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Study of Adverse Drug Reaction in the Inpatient Departments of Medicine

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ABSTRACT

Background: Many of the adverse drug reactions (ADR) are severe that even cost life. In fact, the overall situation expected to be worse rather than better because lacking of legislation and proper drug regulations as well as lack of awareness among physicians. That is why we undertook a study to record and analyze adverse drug reactions among all the diagnosed ADR patients admitted in the hospital as well as patients who developed ADR during hospital stay. **Methods:** This was a retrospective cross sectional study included 600 retrospective inpatient treatment sheets, 200 inpatient treatment sheets from each Departments of Internal Medicine, Dermatology & Venereology and Cardiology of Sylhet MAG Osmani Medical College Hospital (SOMCH) to record the common adverse effects of different drug group, body systems involved due to ADRs and analyze the severity of adverse drug reactions with determining their category. **Results:** Most common drug group was antimicrobial agents (36.66%) causing ADRs and Skin & its appendages (63.33%) were most commonly affected by ADR. About 73.34% of ADR found mild in severity and 70% of ADRs were fall on Category type A. **Conclusion:** It can gives an idea about common drugs responsible for ADRs, common body systems affected by different drugs as well as their impact and severity, thus physician can aware/conscious about their use.

Keywords: Adverse Drug Reactions (ADRs), Medicine, Records, Severity.

INTRODUCTION

Medicines can treat disease as well as can prevent illness which sometimes causes problems. Those problems are called Adverse Drug Reactions (ADRs).[1] Any medicine can cause ADRs. ADRs are one of the causes of hospital admission, prolonged hospital stays, and money spending and time waste on service as well as poor patient compliance. During the last decades ADRs are one of the cause of morbidity and mortality recognized by the healthcare professionals. About 4-10% of all hospital admissions are due to ADRs. Once hospitalized, patients have about 10-30% chance of an unwanted event related to drug the therapy. Some countries spend up to 15-20% of their hospital budget for managing drug complications.[2]

ADRs can be classified as, Type A, Type B and Type C. Type A effects (drug actions) are fairly common, dose related and may often be avoided by using doses which are suitable to the individual patient. Those effects can be studied experimentally and are often can be identified before marketing. Type B effects (patient reactions) are generally rare, unpredictable, dose independent, may be serious and difficult to identify. They include immunologically mediated drug hypersensitivity or non-immune mediated idiosyncratic reactions and occurs in those patients with unknown-predisposing conditions. Those ADRs can only be identified by post marketing surveillance. Type C effects are found in those situations where the drugs are used for unknown reason thus increase the frequency of a spontaneous disease.[3] A few reports published in some scientific journals in Bangladesh, Nahar and her colleagues in 2006 studied on the adverse effects of two anti-tubercular drug regimen in Sylhet M A G Osmani Medical College.[4] In another study conducted in Khulna Medical College revealed 25% of fatality caused by ADRs.[5]

Adverse drug reactions are undesirable effect of a drug beyond its anticipated therapeutic effects which

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occurs during clinical use of a drug. ADR is one of the major causes of iatrogenic disease. It may be on target when there is a clear dose response relationship and may be reversible on reducing or withdrawing the drug and it may be off target when there is uncertain dose response relationship. Some ADRs depend on the genetic susceptibility of the individual that is why those are largely unpredictable and more serious (sometimes fatal). The benefit–harm relationships of ADRs should always be taken into account when prescribing because those are complex process. The presentation of ADRs may also mimic a disease process and therefore, they may need further investigations and treatments. Elderly people or those with multiple long-term diseases or use of more than four prescription drugs are more susceptible to ADRs.[6] So the present study aimed at recording and analyzing the adverse drug reactions among all the diagnosed ADR patients admitted in the hospital as well as patients who developed ADR during hospital stay.

MATERIALS AND METHODS

This retrospective cross sectional study was conducted in the Department of Pharmacology & Therapeutics of MAG Osmani Medical College in collaboration with Department of Internal Medicine, Dermatology & Venereology from Jan to Dec 2015 after taking approval from institutional ethical committee of SOMCH. According to the manual titled "How to investigate drug use in health facilities", minimum encounters for a cross sectional survey is 600.[7] It included total 600 retrospective inpatient treatment sheets, 200 prescriptions each from departments of internal medicine, Dermatology and Venereology and Cardiology of SOMCH. Treatment records of individual cases containing clinical diagnosis were considered as sample and samples were collected by systemic random sampling method. Probability sampling technique in case of retrospective data collection. Treatment records of the inpatients of selected departments kept in the record room was utilized as a source of retrospective data. From those records, necessary retrospective data was collected in a data collection sheet. Patient's registration number was considered as sampling frame. Retrospective data collection was started from the most recently registered in-patient records to gradually backward manner. First total number of the patients of the year was calculated from registered book of the respective ward to calculate sampling interval. Then initially an ID was randomly selected within sampling interval from the top of the front page of the treatment sheet where confirmed clinical diagnosis and patient profile were mentioned. After that the remaining samples were collected in above mentioned process. The treatment records of the diagnosed case of ADR in the register were initially identified and documented in ADR review form.

RESULTS

In this retrospective cross sectional study, when analyzed the classes of drugs causing adverse reactions in order of their frequency, it was found that antimicrobial agents including antibiotics and anti TB drugs caused maximum number of effects [Table 1]. Minimum number of effects were due to anticancer drugs. A large number of those ADRs were in the form of cutaneous reactions 63.33% (Table II), the main culprit being antimicrobial agents [Table 1].

Table 1: Common adverse reactions with different drug group

Drug class	No. of event	Percentage
Antimicrobial agents	11	36.66%
Antibiotics	05	
Anti TB drugs	05	
Anti-cancer drugs	01	
Drugs acting on CNS	06	20%
NSAIDs	10	33.34%
Cardiovascular System	02	6.67%
Others	01	3.33%
Total	30	100%

Table 2: Body Systems involved due to ADRs

System	Number of ADR	Percentage
Skin & appendages	19	63.33%
Hepatobilliary	04	13.34%
GIT	04	13.34%
CNS	02	6.66%
Others	01	3.33%
Total	30	100%

Serious cutaneous reactions included Steven Johnson syndrome (SJS). Antimicrobials were again the main drugs, particularly Cefixime and Cefuroximecausing severe ADRs [Table 3]. Hepatobiliary and gastrointestinal disturbances were the second most common ADR [Table 2]. Among them NSAIDs and anti-TB induced drug reactions were common. In [Table 3] shows that large proportions of ADRs 73.34% to be mild type while 20% of the reactions are of moderate type and only 6.66% severe type of reaction. Table IV shows a large fractions of ADRs fall on type A category of ADRs.

Table 3: Analysis of Adverse Reactions based on the severity

ADR Severity	No	Percentage
Mild	22	73.34%
Moderate	06	20%
Severe	02	6.66%
Total	30	100%

Table 4: Analysis of Adverse Reactions based on Category

Category	No.	Percentage
Type A (Augmented reactions)	21	70%
Type B (Bizarre reactions)	09	30%
Total	30	100%

DISCUSSION

Drug classes associated with ADRs, antimicrobial agents were most common in this regard. This finding is similar to other reports of ADRs in inpatients departments.[8,9] But this report is not supported by another inpatients study where NSAIDs were the most common cause of ADRs.[10] In our study NSAIDs were the second most common cause of ADRs, which is very close to antimicrobial agents which is also similar to another study.[11] The most common ADR involved the skin and appendages in inpatient (63.33%) departments which is similar to the study done by Lei in 2007.[12] Other studies also support this report.[13] Most of our patients had mild reactions, followed by moderate ADRs (20%) then severe ADRs (6.66%) which is similar to other study.[14,15] Many of the studies have included only the patients who admitted to the hospital due to ADR or the patients who developed ADR during hospital stay. The majority of our reactions were type A which is consistent to the meta analysis was done by Lazarou et al in 1998 and other studies also support this data.[16,17] But which is inconsistent with another study was done in India in 2009 by Kumar and his colleagues.[18]

CONCLUSION

Functioning ADR report monitoring cell should be formed in every Hospital to ensure proper reporting of every ADR cases to the proper authority, thus authority can take decision to give restriction to use or withdraw of that specific drug from the market and as well as ventilate and spread this information to physician so that physician aware about use of that specific medicine.

Limitations of the study

The ADR cases and severity based on clinical diagnosis by clinician not by causality assessment and severity grading. The true incidence of ADRs cannot be identified from such data. But through this study we can monitor the safety of drugs as therapeutic agents.

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