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Research Article

A retrospective analysis of adverse drug reactions in a tertiary care teaching hospital at Dehradun, Uttarakhand

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ABSTRACT

Background: Adverse drug reactions (ADRs) are one of the major causes of hospital admissions. The objective of this study was to ascertain the various ADRs occurring in a tertiary care teaching hospital at Dehradun, Uttarakhand.
Methods: The ADRs were collected from January 2010 to June 2014 by the Department of Pharmacology in Shri Guru Ram Rai Institute of Medical & Health Sciences, Dehradun, Uttarakhand. A total of 123 ADRs were collected, analyzed and assessed on WHO causality assessment scale.
Results: A total of 123 ADRs were assessed. Male:female ratio was 1.5:1. Age-wise distribution of ADRs was done: 0-15 years had 15 (12.19%), 16-30 had 50 (40.65%), 31-45 showed 25 (20.32%), 46-60 years 22 (17.88%) and >60 years had 11 (8.94%). 112 (91.05%) ADRs were serious, and 11 (8.94%) were non-serious. As per the WHO causality assessment scale, 91 (73.98%) ADRs were probable, 30 (24.39%) were possible, and 2 (1.62%) were certain. Most commonly occurring ADRs were fixed drug eruption in 42 (34.14%) patients, erythematous maculopapular rash in 20 (16.26%) patients and urticarial rash in 15 (12.19%) patients, followed by others. The drugs most frequently associated with ADRs were non-steroidal anti-inflammatory drugs (NSAIDs), fluoroquinolones, penicillins, cephalosporins and phenytoin sodium, followed by others.
Conclusions: Majority of ADRs were probable according to WHO causality assessment scale. Most common ADR was fixed drug eruption. Most frequent drugs associated with ADRs were NSAIDs. ADRs contribute to increased morbidity and mortality in patients; thereby pose a huge burden on the society.

Keywords: WHO causality assessment scale, Adverse drug reaction, Fixed drug eruption, Non-steroidal anti-inflammatory drugs

INTRODUCTION

According to the World Health Organization (WHO), an adverse drug reaction (ADR) is any noxious or unintended and undesired effect of a drug, which occurs at doses used in humans for prophylaxis, diagnosis or therapy.[1] The risk of ADRs is necessarily an inherent risk of all drug therapy and is modulated by several factors, including dose and frequency of administration, genotype, and pharmacokinetic characteristics of special populations, such as pediatric and geriatric patients and those with hepatic or renal impairment. Due to the high frequency and potentially serious consequences, ADRs may have a dramatic impact in clinical practice, both from a clinical and economic perspective.[2] Several epidemiological studies have been conducted that give an indication of the frequency of ADRs and the related healthcare costs in clinical practice. Such consequences include drug-related hospital admission, prolongation of hospital stay, and emergency department visits.[3]

ADRs contribute to excessive health care costs through increased patient morbidity and mortality. There is an urgent need to create awareness among physicians and masses towards ADR monitoring.[4] Owing to the high incidence and under-reporting of ADRs, a retrospective analysis of ADRs was done in a tertiary care Teaching Hospital at Dehradun, Uttarakhand.

METHODS

The ADRs were collected from January 2010 to June 2014 by the Department of Pharmacology in Shri Guru Ram Rai Institute of Medical & Health Sciences (SGRRIM & HS), Dehradun, Uttarakhand. A total of 123 Pharmacovigilance Program of India ADR forms were collected from various Departments of Shri Mahant Indiresh Hospital at SGRRIM & HS, Dehradun, Uttarakhand. ADRs were analyzed and assessed on WHO causality assessment scale. Statistical analysis was performed using t-test. $p<0.05$ was considered as significant.

RESULTS

A total of 123 ADRs were collected, analyzed and assessed. 74 (60.16%) males and 49 (39.84%) female patients were seen. Age-wise distribution was done. 0-15 years showed 15 (12.19%) patients, 16-30 years had 50 (40.65%), 31-45 years had 25 (20.32%), 46-60 years had 22 (17.88%) and >60 years 11 (8.94%) patients (Table 1). Of 123 ADRs, 112 (91.05%) ADRs were serious and 11 (8.94%) were non-serious, p value was highly significant ($p<0.001$) (Figure 1). Causality assessment was done on WHO causality assessment scale. 91 (73.98%) ADRs were probable, 30 (24.39%) ADRs were possible and 2 (1.62%) ADRs belonged to certain category (Figure 2).

Table 1: Demographic profile.

Parameters	Number (% age)
Total ADRs	123
Male:female	1.5:1
0-15 years	15 (12.19)
16-30 years	50 (40.65)
31-45 years	25 (20.32)
46-60 years	22 (17.88)
>60 years	11 (8.94)

ADR: Adverse drug reactions

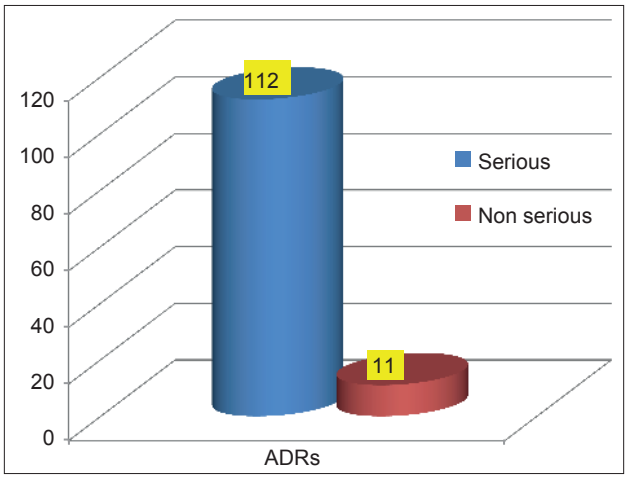

Figure 1: Serious versus non-serious adverse drug reactions.

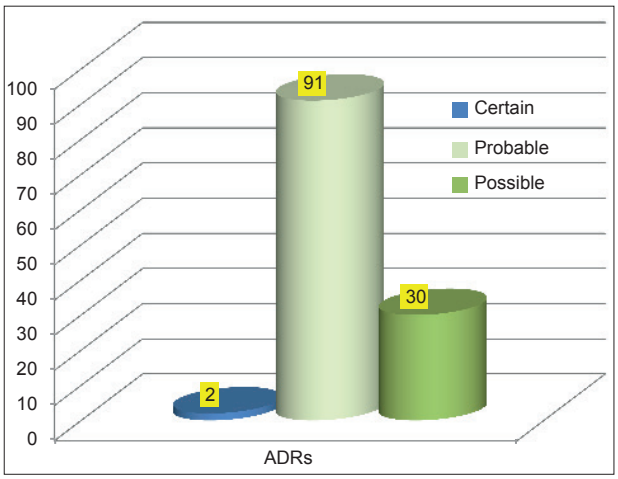

Figure 2: WHO causality assessment.

Most frequent ADR was fixed drug eruption in 42 (34.14%) patients, followed by erythematous maculopapular rash in 20 (16.26%) patients, urticarial rash in 15 (12.19%) patients, erythema multiforme and exanthematous rash in 6 (4.8%) patients each, Steven–Johnson syndrome and maculopapular rash in 5 (4.06%) patients each, anaphylactic reaction, nephrotoxicity, dress syndrome and puffiness of

face in 2 (1.62%) patients each and 16 (13%) ADRs in others category were seen (Figure 3).

The most common drugs associated with ADRs were non-steroidal anti-inflammatory drugs (NSAIDs) which resulted in 35 (28.45%) ADRs, followed by fluoroquinolones which caused 30 (24.39%) ADRs, penicillins 11 (8.94%) ADRs, cephalosporins, phenytoin sodium 8 (6.5%) ADRs each, anti-tubercular drugs 6 (4.87%) ADRs, cotrimoxazole 5 (4.06%), amikacin 2 (1.62%) and 18 (14.63%) ADRs caused by other drugs (Figure 4).

DISCUSSION

The present study was a retrospective analysis of ADRs in a tertiary care teaching hospital at Dehradun, Uttarakhand. A total of 123 ADRs were collected, analyzed and assessed. Majority of ADRs (60.16%) were seen in male patients, which were comparable with previous studies by Shamna et al. where 53.06% males experienced ADRs and Patel and Marfatia where 112 were males and 88 were females.[5,6] Majority of ADRs (40.65%) were seen in 16-30 years age group which was comparable with the previous study by Sharma et al. where 50.4% were in the age group of 21-40 years among the 500 patients of ADRs.[7]

The ADRs were assessed on WHO causality assessment scale and out of 123 ADRs, 112 (91.05%) were serious and 11 (8.94%) were non-serious. This was similar to the previous meta-analysis by Lazarou et al. where majority of ADRs belonged to a serious type.[8] Majority of ADRs were probable 91 (73.98%), followed by possible 30 (24.39%) type and only 2 (1.62%) belonged to a certain type. These data correlate with the study by Shamna et al. which showed 71.42% ADRs belonging to probable type followed by 18.36% belonging to possible type and 10.20% belonged to a definite type.[5] Our finding was similar to other studies by Stavreva et al. Priyadharsini et al. and Jimmy et al. and not comparable to the study by Oshikoya et al. because they reported more number of definite reactions.[9-12] Our study showed fixed drug eruption as the most common ADR occurring in 42 (34.14%) patients. This finding was similar to previous studies by Khondker and Khan where incidence of fixed drug eruptions was 45%, and Patel and Marfatia where it was 30.5%.[6,13] Our study revealed the predominance of cutaneous manifestations, which was similar to other studies which showed the predominance of cutaneous manifestations.[11,12,14] The most common offending drugs responsible for ADRs were NSAIDs in 28.45%, which was similar to studies by Pirmohamed et al. where NSAIDs caused 29.6% reactions and Patel and Marfatia where 22.8% ADRs were caused by NSAIDs.[6,15] This was followed by fluoroquinolones, penicllins and cephalosporins. A study conducted by Stavreva et al. revealed the predominance of cephalosporins, whereas fluoroquinolones were most accounted in a study conducted by Hussain et al. while penicillins were most frequent in the study of Priyadharsini et al.[9,10,14]

CONCLUSIONS

ADRs are one of the leading causes of morbidity and mortality in patients. The results of our study provide an insight to the healthcare providers on the importance

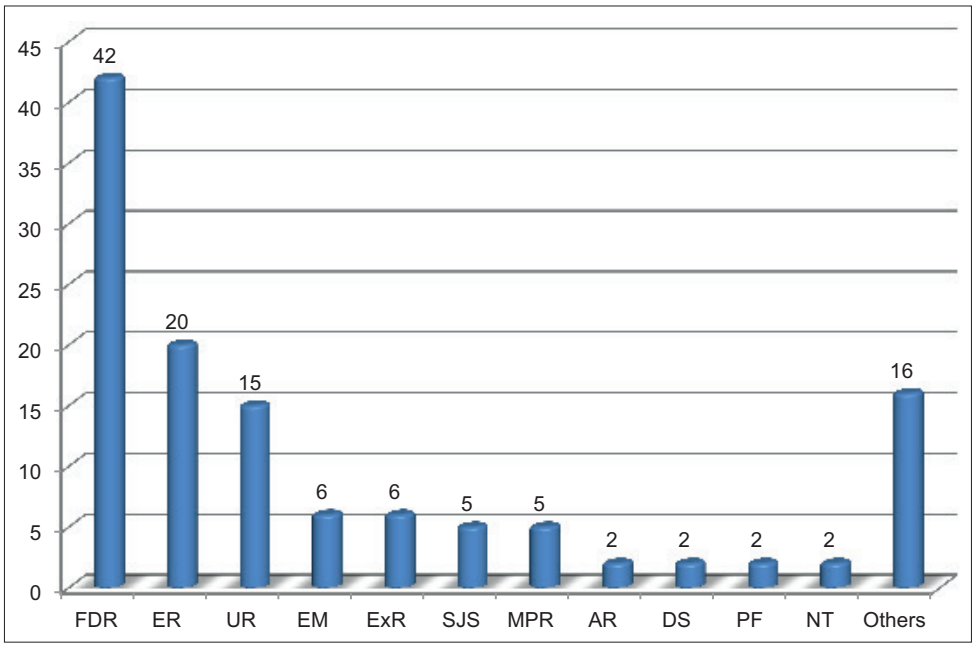

Figure 3: Types of adverse drug reactions, FDR: Fixed drug eruption, ER: Erythematous rash, UR: Urticarial rash, EM: Erythema multiformis, ExR: Exanthematous rash, SJS: Steven–Johnson syndrome, MPR: Maculopapular rash, AR: Anaphylactic reaction, DS: Dress syndrome, PF: Puffiness of face, NT: Nephrotoxicity.

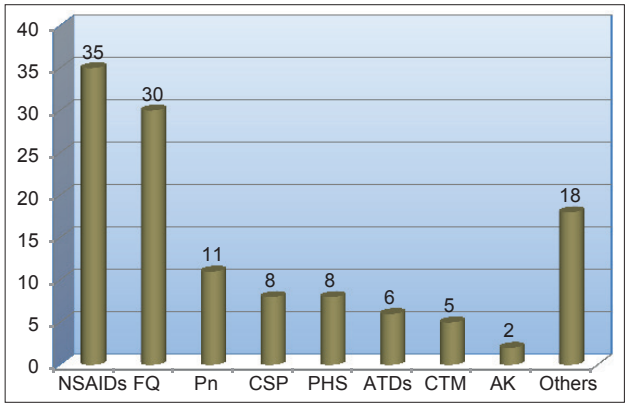

Figure 4: Drugs causing adverse drug reactions, NSAIDS: Non-steroidal anti-inflammatory drugs, FQ: Fluoroquinolones, Pn: Penicillins, CSP: Cephalosporins, PHS: Phenytoin sodium, ATDs: Anti-tubercular drugs, CTM: Cotrimoxazole, AK: Amikacin.

of monitoring and reporting of ADRs. The health care system should promote the spontaneous reporting of ADRs, proper documentation and periodic reporting to regional pharmacovigilance centers to ensure drug safety. It is imperative that the system of ADR monitoring be designed in such a way that it encourages clinicians and other paramedical personnel to report ADRs spontaneously and intensively.

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Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

1. World Health Organisation. International Drug Monitoring: The Role of the Hospital. Technical Report Series No. 42 Clinical and Economic Burden of Adverse Drug Reactions. Geneva, Switzerland: World Health Organisation; 1966.
2. Sultana J, Cutroneo P, Trifirò G. Clinical and economic burden of adverse drug reactions. J Pharmacol Pharmacother. 2013;4(Suppl 1):S73-7.
3. Lacoste-Roussillon C, Pouyanne P, Haramburu F, Miremont G, Bégaud B. Incidence of serious adverse drug reactions in general practice: A prospective study. Clin Pharmacol Ther. 2001;69(6):458-62.
4. Davies EC, Green CF, Taylor S, Williamson PR, Mottram DR, Pirmohamed M. Adverse drug reactions in hospital in-patients: a prospective analysis of 3695 patient-episodes. PLoS One. 2009;4(2):e4439.
5. Shamna M, Dilip C, Ajmal M, Linu Mohan P, Shinu C, Jafer CP, et al. prospective study on adverse drug reactions of antibiotics in a tertiary care hospital. Saudi Pharm J. 2014;22:303-8.
6. Patel RM, Marfatia YS. Clinical study of cutaneous drug reaction in 200 patients. Indian J Dermatol Venereol Leprol. 2008;74:430.
7. Sharma VK, Sethuraman G, Kumar B. Cutaneous adverse drug reactions: Clinical pattern and causative agents – a 6 year series from Chandigarh, India. J Postgrad Med. 2001;47(2):95-9.
8. Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactions in hospitalized patients: A meta-analysis of prospective studies. JAMA. 1998;279(15):1200-5.
9. Stavreva, G, Pendicheva D, Pandurska A, Marev R. Detection of adverse drug reactions to antimicrobial drugs in hospitalized patients. Trakia J Sci. 2008;6(1):7-9.
10. Priyadharsini R, Surendiran A, Adithan C, Sreenivasan S, Sahoo FK. A study of adverse drug reactions in pediatric patients. J Pharmacol Pharmacother. 2011;2(4):277-80.
11. Jimmy J, Padma R, Jimmy GM, Beena J. Adverse drug reactions to fluoroquinolone antibiotics – analysis of reports received in a tertiary care hospital. Int J Risk Saf Med. 2008;20:169-80.
12. Oshikoya KA, Njokanma OF, Chukwara HA, Ojo IO. Adverse drug reactions in Nigerian children. Paediatr Perinat Drug Ther. 2007;8:81-8.
13. Khondker L, Khan MSI. Clinical profile of cutaneous drug reactions. J Pak Assoc Dermatol. 2014;24(2):160-3.
14. Hussain MM, Girhepunje K, Pal R, Siddiqua SS. Incidence of adverse drug reactions in a tertiary care hospital: a systematic review and meta-analysis of prospective studies. Der Pharmacia Lett. 2010;2(3):358-68.
15. Munir P, Alasdair MB. Clinical review – adverse drug reaction. BMJ. 1998;316(25):1295-98.

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