

Detection, Monitoring and Assessment of Adverse Drug Reactions at a Private Corporate Hospital

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Abstract: A prospective-observational study to detect, document, assess and report the suspected Adverse Drug Reaction was conducted in a private corporate hospital. Suspected ADRs were analyzed for causality, severity and preventability using appropriate validated scales. ADR alert card was prepared and given to patients. A total of 44 ADRs were identified in 3237 general medicine ward admissions during the study period. Severity of the suspected ADRs assessed using Modified Hartwig and Siegel Scale, revealed that 2(4.5%) suspected ADRs were severe, 27 (61.4%) ADRs were moderate and 15(34.1%) ADRs were mild in severity. Causality assessment was done by Naranjo scale showed that 26(59.1%) ADRs were possibly drug-related, whereas 18(40.9%) were classified as probably or definitely related to the drug. 9 patients (20.5%) were admitted due to an Adverse Drug Reaction compared to 35(79.4%) who were affected by ADR after hospital admission. The majority (36.5%) of patients who suffered from ADRs were above 30 years. System most commonly affected were Dermatological 16(36.3%), Gastrointestinal 9 (20.4%), CNS 4(9.1%) and Cardiovascular 2(4.5%). The drug class mostly associated with ADR was Antibiotics in 14(31.8%) and NSAID in 8(18%). In 29 (66%) cases the drug was withdrawn, dose altered in 8(18.2%) and no change was made in 7(16%) patients. The final outcome revealed 41(93.2%) got recovered, while in 3(68%) cases the ADRs decreased. No fatal case was reported in our study. Preventability of ADRs were assessed by using Modified Schumock and Thornton scale which revealed that 35(79.5%) ADRs were definitely preventable while 3(6.8%) ADRs were probably preventable. Our study documented an increased risk of suspected ADRs in elderly patients, and almost 85% of reactions were preventable. Intervention was required in all ADRs as it indirectly contributed to affect the patient's Quality of Life. The results were circulated to all the healthcare professionals.

Keywords: adverse drug reaction, antibiotics, dermatological system, naranjo scale.

1. Introduction

Voluntary adverse drug reaction (ADR) reporting was on operation since the early sixties in many Western countries. It enables the health care professionals to report suspected ADRs and there by helps to identify new ADRs and risk factors responsible for recognized ADRs

One year study conducted in UK, reports that despite the 6.5% hospital admission due to ADR²⁰ and 15% experiencing ADR during hospital stay, one fifth patients getting re-admitted to hospital within 1 year of discharge are exclusively due to a suspected ADR in which half of those are definitely or possibly preventable. The study says out of 40% of patients getting re-admitted to the study hospital within one year, 18% were due to ADRs

Being the most common iatrogenic illness worldwide, morbidity and mortality due to ADRs are mainly caused because of immune and non-immune mechanisms. It complicates 5 to 15 percentages of therapeutic drug courses leading to more than 100,000 deaths annually in United States^{8,9,10}. Adverse drug reaction is responsible for 3-6% of hospital admissions. The risk for hypersensitivity drug reactions increases with conditions like Asthma¹¹, Systemic lupus erythematosus¹² and use of beta blockers^{11,12}. Adverse drug reactions can result in hospitalization, permanent or persistent and significant disabilities, congenital anomalies, adversely affecting the quality of life, and can result even in death. Added to this it results in higher health care costs.

"ADR" differs from "side effect", as later may also result to be a beneficial effect and former happens only at normal doses¹

The Pharmacovigilance Programme of India (PvPI) was initiated by the Government of India on 14.7.2010 with the All India Institute of Medical Sciences (AIIMS), New Delhi as the National Co-Ordination Centre for monitoring Adverse Drug Reactions (ADR) in the country for safeguarding Public Health. In year 2010, 22 ADR monitoring centres including AIIMS, New Delhi had been set up under this Programme. To ensure implementation of this programme in a more effective way, the National Coordination Centre has been shifted to the Indian Pharmacopoeia Commission, Ghaziabad, (U.P.) on 15-04-2011. The National Coordinating Centre is operating under the supervision of Steering Committee to recommend procedures and guidelines for regulatory interventions.

2. Materials and Methods

The study was conducted at a Private corporate Hospital in Coimbatore. It is a 750 bedded multi-specialty medical institution and one of the largest hospitals in Coimbatore. The hospital is unique and well known for its service to the people who come from various parts of the country

Inclusion and Exclusion Criteria

i) Inclusion Criteria - Patients of either sex of any age who developed an ADR.

ii) Exclusion Criteria- Patients who developed an ADR due to intentional or accidental poisoning, fresh blood/blood products, overdose and patients with drug abuse and intoxication

Once the suspected ADR was reported, we reviewed patients' medical records and also interviewed patients and or healthcare professionals as appropriate to collect all the necessary and relevant data pertaining to the 'suspected' adverse drug reaction.

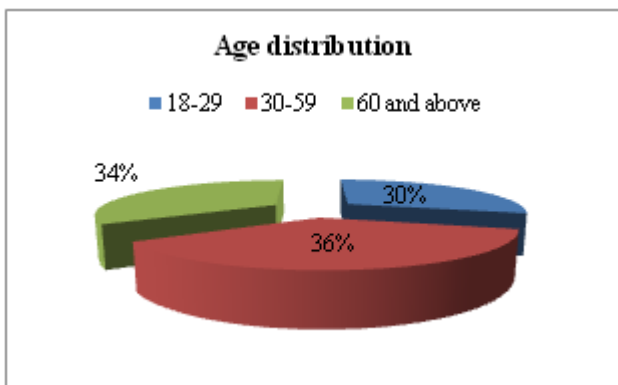
Assessment scales

The causality relationship between suspected drug and reaction was established by using WHO and Naranjo's causality assessment scales. The causality of reported reactions was categorized to any one of the following categories based on the scale used. WHO assessment scale, Naranjo's scale, Severity, Predictability, Preventability

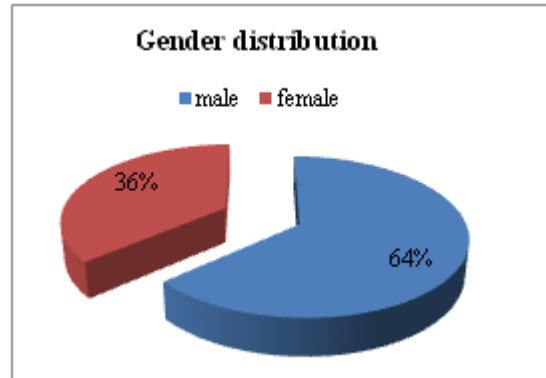
3. Observation and Results

A prospective-observational study on "Detection, Monitoring And Assessment of Adverse Drug Reactions at a Private Corporate Hospital" was conducted at a 750 bedded multi-specialty hospital in the Department of General Medicine over a period of 6 months from March 2014 to August 2014 and cases were assessed for ADRs through a daily ward visit by the pharmacist. Suspected ADRs were analyzed for causality, severity and preventability using appropriate validated scales. ADR alert card was prepared and given to patients. A total of 44 suspected ADRs were identified in 3237 general medicine department admissions during the study period.

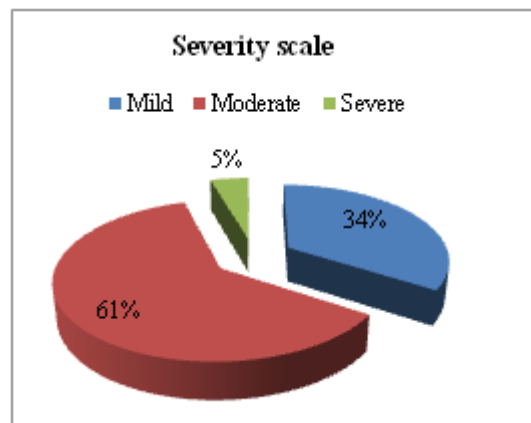
The results of age categorization revealed that the patients of 60 years and above age group experienced maximum Adverse Drug Reaction i.e.,34.1%, followed by 36.4% in age group between 30-59 years and 29.5% in 18-29 years age group.



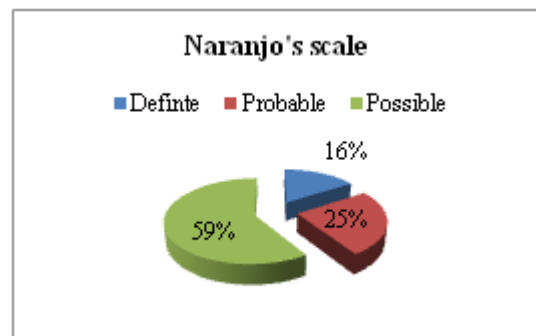
Of the patients who experienced ADR during the study period 28(64%) were male and 16(36%) were female.



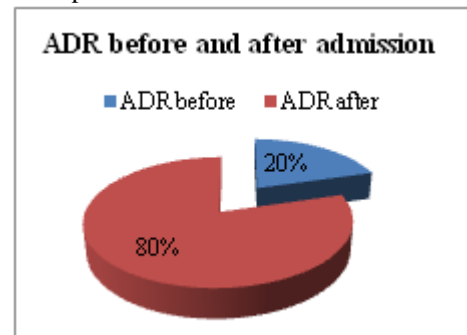
Severity of the suspected ADRs assessed using Modified Hartwig and Siegel Scale, revealed that 2(4.5%) suspected ADRs were severe, 27(61.4%) ADRs were moderate and 15(34.1%) ADRs were mild in severity.



Causality assessment was done by using Naranjo scale. The assessment by Naranjo scale showed that 26 (59.1%) ADRs were possibly drug-related, whereas 11(25%) were classified as probably and 7(15.9%) definitely related to the drug.

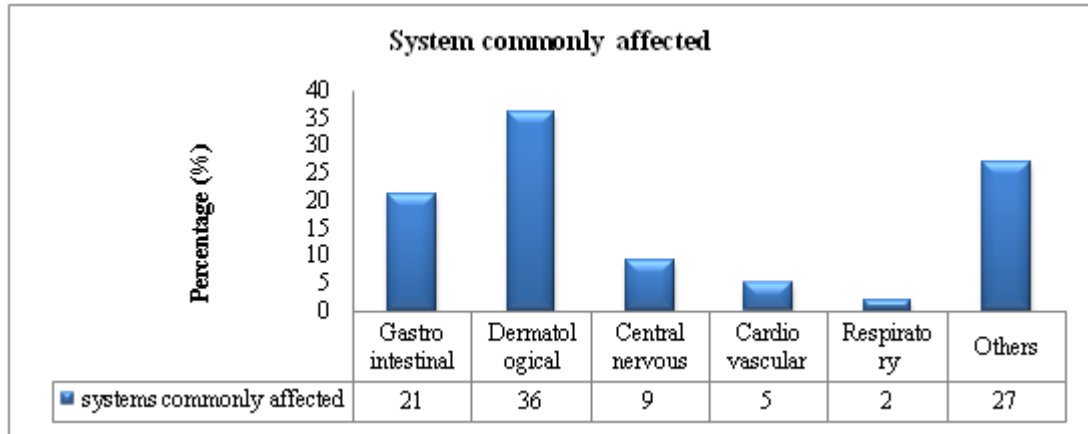


9 patients (20.5%) were admitted due to an Adverse Drug Reaction compared to 35(79.4%) who were affected by ADR after hospital admission.



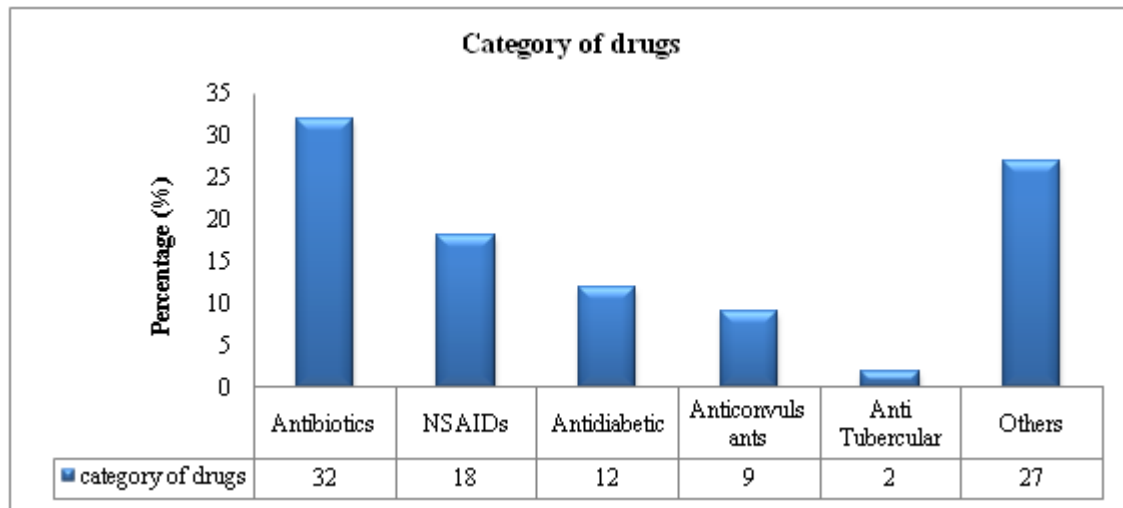
System most commonly affected were Dermatological in 16(36.3%) patients, Gastrointestinal in 9(28.4%) patients,

Central Nervous System in 4(9.1%) patients, followed by Cardiovascular in 2 (4.5%) patients.



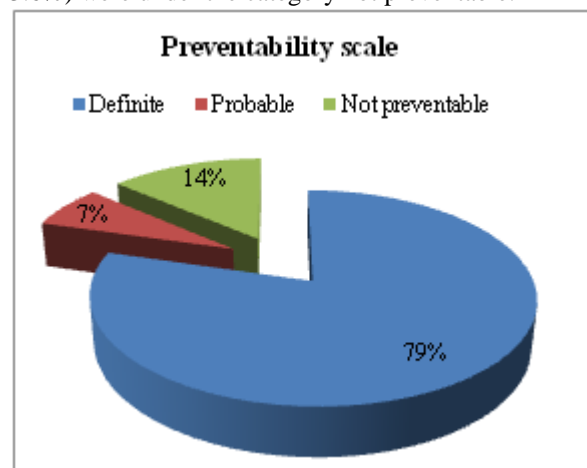
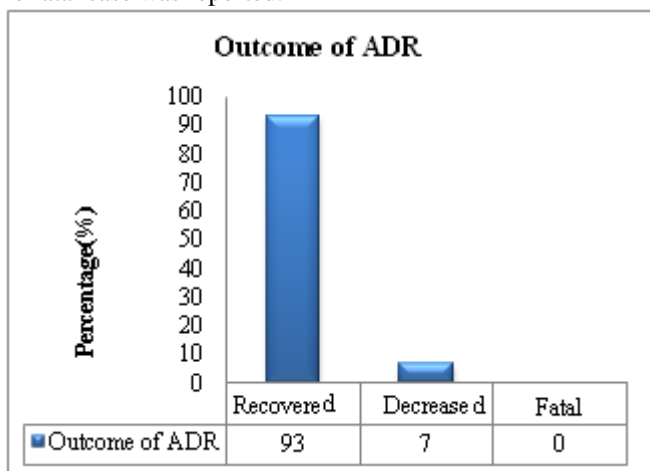
The drug class mostly associated with ADR was Antibiotics in 14(31.8%) cases, followed by NSAIDs in 8(18.2%). In

29(66%) cases the drug was withdrawn, dose altered in 8(18%) and no change was made in 7(16%) patients.



Adverse reactions encountered were treated and the final outcome was measured. About 41(93.8%) patients recovered, while in 3(6.8%) cases the ADR decreased and no fatal case was reported.

while 3(6.8%) ADRs were probably preventable and 6(13.6%) were under the category not preventable.



4. Discussion

Preventability of suspected ADRs were assessed by using Modified Schumock and Thornton scale and the results revealed that 35(79.5%) ADRs were definitely preventable

This study revealed that an increased risk of ADRs is suspected in elderly patients, and that almost 80% of reactions were preventable. Knowledge of pharmacological

principles and how aging affects drug kinetics and response is essential if we are to promote safe prescribing.

Intervention was required in all ADRs indirectly contributed to affect the patient's Quality Of Life. Our ability to anticipate and prevent such ADRs can be facilitated by the establishment of standardized approaches and active reporting of suspected ADRs by all healthcare professionals including physicians, dentists, nurses and pharmacists.

In India the major problem is a lack of proper system of Pharmacovigilance. In this study physician have reported majority of the cases which is encouraging. Reporting by other healthcare professionals could be further improved by encouraging nurses through conducting educational programme on Pharmacovigilance, lectures, newsletters, slogans, banners, personalized letters etc. to aid and increase reporting of adverse reactions.

5. Conclusion

Drugs can be useful tools in the prevention and treatment of symptoms and diseases, but if not used properly, they may be harmful and cause new symptoms or produce suboptimal effects. Potential Drug-Drug interactions are common in elderly people using many drugs and are part of a normal drug regimen and leads to adverse effects. Pharmacist participation with the medical rounding team on a general medicine unit contributes to a significant finding of preventable adverse reactions. The increase in the number of ADRs will continue unless health care professionals as well as the general public, report ADRs in a timely manner. The introduction of many powerful drugs in the last decade also makes it important to balance the anticipated benefits and potential risks.

A large number of powerful drugs, often with a narrow therapeutic window, have reached the market and this makes close monitoring necessary to avoid adverse drug reactions. The most appropriate approach of medication control to minimize the incidence of ADR is screening the total medication of the individual patient by a hospital pharmacist and by taking history of allergy as well as past medication & medical history.

Developing and maintaining electronic documentation of patients' medical records may serve as a valuable tool to detect early signals of potential ADRs. In addition, creating intra net facilities within a hospital may help in easy access for healthcare professionals to the updated patients' medical records resulting in possible detection of ADRs. Also, the implementation of computerized reporting in hospital set-up may hasten reporting of ADRs.

The study strongly suggests that there is greater need for streamlining of hospital based ADR reporting and monitoring system to create awareness and to promote the reporting of ADR among healthcare professionals of the country. Only such centers can greatly influence in bringing reporting culture among healthcare professionals throughout the country. Thus pharmacists have a greater role to play in the area of Pharmacovigilance to strengthen the national Pharmacovigilance programme.

6. Acknowledgement

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