Original Research Article

Evaluation of Adverse Drug Reactions in a Tertiary Care Hospital in Kolkata, West Bengal: An Observational, Cross-sectional Study

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Abstract

Background: In the present world, drugs are inevitable to cure diseases. However, these drugs are reported to cause unwanted complications to the patients.Adverse drug reactions (ADRs) are considered as one of the leading causes of morbidity and mortality, identified globally. Thus, vigilance of these adverse effects is essential in order to reduce patient suffering. Present study thus aimed to collect reports and to evaluate on adverse drug events from patients attending a tertiary care hospital in Kolkata.**Materials &Method:** This is a cross-sectional, observational study conducted for a period of six months at R.G. Kar Medical College and Hospital, West Bengal, India providing tertiary level of healthcare to the community. Data were collected from both outpatient and inpatient departments. Collected datawere evaluated on the basis of different parameters like demographic features of patients, drugs responsible for the adverse effects, symptoms of the adverse effects and causality assessment based on WHO-UMC and Naranjo assessment scale.**Results:** Out of the 100 reports collected on adverse drug reactions, 55% of the patients were female and 45% male. The mean age of the patients was 47 years. Anti-neoplastic and immunomodulating agents was responsible for maximum number (41.78%) of ADR cases. Using the WHO-causality assessment scale, 67% of ADRs were found to be probably drug-related and 33% of the ADRs were possible.Based on the Naranjo-causality assessment scale, 43% ADRs were found to be definite,45% probable and 12% possible.**Conclusion:**Monitoring of ADRs is thus essential to create awareness in the society and to optimize therapy by increasing patient compliance.

Keywords: Adverse Drug Reaction,Causality assessment,Naranjo,Pharmacovigilance,WHO-UMC

Introduction

Since ages immortal drugs have played a significant role in maintaining the normal healthy life of human.However, Thalidomide disaster in 1960s possesses a threat to the safety issues of drugs. Thalidomide, prescribed to pregnant mothers, was responsible for major birth defects in their children [1]. This 'Thalidomide incidence' created a huge sensitization in the medical world regarding the importance of adverse drug effects of drugs. Any untoward medical occurrence resulting from a medical intervention is referred to as adverse drug event (ADE) [2]. This ADE may not be necessarily due to the medical intervention.The relationship between a drug and a suspected reaction is established with the help of causality assessment.The causality assessment is done by Naranjo and WHO-UMC causality assessment. These two scales arebased on sets of questionnaires to assess the causality by definite, possible, probable, doubtful scale(in Naranjo Causality assessment) or by certain, probable, possible, unlikely, conditional,unclassifiable of causality category(in WHO-UMC Causality assessment) [3]. Events that are caused due to the suspected drug is referred to as adverse drug reaction (ADR). World Health Organization (WHO) defined Adverse Drug Reactions (ADRs) as 'any noxious, unintended,and undesired effect of a drug, which occurs at doses used in humans for prophylaxis, diagnosis, or cure of a disease [4]. ADRs turned out to be a major challenge in the field of therapeutics.Age, sex, ethnicity, coexisting disorders, genetic or geographic factors and by drug factors like type of drug, administration route, treatment duration, dosage, bioavailability,polypharmacy,

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etc. are factors responsible for the onset of ADRs [5]. Thus post-marketing surveillance of drugs or Pharmacovigilance became essential for monitoring of ADRs. The programme of Pharmacovigilance was developed worldwide. According to WHO, pharmacovigilance is defined as"the science and activities relating to the detection,assessment,understanding and prevention of adverse effects or any other drug related problems [6]. The aim of the present study was to estimate the prevalence of adverse drug reactions among the patients attending R G Kar Medical College & Hospital, Kolkata and to evaluate them according to the causality assessment scales.

Materials & methods

A cross-sectional, observational study was conducted with prior approval from the Institutional Ethics Committee where photo copies of prescription were collected from the Outpatient department (OPD) & Inpatient department (IPD) of R G Kar Medical College and Hospital, West Bengal for a period of 6 months. Patients aged 18 years and above of either sex attending IPD/ OPD of various departments with complaints or experience of some ADRs and has been identified by the treating physician, willing to participate and provided written informed consent were included in the study. Patients having inadequate / incomplete information regarding diagnosis and or drugs which were recommended in their prescriptions and those disagreed to participate in the study were excluded. Relevant information of prescriptions and reports were collected in a pre-designed data collection form and later assessed on the basis of age,sex distribution, drugs responsible for the adverse events,symptoms of the adverse effect,causality assessment. Causality assessment was done with the help of Naranjo's and WHO-UMC scale of ADRs. The findings were finally represented in number, percentage and figures.

Result

During the study period, a total 100 reports on Adverse Drug Events were collected, from various in-doors & out-door departments in the tertiary care hospital. Present study revealed that the study population comprised of 55%(55) female patients and 45%(45) males(Figure1).

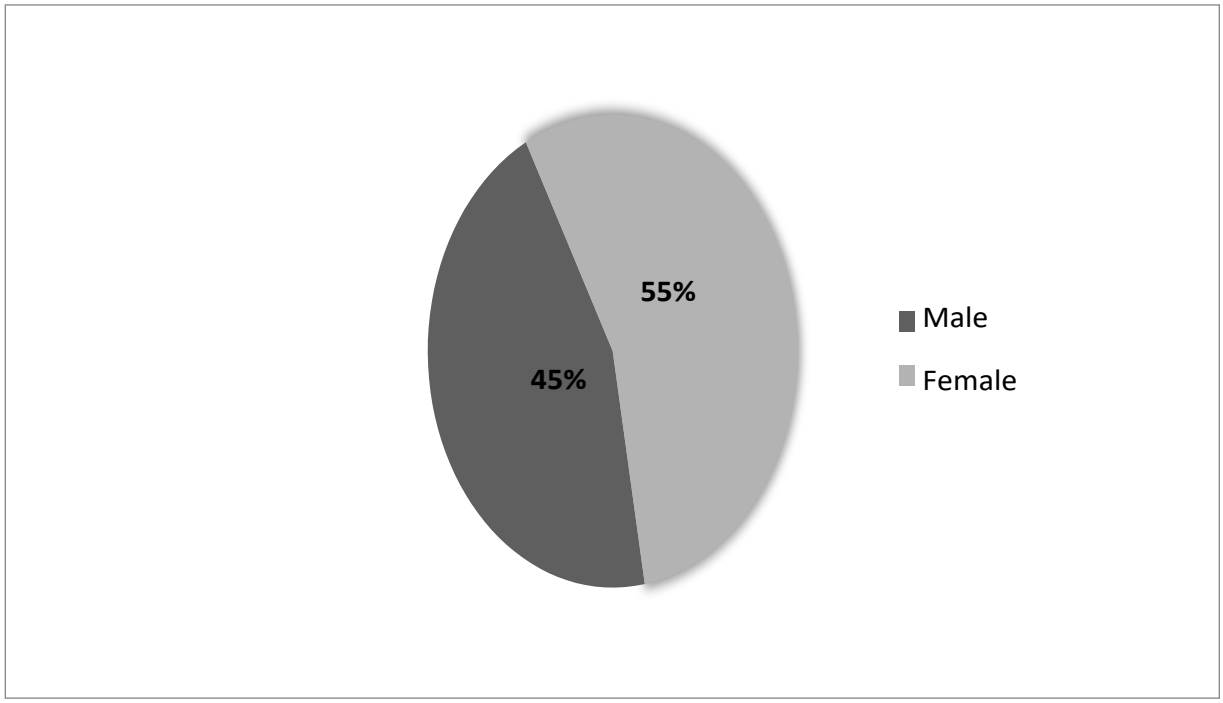

Fig 1:Distribution of patients with respect to gender(n=100)

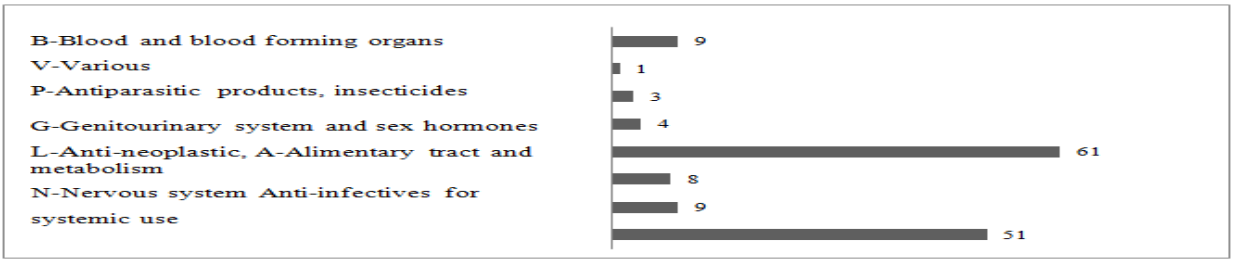

Fig 2:Distribution of Suspected drugs responsible for ADRs based on ATC-drug classification (n=146)

The mean age of the patients reporting ADRs were 47 (± 4.27). Among the different age groups, majority (32%) of the patients experiencing ADRs belonged to age group of 41-50years. Drugs responsible for these adverse drug events were classified based on Anatomical Therapeutic Chemical (ATC) classification system. The number of suspected drugs reported for 100ADRs were146 (n=146). Anti-neoplastic and immunomodulating agents were associated with 41.78% (61) of the reported ADRs. This was followed by anti-infective agents that a counted for 34.93%(51)of the ADRs (Figure2).

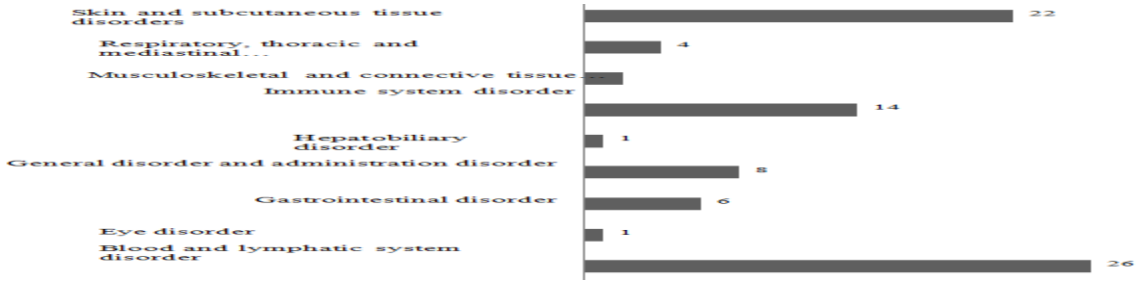

Fig 3:Distribution of symptoms ofADRs(n=84)

The distribution of various symptoms ofADRs was shown in Figure3.Thesymptoms were classified under 8 broad groups and the number of symptoms noted in 100 cases of ADR was 84.Commonly reported symptoms were related to blood & lymphatic system disorders (like anemia), accounting to 30.95% (26). This was followed by 26.19% skin & subcutaneous tissue disorders(like skin eruptions, pruritus,urticarial,etc).

Causality assessment was done based on two scales-Naranjo and WHO-UMC scale.According to Naranjo-causality assessment scale in 100 ADR cases, 43% ADRs were found definite,45%ADRs were found to be probable and 12%ADRs were possible.(Figure 4)

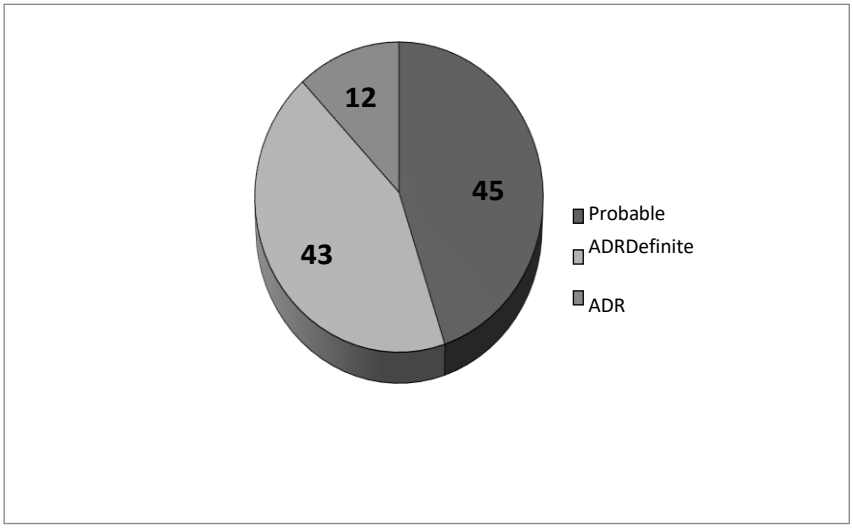

Fig 4:Causality Assessment based on Naranjo-scale(n=100)

According to WHO-causality assessment scale, 67% ADRs were found to be probable and 33%ADRs were possible(Figure5).

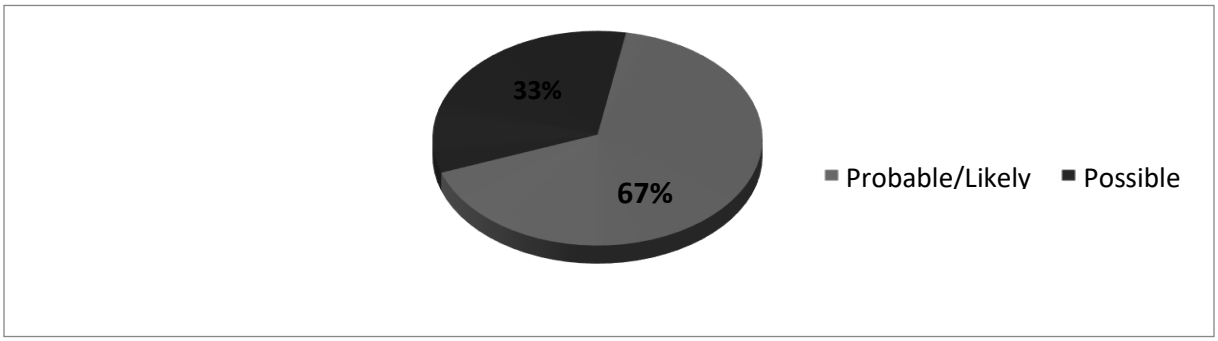

Fig 4:Causality Assessment based on Naranjo-scale(n=100)

Discussion

During the one-year study period, 100 cases of suspected drug reactions were collected amongdifferent departments of R G Kar Medical College and Hospital. Among these patients, 55%were female whereas 45% male. Thus, almost equal distribution of male and female patients was documented in this present study that complied with another study conducted in a tertiary care teaching hospital in South India[7]. However, conflicting results were reported at a tertiary care hospital at Chhatisgarh, India that highlighted a prevalence of ADRs among female patients [8]. Differences in body mass index and fat composition, hormonal effects on drug metabolism, or genetic constitutional differences on various enzymatic levels may be responsible for the difference in the reactions to different drugs among the males and females. Majority of the ADEs (32%) were detected among the age group 41-50 years. This was in agreement with another study in a tertiary care hospital in Gujarat (>40 years) [9]. Similar results were also observed in the studies conducted by different groups of researchers in South India and Chattisgarh [8, 10]. Prevalence of adverse drug reaction is dependent on the age and sex of the patients.The drugs suspected of causing adverse effects in the present study included mostly anti-neoplastic, immunomodulatory agents and anti-infective agents. A study in Brazil indicated40.7% of the ADRs were due to anti-infective agents [11]. Similar results were also reported by Sriram et al. [10] and a regional pharmaco-vigilance centre in Portugal [12]. Both these reports suggested antibiotics were the most common drug involved in adverse reactions. A study performed with Nigerian children by Priyadarshini et. al. also reported antibiotics responsible for 67% of the ADRs [13]. However, it was observed in a national study that diuretics were mostly responsible for ADR in elderly patients [14].These observations, therefore, pose a threat to the use of antibiotics and thus clinicians must remain aware of the ill consequences of incorporating antibiotics in the therapeutic regimen of the patients. The present study showed anaemia was the most prevalent symptom of ADRs accounting to 26.19% of the study population. Skin & subcutaneous tissue disorders like urticaria, and erythematous rashes comprised of 30.95% of the ADR reports in the present study. However,a study in a tertiarycare hospital in Northern Brazil showed prevalence of skin and subcutaneous disorder [15]. This result was in accordance with the study conducted in Portugal where it was observed 21% of the ADRs were skin manifestations [12]. Rashes and skin problems were also prevalent (37%) among the Nigerian children [13]. However,Sriram et al., and Singh et al.,reported contradictory results, documenting gastrointestinal problem to be most prevalent manifestation among the ADR patients [8, 10]. Present study reported 6% of the ADRcases were related to gastrointestinal problems.The causality assessment of ADRs was done using the Naranjo scale.According to causality relationship, 12% were reported as possible because information on drug withdrawal was lacking or unclear, it could have been explained by disease or other drugs and there was a reasonable time relationship to drug intake. 45% were reported as probable and 43% were reported definite. These data correlate with the study of Sriram et al. and Priyadharsini et al. [10,13].

Conclusion

Adverse drug reaction is a significant limitation to the success of therapeutics in the field of medicine. In order to deal with this problem pharmacovigilance is implemented to make the clinicians aware of the drugs responsible for these ill consequences. It is essential to improve the quality and quantity of these ADR reports and to promote surveillance programme in hospitals. Present study depicted an overview of the different types of ADRs encountered in this tertiary care hospital. This knowledge is essential for the clinicians to standardize the therapeutic regimen and to ensures afer treatment to the patients.

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