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Original Research Article

Pharmacovigilance in clinical practice: a retrospective observational study of spontaneously reported adverse drug reactions among patients at a tertiary care hospital

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ABSTRACT

Background: Adverse drug reactions continue to cause problems in day-to-day practice. They increase hospital stay, add to treatment cost, and sometimes can lead to significant morbidity. Pharmacovigilance helps in detecting, assessing, and preventing these reactions. In India, spontaneous reporting through VigiFlow under the Pharmacovigilance Programme of India (PvPI) is the main source of real-world safety data. We analysed all complete ADR reports received at our centre during the year 2023.

Methods: A total of 436 complete spontaneous ADR reports containing 907 reactions were reviewed. Reactions were coded using MedDRA system organ classes. Suspected drugs were coded using the WHO Drug Dictionary, and causality was assessed by the WHO-UMC scale. Only frequencies and percentages were calculated.

Results: Most reports came from adults (282, 64.7%) and elderly patients (123, 28.2%). Females accounted for 295 reports (67.7%). Paclitaxel was the most commonly suspected drug (66 reports), followed by cisplatin (30) and carboplatin (28). The intravenous route was responsible for 292 reports (67%). Gastrointestinal disorders formed the largest group (362 reactions, 39.9%), followed by nervous system (161, 17.8%) and skin disorders (152, 16.8%). The majority of the reactions were non-serious (95.6%) and had recovered (95.4%).

Conclusions: Adult female patients and anticancer drugs dominated the reports. Gastrointestinal, neurological and skin reactions were most frequent. Although most reactions were non-serious and recovered, the serious cases still highlight the need for continuous monitoring.

Keywords: Pharmacovigilance, Adverse drug reactions, Spontaneous reporting, VigiFlow, PvPI, WHO-UMC causality, MedDRA, Drug safety

INTRODUCTION

Medicines are used to prevent, diagnose and treat disease, but they can also cause harm. The World Health Organization defines an adverse drug reaction (ADR) as a noxious and unintended response to a drug that occurs at doses normally used in humans. This classical definition concerns reactions occurring at normal therapeutic doses.¹

Pharmacovigilance is the science and activities concerned with the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.¹ Pre-marketing clinical trials are conducted in selected patients under controlled conditions and for a limited duration. After marketing, a drug is used in a much broader population, including elderly patients, those with multiple comorbidities, renal or hepatic impairment, and

those receiving several medicines concurrently. Uncommon reactions are therefore often recognised only after wider use.¹

In India, spontaneous ADR reports are collected under the Pharmacovigilance Programme of India (PvPI) and entered into VigiFlow.² Regional Monitoring Centres and ADR Monitoring Centres receive the reports, code the reactions and assess causality.³

Spontaneous reporting is limited by under-reporting, yet it remains a practical source of information on the drugs and organ systems involved in routine practice.⁴ The present study examined all complete ADR reports submitted from our centre between 1 January and 31 December 2023. In all, 436 reports describing 907 reactions were analysed with respect to age, sex, suspected drugs, route of administration, system organ class, seriousness and outcome.

The aim was to describe the pattern of ADRs reported to VigiFlow in terms of patient characteristics, suspected drugs and therapeutic groups, routes of administration, system organ class, seriousness and outcomes, and to identify reporting patterns that may help improve recognition and reporting of ADRs.

METHODS

This was a retrospective descriptive study of spontaneous ADR reports submitted by the Regional Monitoring Centre, Loni, to VigiFlow under the Pharmacovigilance Programme of India. All complete reports received between 1 January and 31 December 2023 were included. Incomplete reports were excluded. The final dataset comprised 436 reports describing 907 reactions.

Causality was assessed using the WHO–UMC causality assessment scale. Reactions were coded by MedDRA system organ class, and suspected drugs were coded using the WHO Drug Dictionary. Age, sex, suspected drug, route of administration, system organ class, seriousness and outcome were extracted and summarised as frequencies and percentages. No inferential statistics were applied.

The study used anonymised secondary data and involved no intervention or change in patient care. Patient identifiers were not recorded. Institutional permission to use the data was obtained from the Regional Monitoring Centre. Formal ethics committee approval was not required. Reporting followed the STROBE checklist where applicable to a retrospective descriptive analysis.

RESULTS

In all, 436 reports describing 907 reactions were analysed. Findings are presented by patient characteristics, suspected drugs, route of administration, system organ class, seriousness and outcome.

Patient characteristics

Most reports concerned adults and elderly patients (Figure 1). Adults accounted for 282 reports (64.7%) and elderly patients for 123 (28.2%). Adolescents contributed 19 reports (4.4%), children 10 (2.3%) and infants 2 (0.5%). No neonatal reports were received. Females accounted for 295 reports (67.7%) and males for 141 (32.3%) (Figure 2).

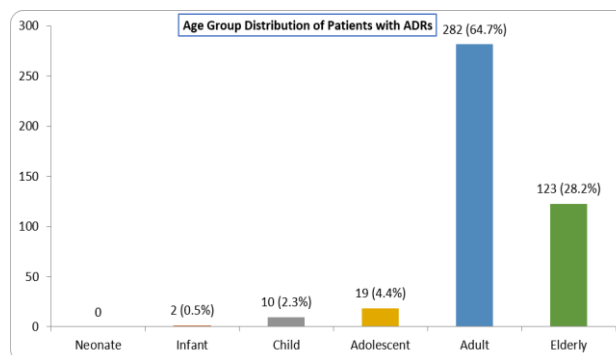


Figure 1: The X-axis represents the age groups of patients, while the Y-axis represents the number of ADR reports. Adults accounted for the highest proportion of ADR reports (64.7%), followed by the elderly (28.2%), adolescents (4.4%), children (2.3%), and infants (0.5%).

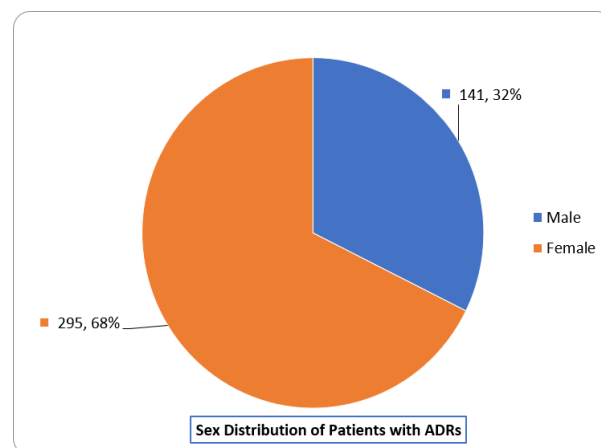


Figure 2: Sex distribution of patients with ADRs (female is 68% and male 32%).

Suspected drugs and route of administration

Anticancer drugs and antibiotics were the most frequently suspected agents. Among the ten most commonly implicated drugs (Figure 3), paclitaxel was reported in 66 cases, cisplatin in 30 and carboplatin in 28. Aspirin was implicated in 14 reports, doxorubicin in 13, ceftriaxone in 12, cyclophosphamide in 11, and mannitol and metronidazole in 10 each. Amoxicillin–clavulanic acid was suspected in 9 reports.

The next tier of drugs is shown in Table 1. Cefuroxime, doxycycline, pembrolizumab and lorazepam were each

implicated in 6 reports. Ferrous ascorbate with folic acid and tramadol were each implicated in 5, and pantoprazole, cefixime and paracetamol in 4 each. A large number of other drugs appeared in only one or two reports. Intravenous administration accounted for 292 reports (67.0%), oral administration for 141 (32.3%), and subcutaneous administration for 3 (0.7%) (Figure 4).

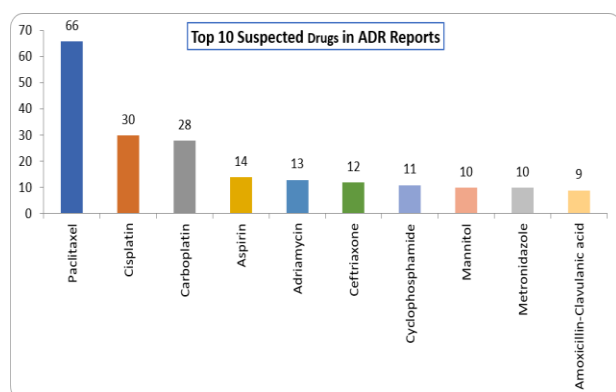


Figure 3: Top 10 suspected drugs in ADR reports where, the X-axis represents the suspected drugs, while the Y-axis represents the number of ADR reports. Paclitaxel was the most frequently suspected drug, with (66) reports, followed by cisplatin (30), carboplatin (28), aspirin (14), doxorubicin (13), ceftriaxone (12), cyclophosphamide (11), mannitol (10), metronidazole (10), and amoxicillin-clavulanic acid (9).

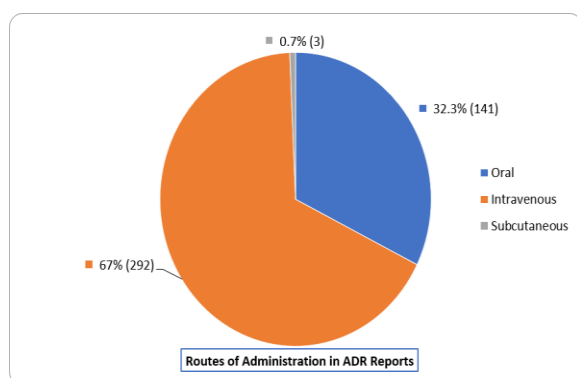


Figure 4: Routes of administration in ADR reports (Intravenous 67.0%, Oral 32.3%, Subcutaneous 0.7%).

System organ class

Gastrointestinal disorders were the most common system organ class, with 362 reactions (39.9%) (Figure 5). Nervous system disorders accounted for 161 reactions (17.8%) and skin and subcutaneous tissue disorders for 152 (16.8%). General disorders and administration-site conditions contributed 76 reactions (8.4%), musculoskeletal and connective tissue disorders 57 (6.3%), and metabolism and nutrition disorders 33 (3.6%). Respiratory disorders accounted for 17 reactions (1.9%),

vascular disorders for 10 (1.1%) and the remaining system organ classes for 39 (4.3%).

Table 1: Additional suspected drugs and ADR counts (including Cefuroxime, Doxycycline, Pembrolizumab, Lorazepam and others).

Drug	ADR Count
Cefuroxime	6
Doxycycline	6
Pembrolizumab	6
Lorazepam	6
Ferrous ascorbate + Folic acid	5
Tramadol	5
Ceftriaxone	5
Pantoprazole	4
Cefixime	4
Dolo	4
Others	Many

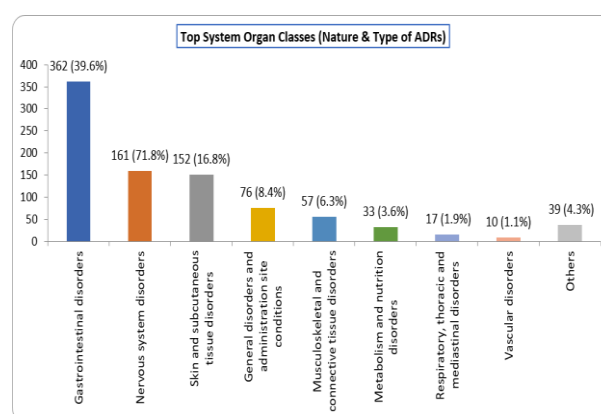


Figure 5: The X-axis represents the System Organ Class (SOC), while the Y-axis represents the Number of ADR Reports. The gastrointestinal system accounted for the highest proportion of ADRs (39.6%), followed by the nervous system (17.8%) and skin and subcutaneous tissue disorders (16.8%), with the remaining reports distributed among other organ classes.

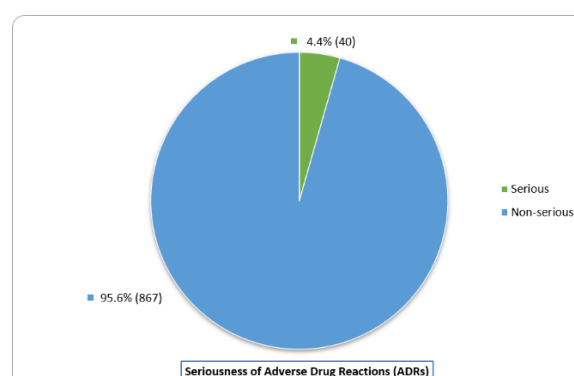


Figure 6: Seriousness distribution of ADRs (non-serious 95.6%, Serious 4.4%).

Seriousness

Most reactions were non-serious (867, 95.6%). Forty reactions (4.4%) met seriousness criteria (Figure 6).

Outcome

Recovery or resolution was recorded for 865 reactions (95.4%). Forty reactions (4.4%) had not recovered at the time of reporting, and the outcome was unknown for 2 (0.2%).

DISCUSSION

This one-year analysis of spontaneous reports from the Regional Monitoring Centre, Loni, included 436 reports and 907 reactions. Several patients had more than one reaction recorded.

Gupta et al in a one-year review of reports from a regional pharmacovigilance centre in North India, found that adults accounted for 78% of suspected adverse drug reactions (ADRs).⁵ In the present study, adults contributed 64.7% of reports and elderly patients 28.2%, so that these two groups together made up more than 90% of cases. Greater medication exposure and healthcare use may contribute to this reporting pattern, although these factors were not measured in the present study. In the elderly, reduced renal and hepatic function, changes in body composition, and concurrent use of several drugs further increase the chance of a reaction.⁶ These age groups therefore need closer monitoring.

Londhe and Dhande analysed 255 ADRs collected in the first year of an adverse drug reaction monitoring centre in Pune.⁷ Women accounted for 67.7% of reports in the present series and men for 32.3%. This difference cannot be read as a higher risk in women. Disease pattern, drugs prescribed, body composition, and healthcare-seeking behaviour can all affect both the occurrence of reactions and the likelihood that they are reported. Evidence of sex differences varies by drug and adverse reaction.⁸ Spontaneous reports can describe the reporting pattern, not incidence.

Kumar et al in a study of reactions to anticancer drugs at a teaching hospital in North India, found taxanes in 24.39% and platinum compounds in 17.07% of reports, with a female predominance.⁹ In the present study, anticancer drugs and antibiotics were the most commonly implicated agents. Paclitaxel led the list, followed by cisplatin and carboplatin. These drugs have well-recognised toxicities and are usually given under observation, which may increase the chance of a report. Both taxanes and platinum agents can cause hypersensitivity reactions, although their timing and underlying mechanisms differ. Taxane reactions often occur during the first or second exposure, whereas platinum reactions commonly develop after repeated treatment cycles.¹⁰

Among antibiotics, ceftriaxone, metronidazole, cefuroxime, doxycycline, cefixime, and amoxicillin-clavulanic acid was reported most often. Gupta et al also reported antibiotics to be the most frequently implicated class, accounting for 36% of reports.⁵ These agents are widely used in hospital practice. Antibiotic-associated disruption of the gut microbiota can contribute to gastrointestinal adverse effects.¹¹ Rational use and continued monitoring remain necessary. Intravenous administration accounted for 67% of reports. This is consistent with the use of injectable anticancer drugs and parenteral antibiotics in a tertiary hospital. Reactions are also easier to notice when the patient is observed during the infusion. Dilution, infusion rate, previous reaction history, and monitoring during administration remain practical points of care.¹²

Kini et al in an analysis of 2,035 spontaneous reports from Belagavi, found gastrointestinal disorders to be the most common system organ class (23.91%), with adults (60.54%) and the elderly (24.67%) most often affected.¹³ Gastrointestinal disorders formed the largest group in the present study (39.9%). Anticancer drugs, antibiotics, analgesics, and iron preparations frequently cause nausea, vomiting, diarrhoea, and abdominal discomfort. Most of these reactions are non-serious, but they can affect intake and adherence. Counselling, antiemetic cover where indicated, hydration, and early symptomatic treatment are the usual measures.¹⁴

Nervous system disorders accounted for 17.8% of reactions and included dizziness, headache, sedation, and neuropathy. Neuropathy is of particular concern in patients receiving anticancer drugs, because it can reduce function and may lead to dose reduction or withdrawal.¹⁵ Skin and subcutaneous tissue disorders made up 16.8%. Most cutaneous reactions are mild, but a spreading rash, mucosal involvement, or systemic features need prompt review.¹⁶

Most reactions (95.6%) were non-serious. Reporting of these events is still useful, because they can affect adherence and the patient's willingness to continue treatment. The 4.4% that met seriousness criteria need separate review for high-risk drugs and preventable factors. Srinivasan et al. (2025), in a retrospective analysis of 6,007 reports from JIPMER, found that antineoplastic drugs and antimicrobials were the most commonly implicated classes, and 19.2% of reports were serious.¹⁷ Differences in case mix, reporting practices and the unit of analysis limit direct comparison with the present reaction-level proportion. Recovery or resolution was recorded for 95.4% of reactions. A smaller number were still ongoing (4.4%) or had an unknown outcome (0.2%). Follow-up and complete recording of outcome would improve the value of later reports.¹⁸

Taken together, the findings support the work of the Pharmacovigilance Programme of India and its regional centres. Adult and elderly patients, anticancer drugs, antibiotics and intravenous therapy accounted for most of

the reporting load. Allergy history, infusion practice, complete documentation and feedback of analysed reports to clinicians are practical measures that may improve safety at this centre.^{2,4,12,18} Spontaneous reporting cannot estimate incidence, and under-reporting remains its main limitation.⁴ It does, however, show which medicines and organ systems are being reported in routine practice.

CONCLUSION

This retrospective analysis of 436 spontaneous reports describing 907 reactions, received at the Regional Monitoring Centre, Loni, in 2023, showed that most reports concerned adults, elderly patients and women. Anticancer drugs and antibiotics were the agents most often suspected. The intravenous route accounted for the largest share of reports, and gastrointestinal disorders were the most common system organ class. Most reactions were non-serious and had recovered or resolved at the time of reporting. The serious and unresolved cases, though fewer, indicate the need for continued monitoring, complete outcome documentation and feedback of analysed reports to clinicians. Periodic review of spontaneous reports remains useful for rational prescribing and for identifying drugs and patient groups that need closer observation.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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