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A Case Series of Different Dermatological Adverse Drug Reactions Attending the Medical Oncology Clinic of a Tertiary Care Hospital Eastern India

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Abstract

Background:

Cutaneous adverse drug reactions (CADRs) are among the most frequent complications of anticancer therapy, affecting the skin, hair, nails, and mucosa. Both conventional cytotoxic chemotherapies and newer targeted agents are associated with a wide spectrum of dermatological toxicities that may impair quality of life and lead to dose modification or treatment discontinuation. Continuous pharmacovigilance is essential for early detection and appropriate management of these reactions as

the safeguard of health by ensuring that the benefits of the use of the anticancer drugs outweigh the risk associated with its use.

Objectives:
To document and analyze the spectrum of dermatological adverse drug reactions in cancer patients receiving chemotherapy and targeted therapies at a tertiary care hospital in Eastern India, and to emphasize the role of pharmacovigilance in improving patient outcomes.

Methods:
This case series included ten patients who developed cutaneous adverse drug reactions while attending the Medical Oncology Clinic of a tertiary care hospital in Kolkata. Clinical details, suspected drugs, temporal association and dermatological manifestations were recorded. Causality assessment of the adverse events was performed based on clinical correlation and temporal relationship with drug administration.

Results:
Among the ten cases, females predominated (n=6). Five patients were above 40 years of age, while five were in the pediatric age group. Frequently implicated drugs included Paclitaxel, Capecitabine, L-asparaginase, Vincristine, Docetaxel, Doxorubicin, Cyclophosphamide, Daunorubicin, and Azacitidine. The observed CADRs comprised nail hyperpigmentation, palmoplantar hyperpigmentation, alopecia, oral ulcers, hyperpigmented plaques, skin nodules, acanthosis. Most reactions were non-life-threatening but contributed to patient distress and potential treatment interruptions.

Conclusion:
Cutaneous adverse drug reactions represent a significant proportion of adverse events associated with anticancer therapy. Early recognition, timely intervention, and close collaboration between oncologists and dermatologists are crucial to minimize morbidity and ensure treatment adherence. Strengthening Pharmacovigilance systems and maintaining robust ADR databases will enhance detection of emerging drug safety signals and optimize cancer patient care.

Keywords: Cutaneous adverse drug reactions, Chemotherapy, Targeted therapy, Pharmacovigilance, Oncology, Eastern India.

Introduction

Drug reactions resulting from chemotherapeutic agents are common and frequently affect the skin. Chemotherapeutics are notorious for their off-target effects and have been implicated in a considerable number of drug- related skin disorders (1). Traditional chemotherapeutic drugs as well as the newer targeted agents are associated with a wide array of cutaneous toxicities. Toxic effects on skin, hair and nails can negatively affect the quality of life and also lead to interruption or discontinuation of these drugs (2). Hyperpigmentation, alopecia, radiation recall, hand-foot syndrome, hypersensitivity, extravasation injuries, and nail dystrophies are among the most common cutaneous reactions. Although most post-chemotherapy side effects are not lifethreatening, they can nonetheless be stressful for the patient, especially if they result in baldness (3).Anticancer therapies can be broadly classified into classic cytotoxic chemotherapies, targeted therapies (eg, small-molecule kinase inhibitors and monoclonal antibodies), immune checkpoint inhibitors and hormonal (endocrine) therapies. Each class is associated with a distinct spectrum of cutaneous adverse effects(4).Cutaneous changes are among the most common side effects from treatment with particular targeted chemotherapeutic agents, especially those that target the epidermal growth factor receptor and small molecule multikinase inhibitors(5). Most of the time, these patients are receiving a multitude of agents and have profound immunosuppression. These factors may alter the more common manifestations of cutaneous eruptions (6). Hence, the assessment and management of dermatological adverse effects of anti-cancer therapy have become a significant part of the care of patients with cancer and require proper and close collaboration between the dermatologists and the oncologists (7). A study was undertaken on a large cohort of Greek patients receiving treatment with several chemotherapeutic agents that showed the dermatologists' role is crucial in effectively managing those reactions and preventing antineoplastic drug dose adjustments or discontinuation of treatment (8).

The Pharmacovigilance Programme of India (PvPI) is an Indian government organization which identifies and responds to drug safety problems. Its activities include receiving reports of adverse drug events and taking necessary action to remedy problems. The Central Drugs Standard Control Organisation established the program in July 2010 with All India Institute of Medical Sciences, New Delhi as the National Coordination Centre, which later shifted to Indian Pharmacopoeia Commission in Ghaziabad on 15 April 2011. The Pharmacovigilance Programme seeks to encourage a culture and social expectation of reporting drug problems (9).One of the successes of the program was detecting adverse effects of people in India using carbamazepine. While this drug is safer among people native to the Europe, people of South Asia have different genetics and are more likely to experience problems when using it. Other countries could not have been able to detect this problem, and the Pharmacovigilance Programme's detection of it was a success story. (10)

The purpose of our study was to document different types of adverse reactions among cancer patients receiving chemotherapy and targeted therapies in a tertiary care hospital in Kolkata. As evidenced by the aforementioned references of cutaneous ADRs of chemotherapeutic agents are a vastly studied area and with the advent of newer agents, newer reactions have been on the rise.

Thus, the process of documenting these reactions and investigating their correlation with the drugs hold immense importance. This study was undertaken as a part of Pharmacovigilance enhancement to improve our understanding and in future to improve the experience of patients on medication.

CASES:

Case 1 (ID NO-MCHK/RG2500245519)

A 55-year-old woman presented with blackening of nails. She was a known case of breast carcinoma for which she was operated earlier in the year 2025. She was receiving Paclitaxel 200mg injection. (fig)

Fig:1

Fig: 2

Case 2 (ID NO-MCHK/RG2500515659)

A 55-year-old woman presented with blackening of palms and soles which started around 24th December, ’25. She was a known case of gall bladder cancer for which she was receiving tablet capecitabine 500mg since the last one year. (fig2)

Case 3 (ID NO-MCHK/RG2501007075)

A 40 months old male child presented with blackish spots over arm and forearm which appeared around 2nd January '26 after a round of chemotherapy. He was a known case of blood cancer for which he was receiving L-asparaginase 5000iu Intramuscular and Vincristine 0.75mg intravenous. (fig3)

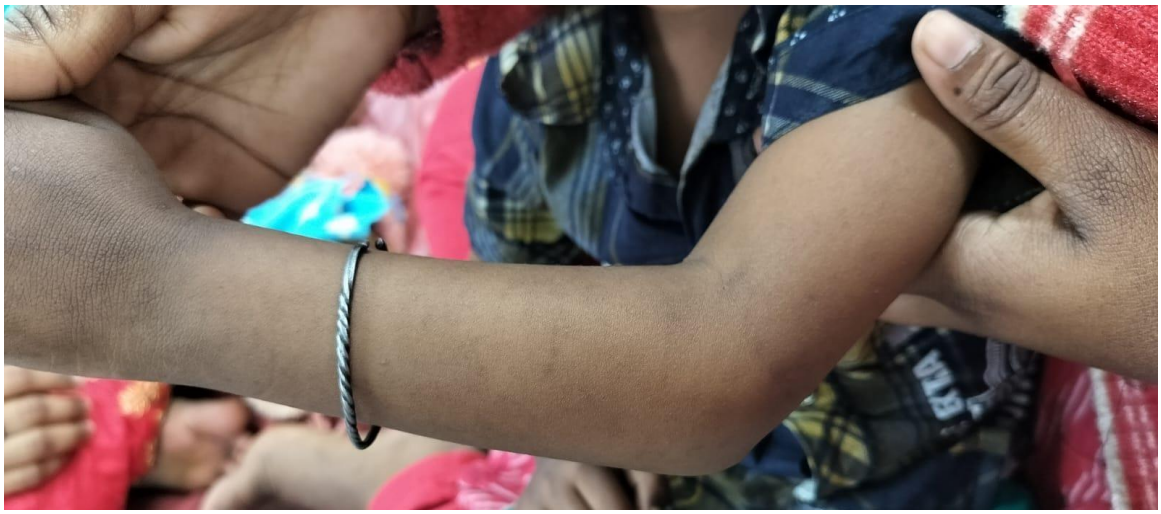

Fig:3

Case 4 (ID NO-MCHK/RG2501069338)

A 42 months old female child presented with alopecia. She was a known case of blood cancer diagnosed in december'25 for which was receiving vincristine, L-asparaginase, Doxorubicin. (fig4)

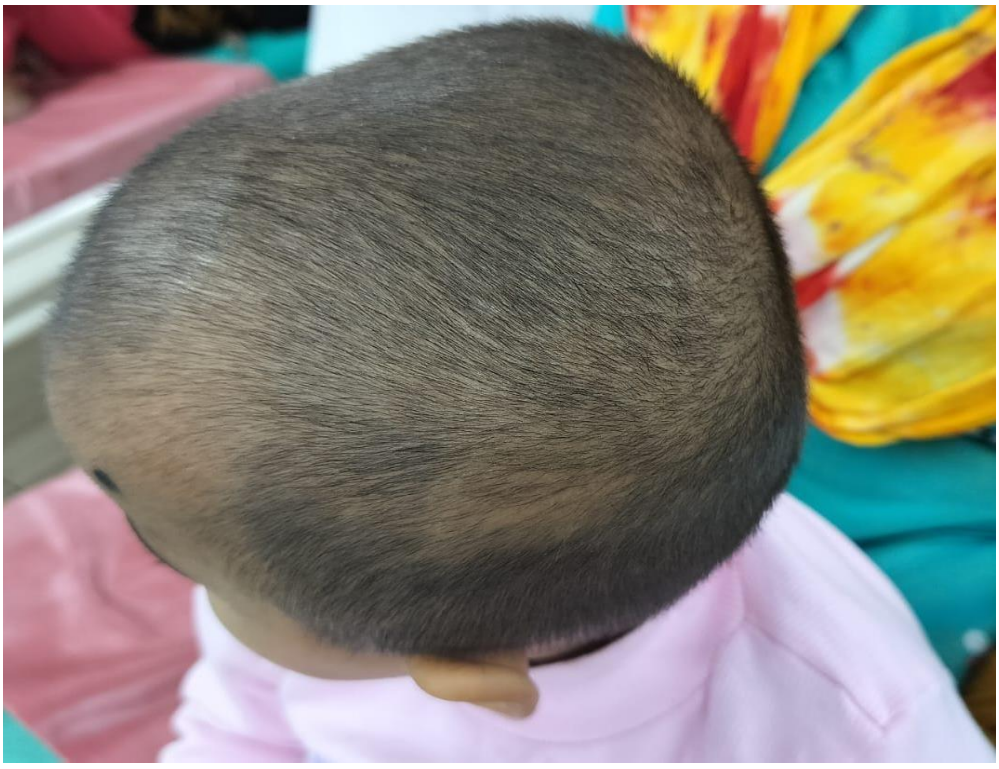

Fig:4

Case 5 (ID NO- MCHK/RG2500897154)

A 5-year-old male child presented with skin nodules over the zygomatic area. He was a known case of blood cancer for which he was receiving injection L-Asparaginase 5000iu intramuscular. (fig5)

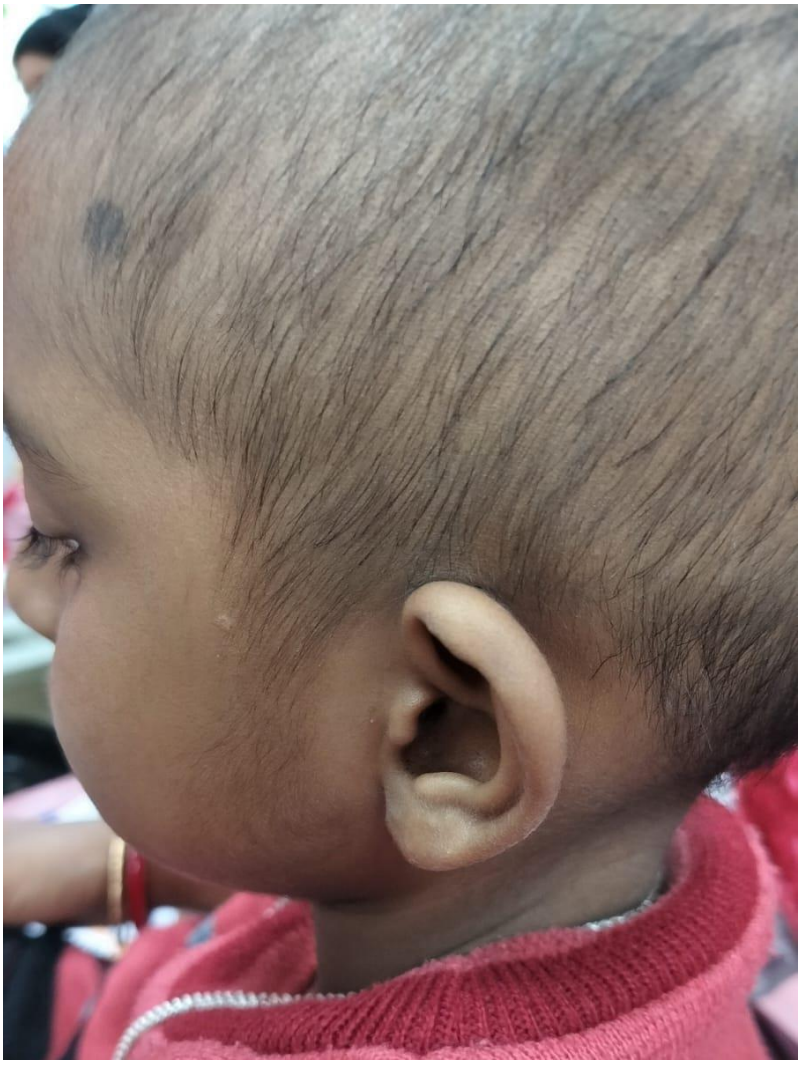

Fig: 5

Case 6 (ID NO-MCHK/RO2500708855)

A 55-year-old female presented with acanthosis and drying and wrinkling of skin over forearm. She was a known case of Invasive carcinoma of left breast for which she was receiving injection Docetaxel 100mg/500ml NS/2hrs. (fig 6,7)

Fig: 6

Fig:7

Case 7 (ID NO-MCHK/RG2300230583)

A 42-year-old woman presented with hyperpigmentation along eyebrows and on cheeks. She was a known case of relapsed carcinoma ovary for which she was receiving injection Paclitaxel 260g/500ml NS/3hrs. (fig8)

Fig:8

Case 8 (ID NO-MCHK/RG2600031862)

A 16 year old girl presented with oral ulcer. She was a known case of Acute Myeloid Leukemia for which she was receiving Azacitadine 600mg and 700mg in two doses one month apart.

Case 9 (MCHK/RG2500699491)

A45 year old female presented with well demarcated, hyperpigmented and thickened plaques with a reticulated texture on the dorsum of hands and anterior surface of forearms. She is a known case of carcinoma of right breast for which she was receiving injection Donorubicin 70mg and injection cyclophosphamide 700mg. (fig 9,10)

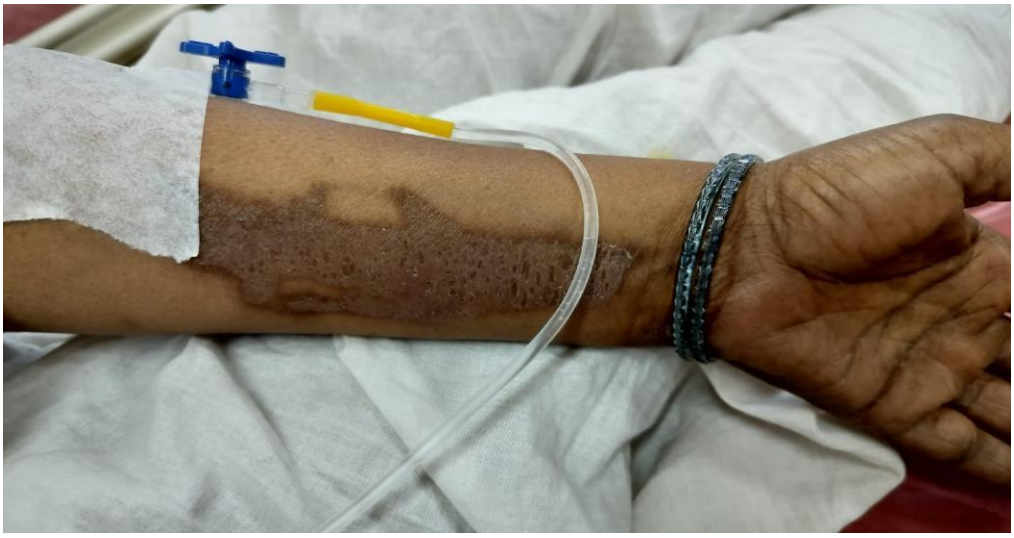

Fig:9

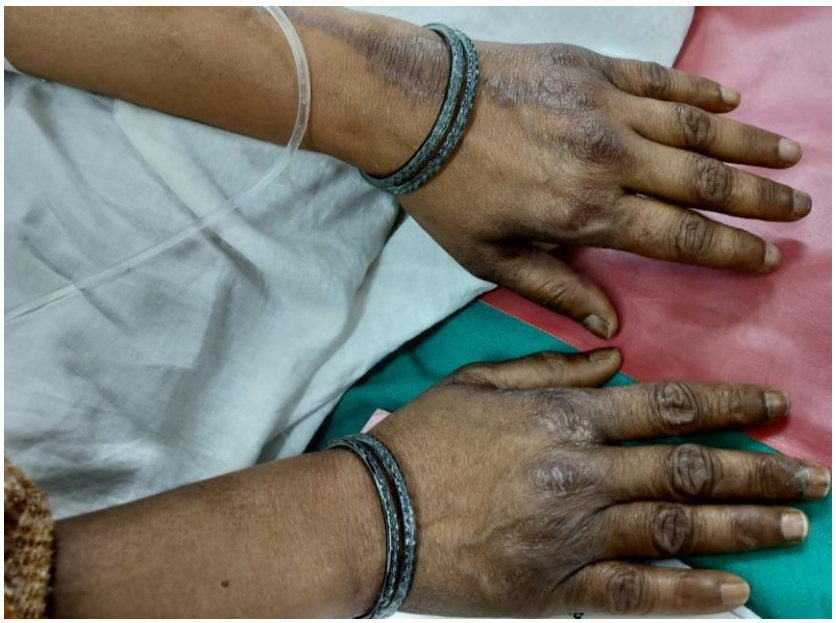

Fig:10

Case 10 (ID NO-MCHK/RG2500747692)

A 45-year-old female presented with transverse black lines on fingernails and blackening of nailbed. She was a known case of carcinoma of left breast for which she was receiving Docetaxel, Doxorubicin and Cyclophosphamide. (fig 11)

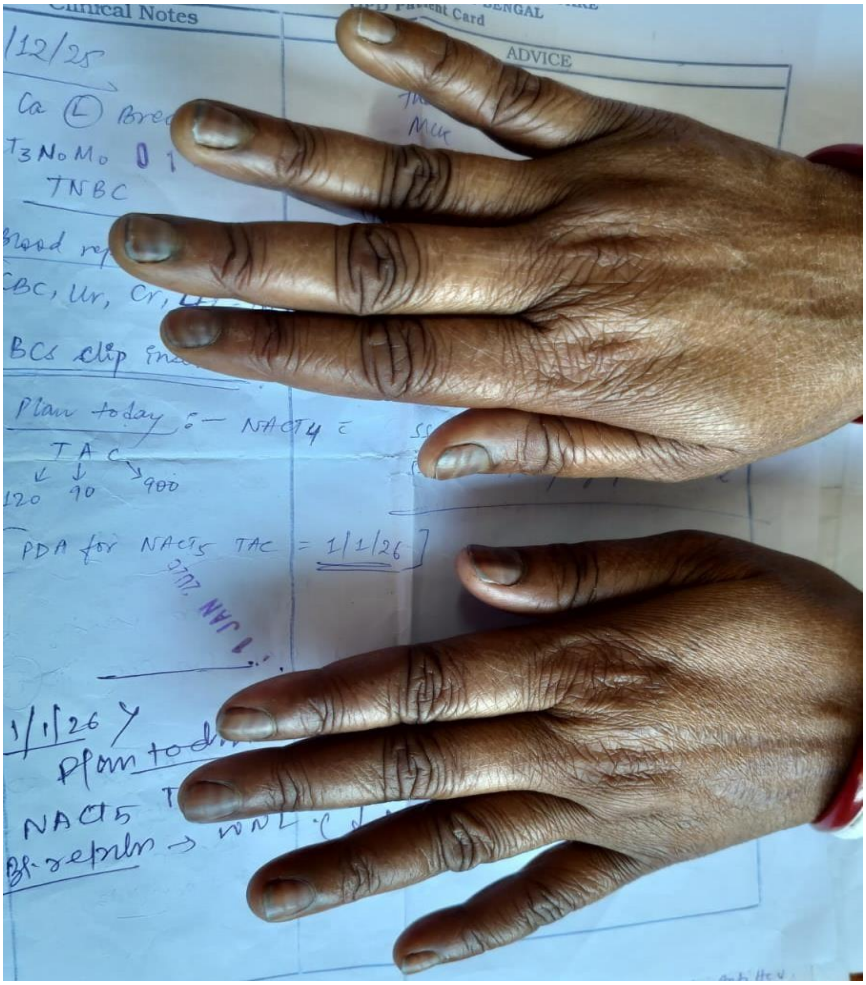

Fig: 11

Discussion

Out of the total 10 cases of CADRs, females were more in number compared to males. 5 cases were above 40 years of age, 5cases were in paediatric age group. We collected the data from patients who attended medical oncology clinic for follow up or receiving routine chemotherapy. It can be inferred that the adverse effects were a result of the drugs received by the patients at clinic since these manifestations appeared after starting therapy. Therefore, as per literature, most common adverse reactions were alopecia and skin hyperpigmentation. Risk factors for adverse drug reactions (ADRs) to chemotherapy are frequently associated with female sex, age over 60, presence of comorbidities, and polypharmacy (11). High-risk factors include increased number of chemotherapy cycles, specific drug combinations (e.g., platinum compounds), and lower body surface area (12). However, adversities like the Stevens–Johnson syndrome, Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) Syndrome, Hand-Foot Syndrome (Palmar-Plantar Erythrodysesthesia), Severe Immune-Related Dermatologic Toxicity, Erythema Multiforme, may result in the high mortality; such cases, therefore, are expected to be deciphered and dealt with cautiously (13). The exact algorithm may be engineered with respect to a general medical history, which would include a drug exposure (dosage, date started, duration, and interruptions in use), use of proprietary remedies, drug use and onset of reaction, previous adverse drug reactions (ADRs), re-exposure to a drug and exacerbation of eruption, improvement after a decrease in dosage, or discontinuation of

drug. Also, important are pathologies that may cause the eruption or act as cofactors, previous family or personal history of skin disease, family history of hypersensitivities, or environmental/ occupational exposure to other substances that may be the etiologic agents (e.g., sunlight). This should be coupled with investigations, such as skin biopsies, hemograms which generally show hyperkeratosis, parakeratosis, eosinophilic infiltration, and perivascular inflammation (14). Other diagnostic tests include patch test applicable especially in cases of maculopapular rash, Fixed Drug Eruption (FDE), and DRESS. Lymphocyte Transformation Test (LTT): An *in vitro* test used to detect drug-specific T-cells. To assess systemic involvement, particularly in severe cutaneous adverse reactions (SCARs) like DRESS:

- Complete Hemogram: To detect eosinophilia (common in DRESS), neutropenia, or atypical lymphocytes.
- Liver Function Tests (LFTs): To monitor for elevated transaminases, which may indicate hepatic involvement.
- Renal Function Tests: To check for creatinine elevation, particularly if suspecting acute renal failure or DRESS.
- Microbiological Studies: Nail clippings for KOH, nail fungal cultures, and swab cultures are necessary to rule out infections (e.g., candida) in cases of paronychia (15).

Conclusion

Management of malignancies with both traditional and novel targeted chemotherapeutic drugs results in numerous mucocutaneous side effects in the patients. There is a need for development of an improved system for classification of these cutaneous adverse events, with greater reflection upon their presentation and severity. Their supreme knowledge is important in management as these side effects are the cause of morbidity and distress to patients. Prophylactic therapies and early detection and intervention with close monitoring of these untoward events are vital to ensure patient compliance and maximize clinical benefit from optimal dosing. Intervening and treating these adverse effects at the right time and also taking preventive measures definitely will help in improving the quality of the health care system.In the present article we found that cutaneous adverse drug reactions are the commonest ADRs (30−45%) and are responsible for 2% hospital admissions. It most commonly occurs in the 45−65 years age-group, but it can occur in the younger age-group as well. The most common drugs include Daunorubicin, Paclitaxel, Capecitabine, L-asparaginase, Cyclophosphamide. Severe CADRs, although rare, have the highest risk of morbidity and mortality. Therefore, it is extremely important to identify a CADR and the causative drug. These robust databases will play a vital role in analysing and detecting new signals and updating the status of existing information of chemotherapeutic drug profile through PvPI. The larger is the data for a drug, the higher for a drug will be likelihood saying with confidence that the conclusions being drawn from that data are significant.

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