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Monitoring Of Adverse Drug Reactions in Elderly Patients in an Indian Tertiary Care Hospital

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ABSTRACT

Aim: Present study was carried out to assess the incidence of adverse drug reactions (ADR) and assessment of causality, severity, preventability and additional financial burden associated with reported suspected ADRs.

Methodology: A prospective spontaneous reporting study was conducted over a period of six months in inpatients of medicine wards and medical intensive care unit at Bharati Hospital, Pune. WHO Probability scale was used for causality assessment. Reported ADRs were classified according to Wills & Brown classification and assessed for severity using scale was developed. Average cost incurred in treating an ADR was calculated.

Results: A total of 319 suspected ADRs were reported and evaluated from 78 patients showing an overall incidence of 9.17%. Most of the ADRs were augmented type, whose pharmacology is known. 66% ADRs were classified as “POSSIBLE” in view of causality, while 87% were found to be “MILD” in case of severity. Preventability was found to be 22.87%. Average cost incurred in treating an ADR in hospitalized inpatients was found to be Rs.1328.71 (US $21.90) in India.

Conclusion: Incidence of ADRs was more in hospitalized patients compared to ADR induced hospital admission. Awareness about ADR reporting is still poor amongst healthcare professionals in India. Average cost incurred for treating ADR leading to hospital admission was higher.

INTRODUCTION

Adverse drug reactions (ADRs) are a major cause of morbidity and repeated ADRs related hospitalizations have consistently increased faster than first-time ADRs among elderly patients [1]. Pharmacovigilance is an integral part of drug therapy. Still, it is not widely practiced in Indian hospitals. In various studies, adverse drug reactions have been implicated as a leading cause of considerable morbidity and mortality [2]. The incidence of adverse drug reactions varies with studies which show incidences ranging from as low as 0.15% to as high as 30% [2-4]. Elderly and hospitalized patients are reported to be more susceptible to ADRs than the adult population (16.6% vs. 4.1%) [2].The overall incidence of serious ADRs in the general hospitalized population of the USA to be 6.7% [4]. It has been reported that the incidence of ADR is much more in geriatric, pediatric and female patients. Females are more susceptible to gastrointestinal and cutaneous allergic adverse drug reactions [5-8]. It has been estimated that 83% of ADR in males and 93% in females are due to dose related effects [8].

The use of medication among the elderly population has increased tremendously over the last decade. However, the benefits of medications are always accompanied by potential harm, even when prescribed at recommended doses based on approved guidelines. The elderly are particularly at increased risk of adverse drug reactions or drug related problems attributed in the main to poly pharmacy and physiological changes affecting the pharmacokinetics and the pharmacodynamics of many drugs or poor compliance due to cognitive impairment or depression.

For reasons that are not inherently obvious, pharmacists have defined, described and quantified adverse drug reactions more extensively than all other categories. In fact numerous papers and books have addressed this topic. Rawlins has categorized adverse events as a type A or type B. Type A reactions are consistent with the pharmacologic actions of the drug occur commonly are usually dose-dependent, and are fairly predictable. Type B reactions represent allergic and idiosyncratic reactions that are independent of drug pharmacology. These are rare, not dose-related, and cannot be predicted. Only those that are idiosyncratic should cause the patient and pharmacist significant problems because one of the assumptions underlying this discussion is that the pharmacist is playing a proactive role in the patient's drug therapy. Through the introduction of a unique knowledge base within the context of a rational treatment plan, the pharmacist can at best eliminate them through effective therapeutic monitoring.

It should be emphasized that when a particular ADR is unavoidable , as in the case of many anti- hypertensive drugs where at least a minor adverse reaction or inconvenience is to be expected or with oral contraceptives where fluid retention is frequently experienced, patient preference and the burdens-to-benefited calculation should be considered an essential part of clinical decision making. This is particularly important when there is some degree of "trade off" involved and a patient may have to select discomfort or convenience from a range of possibilities [9]. Therefore, this study was aimed to identify incidence, types of ADRs and assess their causality, severity and preventability in geriatric population.

METHODOLOGY

Data collection

A prospective spontaneous reporting study approved by the Institutional Ethics Committee (IEC) was conducted over a period of six months. The study was coordinated by PharmD students.

Inclusion

- Patients of either sex above 60 years of age who developed an ADR admitted in medicine ward and medical ICU.

Exclusion

- Patients with intentional or accidental poisoning
- Patients who developed an ADR during transfusion of blood or blood products
- Patients treated on outpatient department (OPD) basis
- Patients with drug abuse
- Patients with surgical reference
- Patients with accidental or emergency cases

WHO definition of an ADR was adopted. Spontaneous reporting system was the method followed for monitoring ADRs. Medical staff, medical post graduates, nursing staff and patients were educated and encouraged to report ADRs by creating awareness through brief presentations and conducting clinical meetings. ADR notification forms were kept in the nursing stations of medicine wards and the ICU. Pharm. D students played a crucial role in monitoring through daily participation in ward rounds and encouraging the physicians to report. Any reaction noted by the student was brought into the notice of the physician, who if convinced enough of the drug cause of reaction filled the notification form. Informed consent was taken from the patient for suspected ADR before documentation. The demographic details of the patient were collected along with the current concern and drug therapy details in a systematically designed patient profile form. All relevant data including the drugs patient received prior to the onset of reaction, respective dose, and route of administration with frequency, date of onset of reaction and the patient's allergic status were noted. In addition to this patient's medication history and other co-morbidities were identified to assess causality relationship between the suspected drug and reaction. Patients were interviewed and the medication order and records were reviewed on daily basis throughout the stay of patient in the hospital. Any drug treatment and/or supportive therapy given for management of the reactions were also noted. The reported suspected ADRs were classified according to the Wills and Brown classification.

Causality assessment of ADR was carried out using Naranjo's scale [10] which categorizes the causality relationship into certain, probable, possible, unassessable/unclassifiable, unlikely, conditional/unclassified. Severity of ADR was graded as per scale developed by Hartwig et al. [11].

Preventability assessment was carried out by Schumock and Thornton scale. Average cost per patient was calculated by total amount spent on treating ADRs divided by the number of patients suspected with ADR. For analyzing the cost, ADR requiring specific drug and supportive therapy were considered. Drugs, laboratory investigation orders, syringes, applicants, etc. were all calculated per unit per patient. Reaction requiring a simple cessation of suspected drug, the cost was considered nil.

RESULTS

A total of 850 hospital admissions during study period, elderly patients were found to be 120. Amongst 120 (male/female percentage) elderly, 319 ADRs were suspected and encountered in 78 patients showing 9.17% of incidence rate. Incidence of ADRs was predominant in female patients (55.48%) shown in **Table 1.**

Table 1. Incidence of adverse drug reactions.

Total No. of patients admitted	No. of patients with ADRs	Incidence %
850	78	9.17

Most of the ADRs are augmented type, whose pharmacology is known and it is predictable reaction like cough, headache, nausea/vomiting, generalized weakness shown in **Figure 1.**

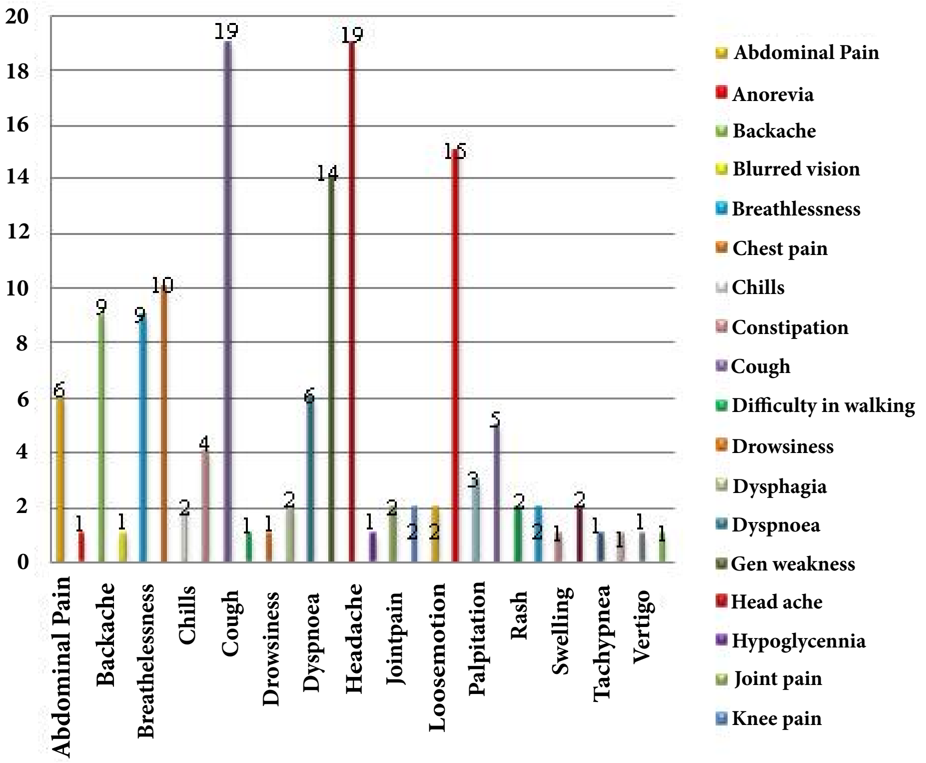

Figure 1. Types of ADRs.

Causality assessment of ADRs was done by using Naranjo's ADR probability scale. Out of 319 adverse reactions, 209 were categorized in possible, 64 were probable and 46 were unlikely shown in **Figure 2.**

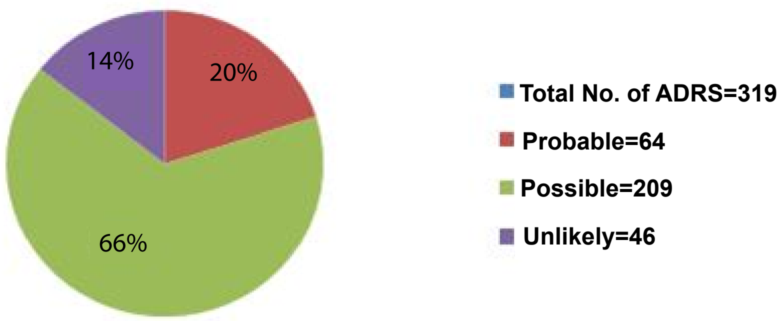

Figure 2. Causality assessment of ADRs.

ADRs are also categorized on the basis of severity, out of 319 events, 300 were mild, 16 were moderate and severe event was found to be 3. Serotonin syndrome & blurred vision were included in severe events shown in **Figure 3.**

Assessment of ADRs on the basis of preventability shows that 246 (77.11%) events were not preventable followed by probably preventable events which were 71 (22.25%) and definitely preventable events were very less, about 2 (0.62%) events as shown in **Figure 4.**

Total cost incurred in managing all ADRs reported was Rs 1, 03,640. The average cost involved in treating ADR per patient was found to be Rs 1328.71 (US $ 21.90) shown in **Table 2.**

Figure 3. Assessment of severity of ADRs.

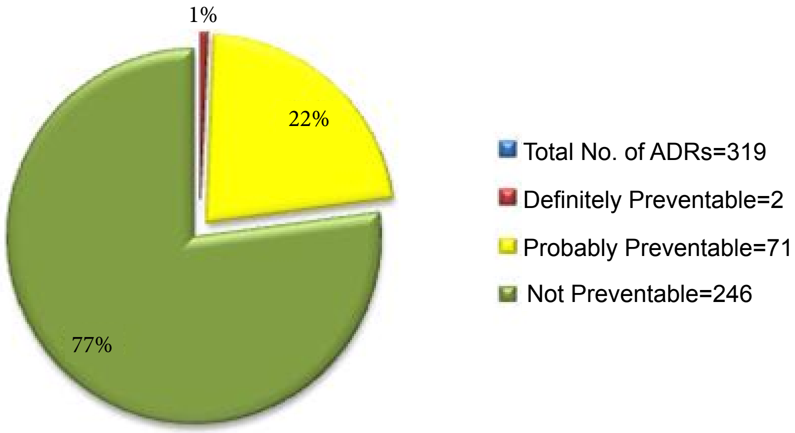

Figure 4. Assessment of preventability of ADRs.

Table 2. Cost incurred in managing adverse drug reactions.

Category of ADR	Total No. of geriatric patients	No. of patients who incurred cost	Total cost incurred in Rs.	Average cost per patient in Rs. (US $)
ADR in hospitalized inpatients	120	78	1,03,640	1328.71 ($ 21.90)

DISCUSSION

There are many problems which can be associated with the interaction of drugs into the human body; Adverse Drug Reactions (ADRs) represents one of eight identified categories of drug related problems. The result of the study showed that suspected ADRs occurred in 78 (65%) patients out of 120 patients. Total numbers of ADRs were found 319. The incidence rate of ADRs were found 9.17% out of 850 patients admitted in hospital during the study period which is lesser than the study conducted by Beijer [2] where the incidence rate was found to be 16.6% in elderly. Adverse drug reactions were found to be 48.33% in female and 51.66% in male patients which differ from various studies carried out by Padma et al. [12] (62.7 female and 37.3% male), Jha et al. [13] (54.1% female and 49.5% male) and Tejal et al. [14] (66% female and 34% male). There is no known underlying explanation for the occurrence but study results reveal female gender most affected with ADRs which was similar to various studies reported.

Adverse events related to drugs are common in hospital care, and many are preventable or ameliorable. Monitoring for and acting on symptoms are important. Of the 120 patients in the study, 78 had adverse drug events with a total of 319 events (4.09 events per patient). As age increases, the patient is more prone to co-morbidity. In the elderly patients, the multiplicity of disorders requires the use of multiple drugs. In addition, their altered pharmacokinetics and pharmacodynamics result in an enhanced sensitivity to many drugs. Polypharmacy is prevalent and associated with increased potential for adverse drug reactions.

3 events (2.06%) were severe, 16 (11.03%) were moderate and 126 (86.89%) were mild (Table no. 10 and 12) which is similar to study of Tejal et al., with a total of 181 events, 24 of the events (13%) were serious, 51 (28%) were moderate, and 20 (11%) were mild [15,16].

Causality assessment was done by using Naranjo's causality assessment scale which revealed that 65.51% of the reactions were categorized as "Possible", 20.06% as "Probable" whereas 14.42% of the reactions were "Unlikely" related to drugs [17]. The study were found to be differ with Palanisamy et al. [18] that showed results Definite 4.17%, 90.62% of ADRs were "Probable", 4.17% of ADRs were "Possible", No ADRs was found in "Unlikely" class.

Preventability of suspected ADRs was assessed by using modified Schumock and Thornton scale which shows that ADRs out of 319, 71 (22.25%) adverse events were Probably preventable while 2 (0.062%) were Definitely preventable and 246 (77.11%) ADRs were not preventable which is being supported by the study carried out by Shanmugam et al. showing considerably same result [19].

CONCLUSION

Incidence of ADRs was more in hospitalized patients compared to ADR induced hospital admission. Geriatrics males were most affected with ADRs. Antimicrobial drugs being mostly affecting class of drugs. Average cost incurred for treating ADR leading to admission was higher than treatment of ADR after hospital admission. There is need for establishing ADR monitoring centre at every multidisciplinary hospital. Also, more original studies need to be conducted in Indian population to know the exact prevalence of ADRs in Indian hospitals.

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