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A CROSS SECTIONAL STUDY TO ANALYSE THE ADR REPORTED IN A HOSPITAL DURING THE PAST THREE YEARS

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Abstract

Introduction: Cross sectional study is a type of observational study that analyzes data from a population, or a representative subset, at a specific point in time—that is, cross sectional data. The causality appraisal is assessment of the probability that the detected adverse event is produced by a specific medication. The most commonly used causality assessment scales are Naranjo Probability Scale and the World Health Organization-Uppsala Monitoring Centre (WHO-UMC) causality scales. The study is to analyze the adverse drug reaction reported in a hospital for the past three years. **Aim:** A cross sectional study to analyze the ADR reported in a hospital during the past three years. **Methodology:** A cross sectional observational study was conducted at Nirmala medical centre, Muvattupuzha. ADR reported in the past three years in this hospital were analyzed. Drug leading to ADR, department, gender, observed reaction, severity, Naranjo probability scale and WHO UMC causality assessment were done. Classification of drugs according to their drug class, classification of ADR according to the system, based on severity, sex, Naranjo score, WHO UMC criteria were done. The data were analysed and represented into graphs. **Result:** A total of 342 ADR reports were analyzed in this study. The key findings of this study include: Skin-related ADRs were the most frequently reported, affecting 27.83% of cases. The majority of reported ADRs were of moderate severity (56.7%). Naranjo probability scale and WHO-UMC causality assessment indicated that most cases were in the probable category, with 63% and 76%, respectively. The general medicine department had the highest number of reported ADRs. Males accounted for the majority of reported ADRs (57.18%). Cardiovascular agents and antibiotics were the drug classes most commonly associated with reported ADRs, at 25.6% and 22.28%, respectively. Among cardiovascular agents, diuretics were found to be the primary culprits, causing 38.66% of reported ADRs. **Conclusion:** This study highlights the importance of monitoring, assessing, and documenting ADRs in healthcare facilities, as it provides valuable insights into the prevalence, severity, and causality of adverse drug reactions. This information can contribute to improving patient safety and the rational use of medications in clinical practice.



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Introduction

ADR is a harmful reaction or unwanted reaction that is followed by the administration of a medicinal product or a combination of drugs under normal conditions of use. ADRs are more severe among older patients. Fatal adverse drug reactions occur mainly in patients older than 75 years of age, according to the World Health Organization's pharmacovigilance database. However, various types of ADRs

have been reported which include type A, type B, type C, type D, type E, type F, and type G adverse reactions. Type A (Augmented) ADRs have been characterized as idiosyncratic reactions that are typically uncommon, unpredictable, and unrelated to the pharmacological actions of the drug. Example for type A reaction is respiratory depression with opioids, whereas type B (Bizarre) have been considered as the idiosyncratic responses that are usually uncommon, unpredictable and not related to the pharmacological actions of the drug. Example for type B is skin rashes with antibiotics. Type C (Chronic) ADRs have been suggested to be associated with drug therapies that last for a long time. An example is osteonecrosis of the jaw with bisphosphonates. Type D (Delayed) reaction becomes apparent some time after the use of a medicine. An example is leucopenia which can occur up to six weeks after a dose of lomustine. Type E reactions (End of use) are associated with the withdrawal of the medicine. An

example is seizures caused by the withdrawal of the phenytoin. Type F reactions (Failure of therapy) is associated with the unexpected failure of the therapy due to drug interaction. Example include St Johns Wort reducing efficacy of combined hormonal contraceptives. Type G reactions (Genetic) are very rare and it cause irreversible genetic damage.

Materials and methods

The study proposal was approved by the research and development cell of the Nirmala college of pharmacy, Muvattupuzha. The concerned authority approved and permitted to conduct the study. The adverse drug reaction assessment forms in the past three years where collected from Nirmala Medical centre, Muvattupuzha. The ADR assessment form mainly consist of the patient information, the suspected drug, description of the reaction, duration of therapy, time of onset of the reaction, concomitant medical products hospitalization preventability assessment and causality assessment by Naranjo scale. It provide details of reaction including date and time of suspected reaction, description of reaction and it's severity. It gives an idea about whether the adverse reaction improve when the drug was discontinued and whether the adverse reaction reappear when the drug was readministered.

A total of 342 ADR assessment forms where analyzed. From the assessment form, prevalence of ADR including sex drug leading to ADR, department in which ADR reported, severity assessment. ADR causality assessment using Naranjo and WHO-UMC scale was done. WHO UMC scale is done based on four criteria's:

- 1) The time relationship between the suspected drug and the reaction
- 2) Whether the reaction is caused by any other drugs or diseases.
- 3) De challenge
- 4) Re challenge

Based on the criteria's met, the ADR where categorized as certain, probable possible and unlikely. The drugs lead to the ADR were classified according to their drug class Classification of ADR based on the system affected classification of ADR based on its severity, classification based on sex, Naranjo score and WHO UMC criteria where done.

From the drug class in which highest number of ADRs reported were again sub classified and the subclass in which highest number of ADRS reported were identified.

The data were analysed and it is made into representations.

Results and Discussions

A total of 342 ADR reports were analyzed in this study. The key findings of this study include:

Skin-related ADRs were the most frequently reported, affecting 27.83% of cases. The majority of reported ADRs were of moderate severity (56.7%). Naranjo probability scale and WHO-UMC causality assessment indicated that most cases were in the probable category, with 63% and 76%, respectively. The general medicine department had the highest number of reported ADRs. Males accounted for the majority of reported ADRs (57.18%). Cardiovascular agents and antibiotics were the drug classes most commonly associated with reported ADRs, at 25.6% and 22.28%, respectively. Among cardiovascular agents, diuretics were found to be the primary culprits, causing 38.66% of reported ADRs.

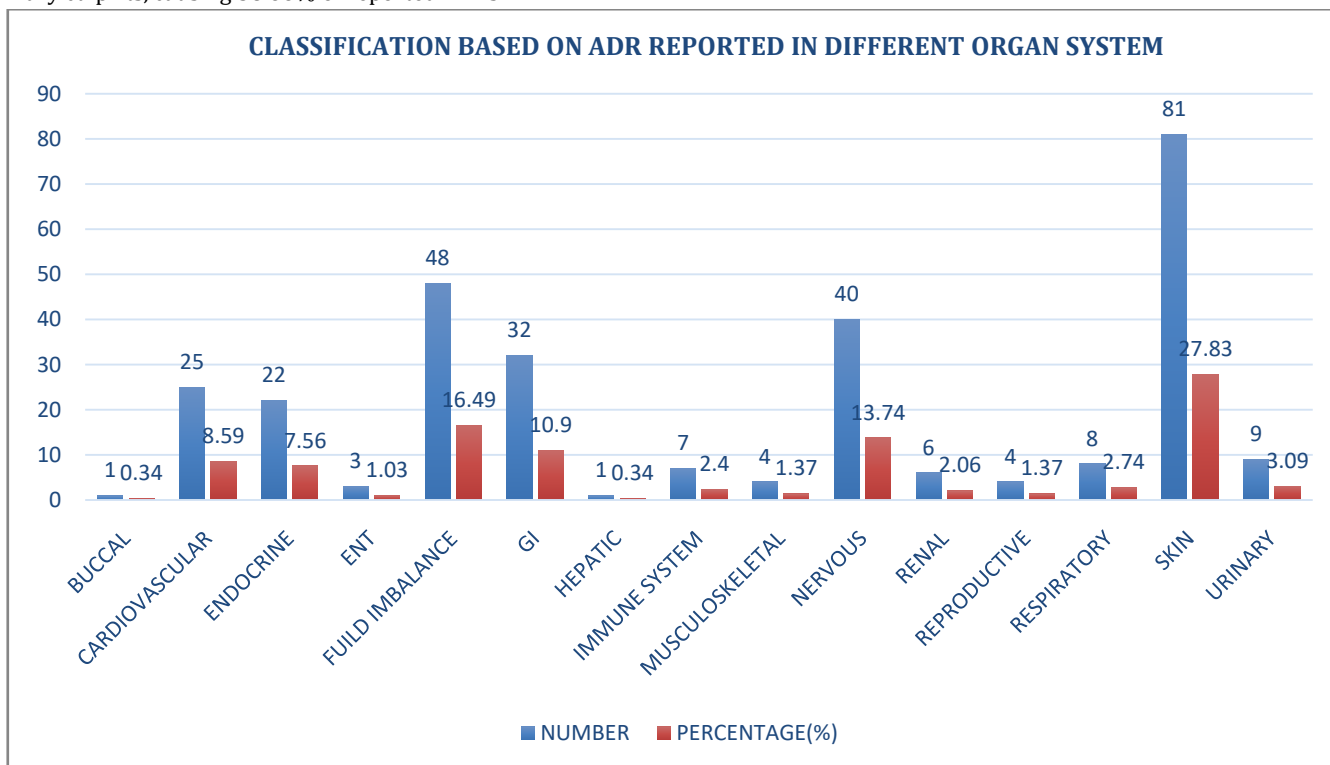


Figure 1: Reported ADRs on organ system

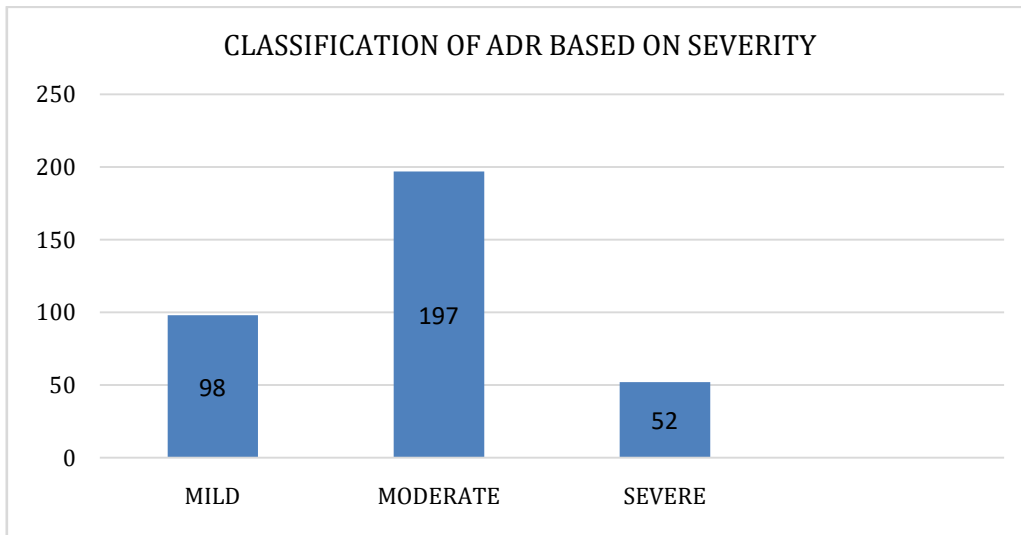


Figure 2: Reported ADRs based on severity

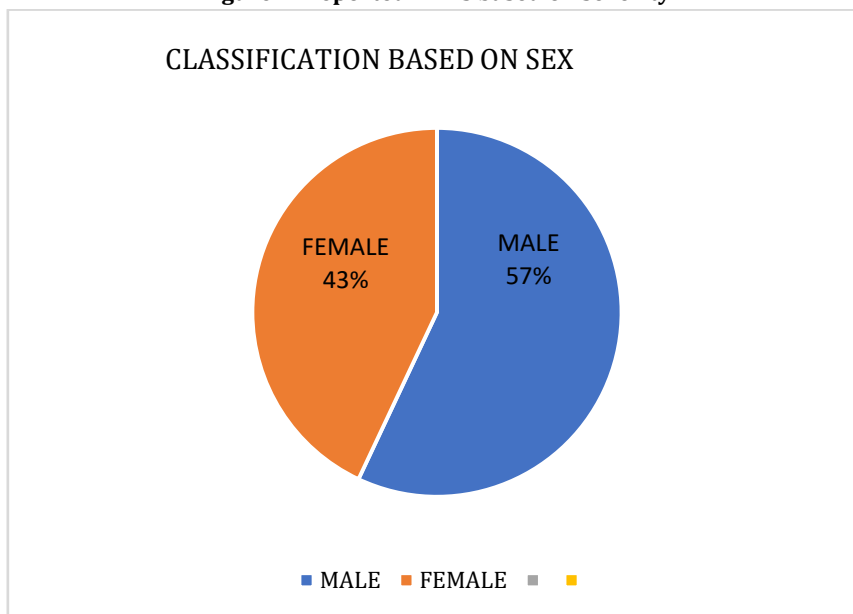


Figure 3: Gender distribution in reported Adverse Drug Reactions

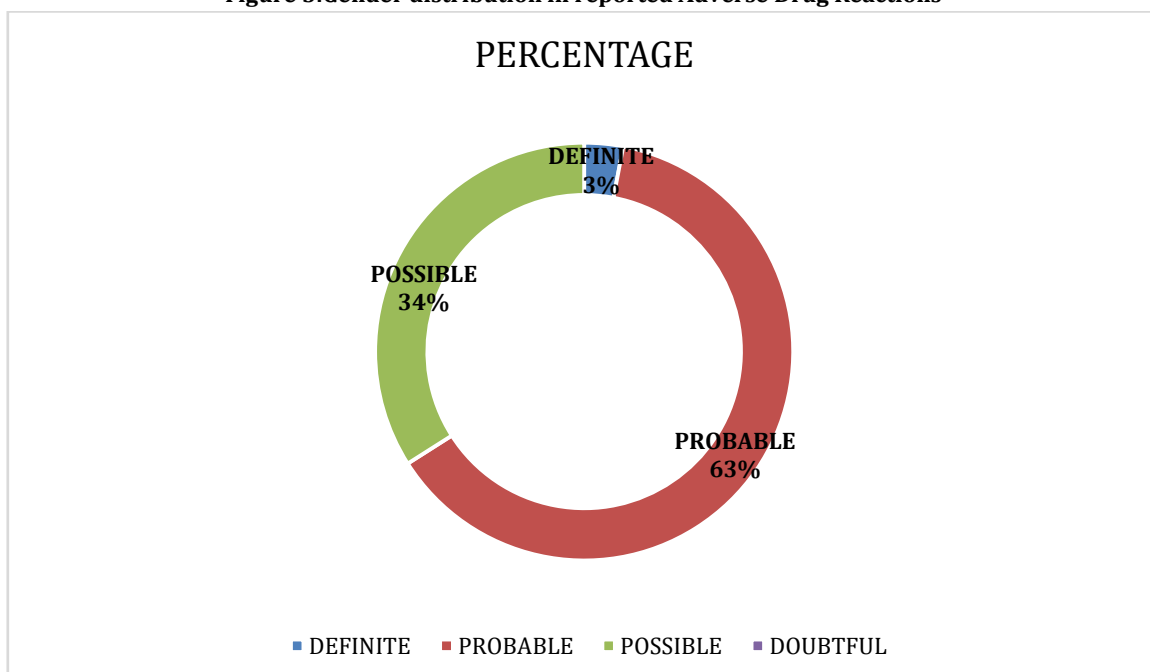


Figure 4: Reported ADRs based on Naranjo score

Various organ systems which are affected by ADRs include buccal(0.34%), cardiovascular system(8.59%), endocrine system (7.56%) ENT system (1.03%), GI system (10.9%) hepatic system (0.34%), immune system(2.40%) musculoskeletal system(1.37%),nervous system(13.74%) renal system(2.06%) reproductive system(1.37%) respiratory system(2.74%) skin (27.83%) and urinary system(3.09%). When we analyze the presentation of reactions, almost 27% showed cutaneous reactions like rashes, itching, pruritis, this was in correlation with the study done by F. SH et al., as well as by Jose J et al. ADRs of the skin may be mild or severe, and can present with a rash or blister that may also affect the mucosal membranes. These reactions may rarely be life threatening, hence the importance of early recognition and withdrawal of the offending drug.

Based on severity, ADRs are classified as mild moderate and severe. Occurrence of mild cases were 28.02%. Occurrence of moderate cases were 56.7% and that of severe cases were 14.9%. In this study, majority of the cases were moderate which were similar study done by Ramesh A et al. Mild or moderate adverse drug reactions do not necessarily mean that people must stop taking a medication, especially if a suitable alternative is available. Reported ADRs were classified according to WHO UMC criteria as probable (76%) possible (26%), certain (2%).

The departments in which the ADRs were reported include cardiology(5.62%) endocrinology (0.29%), gastrology (0.59%), general medicine(64.7%) general surgery (3.84%), pediatrics (0.29%), gynecology(2.95%), hepatology (0.59%), neurology (9.76%).oncology(1.775), orthopedics (1.77%), psychiatry (2.07%), pulmonology (0.88%), nephrology (1.18%).The antibiotics that resulted in the most serious ADRs include quinolones (12.98%), polypeptide (1.29%), cephalosporin (22.07%) glycopeptide (2.59%) oxazolidinone(2.59%), 46.75%) ,antifolate (1.29%)nitroimidazole(1.29%), macrolide(3.88%). nitrofurantoin(1.29%) ,penicillin (sulphonamide (1.29%), carbapenem (1.29%) ,tetracycline (1.29%). Penicillin was discovered to be the antibiotic that results in the most reported adverse drug reactions (ADRs).

Conclusion

This cross-sectional observational study provides valuable insights into adverse drug reactions (ADRs) in a tertiary care hospital over the past three years. It appears that skin reactions are the most common type of ADR (27.83%), with a majority being of moderate severity (56.7%). The study highlights the importance of monitoring and reporting ADRs, especially in the general medicine department, where the prevalence is higher. The need for pharmacovigilance programs and educating healthcare professionals on ADR reporting is emphasized. Furthermore, patient counseling and disclosure of previous drug allergies are crucial for safer and more efficient drug delivery.

Cardiovascular agents(25.6%) and antibiotics (22.28%) was found to cause the most reported ADRs. Among the cardiovascular agents in reported ADRs,diuretics was found to cause the most reported ADRs(38.66%).

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Conflict of interest

Nil

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