

A Retrospective Analysis of Adverse Drug Reactions Before The Covid-19 Infection Era (One-Year Study) in A Tertiary Care Teaching Hospital in North India

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ABSTRACT

Background: Adverse drug reactions (ADRs) represent a significant healthcare problem, contributing to patient morbidity and resource utilisation. This present study aimed to characterise the pattern of ADRs reported at a tertiary care hospital in Dehradun, Uttarakhand, India.

Methods: A retrospective observational study was carried out by the Department of Pharmacology, Shri Guru Ram Rai Institute of Medical & Health Sciences from June 2017 to May 2018. A total of 156 completed forms were analyzed, with data on patient demographics, affected system-organ classes, implicated drug classes, and causality assessed according to the WHO-UMC criteria.

Results: Males accounted for 60.3% of the 156 ADRs, while females made up 39.7%. The age distribution revealed that the majority of people were between the ages of 19 and 60 (82.1%), followed by those over 60 (12.8%), those between the ages of 13 and 18 (3.3%), and those under the age of 12 (1.8%). The gastrointestinal system was primarily affected (42.9%), followed by the cutaneous system (32.1%), the central nervous system (15.4%), and other systems. Antimicrobials were the main implicated class of drug (59.6%), followed by CNS drugs (9.6%), analgesics (8.3%). Causality assessment showed 85.3% probable/likely, 10.9% possible, and 3.8% uncertain.

Conclusions: Among males of working age, antimicrobials were found to be the primary cause of adverse drug reactions (ADRs), primarily affecting the gastrointestinal and skin systems. To reduce the burden of adverse drug reactions (ADRs) and encourage safer prescribing practices, pharmacovigilance must be improved through consistent reporting and education.

Keywords: WHO-UMC causality assessment, antimicrobials, gastrointestinal reactions, adverse drug reactions, Pharmacovigilance Programme of India.

INTRODUCTION

Adverse drug reactions (ADRs) are defined by the World Health Organisation (WHO) as a response to a drug that is harmful and unintended, occurring at doses typically used in humans for the prevention, diagnosis, or treatment of disease, or for altering physiological functions.¹

It is a harmful or unpleasant reaction which is resulting from an intervention related to the use of a medicinal product, which predicts hazard from future administration and necessitates specific management, or modification of the dosage schedule, or cessation of the product.²

The Pharmacovigilance Programme of India (PvPI), which was started in 2010 has greatly improved spontaneous reporting, but under-reporting remains a challenge. Spontaneous ADR Reporting from tertiary care hospitals offers important real-world data on local patterns, which may differ from local trends due to differences in disease rates, prescribing habits and genetic factors. In developing nations like India, this problem is worse due to issues like polypharmacy, self-medication, an increased rate of infectious diseases, leading to an excessive use of antimicrobials and limited systems for monitoring drug safety.^{3,4}

Various studies throughout India have consistently shown that antimicrobials are the most common offenders, often causing skin or stomach issues. However, there is limited data available in northern hilly regions like Uttarakhand. Therefore, this present study aims to describe the most affected systems, the classes of drugs responsible for ADRs and the level of causality.

AIM

To describe the patterns of Adverse Drug Reactions reported in a tertiary care teaching hospital in Dehradun, Uttarakhand, India.

OBJECTIVES

1. To analyse the demographic profile (age and gender distribution) of patients experiencing ADRs.
2. To determine the most common organ systems affected by ADRs.

MATERIALS AND METHODS

Study Design and Setting

This was a retrospective, observational study carried out at the ADR monitoring Centre in the Department of Pharmacology, SGRRIM&HS, Dehradun, Uttarakhand.

Data Source

A total of 156 ADR forms received by the ADR monitoring Centre from various clinical departments during June 2017 to May 2018 were included and analysed.

Data Collection and Analysis

Data included patient demographics (age, gender), drugs causing ADRs, organ system classes affected and the Causality assessment, which was performed using the WHO-UMC criteria.⁵

Descriptive statistics (percentages, frequencies) were used. Graphs and charts were interpreted for visual representation.

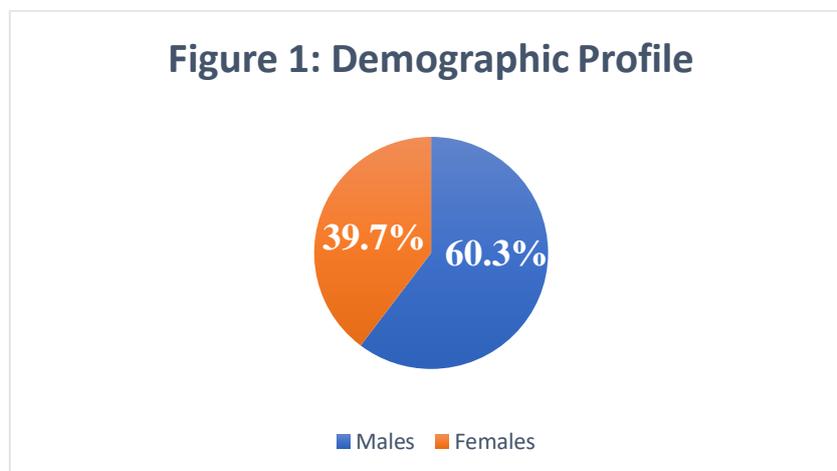
Ethical Considerations

This study was approved by the Institutional Ethics Committee.

RESULTS

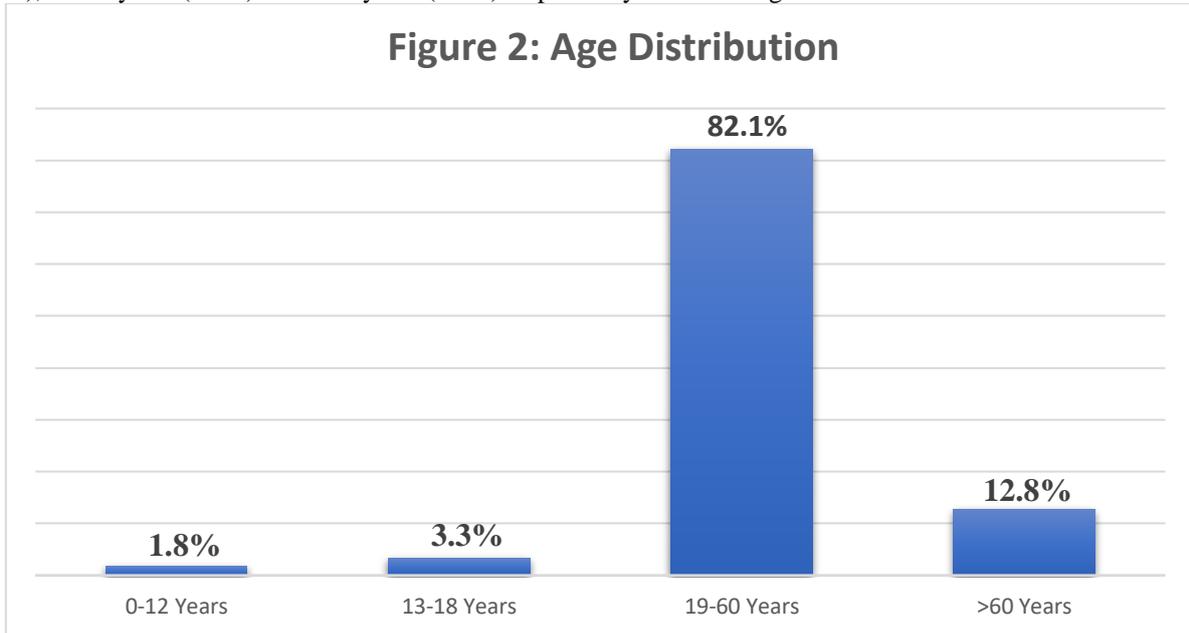
Demographic profile

Out of 156 patients experiencing ADRs, Males accounted for 60.3% of all cases, while females accounted for 39.7% as seen in Figure 1.



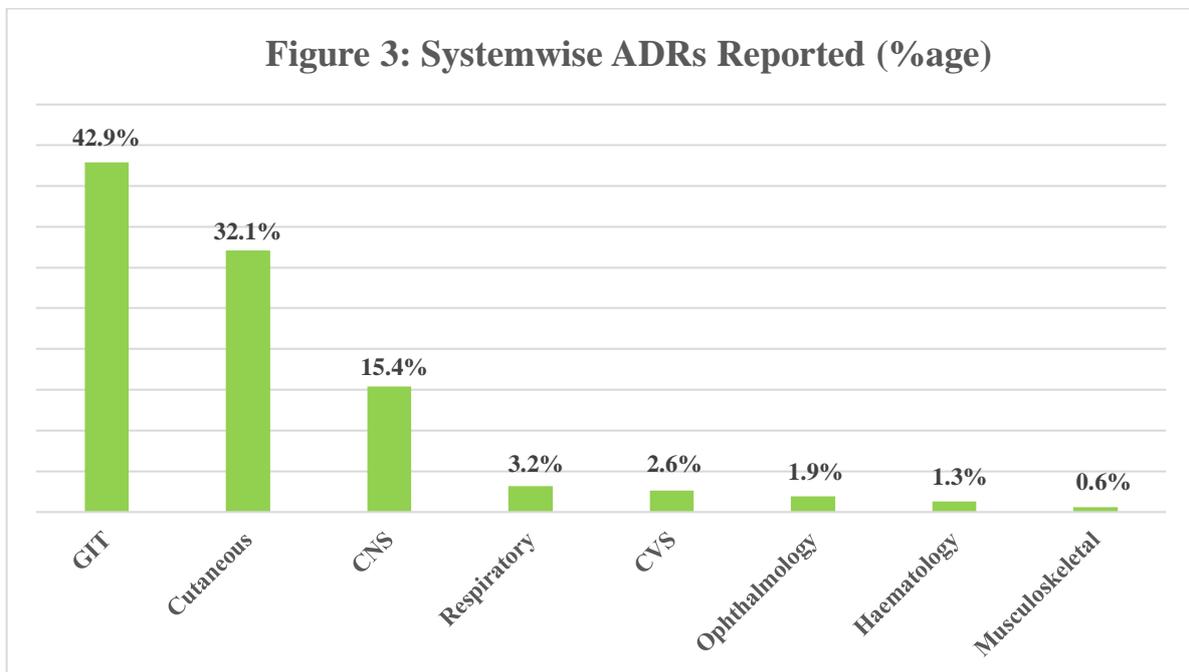
Age Distribution

The majority of patients lay in the working age adult group of 19-60 years (82.1%), followed by elderly > 60 years (12.8%), 13-18 years (3.3%) and 0-12 years (1.8%) respectively shown in Figure 2.



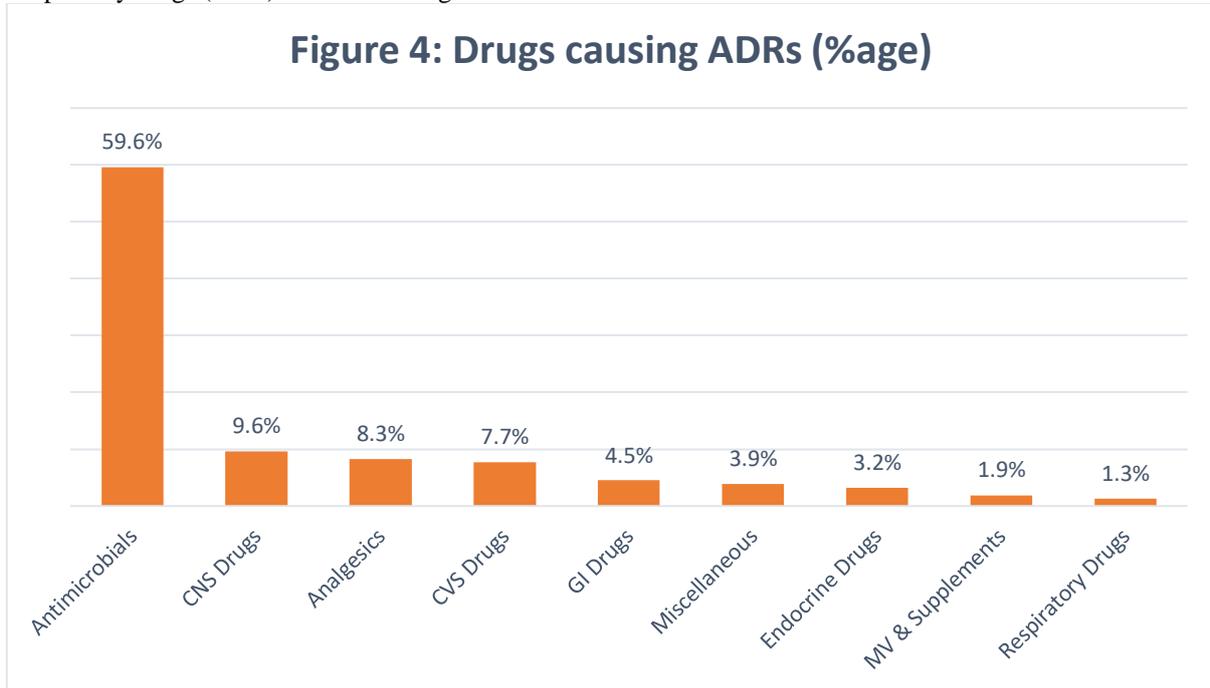
Systemwise ADRs Reported

The gastrointestinal system was most commonly involved (42.9%), followed by Cutaneous (32.1%), Central nervous system (15.4%), Respiratory (3.2%), CVS (2.6%), Ophthalmology (1.9%), Haematology (1.3%) and Musculoskeletal system (0.6), respectively as seen in Figure 3.



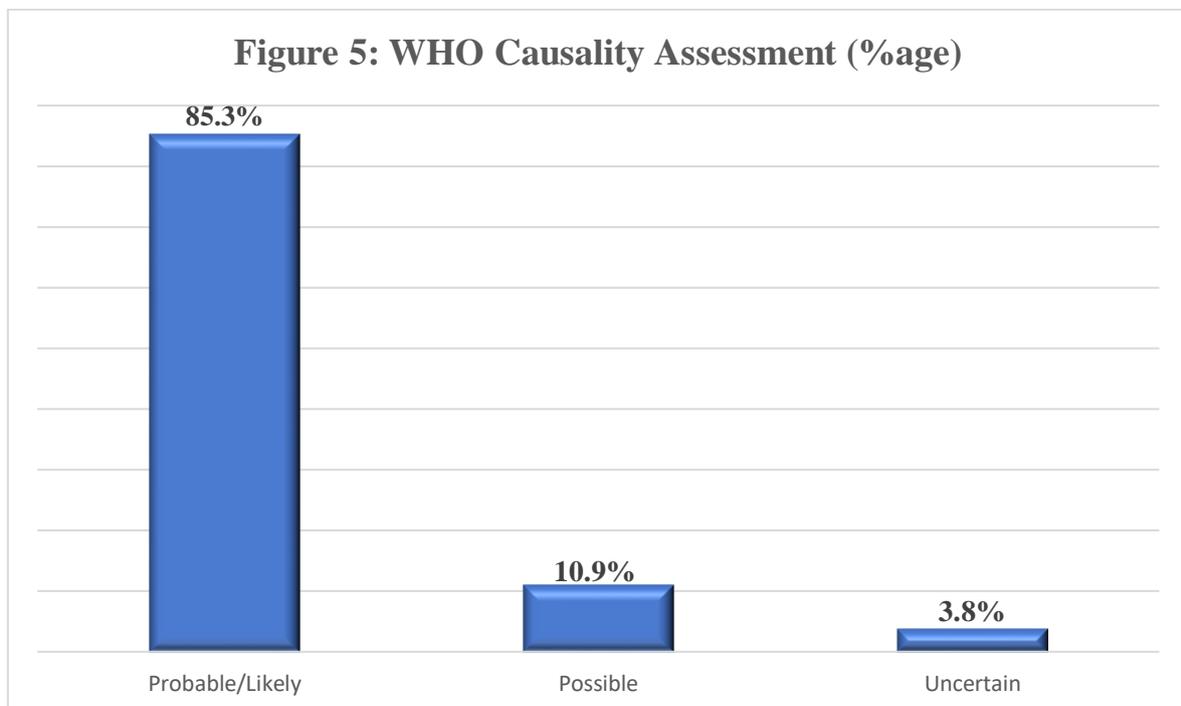
Drug Classes Causing ADRs

Antimicrobials were implicated in the majority of cases (59.6%), followed by CNS drugs (9.6%), Analgesics (8.3%), CVS drugs (7.7%), GI drugs (4.5%), Miscellaneous Drugs (3.9%), Endocrine Drugs (3.2%), MV & supplements (1.9%) and Respiratory drugs (1.3%) as shown in Figure 4.



Causality Assessment (WHO-UMC Criteria)

According to the WHO-UMC causality assessment, Probable/Likely (85.3%) accounted for the majority of cases, followed by Possible (10.9%) and Uncertain (3.8%), respectively as seen in Figure 5.



DISCUSSION

The predominance of ADRs in males reflects higher hospital attendance and exposure to high-risk drugs (e.g., antimicrobials for infections). The peak seen in 19-60 years (63.5%) reflects the economically active population who have greater access to healthcare and have more infectious disease burden.

The gastrointestinal system is the most common organ system affected (42.9%) in this study, which is consistent with reports where antimicrobials disrupt gut flora and irritate the GI mucosa. Antimicrobials being the leading class (59.6%) mirrors national and global trends in tertiary care hospitals, which are attributed to rampant empirical use, especially of drugs like Cephalosporins and Fluoroquinolones. High 'Probable/Likely' (85.3%) in the present study emphasises the need for ongoing clinician education of PvPI reporting.

Dutta S et al in 2015 showed the highest incidence in 16-30 years age group (40.65%) while our data shows the peak in 19-60 years age group (82.1%), reflecting a shift towards older adults over time, due to evolving burdens of the disease as well as improved reporting among the population. Antimicrobials were the leading causative class in both studies; however, our study showed a more pronounced contribution (59.6%) as compared to the previous study showing the role of NSAIDs (28.45%) followed by Fluoroquinolones (24.39%), thus underscoring the greater role of antimicrobials while also highlighting potential reductions in NSAID-related ADRs via targeted interventions.⁶

CONCLUSION

This present one-year study showed that ADRs predominantly affected adult males in the age group of 19-60 years, with Gastrointestinal being the most commonly affected organ systems. Antimicrobials were the most common drugs associated with causing ADRs, and most of the reactions were probable/likely as per WHO-UMC criteria. ADR monitoring has to be an ongoing process, and strengthening pharmacovigilance through awareness, training and feedback is essential for safer drug use and rational prescribing.

Conflict of Interest

No conflict of Interest

ACKNOWLEDGMENTS

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