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Adverse Drug Reactions in Oncology Patients Based on Global Evidence: A Systematic Review

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Abstract

Objective:
To systematically synthesize global evidence on the prevalence, patterns, causality, risk factors, and management strategies of adverse drug reactions (ADRs) in oncology patients.

Methods:
A comprehensive systematic review was conducted by searching major databases and pharmacovigilance sources up to 2025 to identify relevant prospective studies, observational analyses, and mechanistic research on ADRs in cancer patients. Data on ADR incidence, severity, causality, risk factors, and treatment were extracted and analyzed. Quality assessments were performed to ensure reliability of included studies.

Results:
ADRs are frequent in patients receiving systemic anticancer therapies (SACTs), as well as non-cancer medications, contributing significantly to morbidity, mortality, and healthcare costs worldwide. Prevalence rates vary greatly across regions and patient populations, with hematological toxicities, gastrointestinal symptoms, dermatological reactions, and immune-related adverse events predominating. Platinum compounds, taxanes, and antimetabolites are the most common agents implicated. Advanced age, female sex, polypharmacy, multimorbidity, and specific drug regimens are major risk factors. Although many ADRs are predictable based on drug toxicity profiles, a substantial portion remains preventable with early recognition and intervention. Emerging immunotherapies present novel ADR profiles requiring tailored management approaches.

Conclusion:
ADRs in oncology patients represent a critical global challenge that adversely affects clinical outcomes. Multidisciplinary care, integration of clinical pharmacy, personalized dosing strategies, and robust pharmacovigilance systems are essential to improve safety. Standardization of ADR reporting and further research on predictive models can enhance prevention. This review supports the implementation of individualized patient management to reduce ADR burden and optimize cancer treatment efficacy worldwide.

Keywords:

Adverse drug reactions, Oncology, Chemotherapy, Patient safety, Personalized cancer therapy

1. Introduction

Therapeutics for cancer have advanced remarkably, giving patients all around the world more alternatives for therapy. Despite these developments, toxicities associated with therapy continue to be a significant and persistent clinical problem. [1] In cancer patients, adverse drug reactions (ADRs), which are defined as unpleasant or severe reactions to medications that potentially predict future risks and necessitate preventive or therapy modification, are common. A number of variables, including as polypharmacy (using numerous drugs at the same time), multimorbidity (having multiple coexisting medical diseases), and physiological changes linked to age and cancer, make these people more susceptible to adverse drug reactions (ADRs). These complications result in changed pharmacokinetics and pharmacodynamics, which raises the risk of medication toxicity and unfavorable consequences. [2-5]

ADRs significantly increase hospitalizations, make managing cancer more difficult, cause treatment plans to be delayed or stopped, and significantly raise the chance of death for cancer patients. [4] Approximately 10% of hospital admissions worldwide are caused by ADRs, with incidence rates differing significantly by patient demographics, healthcare resources, and locations. Among the most common causes of adverse drug reactions (ADRs), chemotherapy and systemic anticancer medicines are responsible for a significant amount of drug-related morbidity and mortality.[5,9] According to studies, between 36% and 60% of cancer patients have adverse drug reactions (ADRs) linked to chemotherapy, which frequently lead to longer hospital stays and higher medical expenses.[2,6] Moreover, a number of adverse drug reactions (ADRs) are particularly prevalent and have the potential to significantly impair quality of life. These include gastrointestinal problems (e.g., nausea and vomiting), dermatological effects (e.g., alopecia), etc.

Despite increased research efforts worldwide, it is still challenging to establish universally effective preventative and management methods due to the insufficient understanding of the entire breadth and different features of adverse drug reactions (ADRs) in cancer patients.[1-3] Variations in clinical procedures, reporting guidelines, and pharmacovigilance systems all contribute to these information gaps.[7-13] To guide better patient safety practices and maximize treatment results, a thorough and systematic evaluation of the global data on ADR epidemiology, causation, clinical manifestations, risk factors, and management strategies in oncology populations is necessary.[7-9]

This study attempts to compile the most recent data from across the world in order to give a comprehensive picture of the burden of adverse drug reactions (ADRs) in cancer patients and to direct clinical and policy measures for improved pharmacovigilance, individualized care, and multidisciplinary management. [14,15]

Methods

Search Strategy and Selection Criteria

Peer-reviewed research and reports on adverse drug reactions (ADRs) in cancer patients up to 2025 were gathered by conducting a thorough search throughout the main biomedical databases and pharmacovigilance repositories. The retrieval of pertinent material was led by keywords like "adverse drug reactions," "oncology," "chemotherapy toxicity," "polypharmacy," and "cancer pharmacovigilance". ADR incidence, severity, causative agents, risk factors, and therapeutic options in cancer populations were

assessed by the reviewed sources, which comprised retrospective analyses, prospective observational cohort studies, and interventional trials.

Studies were chosen on the basis of their applicability to adverse drug reactions (ADRs) in systemic anticancer treatments, as well as the study's sample size, methodology, and clarity of ADR definitions and evaluation instruments such the WHO-UMC criteria and Naranjo scale. To guarantee a thorough knowledge, both clinical research findings and real-world pharmacovigilance data were incorporated. Common ADR patterns, including hematological toxicities, gastrointestinal side effects, and dermatological manifestations, as well as offending medications such platinum compounds, taxanes, and antimetabolites, may be analyzed thanks to this encompassing methodology.

The compiled data shows that ADR frequency varies by geography and cancer type, with polypharmacy and multimorbidity having significant effects on increasing ADR risk. The gathered information influenced the assessment of ADR management and prevention strategies, highlighting the need of interdisciplinary care and tailored therapy in cancer. In order to guide improved pharmacovigilance and clinical management, this methodological rigor guarantees that the evaluation offers a comprehensive, evidence-based summary of the worldwide ADR burden in cancer patients.

The basis for better patient safety and treatment results is laid by this methodical and structured search, which makes a substantial contribution to our understanding of the epidemiology, clinical significance, and mitigation of ADRs in cancer.

Data Extraction and Quality Assessment

In order to estimate burden and variance among populations, key data retrieved from included studies were research methods (prospective, retrospective, and interventional), patient demographics (age, sex, and comorbidities), cancer types, and ADR prevalence rates. To determine the likelihood that particular medications caused reported adverse drug reactions, causation evaluations were gathered using approved instruments like the WHO-UMC criteria or the Naranjo scale. ADRs were categorized from moderate to life-threatening using severity grading measures (such as CTCAE), which indicated clinical effect. Information on the pharmaceuticals used revealed frequent culprits, particularly chemotherapeutic agents like taxanes and platinum compounds. Polypharmacy, multimorbidity, and other risk variables were examined for correlations with the occurrence of ADRs. In order to comprehend the effects of ADRs, clinical outcomes including hospitalization, therapy interruption, morbidity, and death were evaluated. Standardized checklists specific to the research type were used to evaluate sample size, methodological rigor, ADR evaluation techniques, and bias control strategies in order to assess the quality of the data. A complete and trustworthy synthesis of the worldwide ADR evidence in cancer patients was guaranteed by this meticulous extraction and quality assessment.

Results

Prevalence and Epidemiology

According to global data, adverse drug reactions (ADRs) have a substantial clinical burden among cancer patients; at least 21.5% of these patients were hospitalized as a result of an ADR [Lavan et al., 2019].[15] This indicates that about one out of every five hospitalized cancer patients has problems brought on by or made worse by medication toxicity. ADR-induced emergency admissions have been found to be as high as 35.8% in some populations, especially some cohorts evaluated in resource-constrained settings or high-incidence cancer regions, highlighting the urgent risk these responses offer. [16]

ADR prevalence differs significantly between geographical areas and healthcare systems. Studies from Indian cancer centers show that ADR rates are close to 60%. These findings may be explained by variations in pharmacovigilance procedures, patient demographics, supportive care provision, and chemotherapy techniques. [2,7] European studies, on the other hand, usually indicate ADR rates that are closer to 5%. This lower frequency, however, can be due to more stringent reporting requirements and robust monitoring systems, which may potentially result in the underreporting or underdetection of milder ADRs. ADR frequency variability is a reflection of global cancer epidemiology, patient genetics, environmental variables, and healthcare infrastructure variation.

Crucially, ADRs have a major impact on morbidity and death in susceptible groups, especially the elderly (those over 70). Older persons are more vulnerable to drug toxicities and interactions because they frequently take many drugs at once (polypharmacy) and have multiple chronic conditions (multimorbidity).[13] Drug handling is further hampered by age-related physiological changes, such as altered drug metabolism and reduced renal and hepatic clearance. In older cancer patients, this confluence of characteristics not only increases risk but also makes it more difficult to diagnose and manage ADRs, necessitating individualized evaluation techniques to maximize treatment and reduce damage [Chen et al., 2022; Yamada et al., 2022]. [17,18]

ADRs in oncology are therefore a crucial area of focus for enhancing cancer care outcomes worldwide as they constitute a complicated issue impacted by patient characteristics, treatment complexity, and systemic healthcare determinants.

Patterns and Types of ADRs

Up to 25.3% of cancer patients receiving chemotherapy experience hematological toxicities, especially neutropenia that is frequently exacerbated by infections. This makes it one of the most dangerous and common adverse drug reactions (ADRs) [Pan et al., 2022]. [19] This illness makes people more prone to infections, which frequently calls for dosage adjustments, postponements of therapy, or hospital stays. About 20% of patients experience gastrointestinal adverse drug reactions (ADRs), which include nausea, vomiting, and constipation. [20] These side effects are still among the most upsetting and have a detrimental influence on treatment compliance and quality of life. Even if they are not fatal, dermatological toxicities including rashes and alopecia are common and can cause psychological anguish [Pan et al., 2022].[21]

Platinum-based medications (cisplatin, carboplatin), taxanes (paclitaxel, docetaxel), and antimetabolites such as 5-fluorouracil are important chemotherapy treatments that cause severe effects. In addition to causing severe nephrotoxicity, ototoxicity, and hematological toxicity, platinum drugs also produce DNA crosslinking that hinders the reproduction of tumor cells. Taxanes are less nephrotoxic but alter microtubule dynamics, causing peripheral neuropathy and myelosuppression [Tian et al., 2021; Ismail, 2023]. [22,20] 5-FU increases patient burden by causing hand-foot syndrome, myelosuppression, and gastrointestinal mucositis.

Long-term patient function and comfort are significantly impacted by non-hematological toxicities such mucositis and peripheral neuropathy. Dose-limiting neuropathic pain, numbness, or motor impairment can result from neuropathy brought on by taxanes and platinum analogs, and these symptoms might occasionally last after therapy. Because mucositis weakens mucosal barriers, patients are more vulnerable to infections and nutritional problems. [23-26] The cumulative impact of these side effects on cancer treatment results emphasizes the significance of supportive care, proactive monitoring, and regimen modifications to maximize therapy while reducing toxicity.

Combining platinum and taxane drugs, which are often used to treat ovarian, lung, and breast cancers, uses their unique processes to destroy tumor cells in a synergistic way. However, careful toxicity control is necessary to prevent the occurrence of adverse drug reactions [Tian et al., 2021].[24] In order to reduce these toxicities associated with chemotherapy, premedication procedures, growth factor support, and patient education are essential.

Prevention and Management

Premedications are crucial for improving patient tolerance and minimizing the negative effects of chemotherapy. In order to avoid nausea and vomiting, two of the most prevalent and upsetting side effects of chemotherapy, antiemetics such ondansetron and dexamethasone are frequently utilized.[25] By lowering inflammation and inhibiting neurotransmitters implicated in the vomiting reflex, these medications enhance patient comfort and treatment compliance [Clemmons et al., 2021].[27]

Granulocyte colony-stimulating factor (G-CSF) and other growth factors are essential for avoiding hematologic toxicities like neutropenia, which raise the risk of infection. By encouraging the bone marrow to create more neutrophils, G-CSF reduces the amount of time patients must stay in the hospital owing to infections and allows chemotherapy dosage to continue on time [Ijaz et al., 2025].[28]

Topical treatments for mucositis, a painful inflammation of the mucous membranes that can hinder eating and raise the risk of infection, include mouthwashes, analgesics, and protective gels. It's critical to stay hydrated and modify chemotherapy infusion rates to avoid tissue damage from drug extravasation.

Patient education is very important. Early symptom recognition and reporting by patients results in quicker management, less severe adverse drug reactions, and fewer treatment interruptions [Yan et al., 2024].[29] Despite these efforts, side effect underreporting is still widespread, particularly in places with limited resources, which hinders comprehension and control. For improved ADR identification, reporting, and treatment outcomes worldwide, multidisciplinary cooperation between oncologists, pharmacists, nurses, and patients is essential to bolstering pharmacovigilance.

Causality, Predictability, and Preventability

Clinicians can expect numerous side effects linked to particular chemotherapy drugs because the majority of adverse drug reactions (ADRs) in oncology (~89.3%) are predictable based on well-established drug toxicity profiles [Lavan et al., 2019].[30] According to Huang et al. (2023), 62.6% of these adverse drug reactions may be avoidable with prompt implementation of supportive care, dosage modifications, and proper monitoring. To prevent recurrent exposures to harmful substances, it is essential to carefully identify and record a patient's past medication allergies.[16]

Cancer patients frequently use numerous drugs at the same time, a condition known as polypharmacy. This raises the risk of drug interactions and adverse drug reactions (ADRs), underscoring the significance of careful medication reconciliation. By examining prescription regimens, spotting possible drug interactions, and advising on dose adjustments, pharmacists play a critical role in this process. It has been demonstrated that their participation lowers prescription mistakes and prevents preventable adverse drug reactions.[6]

Despite this understanding, research indicates that preventability rates differ; some report that 30-45% of adverse drug reactions are definitely or probably preventable, while others discover that a sizable portion cannot be prevented because of drug toxicities or patient-specific factors [Ramasubbu et al., 2020; Iqbal et al., 2024].[31] To further reduce avoidable ADRs in cancer treatment, established methods for monitoring, patient education, and interdisciplinary coordination must be put into place.

Risk Factors

One important factor affecting cancer patients' risk of adverse drug reactions (ADRs) is their age. Drug toxicities are more likely to occur in older persons due to their various coexisting conditions (multimorbidity), altered pharmacokinetics and pharmacodynamics, and reduced organ function.[11] This calls for customized evaluations that meticulously weigh the possible advantages of cancer therapy against the dangers of adverse drug reactions in order to maximize therapeutic results and reduce harm [de Lima Lopes et al., 2021].[32]

Due to possible variations in body composition, hormone levels, and drug metabolism enzymes between males and females, female sex has also been linked to a greater occurrence of certain adverse medication reactions.[28] These physiological and biological variations can impact medication toxicity profiles by affecting the distribution, metabolism, excretion, and absorption of chemotherapeutic drugs.

Patients with cancer, particularly those who are older, frequently use numerous concurrent drugs, a practice known as polypharmacy. This increases the likelihood of adverse drug reactions (ADRs) by raising the risk of cumulative toxic effects and drug-drug interactions.[29] In order to reduce avoidable adverse drug reactions, managing polypharmacy through medication review and reconciliation is essential. Drug clearance is hampered by organ failure, especially renal and hepatic impairment, which can result in the buildup and increased toxicity of chemotherapeutic medications.[30] For these patients, dosage modifications are crucial.

ADR risk is further impacted by genetic variations that impact drug-metabolizing enzymes, transporters, and receptors. These variations can lead to interindividual heterogeneity in drug response and toxicity.

Some individuals may be at risk for severe adverse drug reactions (ADRs) due to genetic variations, such as CYP450 enzymes or TPMT; the stage of cancer also affects ADR risk.[33] The risk of toxicity is increased by advanced illness since it might affect organ systems, change how drugs are metabolized, and call for more aggressive regimens. In order to reduce adverse drug reactions and maximize treatment effectiveness, these criteria taken together highlight the vital need for individualized oncology care that incorporates clinical, genetic, and pharmacological concerns.

Emerging Challenges

Pneumonitis and colitis are examples of immune-related adverse events (irAEs) that can result from new immunotherapies such immune checkpoint inhibitors. Immunosuppressant therapy and specialist monitoring are necessary for these adverse effects, which arise from the immune system targeting healthy tissues [Zang et al., 2022].[34] In order to properly treat these complicated interactions, rigorous safety assessments and regular patient monitoring are necessary since combination medications raise toxicity risks owing to cumulative effects. According to international data, about 21.5% of cancer patients are hospitalized as a result of ADRs, and some cohorts report emergency admissions linked to ADRs as high as 35.8% [Lavan et al., 2019].[15] The prevalence is reported to be up to 60% in Indian research, but just 5% in European statistics. This discrepancy may be due to underreporting or disparate detection methods. Particularly in older persons (>70 years), when polypharmacy and multimorbidity greatly increase the risk of ADRs, these responses continue to be a major source of morbidity and death [Chen et al., 2022; Yamada et al., 2022].[16,17]

Discussion

About 20% of patients hospitalized to cancer care facilities develop adverse drug reactions (ADRs), highlighting the significant worldwide effect of ADRs in patients receiving oncology therapy. These reactions include a wide range of clinical manifestations, such as systemic toxicities that affect multiple organ systems, gastrointestinal disturbances like persistent nausea and vomiting that negatively impact patient quality of life, dermatological conditions like alopecia and rashes, and hematological toxicities like neutropenia that significantly increase infection risk [Lavan et al., 2019; Pan et al., 2022].[15,28] The difficulty of cancer pharmacotherapy is shown by this broad range of adverse drug reactions.

Multimorbidity, or having several chronic illnesses at the same time, and polypharmacy, especially in older individuals, increase the risk of adverse drug reactions and make therapeutic treatment more difficult.[34-36] In order to limit damage while preserving efficacy, customized therapy methods are required due to aging-related physiological changes that modify sensitivity to pharmaceutical effects and impede drug clearance [de Lima Lopes et al., 2021; Yamada et al., 2022].[16,17]

Preventability continues to get crucial attention. Research indicates that enhanced pharmacovigilance systems that support early detection, individualized dosage modification based on patient risk, and the deprescribing of hazardous or unneeded drugs might avoid over half of ADRs[37,38]. Clinicians can optimize therapy to balance cancer management with lowering ADR risk by including thorough geriatric evaluation, as recommended by ASCO recommendations, which allows them to account for frailty, concomitant diseases, and functional status [Huang et al., 2023; Chen et al., 2022].[25,29]

Oncology care teams rely heavily on clinical pharmacists. They greatly reduce avoidable ADR occurrences and improve adherence by identifying and mitigating possible drug-drug interactions and educating patients about expected side effects through thorough medication reconciliation and monitoring [Ijaz et al., 2025].[31] However, there are still issues with the literature, such as inconsistent ADR reporting guidelines, inconsistent research designs, and a lack of longitudinal data on recurring ADRs, which makes it difficult to fully comprehend long-term toxicity profiles and actual incidence rates [Lavan et al., 2019].[15]

Advances in digital health, such the integration of electronic health records and machine learning algorithms for predictive modeling, portend a bright future for risk categorization and more accurate ADR surveillance.[39,40] By proactively identifying patients at the highest risk and customizing therapies, these advancements may help improve safety and results [Huang et al., 2023].[31] Future studies should focus on confirming these technologies in actual clinical settings and creating integrated preventative plans that tailor cancer therapies, reduce side effects, and improve the standard of patient care in general.[41-44]

Conclusion

A major worldwide health concern, adverse drug reactions (ADRs) in cancer patients have a negative impact on treatment results, patient safety, and medical expenses. In addition to increasing morbidity and hospitalizations, these toxicities frequently result in dosage adjustments, therapy delays, or cessation, all of which can impair therapeutic effectiveness. In order to improve ADR identification, prevention, and management, multidisciplinary management comprising oncologists, clinical pharmacists, nurses, and geriatric experts is necessary for effective mitigation. Systematic ADR reporting, early signal identification, and real-time data analysis all depend on strong pharmacovigilance systems. This is especially crucial when new treatments with distinct toxicity profiles, including immunotherapies, come to market. In order to customize treatment to patients' physiological circumstances and comorbidities, individualized care approaches—such as thorough geriatric evaluation and customized dosing—are essential, particularly for older persons who are more susceptible to adverse drug reactions. ADR monitoring and management are further enhanced by integrating digital health tools and fortifying the worldwide pharmacovigilance infrastructure. For the purpose of improving predictive models, creating focused preventative measures, and converting knowledge into clinical practice—all of which will contribute to safer, more effective cancer treatment that maximizes patient outcomes globally—continuous international collaboration and research activities are essential.

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