

Prevalence of Serious Adverse Drug Reactions: Is India Vigilant Enough?

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ABSTRACT

Background: Serious Adverse Drug Reactions (sADRs) are one of the important causes of morbidity and mortality. In India, pharmacovigilance practices are evolving but comprehensive regional data on sADRs is lacking. Understanding how sADR prevalence in India compares with global patterns is essential to improve patient safety. **Aims and Objectives:** This study aimed to compare the prevalence of selected sADRs associated with commonly used drugs in India and other countries, and to examine the contributing factors. **Materials and Methods:** A list of drugs was compiled using a generic drug index. A PubMed search was conducted to estimate the prevalence of sADRs in the Indian patient population. Additional data were obtained from Indian Pharmacopoeia Commission publications and FAERS (FDA Adverse Event Reporting System) database. Data was extracted and tabulated for comparison. **Results:** Twenty-two studies (including FAERS data) met the inclusion criteria, and ten drugs with their sADRs were selected for comparison. Indian patients exhibited a higher prevalence of several sADRs- for example, Linezolid-induced neuropathy (93.3% in India vs. 1.6% globally) and Non Steroidal Anti-Inflammatory Drugs (NSAID)-induced nephrotoxicity (27.88% vs. 13%). Lamivudine-induced hearing loss and Pioglitazone-induced bladder cancer showed significantly lower rates of sADRs in Indian studies. **Conclusion:** Marked differences in the prevalence of sADRs between India and other countries highlight the need for sensitising physicians to these differences and associated implications in prescribing and patient management.

Keywords: Adverse Drug Reaction, Adverse Effect, India, Pharmacovigilance, Prevalence.

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INTRODUCTION

Adverse Drug Reactions (ADRs) are one of the significant causes of morbidity and mortality. Serious adverse drug reactions (sADRs) warrant particular attention in both clinical care and research settings. Robust pharmacovigilance systems and reliable sADR reporting mechanisms are essential components of clinical research and healthcare delivery. A meta-analysis covering 18,818 hospitalised patients globally estimated a pooled ADR incidence of 16.88% (Miguel *et al.*, 2012), while another involving over 1.5 million patients in primary care settings reported a prevalence of 8.32% (Insani *et al.*, 2021). In an Indian study, ADRs accounted for 6.89% of all admissions (Patel *et al.*, 2007). However, ADR prevalence varies widely across settings and geographies.

In India, the Pharmacovigilance Programme of India (PvPI) has brought ADR reporting and analysis in line with global standards. However, the data lacks an all-inclusive analysis to understand

the prevalence of ADRs in the genetically and ethnically diverse Indian population for the majority of drugs. Moreover, open access to this data is not available for research in this domain. Thus, global comparisons are drawn with published literature in this context.

The aims and objectives of our study were

- To compile and analyse the prevalence and patterns of serious ADRs in India with those in other countries for commonly prescribed drugs.
- To explore systemic and biological factors contributing to these variations.

METHODOLOGY

Study design

This study aimed at comparing the prevalence of sADRs associated with commonly used drugs in India with international data by ecological study design.

Ethical statement

As this study relies on previously published literature and publicly available data from the FAERS database, ethical approval was not required.



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Search strategy

A list of systemically used oral drugs was compiled from previously published literature that reported ADRs in the Indian population, excluding fixed drug combinations, ayurvedic preparations and nutraceuticals. PubMed search was conducted to identify all studies published between 1 January 1994 and 1 January 2024 using keywords 'Drug', 'Adverse effect', 'ADR', 'Adverse Reaction', 'Adverse Drug Reaction', 'Prevalence' and 'India' in various combinations for selected drugs. Animal studies, case reports, clinical trials, non peer-reviewed publications, studies not in English and those with less than 100 participants were excluded. Additional studies were taken from Indian Pharmacopoeia Commission (IPC) reports and publications. Prospective and retrospective cohort studies, cross-sectional and case-control studies were included. Once the drug, sADR and prevalence in Indian patients were identified, at least 2 international studies were searched using similar methodology (excluding 'India' as a search term) for estimating the prevalence in other countries. If the prevalence of this sADR was comparable (less than 5% difference), it was excluded. Where multiple eligible studies existed, matching of study design and methodology was done between Indian and international literature and the study with the most robust reporting was preferred. Any discrepancies during study selection and data extraction were resolved through consensus and discussion among all authors. In addition, FDA Adverse Event Reporting System (FAERS) data was also extracted for each selected drug and sADR.

Statistical Analysis

Data was compiled in MS Excel sheet, and prevalence rates were compared between Indian and international studies to highlight the differences. The FAERS data was reported as Reporting Odds Ratio (ROR), which is a measure of disproportionality in pharmacovigilance used to identify potential drug-related adverse events. An ROR more than 1 indicates that the adverse event is reported more frequently in association with the target drug than expected, suggesting a potential safety signal.

RESULTS

Study selection

An initial PubMed search was conducted to identify the availability of Indian data as per inclusion criteria. Using combinations of keywords (Figure 1), 3265 Indian records were obtained. Additionally, 48 records were obtained using IPC reports and PvPI publications to further substantiate the selection of drugs and sADRs. Using 'FAERS' as a search term, relevant studies were also identified. Animal studies, case reports, clinical trials, letters, duplicates, and other articles that were not relevant were excluded. 27 studies were excluded on screening as per the inclusion criteria and comparison of search methodology. After

final assessment and discussion, 22 studies including 10 drugs with their sADRs were included (Figure 1, Table 1).

Study findings

The majority of Indian studies reported a higher prevalence of sADRs compared to global counterparts (Table 1). Ethambutol-induced optic neuropathy, for example, was reported in up to 14% of Indian patients, a striking contrast to the 2% prevalence observed among the patients in the United States. Linezolid-associated peripheral neuropathy was observed in 93.3% of Indian patients compared to just 1.6% in international studies. A similar trend was noted for nifedipine, a Calcium Channel Blocker (CCB) that led to gingival hypertrophy in 75% of Indian patients. The prevalence reported in patients in England was only 6.3%. NSAIDs (Non-Steroidal Anti-Inflammatory Drugs) resulted in renal complications in 27.88% of Indian patients, compared to 13% in American populations. In case of certain drugs, reported rates of ADRs were lower in India compared to other countries. For example, Lamivudine-induced hearing loss was lower in India at 3%, as opposed to 35.8% in a Brazilian cohort, and Pioglitazone was associated with bladder cancer in 2% of Indian patients compared to a significantly higher rate (53%) reported elsewhere. FAERS data (Table 2) was found for 6 drugs, all having ROR more than one. The lowest reported ROR (2.45) was that of NSAID-induced renal injury.

DISCUSSION

Our findings highlight marked differences in drug safety profiles and a higher prevalence of serious ADRs among Indian patients for many drugs.

Carbamazepine and Phenytoin have been implicated in drug-induced SJS and TEN in 18.25% (Agarwal *et al.*, 2014) and 13.37% (Patel *et al.*, 2013) of Indian patients, respectively, compared to significantly lower rates in European patients (Gidal, 2011; Rodríguez-Martín S *et al.*, 2019). HLA-B1502 has been shown to present carbamazepine directly to cytotoxic T cells without prior antigen processing, triggering an immune response. National PvPI data indicate that 2% of suspected bladder cancer cases were due to Pioglitazone (Bhushan *et al.*, 2019). In contrast, U.S. reports show 53% of pioglitazone-related individual case safety reports involving suspected bladder cancer. Authors postulate that differences in the genetic metabolism, cigarette smoking could influence this varied prevalence. An Indian study across 8 tertiary centres reported a prevalence of 27.88% for NSAID-induced renal complications (Chatterjee S *et al.*, 2015). A study in the US population, with more than 12,000 participants, demonstrated 13% of patients developing Chronic Kidney Disease (CKD) with use of NSAIDs (Platinga L *et al.*, 2011). NSAIDs-mediated inhibition of prostaglandin synthesis can impair renal blood flow, culminating in kidney injury. Gum hyperplasia induced by Nifedipine and Amlodipine was reported

Table 1: Comparison of prevalence of ADRs of drugs in India and other countries.

Drug	ADR	Prevalence (Indian studies) (n=9) (Cao <i>et al.</i> , 2022; Chatterjee <i>et al.</i> , 2015; Gidal, 2011; Gopal <i>et al.</i> , 2015; Insani <i>et al.</i> , 2021; Miguel <i>et al.</i> , 2012; Patel <i>et al.</i> , 2007; Piccinni <i>et al.</i> , 2011; Prisant <i>et al.</i> , 2002)	Prevalence (other countries) (n=8) (Dash <i>et al.</i> , 2015; Dosemane <i>et al.</i> , 2018; Gidal, 2011; Hatahira <i>et al.</i> , 2017; Kumar <i>et al.</i> , 2024; Mishra <i>et al.</i> , 2024; Patel <i>et al.</i> , 2013; Plantinga <i>et al.</i> , 2011; Rodríguez-Martín <i>et al.</i> , 2019)
Carbamazepine	Stevens Johnson Syndrome (SJS)	18.25%	1 to 6 per 10,000 patients exposed
Phenytoin	SJS and Toxic Epidermal Necrolysis (TEN)	13.37%	68.9 per 100,000 patients exposed
Pioglitazone	Bladder cancer	2%	53%
Zidovudine	Anemia	14.4%	40.25%
NSAIDs	Nephrotoxicity- Renal injury, Chronic Kidney Disease (CKD)	27.88%	13%
Nifedipine	Gingival hyperplasia	75%	6.3%
Amlodipine	Gingival hyperplasia	31.4%	1.7%
Lamivudine	Hearing impairment	3%	35.8
Ethambutol	Optic neuropathy	6-14%	2%
Linezolid	Peripheral neuropathy	93.33%	1.6%

Table 2: Reporting Odds Ratio (ROR) of ADRs of drugs as per FAERS database.

Drug	ADR	ROR in USA (FAERS database) (Roussos <i>et al.</i> , 1970; Shao <i>et al.</i> , 2021; Silva <i>et al.</i> , 2011; Thiriot <i>et al.</i> , 2021; Zou <i>et al.</i> , 2024)
Nifedipine	Gingival hyperplasia	9.3
Amlodipine	Gingival hyperplasia	20.9
Carbamazepine	Steven Johnson Syndrome (SJS)	24.5
Phenytoin	Agranulocytosis	26.3
Linezolid	Peripheral neuropathy	8.23
Pioglitazone	Bladder cancer	4.3
NSAIDs	Nephrotoxicity- Renal injury, Chronic Kidney Disease (CKD)	2.45

in 75% and 31.4% of Indian patients respectively (Gopal *et al.*, 2015). These numbers were significantly higher than that reported in 6.3% and 1.7% of 911 patients in England (Prisant & Herman,

2002). CCBs downregulate connective tissue degradation with increased production of collagen by gingival fibroblasts.

Lamivudine can result in hearing loss. An Indian study reported that hearing loss was observed in 3% of the patients receiving Highly Active Antiretroviral Therapy (HAART) (Doseman D *et al.*, 2018), compared to a Brazilian study where 35.8% of 106 patients complained of hearing loss (Silva *et al.*, 2011). Lamivudine-induced mitochondrial dysfunction via polymerase gamma inhibition contributes to this adverse effect. Zidovudine causes anemia through bone marrow suppression and mitochondrial toxicity. In India, the prevalence of zidovudine-induced anemia has been reported to be 14.6% (Dash KR *et al.*, 2015), which is notably lower than the pooled global prevalence of 39.7% (Cal G *et al.*, 2022). The prevalence of Ethambutol-induced optic neuropathy in India is reported to be 14% (Kumar SR *et al.*, 2024), compared to 2% in the US population (Roussos & Tsolkas, 1970). High prevalence of Tuberculosis with extensive use of this drug could be contributory. Selective damage to the papillomacular bundle with mitochondrial dysfunction are important mechanisms. Linezolid can cause peripheral neuropathy and anemia due to ribosomal dysfunction. An Indian study reported that 93.33% patients developed peripheral neuropathy (Mishra *et al.*, 2024) compared to a Belgian study with significantly low prevalence (Thiriot *et al.*, 2021), and the FAERS database with peripheral neuropathy in 36.04-46.37% (Zou *et al.*, 2024).

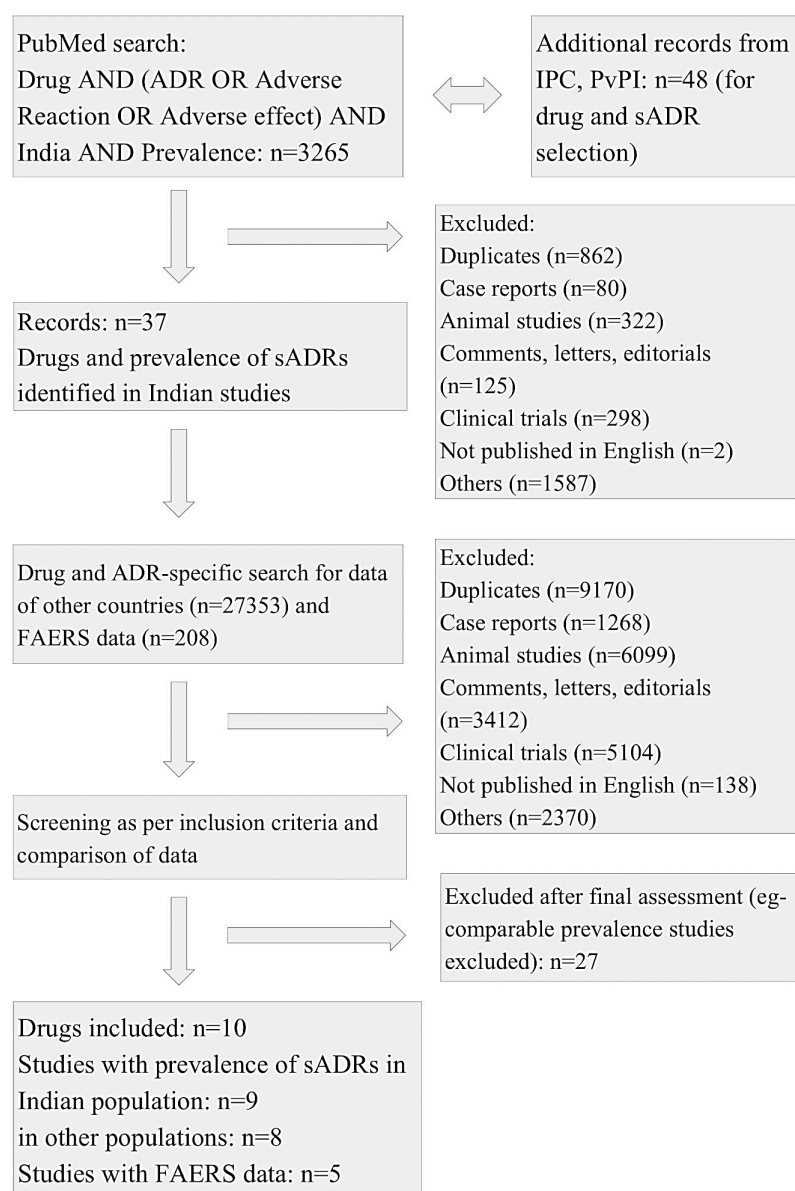


Figure 1: Study methodology: Selection of studies for comparison of prevalence of sADRs in Indian population and in other countries.

We observed that while serious ADRs are reported in global pharmacovigilance systems, their prevalence is notably higher in Indian patients for most drugs. An analysis of the FAERS data (Borrelli *et al.*, 2018; Hatahira *et al.*, 2017; Piccinni *et al.*, 2011; Shao *et al.*, 2021; Zou *et al.*, 2024) (Table 2) revealed that Indian prevalence rates were significantly higher than the corresponding ROR. Indian data show a 75% prevalence of gingival hyperplasia with Nifedipine, significantly higher than the 9.3 ROR in the FAERS database. Similarly, Linezolid-induced peripheral neuropathy exhibited a 93.33% prevalence in India compared to a relatively low ROR of 8.23 in FAERS. Drug induced serious ADRs could be manifested due to several reasons. Among the drugs examined, genetic predisposition is implicated in the adverse effects of carbamazepine, phenytoin and pioglitazone. In other

cases, ADRs appeared to be extensions of the pharmacological action of the drug, as observed with NSAIDs, CCBs, lamivudine, zidovudine, linezolid, and ethambutol. This suggests the influence of genetic variability, environmental exposures, healthcare delivery standards, and pharmacovigilance infrastructure. The evidence strongly supports the need for more robust, localized pharmacovigilance systems in India to detect, report, and manage ADRs effectively, thereby ensuring safer medication practices tailored to Indian populations.

CONCLUSION

For the majority of the drugs evaluated, prevalence of sADRs was higher in the Indian population. A transparent and supportive reporting environment reinforced by policy incentives and public

access to a comprehensive database is essential to understand the prevalence, etiology, and mechanisms for these observed differences of sADR in the Indian population.

LIMITATIONS

This study focused on few drugs due to limited availability of comprehensive, quality Indian data. The studies varied in sample size, design, and methods of data collection, making generalisability difficult. We cannot exclude publication bias as ADRs that were serious were more likely to be reported and published.

ABBREVIATIONS

ADR: Adverse Drug Reaction; **sADR:** Serious Adverse Drug Reaction; **PvPI:** Pharmacovigilance Programme of India; **IPC:** Indian Pharmacopoeia Commission; **FAERS:** FDA Adverse Event Reporting System; **ROR:** Reporting Odds Ratio; **CCB:** Calcium Channel Blocker; **NSAID:** Non-Steroidal Anti-Inflammatory Drugs; **CKD:** Chronic Kidney Disease; **HAART:** Highly Active Antiretroviral Therapy; **SJS:** Stevens–Johnson Syndrome; **TEN:** Toxic Epidermal Necrolysis.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

AUTHOR CONTRIBUTIONS

Pravartika Gandhi and Ranveer Sahrawat conducted literature search and data extraction. Preeta Kaur Chugh conceptualized the study, resolved discrepancies, and finalized the manuscript. All authors read and approved the final manuscript.

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