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Research Article

Implementing Pharmacovigilance at Bathalapalli Hospital to Monitor Adverse Drug Reactions and Improve Patient Care

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A B S T R A C T

Introduction: Although adverse drug reaction (ADR) monitoring is widely known, it is not practised in underdeveloped nations due to a lack of awareness and the absence of a central coordinating agency. The recent implementation of the National Pharmacovigilance Programme has encouraged ADR monitoring in some centres.

Methods: The purpose of this study was to evaluate the sternness of described ADRs, the additional financial costs associated with ADRs, and the present load of ADRs at a Rural Development Trust (RDT) Hospital in Bathalapalli, Andhra Pradesh, India. The study was carried out over 26 months of inpatient admissions to the medical wards.

Results: 37 of the 74 adverse drug events (ADEs) that were reported by 56 individuals were indeed ADRs. There were 521 patients admitted, and 9.7% of those ADRs occurred during hospitalisation. Males (56%) had ADRs more often than females (44%). During the hospital stay, no discernible difference between males and females was seen. ADR rates were 19.0%, 20.0%, and 61.0 % for paediatric, geriatric, and adult patients, respectively. Based on ADR severity, more than half of the reported reactions (76.49%) were in the moderate category, followed by mild (13.51%) and severe (10%) categories. 39.6% of patients recovered from the incident. The majority of the responses showed that the ADRs were unexpected and possibly avoidable.

Conclusion: According to the study's findings, 90% of ADRs might be prevented, saving the health system money and decreasing patient expenditures. To prevent unknown and severe ADRs, new medications should be continuously monitored.

Keywords: Adverse Drug Reaction, Awareness, Hospital, Patients, Pharmacovigilance

Introduction

Adverse drug reactions (ADRs) are one of the biggest preventable risk factors while using drug therapy.[1,2] They are hazardous, unexpected, or unintentional effects of a medicine that happen at doses used in humans for prevention, diagnosis, or therapy, according to the World Health Organization (WHO). They place a significant burden on the system's limited health resources and significantly contribute to morbidity. ADR susceptibility is influenced by several factors, including different medication therapies, disease severity, age, and the kind and quantity of prescribed pharmaceuticals.[3,4] Between affluent and developing nations, there are pronounced disparities in disease prevalence, drug availability, drug use habits, and drug management systems, and these variations have an impact on the frequency and makeup of ADRs.[5,6]

Pharmacovigilance is the study and practice of recognising, assessing, comprehending, and avoiding negative effects and other issues associated with medications or vaccines. Before being approved for use, all medications and vaccines go through comprehensive safety and effectiveness testing in clinical trials.[7-9]

ADRs are regarded as a frequent cause of hospital admissions and are quite expensive for patients.[10-12] The goal of hospital ADR monitoring and reporting programmes is to identify and measure the risks related to the use of medications given in a hospital environment. This information can enhance the prescriber's capacity to more adeptly manage ADRs and assist in the identification and reduction of avoidable ADRs.[13-15]

Materials and Methods

The research was done at a Rural Development Trust (RDT) Hospital in Bathalapalli, AP, India. The least affluent segments of society are served by this 245-bed secondary care facility. In an attempt to close this gap, RDT launched its first rural hospital and rural awareness campaign in 1978, but these initiatives proved ineffective. The RDT Hospital was discovered by Vicente and Anne Ferrer. They planned to build a medical infrastructure in a rural area to offer high-quality healthcare at an affordable price. The hospital has various departments and details regarding ADRs were procured from all departments.

Ethical Approval

The study received ethical approval from the Institutional Health Research Ethics Review Committee of RIPER - Autonomous in Anantapur (reference number SOP PP-21/10-2017). Permission was also obtained from RDT Hospital, Bathalapalli, ensuring adherence to ethical guidelines and protecting the participants' rights and well-being.

Method

A 26-month prospective study was carried out at this hospital from November 2017 to January 2020. Doctors, nurses, and pharmacists collaborated to plan the study. It was conducted through voluntary reporting. All patients suspected of having ADR provided informed consent before documenting. Thirty-one male and twenty-five female patients from the hospital's medical departments and intensive care unit participated in the study. Patients who had purposefully or unintentionally poisoned themselves, including drug users, were disqualified from the trial. The hospital didn't have an established pharmacovigilance programme before the experiment.

When creating several forms, the study's goals were taken into consideration. They contained forms for reporting, documenting patients' replies, and evaluating and grading ADRs. The notification forms were kept by the participating stations. All hospitalised patients were evaluated for ADRs throughout the investigation. The patients' medical and prescription histories were gathered in cases of suspicion. We conducted patient interviews and daily patient observations.

While their hospitalisations and medical records were examined, suspected cases of ADRs underwent a rigorous investigation and documentation process. Along with any medications the patient had taken before the reaction started, its dosage, delivery method, frequency, and date of initiation were all documented.[16,17] Comorbidities and the patient's medical background were additionally noted. A panel of four medical experts and a clinical pharmacist were formed at RDT Hospital to examine ADR complaints and establish the causes and confirmation of ADRs. The panel examined and assessed the ADE reports at monthly meetings.[18]

After that, confirmed ADRs were categorised and given a severity rating. When reviewers disagreed on whether a specific occurrence satisfied the requirements for ADR, the issue was debated until a consensus was reached. In this instance, the treating doctor's judgement was given more weight. The report was labelled as "unconfirmed" if a compromise could not be reached. It was assessed if the reported pharmacological therapy might have contributed to ADRs.[19,20]

Mild responses that might resolve on their own over time and without treatment, were self-limited and did not add to the length of the stay. A moderate ADR required a day in the hospital and a significant amount of therapeutic intervention, but that was precisely managed to avert a worse outcome or was resolved in less than 24 hours. Serious ADRs were those that required immediate medical attention, were deadly, incapacitating, necessitated

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extended hospitalisation, or were life-threatening. Patient outcomes included death, complete recovery, partial recovery, and unknown.[21-23]

The study evaluated the actual direct costs associated with ADRs and compared them with the costs without ADRs. This assessment was based on the expenses related to treatment, hospitalisation, and laboratory investigations, considering a "normal" length of stay without ADRs as a reference point for comparison (All situations involving expenditures for prescription drugs, laboratory work, injections, etc. were included when figuring out hospital charges. The additional cost of care was factored into the overall cost in case the patient had to be moved from the ward where he was previously treated to the ICU for the treatment of ADRs.

The rent for the hospital room was not included in the cost calculation because it depended on the kind of room the patient was staying in. The cost did not additionally cover nursing and medical services. All those who completed the reporting forms received thank-you cards and printed fact sheets with updates on hospital-generated ADRs.

Statistical Analysis

As a percentage of the inpatient population treated, rates of ADR-related expenses and ADR occurrence throughout the hospital stay were predetermined. Student's t-test was used to compare means. Other variables were subjected to the chi-square test. The threshold for statistical significance was a two-tailed p value of 0.05.[24,25]

Results

Out of 521 patients, 74 met the WHO criterion of ADR. Of the 56 people who participated in the study, 31 were men and 25 were women. The majority of the cases fell into the adult patient category (aged 18-60 years). 13 patients were under the age of 18 years, 42 patients were 18-60 years old, and 19 were elderly (> 60 years of age) (Figure 1).

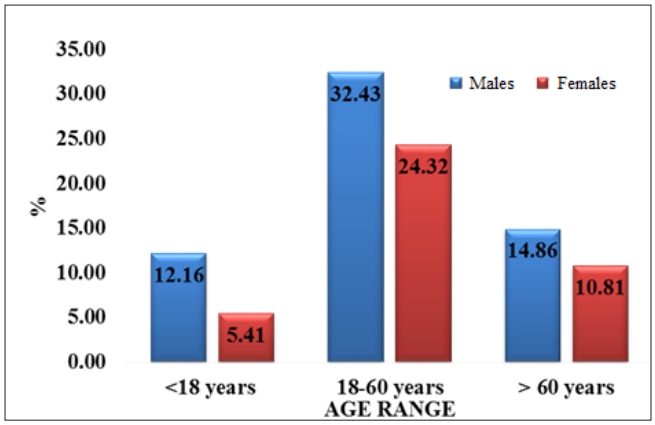

Figure 1.Age Distribution of Participants

The department-wise distribution of ADRs was as per Figure 2.

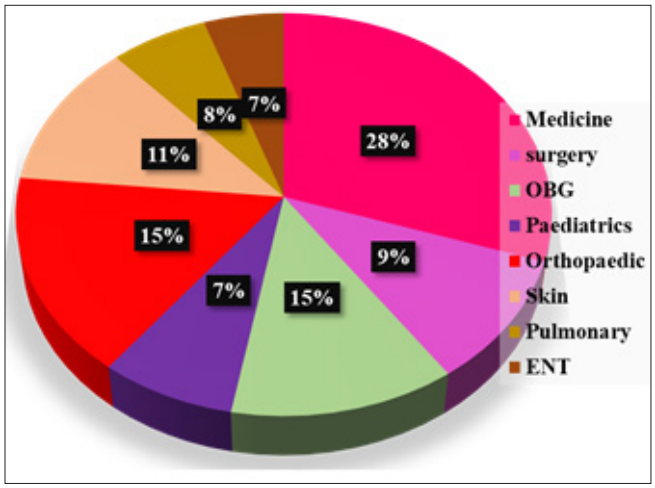

Figure 2.Distribution of ADRs (Department-wise)

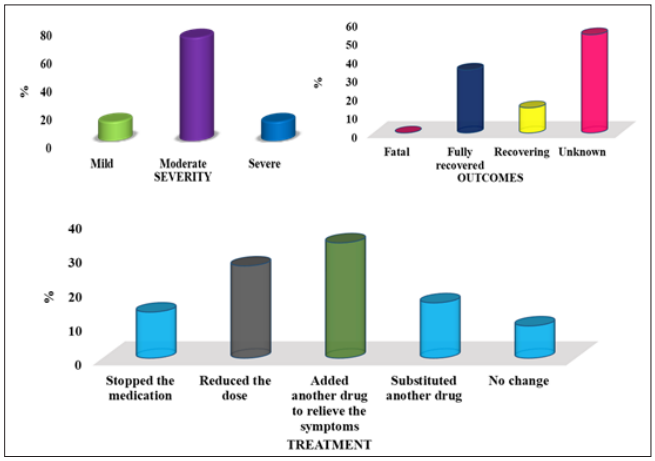

Figure 3.Graphical Glimpses of the Severity, Outcomes and Treatment for ADRs

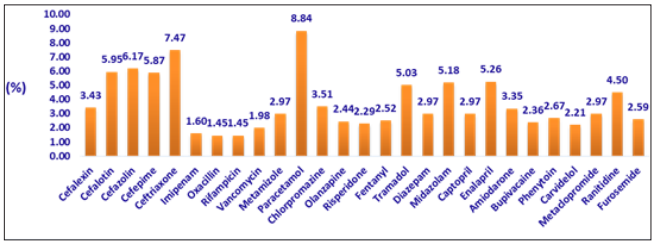

Figure 4.Various Drug Classes of ADRs

The severity, outcomes and treatment for the ADR were as per Figure 3.

Various drug classes of ADRs have been shown in Figure 4.

Figure 5 shows the various types of ADRs.

Discussion

74 ADRs were reported by 56 individuals, and during the 26-month trial, they were verified. 14.2% of the ADRs,

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which involved 521 individuals, happened while they were hospitalised. More men (56%) than women (44%) had ADRs. Such observations were also made by Yan et al.[26] with 52.3% of women patients. In terms of hospitalisation, there was no appreciable variance between men and women. In paediatric, geriatric, and adult patients, the ADR rates were 19%, 20%, and 61%, respectively. Some factors, including more variety of medicines used concurrently, have contributed to ADRs. To evaluate associated causes, we calculated the median number of prescriptions per patient, which was 6.8% of all prescriptions. It was believed to be the source of ADRs. Most of the cases (42) which were classified as adult patients belonged to the 18-60 years age group and 13 patients were under the age of 18 years.

The Department of Medicine in the current study had the most number of ADRs. This can be a result of the higher patient volume in this department. The orthopaedics and OBG departments were in second place. Similar reports were observed by Kumar with more medicine department-oriented ADRs[27] and also by Nayak and Acharjya[28].

The researchers also discovered an elevated risk of negative drug interactions in 7.4% of individuals who were taking more than six drugs. Among the various drug classes that produced ADR, paracetamol stood first (9.46%) followed by cefazolin and fentanyl (6.76%). Based on ADR severity, more than half of the reported reactions (76.49%) were in the moderate category, followed by mild (13.51%) and severe (10%) categories. ADR patients made a partial recovery in 33.78% of cases, continued to improve 10% more, and had uncertain results in 39% of cases. Treatment options included stopping the medication (13.51%), lowering the dose (27.02%), adding another medication to manage the symptoms (33.78%), switching to a different medication (16.21%), and doing nothing (9.45%).

Antibiotics made up approximately 35.37% of the medications, followed by analgesics (11.81%), antipsychotics (8.23%), opioids (7.55%), benzodiazepines (8.15%), ACE inhibitors (8.23%), antiarrhythmics (3.35%), local anaesthetics (2.36%), anticonvulsants (2.67%), beta-blockers (2.22%), antiemetics (2.97%), H2 receptor antagonist (4.5%) and diuretics (2.59%). Antibiotic-related ADR was studied by Jung et al. in South Korea who observed that 58.2% of ADRs were experienced in the case of antibiotics.[29]

Among the adverse reactions produced, skin rashes (20.27%) were predominant followed by headache (14.86%) and diarrhoea (10.81%). More skin rash cases were also reported by Lithiije et al. in 2017 (36.8%).[30] Diarrhoea (49.2%) was seen due to antibiotic therapy studied by Giardina et al. who observed ADRs in hospitalised patients.[31]

Conclusion

The majority of medication responses were moderate and avoidable. The intensity of the reactions, how to avoid them, and the patient's medical background, however, are all generally poorly understood. This study is merely a drop in the ocean for such data. More such studies must be conducted to improve the information and knowledge about ADRs. Healthcare professionals need to be informed about the side effects of drugs at a young age to stop the reaction before it worsens. Patients should also be made aware of any potential drug side effects and responses so that they may seek medical attention before things get worse.

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Conflict of Interest: None

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