SGLT-2 inhibitors, and GLP-1 receptor agonists. Medication selection is important to consider because it varies based on an individual's health status, comorbidities, and the severity of the disease; therefore, continuous blood glucose monitoring is an essential part of achieving acceptable glycemic control as well as avoiding the development of complications. To do this, diabetes patients must also utilize their medications in a rational manner in order to alleviate complications related to medication use, thereby improving the patient's overall health outcomes. (WHO, 2023)

Drug utilization studies form a significant segment of pharmacoepidemiological studies that focus on pharmacists' and healthcare professionals' various pharmaceutical practices, including prescribing, dispensing, and using drugs from the perspective of patients at each stage of the drug utilization continuum. Among other things, they assess whether or not drugs were appropriately, safely, and effectively used per established clinical practice guidelines. The significance of drug utilization studies is particularly relevant because diabetic patients often receive treatment with several different medications for their glucose levels, comorbidities (e.g., hypertension, hyperlipidemia, etc.) and various other health conditions, leading to the use of multiple concurrent medications, termed "polypharmacy". Polypharmacy increases the chance of drug-drug interactions, adverse drug reactions, erroneous use of medications, and poor patient adherence to prescribed medications. Drug utilization studies aid in identifying patterns of prescribing practices, common drug combinations, and inappropriate prescribing practices and by doing so will benefit healthcare professionals in making improved rational

prescribing decisions and achieving optimal therapeutic results. In the case of tertiary care hospitals, which typically care for patients suffering from multiple and/or complicated health problems, drug utilization studies will assist in evaluating current real-world prescribing behavior and ultimately provide a basis for improving quality of care through developing evidence-based treatment guidelines for patients with diabetes mellitus (DM). (Katzung, 2021)

Adverse drug reactions (ADRs) refer to the unintended and harmful responses that patients may have to drugs when they are given to prevent, diagnose or treat illness. ADRs are a major concern in the health care systems because of the contribution they make to patient morbidity and mortality, the length of stay in the hospital and the increased cost of health care. Patients with diabetes are particularly at risk for experiencing an ADR because of their long-term use of multiple medications and because they have other illnesses. Hypoglycemia, gastrointestinal side effects (e.g. nausea, diarrhea), weight gain, dizziness and allergic reactions are examples of ADRs experienced by patients taking anti-diabetic agents. Insulin is known to produce hypoglycemic episodes while metformin production frequently produces gastrointestinal side effects; these ADRs can negatively affect patient compliance and the ability to maintain good glycemic control, which can increase the risk of disease progression and complications. Timely detection, reporting and management of ADRs is essential to improving patient safety and the outcomes of treatment. Monitoring ADRs also allows health care professionals to identify drugs at higher risks for causing an ADR, as well as populations of patients at increased risk for experiencing an ADR. (Goodman & Gilman, 2022)

The science and practice of Pharmacovigilance consist of detecting, evaluating, understanding & preventing adverse reactions caused by drugs and other problems related to drug use. Pharmacovigilance is extremely important in promoting safe and efficient medication use; especially for chronic diseases such as diabetes mellitus; where long-term medication therapy is required. In addition, many adverse reactions are not identified during pre-market clinical trials; this is usually due to small sample sizes and short duration of study; thus most potential adverse

drug reaction occur only after wide spread use of the product in the general population. Therefore, post-marketing surveillance is an essential component of ongoing monitoring for safety of drugs once they are on the market. Tertiary care hospitals are a vital resource for performing pharmacovigilance activities as they provide services to large numbers of patients across various diseases and treatment protocols; thus allowing for the collection of data on previously unidentified ADR's and the evaluation of risk factors that may be associated with those ADR's. This information can improve prescribing practices and assist regulatory agencies with the updating of safety information of approved products as well as making clinical decisions. By strengthening pharmacovigilance systems; ultimately; medication safety; and quality of health care will be improved. (Rang & Dale, 2020) Evaluating how drugs are used and how they may cause harm, with respect to diabetic patients, is critical in order to promote safe use of medications for patients and to enhance patient safety. Studies such as these offer great value in assessing real-world prescribing and identifying situations of non-rational drug utilization, over-prescribing and combinations of medications that may not be rational. Additionally, these studies will also assess adherence to standard guidelines for managing diabetic patients. Secondly, monitoring adverse drug reactions (ADRs) will provide important information regarding the safety, tolerability and risk profile of antidiabetes drugs. The importance of this information is even greater in tertiary care centres, where patients may have many different comorbidities and treatment regimens that require highly individualised treatment. The results of this type of work will assist clinicians in optimising their treatment approaches, reducing issues due to the use of medications, and improving the adherence of their patients to their treatment regimens. Through the completion of assessments such as these, healthcare systems will be able to enhance pharmacovigilance systems and promote evidence-based clinical practice. Ultimately, the results of such studies will improve patient therapeutic outcomes, reduce the burden on the healthcare systems, and improve the quality of life of patients with diabetes. (Lancet Diabetes & Endocrinology, 2022)

Requires long-term treatment with multiple antidiabetic drugs

Chronic metabolic disease Diabetes mellitus has signs of high glucose levels because of weakness in the ability to produce insulin, use insulin or both. Diabetes has become one of the fastest expanding non-infectious diseases globally and has generated significant concern for public health. The growing number of diabetes patients is related to an inactive lifestyle, unhealthy eating patterns, being overweight, family history of diabetes and the increase in the aging population. Uncontrolled diabetes can result in serious complications, including cardiovascular disease, kidney damage (nephropathy), nerve damage (neuropathy), eye damage (retinopathy) and stroke. These complications drastically reduce the quality of life for people with diabetes and will increase the chance of death from the complications. Management of diabetes will require medication for life, regular checks of blood sugar, dietary modifications, and medication. Metformin, insulin, sulfonylureas, SGLT2 inhibitors and DPP4 inhibitors are examples of medications for diabetes. The most appropriate medication protocol will be determined based on the patient's health status, diabetes severity and whether the patient has other medical conditions. Diabetes is a lifetime condition, making it critical to ensure medically appropriate diabetes medications are used safely and effectively to minimize the risk of complications from diabetes. Continuous monitoring of diabetes and therapy tailored to the individual are essential for achieving glycemic control. (Skylar et al., 2017)

The purpose of drug utilization studies is to assist in an environment where medicines are used and where medications are prescribed, given, or consumed in healthcare institutions (pharmacoepidemiology). These studies enable clinicians to assess whether medicines have been appropriately, safely, and effectively used according to the guidelines established for treating patients in order to meet their needs. For example, patients who have diabetes usually take a considerable number of different medications to assist them with not only maintaining their glycemic levels but also managing their hypertension and dyslipidemia leading to polypharmacy. The prescribing of so many

medicines may result in complications or risks, such as drug-drug interactions, medication errors, adverse drug reactions, and non-compliance. Therefore, drug utilization studies are also beneficial in identifying medication prescribing trends as well as identifying inappropriate medication prescribing; if there are commonly prescribed combinations of medications. Furthermore, these studies can promote rational prescribing practices and result in improved therapeutic benefits. In tertiary care hospitals, drug utilization studies can be useful in evaluating prescribing behaviours in a real-world environment while improving the efficacy of clinicians treating patients for cost-related issues. Data collected from drug utilization studies can help clinicians make better informed clinical decisions; thereby allowing clinicians to provide the highest quality of care to patients with diabetes. (Holloway & van Dijk, 2011)

Any unintended and harmful response to a medication that occurs at an appropriate dose meant for treating, diagnosing or preventing a specific condition is considered to be an adverse drug reaction (ADR). ADRs are a concern to all areas of health care, as they can lead to increased levels of patient morbidity, hospitalisation, prolonged hospital stays and increased health care costs. Diabetics may be more susceptible to developing ADRs than other patients, due to the long-term use of multiple medications. Hypoglycemia, gastro-intestinal disturbances, weight gain, dizziness and allergic reactions are all examples of common ADRs. Hypoglycaemia is primarily associated with insulin and gastro-intestinal problems are seen with metformin. ADRs can decrease the likelihood that a patient will adhere to their prescribed therapy; therefore the potential for poorly controlled blood glucose levels and subsequently increased risk for disease progression will increase if ADRs and their management are not properly monitored. Therefore, a health care provider must monitor ADRs in order to improve patient safety. The presence of ADRs will allow health care providers to identify potentially dangerous medications and patients at risk for developing ADRs; therefore providing an environment that is safer for prescribing. (Aronson, 2009)

The field known as pharmacovigilance comprises both the science as well as the practice of

analysing, evaluating, understanding, and preventing adverse drug reactions (ADRs) and other drug-related problems. It has an integral part in promoting the safe and effective use of drugs or medications (i.e., therapeutic agents) used in treating chronic diseases such as diabetes mellitus, where long-term pharmacotherapy is often a necessity. Due to both small sample sizes for clinical trials pre-marketing and small duration of clinical trials, many adverse effects that will occur with the use of a particular drug are not evident until the drug becomes universally available and is being prescribed and used extensively. This is why it is critical to have continued surveillance of drug safety following marketing; otherwise, the risk of ADRs associated with the drug's long-term use cannot effectively be monitored. Tertiary care hospitals (e.g., general hospitals) have large numbers of patients who are receiving a variety of therapies, thus making them valuable centres for pharmacovigilance. As such, they provide valuable data that helps to identify and prevent previously unrecognised ADRs, as well as improve prescribing practices. Pharmacovigilance also assists regulatory agencies with the ongoing development and updating of drug safety guidelines and improving the quality of patient care. Ultimately, by improving the effectiveness of pharmacovigilance systems, medication safety and the quality of our healthcare system will be improved. (Lazarou et al., 1998)

Rational drug therapy and safety have both increased as a result of evaluating the use of the drugs that diabetic patients receive, including the number of adverse drug reactions experienced by these patients as a result of taking those medications. These studies give an important overall picture of how often drugs used to treat diabetes are actually prescribed in the real world and provide a way to identify any irrational uses of medications, overuse or inappropriate combinations of medications as well as how well healthcare practitioners follow the standard treatment guidelines for diabetes. At the same time, by monitoring and reporting adverse drug reactions, healthcare practitioners have a better understanding of the safety, tolerability and risk associated with the use of the drugs used to treat diabetes; which is especially true within tertiary care facilities, where patients present with

multiple co-morbidities or require complex treatment with individualized therapies. The findings that these studies yield allow healthcare practitioners to make the best choices when it comes to treating diabetic patients and limit the number of medication related issues (e.g. medication adherence) as a result of the data that are collected through these studies on an ongoing basis. Additionally, these assessments support pharmacovigilance, provide further evidence-based support for clinical decisions, and ultimately create better outcomes from therapy, decrease the financial burden associated with healthcare, and improve a diabetic patient's quality of life. (WHO, 2020)

Common drugs: metformin, sulfonylureas, insulin

This will soon be one of the biggest-growing chronic, non-communicable diseases globally; therefore, the public health implications of diabetes are immense. Diabetes is becoming increasingly prevalent due to a range of factors such as prevailing sedentary lifestyles, obesity, unhealthy/dietary habits, genetic predisposition, and increasing age of the population. Common medications used to treat diabetes include metformin, sulfonylureas and insulin: these medications form the foundation of most people's therapies. Complications from diabetes are serious if they are not controlled adequately. These include cardiovascular disease, nephropathy, neuropathy, retinopathy, and stroke (these all decrease people's quality of life, and increase mortality risks). In order to achieve optimal management of diabetes, people require lifelong treatment, repeated monitoring of blood sugar levels, dietary regulation, and individualized pharmaceutical therapy. Selection of drug therapy is based on disease severity, individual patient status, and other related conditions (comorbidities). Achieving glycemic control and preventing the long-term complications associated with diabetes require rational use of antidiabetic agents. Continuous monitoring and dose adjustment of antidiabetic medications are needed to enhance the effectiveness of therapy and improve patient safety. (Johnson et al., 2020) Evaluating the way that people use medicines is one important aspect of pharmacoepidemiology and is done through drug utilization studies. These studies can help provide data to determine

whether prescribed medicines are being used appropriately, safely, and effectively based on evidence-based guidelines for the treatment of conditions such as diabetes. For patients with diabetes, examples of common medications prescribed are metformin, sulfonylureas and insulin; therefore, the treatment of patients with diabetes can become complicated because of the potential for different combinations of medications to be used in treating patients with diabetes, increased number of medications that can lead to polypharmacy, increased risk for drug interactions, increased likelihood of making medication errors and decreased adherence to medication regimens. Drug utilization studies provide insight into current prescribing patterns, irrational use of medications and common medication combinations. The results of such studies may support more rational prescribing and improved clinical outcomes in patients treated at tertiary-care facilities by allowing for a better understanding of how doctors prescribe medications in the real world and helping to improve cost-effective therapies. Drug utilization studies provide important information to help healthcare providers determine how best to treat their patients and achieve positive outcomes. (Brown et al., 2021)

Negative reactions to drugs (ADRs) refer to unintentional, harmful responses to medications given at recommended doses for therapeutic purposes, estimated to occur in 1/4 - 1/3 of patients given certain classes of drugs at the time of surgery (1). Many patients with type 2 diabetes (T2D) have used numerous drug classes for long periods of time, e.g., metformin, sulfonylureas, insulin). Diabetic patients may experience many of the ADRs associated with both anti-diabetic and non-anti-diabetic drugs, including hypoglycemia (more common with insulin and sulfonylureas), gastrointestinal disturbances (primarily related to metformin), weight gain, dizziness, and allergic reactions. ADRs may negatively impact compliance with therapy and control of blood glucose levels; thus, increasing the risk of disease progression. If hypoglycemia is not treated quickly enough, it may require hospitalization for treatment of emergency hypoglycemia. Prevention and early reporting of and intervention with ADRs can help enhance patient safety and improve patient treatment

outcomes. Monitoring ADRs can also help identify high-risk medications and patients, which aids prescribers (physicians) to write prescriptions that are safer. Patient pharmacotherapy is continuously monitored throughout the patient's life so that complications associated with drug use can be reduced and the quality of patient care is improved. (Smith et al., 2019)

The discipline and application of pharmacovigilance has a fundamental role in the detection, evaluation, understanding and prevention of adverse drug reactions, in addition to observing additional drug-related issues. The proper use of pharmacovigilance will help ensure safe and effective medication usage, as it relates to long-term medication therapy in chronic diseases like diabetes mellitus, with the use of medications like Metformin, Sulfonylureas, and Insulin. Many adverse drug events are not identified during the pre-marketing phase of the drug's development process (clinical trials) due to the small size of the patient population used for FDA approval and the limited time during which these studies were conducted; as a result, many of these events will not be recognized until there is an extensive body of medical literature regarding the drug's safety profile following the drug's introduction into the marketplace. For these reasons, post-marketing surveillance is necessary to continuously monitor the safety of medications. Tertiary-care hospitals are excellent settings for pharmacovigilance due to their high volume of patient visits and variety of treatment options. By conducting pharmacovigilance in these types of hospital settings, pharmacovigilance data can be obtained to assist in identifying unrecognized adverse drug reactions and to improve the prescribing habits of health care providers. Additionally, pharmacovigilance supports regulatory agencies in creating and/or updating drug safety guidelines, and improving patient outcomes. (Williams et al., 2022)

The evaluation of drug-use habits and possible side effects of medicines used by those who have diabetes is essential in ensuring that a patient receives the right medicine(s), in the right amount, at the right time, for as long as necessary to improve his or her health. Establishing a pattern of prescribing for metformin, sulfonylureas and/or insulin can help to determine whether those medications are being

prescribed correctly according to established medical guidelines and to identify indiscriminately prescribed medications, as well as potentially harmful interactions between two or more medications, and to identify areas of concern for patients with diabetes related to polypharmacy. Documentation and monitoring of adverse drug reactions (ADRs) also provide valuable information about how safe or effective antidiabetic medications are when they are used in the clinic setting. This is even more critical in the setting of a tertiary care facility where patients typically present with multiple medical problems and require complex treatment regimens that require medications to be tailored to the individual patient. The treatment strategies identified through the evaluation of drug-use and ADR information for patients with diabetes will assist in developing the best plan for each individual patient, decreasing the likelihood of medication-related problems and increasing patient compliance. In addition, the results of these studies will strengthen pharmacovigilance programs and support evidence-based clinical decision-making, resulting in improved quality of care and patient outcomes. (Taylor et al., 2023)

Drug utilization studies assess prescribing patterns and rational use

The primary method of determining the safety and rationality of drug use in the healthcare system is by conducting a drug utilization study, which looks at the way in which drugs are selected, prescribed, dispensed, and given to patients in real clinical settings. This enables us to determine whether drugs are being used according to accepted guidelines. An example of this type of study would be to evaluate the different classes of drugs used for chronic diseases (e.g., diabetes mellitus) that require long-term treatment. Some of these common medications/agents include metformin, sulfonylureas, and insulins, which all provide data on how the drug prescriber has utilised a drug, how to detect drug misuse, and the variations in the way each prescriber treats his/her own patients. In addition, drug utilization research provides insight into the different behaviours and patterns of drug use in real-life settings. Therefore, drug utilization studies can provide assistance in expanding our understanding of drug utilisation patterns, and in

improving the planning of the delivery of healthcare services at the community level. In summary, drug utilization studies also help to ensure the delivery of appropriate healthcare to patients through the provision of rational prescribing techniques. Overall, drug utilization studies help to ensure that drug therapy is safe, effective and cost-effective within the clinical setting. (Hepler et al., 2019)

Rational drug use is defined as correctly prescribing medicines based on need, proper dosage, and sufficient length of time for the intended use of a drug. Drug utilization studies (DUS) can be used to evaluate the extent to which prescriptions reflect established treatment guidelines, and therefore rational drug use. For example, rational drug use for diabetic patients would be taking the appropriate medications; which are metformin, sulfonylureas, or insulin as indicated. Examples of irrational prescribing would include, polypharmacy (multiple medications prescribed to treat one condition), inappropriate combinations of medications prescribed for one patient, and incorrect dosing. DUS can assist in identifying irrational prescribing and supporting evidence-based prescribing practices, providing feedback to practitioners on their prescribing practices, to improve their prescribing habits, and to decrease the incidence of adverse drug reactions. By utilizing rational drug prescribing and/or rational drug use, therapeutic outcomes, adverse drug reactions, and patient compliance can be improved. Additionally, using rational drug prescribing/rational drug use will reduce the overall cost of healthcare by decreasing the amount spent on ineffective treatment, while also creating a more efficient system of patient care. (Murray et al., 2020)

Drug utilization research is vital in evaluating prescribing practices for hospitals, particularly at the tertiary care level. These studies look at the frequency of prescribing specific drugs and how they were used with one another. There has been a lot of research done on prescribing patterns of metformin, either alone or in combination with sulfonylureas or insulin, for diabetes management. The findings of these studies provide information about whether or not physicians adhere to established guidelines for treatment. The findings also highlight discrepancies between the

prescribing practices of healthcare providers. Understanding the prescribing patterns of healthcare providers is critical in improving clinical decision-making and providing standardised treatment methods. Study results are also beneficial in assisting hospital formulary management by identifying the most effective as well as least costly drugs for patient care. Study results ultimately allow healthcare administrators to improve policies for the availability and use of drugs. In conclusion, drug utilisation studies enhance the quality of prescribing and improve outcomes for patients with chronic diseases such as diabetes. (Peterson et al., 2021)

Drug utilization studies can also contribute to improving patient safety through their impact on the reduction of medication-related events (MREs). By evaluating the utilization of medications, it is possible to identify medication-related problems (e.g., adverse drug reactions, drug interactions and medication errors) that a diabetic patient may experience if they are prescribed multiple medicines. If multiple medicines are prescribed to a patient with diabetes, risks of adverse drug reactions, gastrointestinal upset and hypoglycemia will be increased due to the use of those medications. Drug utilization studies can assist healthcare professionals in identifying potential problems early and encouraging the use of safer prescribing habits. The real-life data generated by drug utilization studies also supports pharmacovigilance programs to allow healthcare professionals to modify treatment as necessary to reduce risk of patient harm. Drug utilization studies also provide education to prescribers regarding safe and rational medication prescribing and using medication judiciously. Collectively; drug utilization studies are key components to increasing the safety and quality of drug therapy within clinical practice. (Anderson et al., 2018)

Healthcare economics and policy development will be positively affected by Drug Utilization studies since they enable the evaluation of prescribing practices. Drug utilization studies will provide the ability to determine the appropriateness of prescribing practices, identify overuse and underuse of drugs, and the best use of limited healthcare resources for chronic diseases (e.g. diabetes) when patients face

increasing costs due to ongoing treatments. By using Drug Utilization studies to guide rational prescribing, physicians can provide therapy without creating an undue financial burden upon the patient or the healthcare system and make the best possible use of available healthcare resources. Moreover, Drug Utilization studies have contributed to the development of clinical guidelines and hospital-based drug policies. Drug Utilization studies provide an empirical basis for the selection of essential medicines and the improvement of formulary decisions and also provide a mechanism for monitoring the effectiveness of interventions designed to improve the prescribing habits of physicians. Drug Utilization Studies are critical to improving efficiency in the healthcare system, ensuring that drugs are used rationally, and ultimately improving patient outcomes through the practice of clinical medicine. (Richards et al., 2022)

Polypharmacy is common in diabetic patients

Diabetic individuals are at a higher risk of having dangerous drug-drug interactions due to taking multiple medications (known as polypharmacy), which can negatively impact the effectiveness of their therapy and cause side effects. With multiple medications prescribed, the chances for both pharmacokinetic and pharmacodynamic interactions are high. For example, if someone takes both insulin or sulfonylureas and another form of glucose-lowering agent, this may cause an individual to experience hypoglycemia (low blood glucose). Antihypertensive and cholesterol-lowering medications are often combined with antidiabetic therapy and these two classes of medications can also have an impact on how the drug works in their body. These reactions may result in less effective treatment or be more toxic than expected. Drug utilization studies are important tools for identifying and understanding these types of interactions in order to provide a safer prescribing environment. Regular review of medication regimens is essential to prevent harmful effects from occurring. All medications prescribed to patients should be thoroughly reviewed by a healthcare professional before they are filled to ensure there are no unnecessary similarities between the medications. (Viktil et al., 2020)

Poor medicine compliance is another common outcome of patients who have diabetes using

multiple medications (polypharmacy). Patients may struggle to comply with prescribed medication regimens because of the potential for complex medication management as the number of prescribed drugs grows (increased complexity). In particular, patients may miss doses, incorrectly administer medications, or quit therapy altogether because of these challenges. Additionally, the negative impact of poor medication compliance on glycemic control can increase the risk of the development of complications associated with diabetes. Other elements that can contribute to decreased medication compliance in polypharmacy situations include low health literacy, financial hardships, and complicated drug dosing regimens. To help improve patient adherence and prevent detrimental effects of having multiple medications prescribed, providers can simplify medication regimens, use fixed-dose combination products when appropriate, and counsel / educate their patients on proper medication use (via regular follow-up and medication reviews). (Guthrie et al., 2019)

The increased prevalence of polypharmacy leads to an increase in the financial burden placed upon patients and the healthcare system, including increased prescription costs; increased number of hospital visits; and increased risk of hospitalization due to adverse drug reactions. In developing countries, this burden on cost has an effect on the availability of essential medications to patients and therefore it is important to have cost-effectiveness in prescribing practices to reduce inappropriate use of medications. Studies of medication utilization can be helpful in identifying expensive or non-necessary combinations of medications for example to promote rational drug prescribing. Through the development of evidence-based guidelines, healthcare systems may also reduce costs by optimizing treatment recommendations; and through the promotion of evidence-based treatment. The rationalization of drug therapy will not only result in improved patient outcomes, but will also allow for a reduction in healthcare expenditures. (Miller et al., 2021)

It is important to work together with physicians, nurses and pharmacists to have a team approach to the care of individuals with diabetes who are experiencing polypharmacy. Medication

reconciliation and review on an ongoing basis is necessary to identify duplicate or unnecessary medications in the diabetes patient population. Clinical pharmacists have an important role in assessing the appropriateness of medication therapy and determining if there are alternatives available to reduce the risks of polypharmacy. Individualizing therapy for diabetes patients based on their current clinical condition, comorbid conditions, and other risk factors is essential to decreasing the complications associated with polypharmacy. Patient education is also a valuable tool to improve the patient's understanding of their medication therapies and help them be compliant with their therapy. The establishment and implementation of clinical practice guidelines and decision support systems can also contribute to the endeavours of optimising prescribing practices. In conclusion, effective management of polypharmacy is critical to ensuring that diabetic patients are receiving safe, effective, and rational medication treatment. (Kantor et al., 2019)

Conclusion

A person who has been diagnosed with diabetes mellitus has a chronic disease requiring long-term management and may be treated using several different types of medications, including metformin, sulfonylureas, and insulin. The objective of assessing drug utilization patterns is to determine whether prescribers are appropriately prescribing drugs to allow optimal glycemic control and the avoidance of complications. Drug utilization studies provide valuable information to identify trends in prescribing, irrational drug use, and variations in the practice of clinical medicine, particularly at the level of tertiary care hospitals where patients often have multiple comorbidities when they present. These studies also evaluate the appropriateness of drug therapy and can determine the results of adherence to established treatment guidelines. The presence of adverse drug reactions continues to be a major issue for patients with diabetes due to their use of polypharmacy and the long-term nature of their treatment; therefore, pharmacovigilance and ongoing monitoring of patients using medications is a critical component of providing quality care to these patients. Implementing effective strategies for managing diabetes

including routine evaluation of patients' medications and education of patients regarding their medications can alleviate the incidence of medication-related problems and enhance patients' responses to treatment. In conclusion, a structured approach to drug utilization and adverse drug reaction monitoring fosters the appropriate use of drugs, enhances the safety of medication therapy for patients, and will subsequently improve the quality of life for patients with diabetes.

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