Section: Pharmacology

Original Research Article

STUDY OF ADVERSE DRUG REACTIONS AT TERTIARY HEALTH CARE CENTRE OF SOUTH-WEST BIHAR

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Received : 10/03/2023
Received in revised form : 13/04/2023
Accepted : 26/04/2023

Keywords:
ADR, Pharmacovigilance, Medication.

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DOI: 10.47009/jamp.2023.5.3.368

Source of Support: Nil,
Conflict of Interest: None declared

Int J Acad Med Pharm
2023; 5 (3); 1854-1859

Abstract

Background: Drugs prescribed for disease are often themselves the cause of serious amount of adverse reactions ranging from mere inconvenience to permanent disability and death. It has been reported that ADRs account for 5% of all hospital admissions and occur in 10–20% of hospitalized patients. An overall incidence of serious and fatal ADR among hospitalized patients is 6.7% and 0.32%, respectively. To study the adverse drug reaction pattern in tertiary health care centre of southwest Bihar and to identify the pattern of adverse drug reaction. **Materials and Methods:** It was retrospective study as patients admitted to various wards in the Narayan Medical College & Hospital during 18 months were taken up for study. A total of 94 cases giving information suggesting of ADR were included in the study. The ADR were defined and assessed as per standard WHO guidance. The characteristics of patients, their demographics profile, diagnosis, drugs, administered, and investigations were all considered. The ADR have thus been supplemented also with such epidemiological information. **Result:** This study revealed that, all the cases required discontinuation of drug and management. Majority 56% instance were mild type and around 41.5% were moderate symptomatic logically in ADR. The ADRs were further categorized as : certain 3.2 %, possible 26.6% and probable 70.2% as per the epidemiological aspects as less drugs and diseased associated with the ADR pattern has also been analysed. **Conclusion:** It can conclude that the observation at NMCH regarding suspected ADR studied by proactive enquiry with the patients gave data that exhibited major consistency with observations reported by other studies in the country. The specific of differences have been discussed.

INTRODUCTION

An Adverse Drug Reaction (ADR) is defined by World Health Organization (WHO) as ‘‘a response to a medicinal product which is noxious, unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function”.[1-4] It is universally accepted that ‘‘No drug absolutely free from side effects”. From the literature it is observed that 5% of all hospital admissions were related to drug-induced problems and 10–20% of hospitalized patients are developing ADRs, it is estimated that ADRs are the fourth to the sixth leading cause of death. (MedaVenkatasubbaiah).[5-14]

The recent epidemiological studies have estimated that adverse drug reactions are the fourth to sixth leading causes of death. Moreover, detection of ADRs has become increasingly significant because of introduction of a large number of potent toxic chemicals as drug in last two or three decades. Thus, it became very crucial to monitor both known and unknown adverse effects of medicines. (Ratan J. Lihite).[15-17]

Drugs prescribed for disease are often themselves the cause of serious amount of adverse reactions ranging from mere inconvenience to permanent disability and death. According to DJP Barker, ‘‘There are three

ISSN (O): 2687-5365; ISSN (P): 2753-6556

actions of a drug: The one you want the one you don't want, and the one you don't know about".[13-16] Since drugs are intended to relieve suffering, patients find it particularly offensive that they can also cause disease. It has been reported that ADRs account for 5% of all hospital admissions and occur in 10–20% of hospitalized patients.8-10 An overall incidence of serious and fatal ADR among hospitalized patients is 6.7% and 0.32%, respectively. Sometimes, ADR-related costs, such as hospitalization, surgery and lost productivity, exceed the cost of the medications. While prominent adverse drug reactions are more or less characterized for most clinically used drugs. The contexts under which they manifest make an important learning.

'Pharmacovigilance' are the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems, including herbal medicines. The WHO Collaborating Centre (WHOCC) for International Drug Monitoring at Uppsala Monitoring Centre (UMC), Sweden, promotes pharmacovigilance at the national level. The national data from the participating countries are shared with the UMC and compiled to generate a global ADR) database. India is one of the global partners in the global programme and participates under the Ministry of Health and Family Welfare via the Pharmacovigilance Programme of India (PvPI). (Megha Sharma)[18-23] .The National Programme of Pharmacovigilance (NPP) was established in 2005 which was then changed to the Pharmacovigilance Programme of India (PvPI) in 2010.[23] Currently, there are 250 PvPI established ADR monitoring centers across the country. The information acquired from the research may be valuable in recognizing and reducing unnecessary ADRs, as well as improving healthcare personnel's abilities to control ADRs more effectively in general. When we consider that India is home to around 15% of the world's population, this enormous number represents barely 1-2 percent when seen in a global context (Khupngai Lalthanpuii).[24,25]

Drug reactions may be classified as:

Type A: Dose-related reactions (adverse effects at either normal dose or overdose), e.g. serotonin syndrome or Anticholinergic effects of Tricyclic agents.

Type B: Non-dose-related reactions (i.e., any exposure is enough to trigger such a reaction), e.g. Allergic or Anaphylaxis reactions

Type C: Dose and time-related reactions, e.g. due to dose accumulation, or with prolonged use (e.g. adrenal suppression with corticosteroids)

Type D: Time related reactions, i.e., due to prolonged use in a drug which doesn't tend to accumulate (e.g. Tardive Dyskinesia from Antipsychotics)

Type E: Withdrawal reactions, i.e., the undesired effects of ceasing the drug (for example, opiate withdrawal)

Type F: Unexpected failure of therapy, where a drug undesirably increases or decreases in efficacy- for example, the decreased clearance of a drug by dialysis, or the decreased effect of antibiotics due to resistance. (Alex Yartsev).[26-29]

ADRs are one of the great mimics in healthcare, often emulating 'traditional diseases' and manifesting in all systems of the body. Drug-related problems in patients admitted to hospital may present in many different ways, including weakness or drowsiness, biochemical or hematological derangements (such as acute kidney injury, electrolyte imbalance or anemia), bleeding, gastrointestinal disturbances, hypoglycemia or healthcare-associated infections such as Clostridium difficile. However, rarer manifestations – such as drug-induced lupus, fixed drug eruptions, drug-induced eosinophilia or angioedema – require a level of vigilance and suspicion on behalf of the clinician who should look very hard to identify a causative agent. A comprehensive medication history is fundamental in identifying any possible connection between a presenting complaint or subsequent finding and an ADR, as well as preventing future ADRs (Jamie J Coleman).[30-32]

If the culprit is fairly clear, a benefit-risk decision needs to be taken about the need for the drug (are there equally effective substitutes that are unlikely to produce the same adverse drug reaction?), the severity of the reaction, and its potential for treatment. Instances of several medication being causative can be encountered requiring strategy on sequences for their dose reduction and withdrawal. The understanding required shall also be the rate of their elimination for ADR to abate. Choices may be exercised for alternative medicine for the diseased being treated. Sometimes, complex situation may be encountered where the suspected ADR may not be resolved even with drug withdrawal requiring detailed bodily derangement. In treating ADR the prudence of avoiding polypharmacy and restricting the use of essential medicines, often will be established. Thus the imperative is to have clear therapeutic objective in mind: to administer medications no longer than it is necessary and to review the patients regularly looking for ways to simplify management (IRalph Edwards). So the aim of this study was to study suspected adverse drug reaction scenario locally in accordance to prescribed definitions and existing knowledge of pharmacology, among the indoor cases in Narayana Medical College and Hospital, South Bihar.

MATERIALS AND METHODS

Study Area: This study conducted in Department of Pharmacology, Narayan Medical College & Hospital, Jamuhar, Sasaram, Bihar.

Study Population: 94 cases, were enrolled for the pharmacovigilance programme at the Narayana Medical College.

Study Duration: The duration of this study total a period of 19 months.

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Data Collection

The clinical wards were visited and admitted patients were studied. Their identity was noted and details of demographic profile were collected these included the case and consequent categorization in range of 10 years, gender profile was noted. Their rural and urban domain was noted. Economic profile was noted and categorized as upper middle, lower middle, upper lower and lower. Education profile was noted and was categorized as above high school, high school, literate and illiterate.

The medical background was appraised as follows:

- the department or specialty of the patient was noted
- the diagnosis of the case for which patient was admitted was noted.
- liver function profile and kidney function profile was recorded as examined or otherwise was categorized as normal, abnormal, not done and within normal limit of those examined.
- the day of hospitalization since admission was recorded.
- the medication prescribed was recorded.
- adverse reaction understood as a new symptom arising after hospitalization were recorded based on the study of prescribed medication. their adverse drug reaction profile was taken into concentration.
- patient were then proactively enquired about experience of any such adverse reaction that could arise from the medication consumed by them.
- Finally, both spontaneously reported and the actively enquired information on ADR were taken together.
- as per WHO UMC appraisal of ADR, the observed categories were made: PROBABLE: associated since administration of medication. POSSIBLE: such as are reported with the drug toxicity profile. CERTAIN: reaction which are subsiding with withdrawn of suspected drug (de-challenge, re-challenge), reappearing of start of drug.

    - Reaction was further graded as mild, moderate, and severe.

RESULTS

The [Table 1] illustrated that the distribution of study subjects in various departments. It was found that out of 94 patients, 36 were from Medicine department followed by 26 from Pediatrics and 16 from Obstetrics and Gynecology. In the present study found the suspected ADRs were amongst the age group >30 yrs and least in>70yrs of age group. This result revealed that, economic background majority (54%) were in lower middle-class group again this may indicate the kind of segment that preferred treatment in the private tertiary care Hospital. there were no patient from upper category, lower category also had minimum (10%) while upper middle class had (35%) incidence of suspected ADR. In this study, 57% of suspected ADR patients were from rural areas. As per diagnosis, fever appears to be an important feature compared to others for complaints of ADR. 17% patients who complained of ADR had fever, hypertension was next contributing to about 10% ADR cases. The reason for fever, hypertension being relatedly higher in association with ADR may involve multiple medication and interactions. Majority of ADR cases had oral administration of suspected drug but the relative incidence of suspected ADR with respective routes of administration may simply be as per the commonest route of the administration of drug in patient population. the apparent patient complaints of suspected ADR were most commonly nausea, vomiting 27% followed by diarrhea, stomachache 15%, urticarial rash 7.5% and leg swelling 7.5%. other complaints were less frequent.

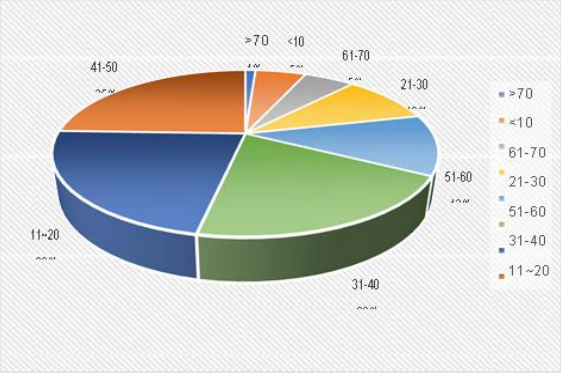

Figure 1: Distribution of age

Table 1: Distribution of department among study subjects: as per the department of admission.

Ward	Frequency	Percentage
Dermatology	1	1.1
Neurology	1	1.1
Ophthalmology	2	2.1
Surgery	12	12.8
Obstetrics & Gynecology	16	17
Paediatrics	26	27.7
Medicine	36	38.3
Total	94	100

Table 2: Distribution of Gender among study subjects:as per the sex

Sex	Frequency	Percentage

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Female	39	41.5
Male	55	58.5
Total	94	100

Table 3: a. Distribution of socio-economic among study subjects

Socioeconomic status	Frequency	Percentage
Lower	10	10.6
Upper Middle	33	35.1
Lower Middle	51	54.3
Total	94	100

Table 4: distribution of study subject as per diagnosis

	Frequency	Percentage
Generalized weakness	1	1.1
Dyslipidemia	1	1.1
Pulmonary tuberculosis	2	2.1
Malaria	2	2.1
UTI	3	3.2
Skin disease	3	3.2
Seizure under evaluation	3	3.2
Gastroenteritis	4	4.3
Surgeries	5	5.3
Severe anemia	5	5.3
Diabetes type II	5	5.3
RTI	6	6.4
COPD	8	8.5
Others	8	8.5
Hypertension	9	9.6
Gynecological disorders	13	13.8
Fever	16	17
Total	94	100

Table 5: Distribution of study subjects as per medication prescribed

	Frequency	Percent
Anti tubercular drug 1st line	2	2.1
Mutiple drug therapy	2	2.1
Antiepileptics	5	5.3
Haematinics	6	6.4
Antihypertensive	11	11.7
Others	28	29.8
Antibiotics	40	42
Total	94	100

Table 6: distribution of study subject as per route

Inhalational	Frequency 1	Percentage 1.1
TOPICAL	2	2.1
I.M.	5	5.3
I.V.	19	20.2
ORAL	67	71.3
Total	94	100

Table 7: distribution of study subject as per complaints after medication

Decreased hearing sensation	1	1.1
Decreased vision in right eye	1	1.1
Dizziness, weakness	1	1.1
Dry cough	1	1.1
Dryness of mouth, nausea, throat, tachycardia	1	1.1
Pain abdomen, diarrhea	1	1.1
Weight gain	1	1.1
Metallic taste, rash, flushing	1	1.1
Thrombophlebitis of vein	1	1.1
Tremors	1	1.1
Redness in right eye	1	1.1
Weight gain	1	1.1
Headache, bilateral edema, gastritis	2	2.1
Itching	2	2.1
Facial eruption and bloating	3	3.2
Myalgia	3	3.2
Pain in left great toe, muscle cramp, restlessness	3	3.2
Pain at the site of injection, headache, flushing, palpitation	5	5.3

ISSN (O): 2687-5365; ISSN (P): 2753-6556

Palpitation, restlessness, ankle edema	5	5.3
Swelling of both legs	7	7.4
Urticarial rash	7	7.4

DISCUSSION

Distribution of study subject as per department of admission it was observed that majority of the ADR cases were from Medicine, Paediatrics, Obstetrics and Gynaecology, surgery ward which may be an indication for higher number of patients present in such wards as well as the use of multiple therapeutic agent. Studies like Sri Ram et al (2011),[33,34] have found similar pattern of admission in the departments. Rayees N M et al (2019),[35] have also got the very same trend of admission of suspected ADR admission in the departments.

Distribution of study subject as per age, it was observed that in the present study the majority of suspected adverse drug reaction occurred in age group of >30yrs. Other studies like Sri Ram et al (2011),[33,34] have found 33% in age group of 30-50 yrs., 11% in 18-29 yrs. Similarly Rayees N M et al (2019),[35] have also got 30% ADR in >30 yrs. age group. Younger age groups may not be predominant in hospital admission. The two young age groups may have lesser instances because of keen paediatrics judicious prescriptions. Also the elder age group were prescribed less medications

Distribution of study subject as per sex it was observed that the frequency of suspected ADR was little higher in the males but again that could be associate with relative population of male and female patients in the hospital. S. Surekha et al (2021),[36,37] have found double the incidence of ADR in males compared to females. Similarly, Rayees N M et al (2019),[35] got double the incidence of ADR in males. Chawala et al (2017),[37-40] near had 59 % of ADR in males. This information while supporting our findings no other explanation for the reference may to tendered.

Distribution of study subject as per socioeconomic status it was observed that as record of economic background majority (54%) were in lower middle-class group again this may indicate the kind of segment that preferred treatment in the private tertiary care hospital. 4b. Even 57% of the patients were from rural demographic area amongst the ADR suspected. There were no patient from upper category, lower category also had minimum (10%) while upper middle class had (35%) incidence of suspected ADR. The result may be indicating the patient's preference from different financial status for this hospital as per other conduct by Harsha et al (2013),[37,38] 40% of the suspected ADR were from lower middle class of the society.

Distribution of study subject as per diagnosis, it was observed that, fever appears to be an important feature compared to others for complaints of ADR. thus 17% patients had fever who complained of ADR, hypertension was next contributing to about 10% ADR cases. The reason for fever, hypertension being relatedly higher in association with suspected ADR may involve multiple medication and interactions, as one explanation. Further there may be variety of somatic symptoms that associated with fever and hypertension. No other diagnoses appeared to be too frequent with association with the ADR.

Distribution of study subject as per medication prescribed it was observed that, in our study the most frequent medication associated with suspected ADR were antibiotics 42% followed by 11.7% antihypertensive agents. Other studies done Murshida et al (2019),[37-39] had found that 44.5 % suspected ADR was due to antibiotic drugs followed antihypertensive agents. Our study in described patient at NMCH achieved to behold the patterns of drugs that often associate with the ADR. As per Richa et al (2015),[42] found 16% of suspected ADR were due to antibiotics given to the patient.

Distribution of study subject as per route of administration, it was observed that Majority of suspected ADR cases had oral administration of suspected drug but the relative incidence of suspected ADR with respective routes of administration may simply be as per the commonest route of the administration of drug in patient population. It was found in the conduct done but Richa et al (2015),[42] that majority of suspected ADR were through I.V. route does not yield any inferences.

Distribution of study subject as per complaints after medication it was observed that the apparent patient complaints of suspected ADR were most commonly nausea, vomiting 27% followed by diarrhoea, stomach-ache 15%, urticarial rash 7.5% and leg swelling 7.5%. Other complaints were less frequent. Whereas conduct done by another study38found skin rashes in 22% of the suspected ADR followed by pruritus in 21%.

It appears our pattern of suspected ADR symptoms to be consistent with other studies. However gastrointestinal symptoms had much higher occurrence almost 42% while skin complaints were slightly lower only 7.5%.

CONCLUSION

This study concludes that adverse drug reactions are important subject of study. Their occurrences and determinants help to improve the quality of care, give clues to evidence based individual therapy, vision of drug pharmacology and toxicology in population at large.

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ISSN (O): 2687-5365; ISSN (P): 2753-6556