IJPSR (2024), Volume 15, Issue 3 (Research Article)

INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES AND RESEARCH

Received on 29 July 2023; received in revised form, 16 October 2023; accepted, 30 December 2023; published 01 March 2024

THE INCIDENCE AND NATURE OF DRUG-RELATED PROBLEMS AMONG INPATIENTS IN A TERTIARY CARE HOSPITAL IN NORTHERN INDIA: A PROSPECTIVE STUDY

Shanu Raina [1], Kunal Sharma [2], Navpreet Kaur [*3] and Priya Jaswal [3]

Department of Pharmacology [1], Gian Sagar Medical College and Hospital, Rajpura - 140401, Punjab, India.
Department of Pharmacology [2], Government Medical College, Haldwani - 263145, Uttarakhand, India.
Department of Pharmacology [3], Maharishi Markandeshwar Medical College & Hospital, Solan - 173229, Himachal Pradesh, India.

Keywords:

Drug related problems, Adverse drug reaction, Gastrointestinal system, Pharmacovigilance

Correspondence to Author:
Navpreet Kaur

Professor, MD Pharmacology, Department of Pharmacology, Maharishi Markandeshwar Medical College & Hospital, Solan - 173229, Himachal Pradesh, India.

E-mail: dr.np21kaur@gmail.com

ABSTRACT: The advancement of drug therapy has undoubtedly elevated patient care standards. However, it has also led to an increase in Drug-Related Problems (DRPs), which can have a significant impact on health outcomes. In an 18-month prospective observational study involving 2,000 patients, we meticulously assessed DRPs using the Hepler and Strand classification system. These DRPs encompassed a range of issues, including adverse drug reactions (ADRs), untreated medical indications, non-compliance with prescribed regimens, improper drug selection, and more. Our data collection adhered to a well-validated and pre-tested format. Among 2,000 patients, 106 (5.3%) experienced 117 DRPs, averaging 1.1 per patient. Adverse drug reactions (ADRs) accounted for 47.01% of cases, non-compliance 35.89%, and drug use without indication 11.32%. ADR incidence was 2.75%, primarily affecting the Gastrointestinal (GIT) system. Antibiotics were frequently associated with ADRs in various drug classes. Vigilant monitoring, robust reporting mechanisms, and patient education are pivotal strategies in the prevention of drug-related issues. Pharmacovigilance, the systematic monitoring and evaluation of drug safety and efficacy, plays a fundamental role in ensuring the delivery of high-quality healthcare. Through the effective implementation of robust pharmacovigilance practices, we can successfully diminish the occurrence of DRPs, leading to safer and more efficacious outcomes in drug treatment.

INTRODUCTION: Medications are at the heart of modern therapeutics. Medications have enabled physicians to treat diseases that were once untreatable. In recent years, advances in drug therapy have enhanced patient care, but have also caused an increase in Drug Related Problems (DRPs), which are unwelcome and unpleasant to patients [1, 2].

QUICK RESPONSE CODE

DOI: 10.13040/IJPSR.0975-8232.15(3).854-59

This article can be accessed online on www.ijpsr.com

DOI link: https://doi.org/10.13040/IJPSR.0975-8232.15(3).854-59

DRP occurs when the outcome of drug therapy is less than ideal [3, 4] and is defined as an event or circumstance that interferes with the desired health outcomes [5]. A headline in Pharmacy Today, year 2001,"Drug-related issues: Once a 76.6 Billion headache, now a 177.4" illustrates not only the economic consequences of drug-related dispute, but also their chronic morbidity and mortality [6].

Patients and society as a whole are greatly burdened by DRPs due to their physical, psychological, and economic effects. Therefore, optimizing drug therapy may have a positive effect on health care costs, provide a potential source of life saving, and enhance the quality of life of patients [7].

Various health professionals often deal with new and experimental therapies and use drugs extensively in hospitals. By using Adverse Drug Reaction (ADR) monitoring and reporting programs in hospitals, drug risks can be identified and quantified [8]. This information may assist prescribers in identifying and minimizing preventable DRPs, while generally improving their knowledge to deal with them more efficiently. Therefore, this study aimed to assess the incidence and nature of DRPs among indoor patients at the department of internal medicine, in the tertiary care hospital settings (Maharishi Markandeshwar Institute of Medical Science & Research, Mullana).

MATERIALS AND METHODS:

Study Set up: Hospital based study.

Study Design: A prospective, observational study.

Duration of Study: 18 months.

Legal Approval: Institutional Ethics Committeeof Maharishi Markandeshwar Institute of Medical Science & Research, Mullana (Ref no: MMIMSR/IEC/11/334).

Inclusion Criteria: All patients of either sex or age ≥18 years admitted in the internal medicine wards during the study period.

Exclusion Criteria: Out Patient Department (OPD) patients, patients on contrast media, patients discharged or transferred to other departments within 48 hours of admission, patients admitted to Intensive Care Unit (ICU) and those who did not give written consent.

Monitoring of DRPs: As part of the admission process, each patient was interviewed and information concerning descriptive demographic characteristics, relevant history, examination details, investigations, and medication was collected and recorded. Follow-up visits were made daily until the patient was discharged. Daily visits to the ward and examination of the medical records provided details about the drugs prescribed. A proforma was used to record information from a physician's physical examination, laboratory tests, and results of diagnostic tests. An untoward event was only labeled DRP or ADR with the consent of the treating physician. The Hepler and Strand classification system [9, 10] was used to identify DRPs. If an adverse event was related to one of the eight predefined classifications such as (Untreated indications, Improper drug selection, Sub therapeutic dosage, Failure to receive drug, Overdosage, Adverse drug reaction, Drug interactions, Drug use without indication), it was classified as a DRP. Data was then further analysed for ADRs. Causality assessment was done using Naranjo scale [11]. Assessment of severity of ADRs was determined by using the Hartwig and Seigel scale [12]. Assessment of preventability was done on the basis of the criteria by Schumock and Thornton [13]. Individual reactions were classified as Type A (Augmented-dose dependent, predictable) and Type B (Bizarre-idiosyncratic, non-predictable) on the basis of classification by Rawlins and Thompson [14]. Data was also evaluated to determine the class of drugs and the organ systems frequently associated with ADRs.

Statistical Analysis: The data was analyzed using SPSS 20 (IBM Chicago USA) (Statistical Package for Social Sciences). The frequency distribution was expressed as a percentage. Statistical analysis of continuous data is based on Mean and Standard Deviation. Chi-square test was applied to show relationships between categorical data, and a p-value of 0.05 was considered statistically significant.

RESULTS: Out of 2000 patients studied, 106 (5.3%) had clinically relevant DRPs **Fig. 1** and the incidence of DRPs is more in female (5.36%) than male (5.25%) **Fig. 2**. In terms of DRPs, ADRs ranked highest (47.01%), followed by non-compliance (35.89%), and drug use without indication (11.32%) **Fig. 3**. There were 2.75% of ADRs, which accounted for 47.01% of DRPs. It was found that 75.45% of ADRs attributed to reaction type A compared to reaction type B. Gastrointestinal system was the most commonly affected system (49.09%), followed by skin (14.54%), and brain (10.9%) **Fig. 4.** Antibiotics were the most commonly reported drug class associated with ADRs (45.45%) **Fig. 5.** As a result of causality assessment, 56.36% were probable ADRs. As far as severity is concerned, the maximum ADRs were mild (78.18%) with an overall non-preventable rate of 69.09%.

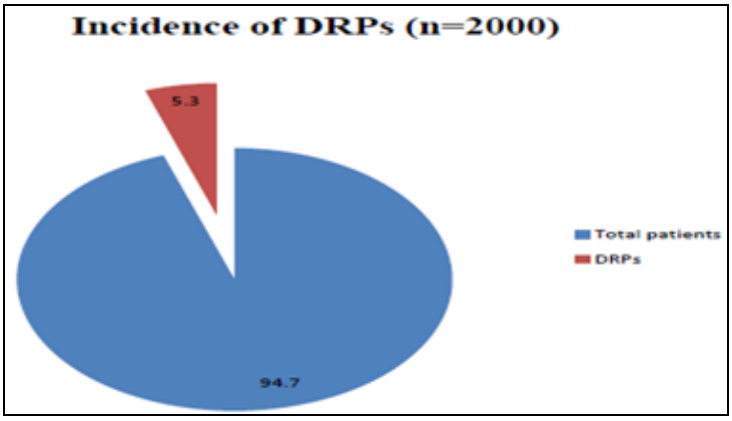

FIG. 1: INCIDENCES OF DRPS AMONG TOTAL STUDY POPULATION

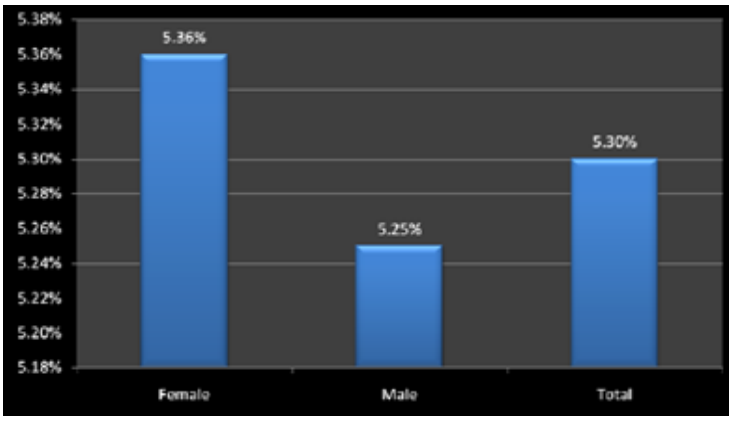

FIG. 2: INCIDENCES OF DRPs ACCORDING TO SEX

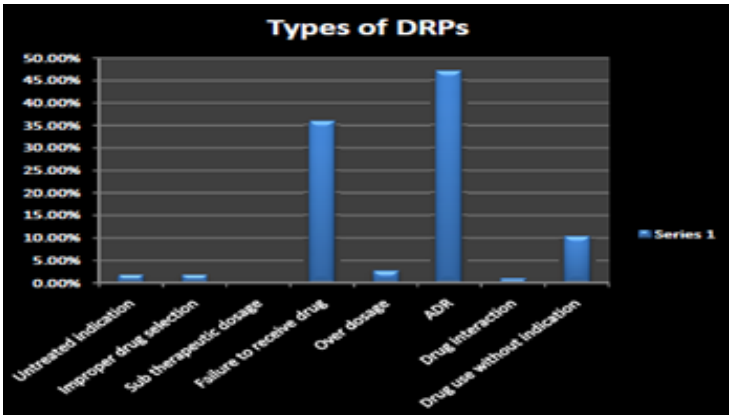

FIG. 3: TYPE OF DRPs

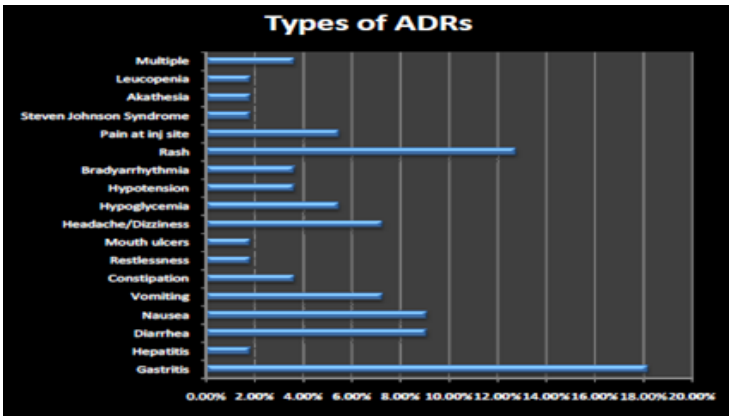

FIG. 4: ORGAN SYSTEM FREQUENTLY ASSOCIATED WITH ADRs

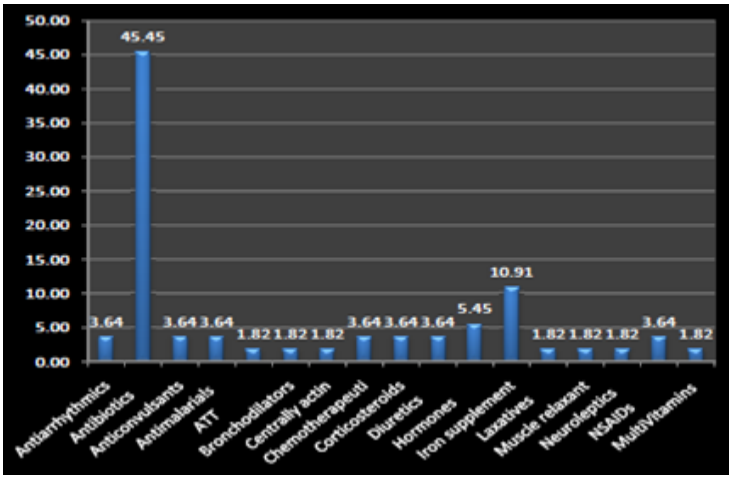

FIG. 5: DRUG CLASSES ASSOCIATED WITH ADRs

DISCUSSION: As per earlier studies, it was established that non-compliance emerged as the primary factor leading to hospitalizations associated with drug-related issues, contributing to 3.31% of the reported cases [15]. Another study documented an incidence rate of 5.01%, with non-compliance emerging as the predominant factor, followed by ADRs and drug overdoses [16]. Differences in the reported incidence of drug-related problems across various studies can be attributed to variations in how they classify and detect these issues, the complexity of the treated conditions, and the infrastructure in place for detecting and reporting such problems. According to another study, it was noted that 81% of patients experienced DRPs, with an average of 2.1 clinically relevant DRPs per patient [17].

Literature also supports this fact that increased drug use in the elderly led to a higher likelihood of adverse interactions [18]. In our study, we observed an incidence of adverse drug reactions (ADRs) at a rate of 2.75%, constituting a significant portion, specifically 47.01%, of the total DRPs. This trend aligns with findings from two other studies, where they reported similar ADR incidences of 2.17% [19] and 1.82%, respectively [20, 21]. There was an another study reported a lower incidence of 3.7% ADRs among hospitalized patients in India, highlighting the need to investigate the reasons for this discrepancy, including under-reporting and inadequate pharmacovigilance systems [22]. In our study, the majority of adverse drug reactions (ADRs) were classified as Type A according to Rawlins and Thompson's classification, consistent with the established observation that approximately 80% of ADRs fall into this category, while the remaining 20% are categorized as Type B [23]. This finding is further substantiated by two additional studies [24, 25]. Causality assessment using Naranjo's Algorithm [11] indicated that probable ADRs accounted for 56.36% of cases, similar to the findings of some another literature studies [24].

In terms of severity [12], based on the criteria developed by Hartwig and Seigel scale, 78.2% of ADRs in our study were mild. The most common system associated with ADRs in our study was the Gastrointestinal (GI) system, accounting for 49.09% of cases, with gastritis being the most frequent ADR in this system. Skin reactions accounted for 14.54% of cases, followed by the Central Nervous System (CNS) at 10.9%.

These findings are consistent with the literature study [20], where the GI system (37%), skin (25%), and CNS (12%) were the most commonly affected systems. Another study also reported a high incidence of GI ADRs (42.1%), followed by skin and subcutaneous tissue (33.8%) [24]. The most common individual ADRs in our study were gastritis (18.18%), skin rash (12.73%), diarrhoea and nausea (9.09% each). The most commonly implicated drug class in our study was antibiotics, accounting for 45.45% of cases. Following antibiotics, iron supplements were involved in 10.91% of ADRs, and hormones in 5.45%. This aligns with our study's findings, where antimicrobials, specifically antibiotics, were the most frequently reported culprits [26]. Research studies indicate that non-compliance accounted for 46.6% of drug-related hospitalizations, with ADRs

and drug overdose being the primary reasons for drug-related incidents [27]. In our study, 11.32% of DRPs were due to drug use without indication, predominantly associated with multivitamins. Other identified DRPs included over dosage (2.56%), untreated indication (1.71%), improper drug selection (1.71%) and drug interactions (0.85%). These findings emphasize the importance of implementing a proper pharmacovigilance system.

The establishment of standardized approaches and active surveillance by healthcare professionals such as (physicians, nurses, and pharmacists) can help anticipate and prevent such DRPs leading to safer and more rational drug therapy.

CONCLUSION: ADRs and non-compliance have consistently emerged as the major contributing factors to DRPs, and this study aligns with those findings. The occurrence of many DRPs can be prevented through active monitoring and reporting of ADRs, as well as by providing proper patient education.

Therefore, it is concluded that pharmacovigilance plays a crucial role in ensuring the safe and effective use of drug therapy and in delivering high-quality healthcare. By implementing robust pharmacovigilance practices, confidence and trust in medications can be instilled among patients and healthcare professionals, ultimately leading to elevated standards of medical care.

ACKNOWLEDGEMENT: I would like to express my heartfelt gratitude to all those who contributed to the successful completion of this research work (Maharishi Markandeshwar Institute of Medical Science & Research, Mullana). Special thanks to my supervisor for their valuable guidance and encouragement throughout the project. I am also grateful to the participants who willingly took part in the study. Additionally, I extend my appreciation to the library staff and research assistants for their assistance. Finally, I want to thank my family and friends for their unwavering support and understanding during this endeavour.

Funding: This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

CONFLICT OF INTEREST: Declared None.

REFERENCES:

1. Vichapat T, Krongtong P and Phantipa S: Drug-related problems identified during pharmaceutical care interventions in an intensive care unit at a tertiary university hospital. SAGE Open Medicine 2022; 10(6): 2050312122109088.
2. Kempen TG, Hedman A and Gillespie U: Drug-related emergency department visits in older patients: an applicability and reliability study of an existing assessment tool. International Journal of Clinical Pharmacy 2022; 44(4): 1078-1082.
3. Freitas GR, Neyeloff JL, Balbinotto NG and Heineck I: Drug-related morbidity in Brazil: A cost-of-illness model. Value in Health Regional Issues 2018; 17: 150-7.
4. Nivya K, Sri KV, Ragoo N, Jayaprakash B and Sonal SM: Systemic review on drug related hospital admissions-A Pubmed based search. Saudi Pharmaceutical Journal 2015; 23(1): 1-8.
5. Giardina C, Cutroneo PM, Mocciaro E, Russo GT, Mandraffino G, Basile G, Rapisarda F, Ferrara R, Spina E and Arcoraci E: Adverse drug reactions in hospitalized patients: Results of the FORWARD (facilitation of reporting in hospital ward) study. Frontiers in Pharmacology 2018; 9: 350.
6. English T: Drug-related problems: Once a $76.6 Billion headache, nowa $177.4 Billion migraine. Pharmacy Today 2001; 7(3): 1-10.
7. Noe G, Nuria S, Beatriz L, Laia M, Desiree M, Ana RT, Laura GM and Nuria F: Drug related problems in clinical practice: a cross-sectional study on their prevalence, risk factors and associated pharmaceutical interventions. Scientific Report 2021; 11: 883.
8. Mohiuddin AK: Medication Risk Management. Journal of Pharmaceutical Innovation 2019; 10(1): 9.
9. Gopineni D, Reddy M, Kumar K: Heralding the drug related problems by using Hepler-strand classification in a tertiary care teaching hospital. Global Journal of Pharmacy and Pharmaceutical Sciences 2020; 7(5): 555725.
10. Alsayed AR, Al-Dulaimi A, Alnatour D, Awajan D and Alshammari B: Validation of an assessment, medical problem-oriented plan, and care plan tools for demonstrating the clinical pharmacist's activities. Saudi Pharmaceutical Journal 2022; 30(10): 1464-72.
11. Bereda G: Classifying causality of an adverse drug reaction: Naranjo algorithm. International Journal of Pharmaceutical Chemistry 2021; 7(6): 125.
12. Gupta S, Zaki SA, Masavkar S and Shanbag P: Causality, severity, and avoid ability of adverse drug reactions in hospitalized children: A prospective cohort study. Cureus 2023; 15(1): e33369.
13. Jiang H, Lin Y, Ren W, Fang Z, Liu Y, Tan X, Lv X and Zhang N: Adverse drug reactions and correlations with drug–drug interactions: A retrospective study. Frontiers in Pharmacology 2022; 13: 923939.
14. Coleman JJ and Pontefract SK: Adverse drug reactions. Journal of Clinical Medicine 2016; 16(5): 481–485.
15. Ayalew MB, Tegegn HG, Abdela O: Drug related hospital admissions; A systematic review of the recent literatures. Bull Emerg Trauma 2019; 7(4): 339-46.
16. Ganesan S, Sandhiya S and Subrahmanyam DK: Frequency of ADRs and their economic impact in a tertiary care public sector hospital in south India. SBV Journal of Basic, Clinical and Applied Health Science 2020; 3(1): 23-31.

17. Abunahlah N, Elawaisi A, Velibeyoglu FM and Sancar M: Drug related problems identified by clinical pharmacist at the Internal Medicine Ward in Turkey. Int J Clin Pharm 2018; 40(2): 360-7.
18. Dagnew SB, Tadesse TY, Zeleke MM, Yiblet TG, Addis GT and Mekonnen GB: Drug–drug interactions among hospitalized elderly in patients at medical wards of Northwest Ethiopia's Comprehensive Specialized Hospitals: A multicenter observational study. SAGE Open Med 2022; 10: 205031212211358.
19. Raja S, Rani J and Kala: Pattern of adverse drug reactions in a tertiary care teaching hospital: A cross-sectional study. Asian Journal of Pharmaceutical and Clinical Research 2017; 10(3): 170-3.
20. Dinakaran A, Rao PS, Khanam QA, Sultan S, Fathima U and Uddin MA: Assessment of adverse drug reactions on cardiovascular drugs in hospitalized patients of a tertiary care hospital-a prospective analysis. Asian Journal of Pharmaceutical and Clinical Research 2022; 15(10): 42–6.
21. Kumar AP, Bhoopathi D, Sunkara H and Chalasani SH: An overview of various scales used in causality assessment of Adverse Drug Reactions. International Journal of Pharmacy and Pharmaceutical Sciences 2020; 12(5): 1-5.
22. Datta S, Sengupta S: An evaluation of knowledge, attitude, and practice of adverse drug reaction reporting in a tertiary care teaching hospital of Sikkim. Perspect Clin Res 2015; 6(4): 200-206.
23. Gupta S, Kumar D, Yadav C, Goyal RK and Singh SP: Incidence of adverse drug reaction and its outcome among patients in tertiary care hospital, Uttar Pradesh. International Journal of Health Sciences 2022; 6 (10): 797–806.
24. Kumar A, Kansal D, Sharma PK, Bhardwaj A and Sawaraj S: To study the pattern of adverse drug reactions among patients hospitalized in the medical wards of a tertiary care hospital. International Journal of Basic & Clinical Pharmacology 2017; 5(5): 1972-1977.
25. Sharma M, Baghel R, Thakur S and Adwal S: Surveillance of adverse drug reactions at an adverse drug reaction monitoring centre in Central India: a 7-year surveillance study. BMJ Open Journal 2021; 11(10): 052737
26. Bloor SR, Schutte R and Hobson AR: Oral iron supplementation-gastrointestinal side effects and the impact on the gut Microbiota. Microbiology Research Journal 2021; 12(2): 491–502.
27. Kumar DP: Patterns of adverse drug reactions: a study in a tertiary care. International Journal of Basic and Clinical Pharmacology 2019; 8(7): 1497-1502.

How to cite this article:
Raina S, Sharma K, Kaur N and Jaswal P: The incidence and nature of drug-related problems among inpatients in a tertiary care hospital in northern India: a prospective study. Int J Pharm Sci & Res 2024; 15(3): 854-59. doi: 10.13040/IJPSR.0975-8232.15(3). 854-59.