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A Review Adverse Drug Reaction & Side Effect Monitoring of Anticancer Drug

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ABSTRACT

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Anticancer drugs are essential in cancer therapy but are often associated with severe adverse drug reactions (ADRs), impacting patient safety and treatment efficacy. Effective adverse drug monitoring helps in detecting, assessing, and preventing these toxicities. This review highlights the classification of anticancer drugs, newly discovered herbal and synthetic agents, common side effects, ADR reporting systems, and risk mitigation strategies. Emphasizing the importance of pharmacovigilance, the review also explores the role of advanced technologies in improving ADR detection, ensuring better patient outcomes in oncology.

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INTRODUCTION

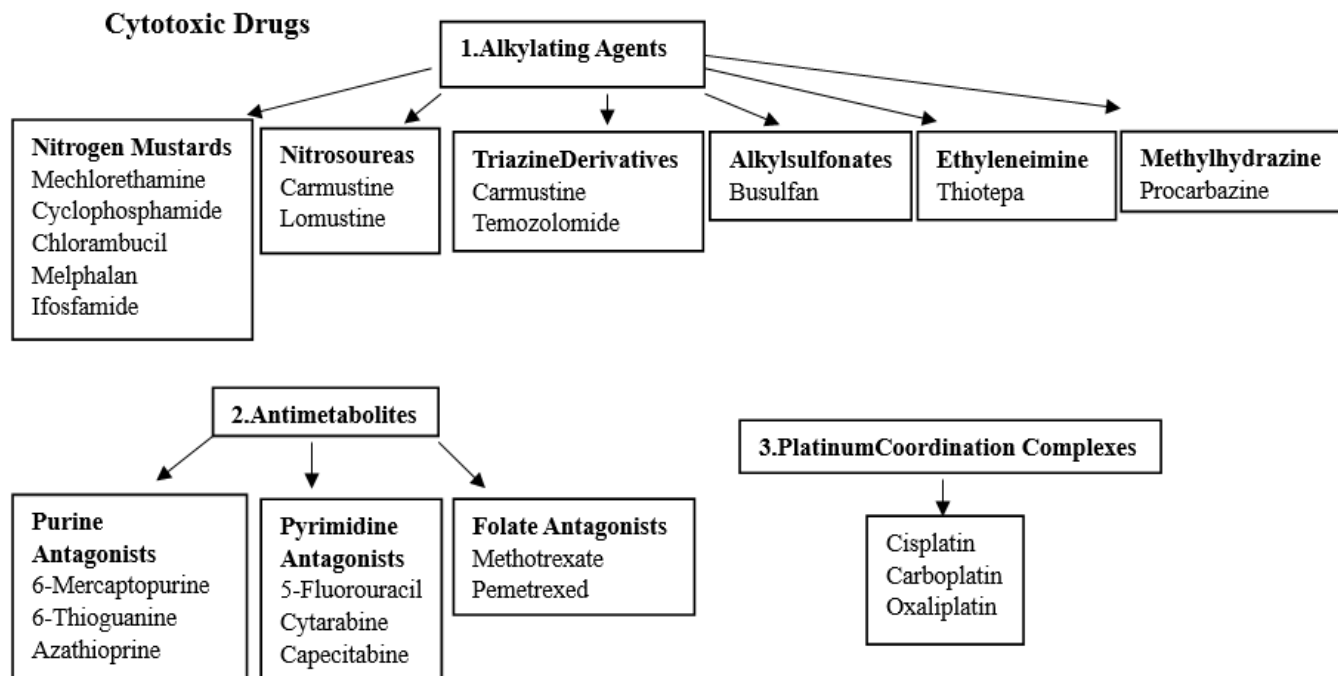
Cancer remains one of the leading causes of morbidity and mortality worldwide, necessitating the use of potent chemotherapeutic agents for its management. Anticancer drugs, while effective in targeting and destroying malignant cells, are also notorious for their narrow therapeutic index and potential to cause significant adverse drug reactions (ADRs). These reactions not only affect patient compliance and quality of life but can also result in treatment delays, dose modifications, or even therapy discontinuation^[1-2]. The complexity of cancer treatment regimens, often involving combinations of cytotoxic agents, targeted therapies, and immunotherapies, further increases the risk of adverse events.

Additionally, cancer patients frequently have comorbidities and are prescribed multiple medications, which raises the potential for drug-drug interactions and compounded toxicity. Hence, systematic monitoring and management of ADRs in oncology settings is of paramount importance. Adverse drug monitoring (also known as pharmacovigilance) is a structured approach to detecting, assessing, understanding, and preventing adverse effects or any other drug-related problems^[3-4]. In the context of anticancer therapy, it plays a crucial role in ensuring patient safety, optimizing therapeutic outcomes, and guiding clinical decisions. This review aims to explore the current strategies, challenges, and advancements in the adverse drug monitoring of anticancer agents,

highlighting the importance of vigilant pharmacovigilance practices in oncology^[1-2].

List of Anticancer Drugs Anticancer drugs are categorized into various classes based on their Cytotoxic Drugs

mechanism of action. Some of the widely used drugs include ^[1].



NEW DRUG DISCOVERY: HERBAL AND SYNTHETIC ANTICANCER AGENTS^[3].

SYNTHETIC DRUGS

Recent advances in drug discovery and molecular biology have enabled the development of highly targeted synthetic anticancer agents. These agents are designed to interfere with specific pathways or molecular targets associated with cancer growth and progression^[2].

Sotorasib

Target: KRAS G12C mutation

Indication: Non-small cell lung cancer (NSCLC)

Mechanism of Action: Sotorasib is the first-in-class small molecule that specifically inhibits the KRAS G12C mutated protein, a previously "undruggable" oncogene. By locking KRAS in its inactive GDP-bound state, it prevents downstream signaling and halts tumor cell proliferation^[2-3].

Lisocabtagene Maraleucel (Liso-Cel): Type: Chimeric Antigen Receptor (CAR) T-cell therapy

Indication: Relapsed or refractory large B-cell lymphoma

Mechanism of Action: Liso-Cel involves genetically modifying a patient's own T-cells to express CARs that specifically recognize and attack CD19-positive cancer cells. It enhances the immune system's ability to seek and destroy malignant B-cells^[2-4].

Dostarlimab

Target: Programmed Death-1 (PD-1) receptor

Indication: Endometrial cancer (especially mismatch repair-deficient tumors)

Mechanism of Action: Dostarlimab is a humanized monoclonal antibody that blocks PD-1, thereby restoring T-cell activity and promoting immune-mediated destruction of tumor cells. It is particularly effective in tumors with high microsatellite instability (MSI-H)^[5].

HERBAL DRUGS

Natural compounds derived from medicinal plants have attracted significant interest due to their multi-targeted actions, lower toxicity profiles, and ability to modulate several signaling pathways simultaneously^[3-4].

Curcumin

Source: *Curcuma longa* (Turmeric)

Pharmacological Action: Anti-inflammatory, antioxidant, and pro-apoptotic

Mechanism of Action: Curcumin modulates various molecular targets such as NF- κ B, STAT3, and COX-2. It induces apoptosis, inhibits angiogenesis, and suppresses tumor metastasis. Curcumin is also known to enhance the efficacy of conventional chemotherapeutic agents.

Resveratrol

Source: Grapes, berries, and peanuts

Pharmacological Action: Antioxidant and cell cycle modulator

Mechanism of Action: Resveratrol affects multiple pathways including p53, AMPK, and mTOR. It promotes apoptosis, inhibits proliferation, and arrests the cell cycle in the G1/S phase. Its anti-inflammatory properties also help mitigate cancer progression.

Berberine

Source: *Berberis* species (e.g., *Berberis vulgaris*)

Pharmacological Action: Antiproliferative, anti-inflammatory, and antimicrobial

Mechanism of Action: Berberine targets multiple pathways including MAPK, PI3K/Akt, and Wnt/ β -catenin. It causes mitochondrial dysfunction leading to apoptosis and also inhibits metastasis and angiogenesis in various cancer types.

SIDE EFFECTS AND ADVERSE DRUG REACTIONS (ADRS) OF ANTICANCER DRUGS [6-9].

1. Hematological Toxicities

These are among the most common and serious side effects of chemotherapy and some targeted therapies, due to the drugs' effect on rapidly dividing bone marrow cells.

Neutropenia:

A reduction in neutrophils (a type of white blood cell), which increases the risk of infections. Febrile neutropenia is a medical emergency that may require hospitalization and administration of growth factors like G-CSF.

Anemia:

Caused by decreased red blood cell production. Patients may experience fatigue, shortness of breath, and palpitations. Erythropoiesis-stimulating agents or blood transfusions are often used as supportive care.

Thrombocytopenia:

A drop in platelet count, increasing the risk of bleeding and bruising. Severe cases may necessitate platelet transfusions and temporary discontinuation of treatment.

2. Gastrointestinal Toxicities

These occur due to the impact of anticancer drugs on the rapidly proliferating epithelial lining of the gastrointestinal tract.

Nausea and Vomiting:

Common with many chemotherapeutic agents. Managed with antiemetics such as 5-HT₃ receptor antagonists (e.g., ondansetron), NK1 receptor antagonists, and corticosteroids.

Diarrhea:

Can lead to dehydration and electrolyte imbalance. Agents like loperamide are used to manage symptoms. Severe cases may require dose reduction or therapy interruption.

Mucositis:

Inflammation and ulceration of the mucous membranes of the mouth and digestive tract, leading to pain and difficulty eating or swallowing. Preventive oral care and topical treatments are essential.

3. Cardiotoxicity

Anticancer drugs, especially anthracyclines (like doxorubicin) and some targeted therapies, can have detrimental effects on heart function.

Arrhythmias:

Irregular heart rhythms that may be mild or life-threatening. Continuous ECG monitoring may be required during treatment.

Congestive Heart Failure (CHF):

Results from cumulative cardiotoxicity,

especially with high doses of anthracyclines or HER2-targeted therapies (like trastuzumab). Baseline and periodic echocardiograms are recommended.

4. Neurotoxicity

Neurotoxic effects may be reversible or permanent and often affect the quality of life of cancer patients.

Peripheral Neuropathy: A common side effect of drugs like taxanes (paclitaxel) and platinum compounds (cisplatin). It manifests as tingling, numbness, or pain in the hands and feet.

Cognitive Dysfunction ("ChemoBrain"): Refers to problems with memory, attention, and executive function. Often subtle but distressing, and may persist even after treatment ends.

5. Renal and Hepatic Toxicities

The kidney and liver are vital organs for drug metabolism and excretion, and are particularly vulnerable to toxicity.

Nephrotoxicity:

Common with agents like cisplatin and methotrexate. It may lead to acute kidney injury.

ADR

Hydration and dose adjustment based on renal function are crucial.

Hepatotoxicity:

Drugs like methotrexate and tyrosine kinase inhibitors can cause liver damage, reflected by elevated liver enzymes. Monitoring liver function tests (LFTs) is essential.

6. Dermatological Reactions

Skin and hair are often affected due to the rapid turnover of skin cells.

Rashes:

Especially common with targeted therapies like EGFR inhibitors (e.g., erlotinib). Though uncomfortable, rashes may correlate with drug efficacy.

Alopecia:

Hair loss is a common and visible side effect of many chemotherapeutic agents, particularly anthracyclines and alkylating agents. It's usually reversible after treatment ends.

Hypersensitivity Reactions: Includes drug-induced allergic reactions, which can range from mild rashes to severe anaphylaxis. Premedication and desensitization protocols are sometimes used.

Reporting Systems for Anticancer Drugs ^[10-12].

Category	System/Program	Managing Body	Purpose	Data Sources	Key Features	Application in Anticancer Drugs
Spontaneous Reporting Systems (SRS)	FDA MedWatch	U.S. FDA (Food and Drug Administration)	Collect voluntary reports of adverse events	Healthcare professionals, consumers, manufacturers	Online submission, confidential reporting, FDA monitors safety signals	Identifies unexpected side effects of chemotherapy, targeted therapy, immunotherapy
	WHO VigiBase	WHO - Uppsala Monitoring Centre (UMC), Sweden	Global ADR database for pharmacovigilance	National pharmacovigilance centers of WHO member states	Over 30 million reports, standardized WHO-ART coding	Used to identify global safety concerns related to anticancer medications
Active Surveillance Programs	Patient Registries	Regulatory agencies, research institutions	Systematic collection of data on specific patient populations	Longitudinal patient data, disease-specific cohorts	Tracks safety and effectiveness in real-world use	Used in post-approval monitoring of drugs for breast, lung, colorectal cancer etc.
	Electronic Health Records (EHRs)	Hospitals, health networks, government bodies	Continuous monitoring via clinical records	EHR systems, clinical databases	Automated data extraction and signal detection	Detects ADRs in cancer patients undergoing treatment in real-time settings

Post-Marketing Surveillance	Real-World Evidence (RWE) Studies	Pharmaceutical companies, academic institutions	Assess safety and efficacy in uncontrolled settings	Claims data, EHRs, patient surveys	Observational in nature, retrospective or prospective	Helps refine dosing, assess rare ADRs of oncology drugs
Pharmacovigilance Programs	National Cancer Institutes	E.g., NCI (USA), ICMR (India)	Monitor drug safety in national cancer research and care	Clinical trials, population-based studies	Collaborates with drug regulatory authorities	Identifies long-term ADRs, resistance, toxicity patterns in anticancer regimens
	Regulatory Agencies	FDA (USA), EMA (Europe), CDSCO (India), etc.	Oversight of drug safety post-approval	Reports from SRS, active surveillance, studies	Issues safety alerts, updates labels, withdraws harmful drugs	Ensures ongoing risk-benefit analysis of anticancer drugs

Conclusion: Adverse drug monitoring is an essential aspect of oncology treatment. A robust pharmacovigilance system, combined with technological advancements, can mitigate risks, improve patient outcomes, and ensure safer use of anticancer drugs. Future research should focus on integrating AI-driven monitoring tools and personalized medicine approaches for better ADR detection and management.

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