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RETROSPECTIVE ANALYSIS OF REPORTED ADVERSE DRUG REACTIONS

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Abstract:

Pharmacovigilance also known as drug safety is defined as the science and activities relating to the collection, detection, assessment, monitoring and prevention of adverse effects or any other drug- related problems. The World Health Organization (WHO) defines an ADR as 'a response to a drug that is noxious, unintended and occurs at doses normally used in man for the prophylaxis, diagnosis, therapy of disease, or for modification of physiological function'. The study conducted was a cross sectional retrospective study using modified ADR form from Central Drugs Standard Control Organization (CDSCO) and assessment was performed using different scales.

This is a retrospective observational study, conducted on reported ADRs at a quaternary care hospital from 2009 – 2014. The main aim of this study is to assess the incidence, pattern of ADRs, causality, offending drugs, and to prevent the occurrence. Each reported ADR was assessed for its causality by using Naranjo's scale. The severity of each reported ADR was assessed using modified Hartwig & Siegel scale and preventability of ADRs by modified Schumock & Thornton scale.

The adverse drug reactions which occur in this quaternary care hospital reaction had a large number of reactions but most of which were in mild to moderate range. The prescribing of large number of medications causing low intensity of ADRs indicates the use of cautious responsibility due to direct liability and awareness.

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INTRODUCTION:

Pharmacovigilance ensures medications are used to maximal benefit while minimizing the risks of treatment. Adverse drug reaction monitoring can predict hazards from future administration and warrants prevention, specific treatment, alteration of the dosage regimen, or even withdrawal of the product. This has the potential to minimize harm through promoting broader safety concerns for newly introduced as well as already established products.

Adverse drug events can occur from single dose or prolonged administration of a drug or results from the combination of two or more drugs. The importance of adverse drug reactions is often underrated, they can be life threatening and unnecessarily expensive since there are a wide range of drugs available. The manifestation of toxicity varies and can affect any organ system. The pattern of toxicity is likely to change with the introduction of new products.

Tracking of adverse drug reactions is now required by regulatory agencies in order to identify and prevent adverse drug reactions. Methods that can accurately predict those most at risk for an adverse drug reaction have been developed. The most commonly used method is the spontaneous adverse drug reaction reporting scheme also known by the yellow card system in the United Kingdom [1]. The yellow card scheme is important in identifying previously undetected adverse reactions and has provided early warnings of drug safety hazards to allow appropriate drug regulatory actions to be taken [2].

METHODOLOGY:

Study design

- Retrospective observational study.

Source of data

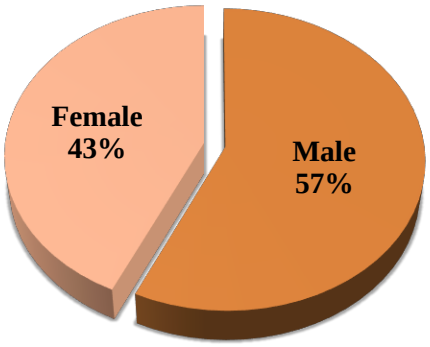
- Reported data during period 2009-2014.

Analysis:

- ADRs were assessed for causality using Naranjo scale
- Severity assessment was performed
- using Hartwig's severity assessment scale
- Preventability of ADRs by modified Schumock & Thornton scale
- Statistical analysis by Microsoft Excel

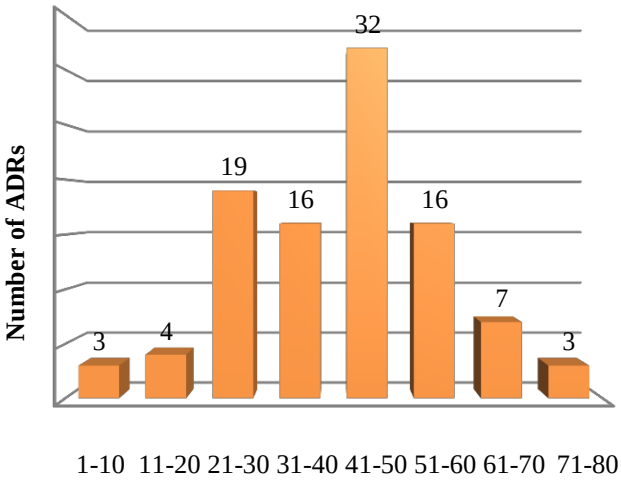
RESULTS & DISCUSSION:

Gender Distribution



Our retrospective study showed the incidence of ADRs during treatment was more common in men (57%) compared to women (43%). A study conducted by Sriram S et al in private tertiary care hospital in south India there were 57 documented ADRs from the 3,117 admitted to the General Medicine ward. The incidence was more common in males than female [3]. The above indictaes that the incidence of ADRs depends on the population involved in the study and the incidence of ADR(s) does not significantly differ with men or women.

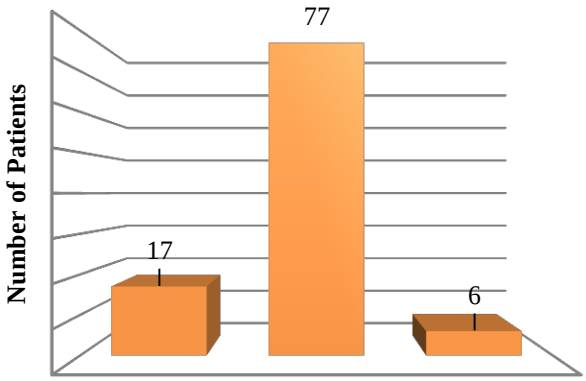
Age Group Distribution



Highest numbers of patients with ADRs were found in the age group of 41-50 and lowest numbers of patients with ADRs were found in the age group between 1-10 & 71-80. A study conducted by Sriram et al, in a private tertiary care hospital, results of age categorization revealed that patients of 60 years and above age group experienced maximum ADRs, followed by age group between 30-59 years and 18-29 years age group [3].

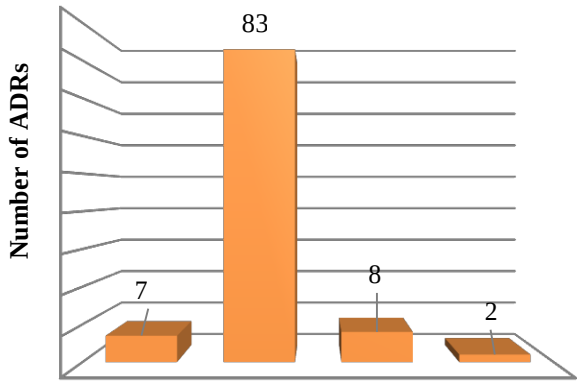
The above shows the incidence of ADRs among age groups depends on the population involved in the study although the incidence of ADRs increases greatly after the age group of 35 this also can differ significantly according to the population being studied.

Severity Assessment



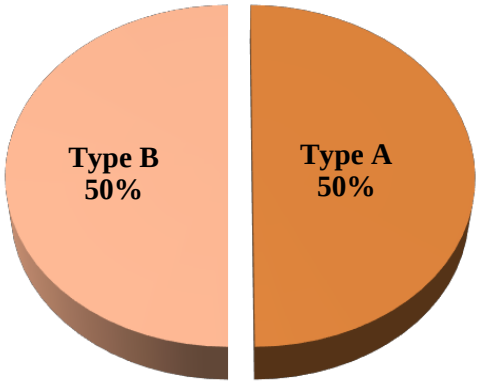
According to Severity Assessment by Modified Hartwig and Siegel Scale our retrospective study shows that ADRs were of moderate severity (77%) followed by mild (17%) and severe (6%). Sivanandy Palanisamy et al conducted a study on assessment, monitoring and reporting of adverse drug reactions in Indian Hospital. According to Severity Assessment by Modified Hartwig and Siegel Scale showed that 35 (58.33%) ADRs were moderate, 21 (35%) ADRs were mild and 4 (6.66%) ADRs were severe. No lethal effects were observed or produced [4]. Our retrospective analysis resulted in very few occurrences of severe ADRs possibly due to intervention and majority of ADRs were of moderate severity.

Causality Assessment Scale



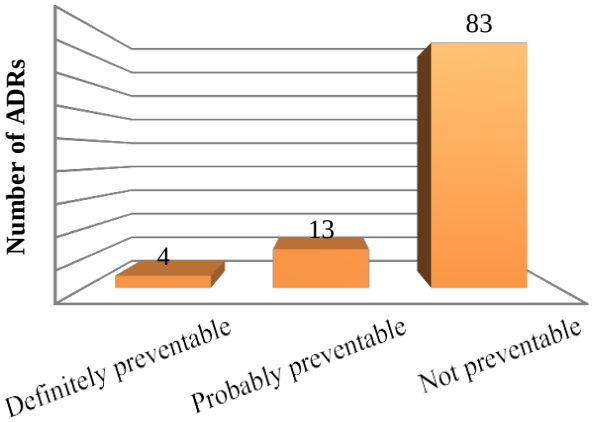
Naranjo causality scale assessment for our study showed that out of 100 ADR's 83 (83%) ADR's were probable, 8 (8%) were classified as possible and 7 (7%) were highly probable and unlikely 2 (2%). A study in Indian hospital on ADRs, assessed by Naranjo's scale showed out of 60 ADRs 44 (73.33%) were possible, 16 (26.67%) were classified as probable and 0 (0.0%) were definitely related to the drug. [4] Our study found majority of ADRs reported were probable according to Naranjo's causality assessment scale. This may be due to fact that most of the ADRs were not confirmed by re-challenge of drug.

Rawlings and Thompson's Classification



According to Rawlings and Thompson's classification ADRs are classified into type A and Type B, analysis of reported ADRs by this method shows incidence of both the type of ADRs were in ratio 1:1. Type A reactions are dose related and thus were preventable from their known pharmacology and therefore all of them were potentially avoidable. Type B reactions comprise approximately 10–15% of all ADRs and include hypersensitivity drug reactions [5].

Preventability Assessment

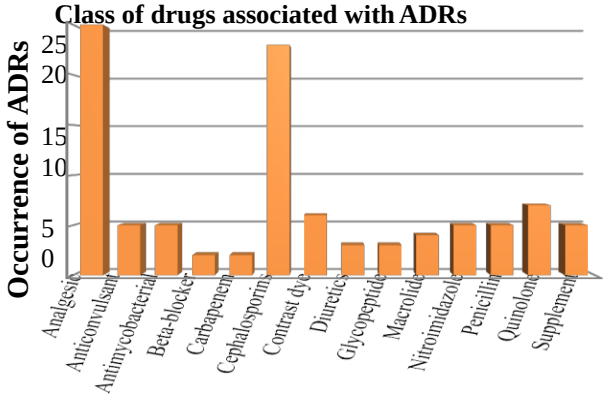


Preventability analysis through modified Schumock and Thornton scale for retrospective study revealed the majority of reactions were not preventable (82%) followed by probably preventable (13%) with only few reactions being not preventable (4%).

According to a study conducted by Bates, antibiotics were responsible for 9% of preventable ADRs and 30% of non-preventable ADRs [6]. Our study resulted in most of reactions being not preventable and probably preventable.

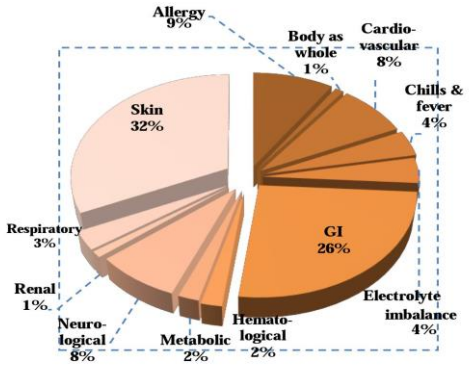
Whereas actual preventable ADRs were fewer in number, reflecting occurrence of ADRs due to medication errors such as incorrect dose, route of administration, duration or even inappropriate drug were not common in this hospital.

Class of drugs associated with ADRs



In our retrospective study ADRs were commonly associated with Analgesic (25%) followed by Cephalosporins (23%), Quinolones (7%) and Contrast Dye (6%). A study by S Sriram et al on Prevalence of adverse drug reactions in a private tertiary care hospital in South India associated Antibiotics as 23% followed by NSAIDs as 19% of drug classes causing ADR [3].

Organ Systems affected by ADRs & commonly occurring reactions



Our retrospective data shows the organ systemsmost commonly affected by ADRs were Skin (32%) followed by Gastrointestinal System (26%), Allergies (9%) and Neurological (8%). Study by S Sriram et al showed organ systems most commonly affected by ADRs were Gastrointestinal in 37% of patients, Dermatological in 25% of patients, Central Nervous System in 14% of patients, followed by Cardiovascular in 12% of patients.[3] Our results were comparable with an international study conducted by Suh et al, which revealed that the system most badly affected was the dermatological and gastrointestinal system [7].

CONCLUSION:

This study strongly suggests there is a need for streamlining hospital based ADR reporting and monitoring system in order to create awareness and to promote the reporting of ADR among HCPs. The present study concludes pharmacists involvement greatly increases the reporting rate as well as quality of reporting. Conducting educational classes for HCPs, developing and maintaining electronic documentation of patients medical records may serve as a valuable tool to detect early signals of potential ADRs.

Therefore it is important for health care professionals to be aware of the toxicity profile for drugs being

prescribed and to be vigilant for the occurrence of unexpected adverse reactions [8], even though it is impossible to be absolutely certain of a causal link between a drug and an ADR.

In conclusion adverse drug reactions results in increased health care costs, diminished quality of life, increased physician visits, hospitalizations, and sometimes even death. The role of the health care professionals is to identify potential and actual drug related problems, resolve problems, and prevent potential drug-related problems.

Encouraging and educating health care providers in order to take responsibility in development of Adverse Drug Reaction Monitoring and Reporting Programs leads to heightened awareness of ADRs, increased reporting of ADRs, and increased opportunities to review drug selection according to risk & benefits ratio and prescribing practices resulting in better patient outcome [9].

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