

Original Research Article

Monitoring, reporting and causality assessment of adverse drug reactions among admitted adult patients at a tertiary care teaching hospital: a prospective observational study

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ABSTRACT

Background: Adverse drug reactions (ADRs) add avoidably to illness, lengthen hospital stays and cost lives, yet they go under-reported in many wards. We set out to capture and report ADRs in admitted adult patients and to characterise their pattern, causality, severity, preventability and management at a tertiary care teaching hospital.

Methods: Over six months (21 March 2023 to 21 September 2023) we ran a prospective, cross-sectional, observational study based on spontaneous reporting among patients older than 18 years admitted to General Medicine, Surgery, Dermatology and Psychiatry. Suspected reactions were weighed for causality with the World Health Organization-Uppsala Monitoring Centre and Naranjo scales, for severity with the Hartwig and Siegel scale, and for preventability with the Schumock and Thornton criteria. Data were summarised with descriptive statistics and the chi-square test.

Results: Fifty-four ADRs arose in 38 patients across 5192 admissions, an incidence of 1.04 per 100 admissions. Reactions clustered in the 46–60-year age group and were more common in males (35.08%). Predictable type A reactions dominated (88.89%). The endocrine system was affected most often (22.22%), and hypoglycaemia was the single commonest event. Antidiabetics (19.29%) and antibiotics (12.28%) were the drug classes implicated most frequently. On Naranjo assessment the majority were probable (83.33%), and 94.44% were of moderate severity. Stopping the suspected drug (70.37%) was the mainstay of management, and 83.33% of patients improved.

Conclusions: The reactions seen here were largely predictable, moderate and preventable, driven chiefly by polypharmacy and coexisting illness. Disciplined spontaneous reporting and prescriber education are key to safer medicine use.

Keywords: Adverse drug reaction, Causality assessment, Hospitalised patients, Pharmacovigilance, Preventability, Spontaneous reporting

INTRODUCTION

Every medicine carries a shadow. Alongside the therapeutic gains of the past few decades has come a steady rise in unwanted drug effects, and the two have grown together. The World Health Organization (WHO)

describes an adverse drug reaction (ADR) as a response to a medicinal product that is noxious and unintended and that occurs at doses ordinarily used in humans for prophylaxis, diagnosis or treatment, or to modify physiological function.¹ Watching for such responses, weighing them and acting to prevent them is the work of

pharmacovigilance, and it sits at the heart of safe prescribing.¹

How often ADRs appear depends heavily on who is studied and how a reaction is defined. Broadly, they underlie somewhere between 5% and 10% of hospital admissions. Some reactions are the reason a patient is admitted; others surface only after admission, during the hospital stay itself. Estimates put the first group at roughly 5% of admissions, with a spread of 2% to 20%, while at least one reaction is thought to develop in one in five to one in ten in-patients.^{2,3}

Older patients bear a disproportionate share of this burden. Ageing shifts the way drugs are handled and how the body responds to them, and it rarely travels alone: multiple illnesses, several medicines at once and a tendency towards irrational drug use all cluster in this group. Untangling the contribution of age from everything that accompanies it is, for that reason, far from straightforward.⁴

In India the discipline is still finding its feet. The Pharmacovigilance Programme of India, run under the Ministry of Health and Family Welfare with the Indian Pharmacopoeia Commission acting as its National Coordination Centre, has nonetheless nudged reporting upward year on year as clinicians grow more willing to file reports.⁵

Looking back at the ADRs a single hospital records has a practical value. It reveals the local pattern of reactions and points to where prescribing might be made safer, and the reports themselves feed the larger national and global pools that shape regulatory decisions, labelling changes and patient advice. With that in mind, we set out to capture and report the ADRs occurring in admitted adult patients at our tertiary care teaching hospital, and to characterise their pattern, causality, severity, preventability, predictability and management.

METHODS

The prospective, cross-sectional and observational study built on spontaneous reporting over a six-month period, from 21 March 2023 to 21 September 2023, in the in-patient wards of S. N. Medical College and H.S.K. Hospital and Research Centre, Bagalkote, Karnataka, a tertiary care teaching hospital. Adults older than 18 years admitted under General Medicine, Surgery, Dermatology or Psychiatry who developed a suspected reaction during their stay were eligible for inclusion.

Certain reactions were deliberately left out. We excluded events traceable to medication errors, over-prescribing or excess dosing, along with those arising from drug-drug or drug-food interactions or from the concurrent use of alternative systems of medicine. Reactions occurring in out-patients were also set aside. For analysis, patients were grouped by age following the International Conference on

Harmonisation harmonised tripartite guideline: young adults of 18 to 30 years, adults of 31 to 45 years, and older adults of 46 to 60 years.

Information was drawn from care notes, treatment charts, laboratory records and direct conversation with patients. Suspected-ADR notification forms were placed at the nursing stations and across the wards, and the clinical pharmacy team collected the completed forms from clinicians and reporting staff during daily rounds. To keep reporting active, the team held awareness sessions encouraging doctors, nurses and patients alike to flag reactions. Only events meeting the eligibility criteria were transcribed onto a structured reporting and documentation form, and for each we reconstructed a full medication and disease history from case records, drug charts and interviews with patients and their attendants.

Causality was judged with two instruments in parallel, the WHO-Uppsala Monitoring Centre system and the Naranjo algorithm.⁶ Severity was graded on the Hartwig and Siegel scale and preventability on the Schumock and Thornton criteria.^{7,8} Each reaction was further labelled predictable (type A, augmented) or unpredictable (type B, bizarre), consistent with the classification adopted by WHO, the American Hospital Formulary Service and the Australian Medicines Handbook. Documented cases were reviewed each day to track their outcome, and the reporting clinicians received feedback on management through a drug information service.

The study was approved by the Institutional Ethics Committee of Hanagal Shri Kumareswar College of Pharmacy, Bagalkote (reference number HSKCOP/IEC/23/8a). Analysis relied on descriptive statistics such as frequencies, percentages and proportions, while the chi-square test was used to look for associations, with p below 0.05 taken as significant.

RESULTS

During the study period, a total of 54 ADRs were reported in 38 patients among 5192 admissions, giving an overall incidence of 1.04 ADRs per 100 admissions (Table 1). Reactions were more frequent in males (20 patients; 35.08% of ADRs) than in females (18 patients; 31.57% of ADRs); however, the difference in ADR occurrence between the sexes was not statistically significant (chi-square=1.366; $p=0.242$) (Table 1). The 46–60-year age group accounted for the largest share of reactions in both men and women (Figure 1).

The majority of reactions were type A (augmented), which accounted for 48 ADRs (88.89%), while type B (bizarre) reactions accounted for 6 ADRs (11.11%). Within type A reactions, common reactions predominated (76%), followed by infrequent (20%) and rare (4%) reactions; among type B reactions, common reactions accounted for 71.42%, with infrequent and rare reactions accounting for 14.28% each (Table 1).

The endocrine system was the organ system most frequently affected (22.22%), followed by the hematological system, the gastrointestinal system and the hepatic system. Drug-induced hypoglycaemia was the single most common reaction observed (Figure 2). Among drug classes, antidiabetic agents were implicated most often (19.29%), followed by antibiotics (12.28%), non-

steroidal anti-inflammatory drugs (10.52%), antihypertensives (8.77%) and antivirals (8.77%); metformin and insulin among the antidiabetics, and ceftriaxone and azithromycin among the antibiotics, were the individual agents most frequently reported (Table 2, Figure 3).

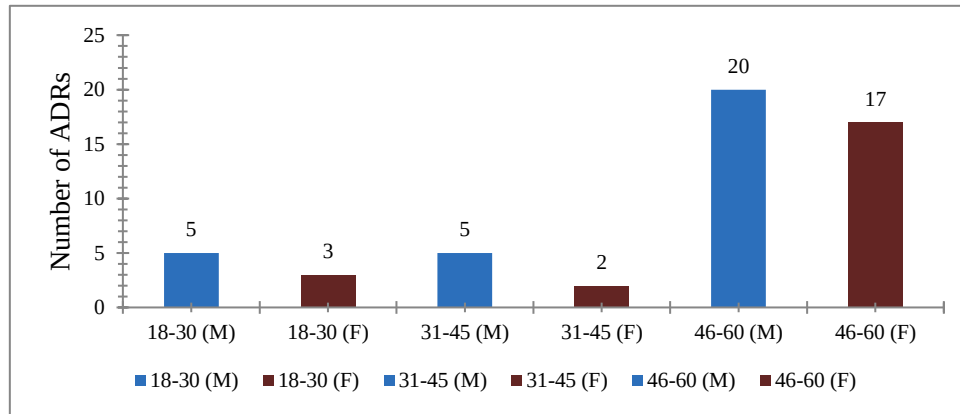


Figure 1: Distribution of adverse drug reactions by age group and sex.

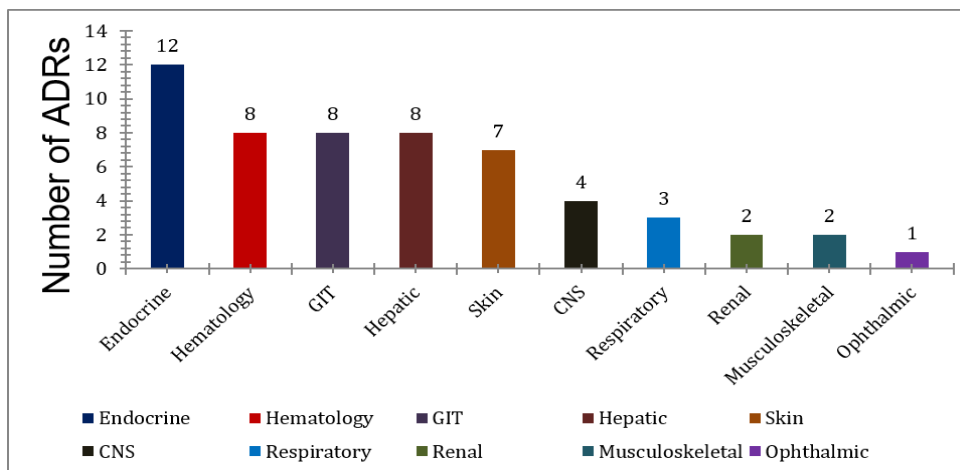


Figure 2: Organ systems affected by adverse drug reactions.

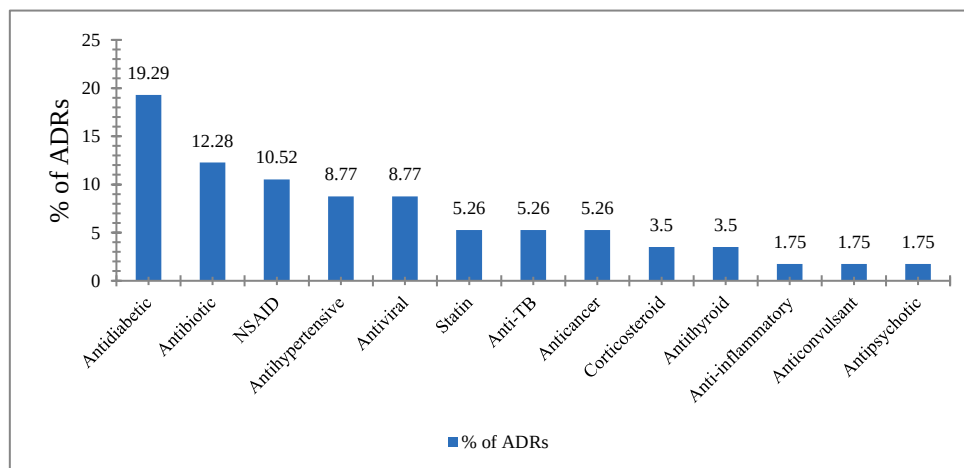


Figure 3: Percentage distribution of drug classes causing adverse drug reactions.

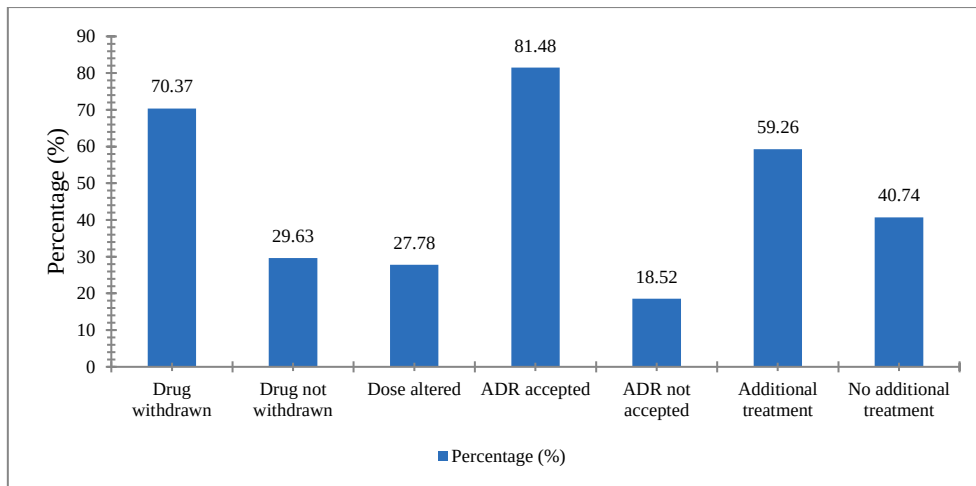


Figure 4: Management of adverse drug reactions

On causality assessment by the Naranjo algorithm, most reactions were rated as probable (45; 83.33%), followed by definite (7; 12.96%), possible (1; 1.85%) and unlikely (1; 1.85%). By the WHO-Uppsala Monitoring Centre system, reactions were rated as probable (42; 77.78%), certain (11; 20.37%) and unlikely (1; 1.85%), with no reaction rated possible or conditional. On severity grading using the Hartwig and Siegel scale, the great majority of

reactions were of moderate severity (51; 94.44%), with mild and severe reactions accounting for 3.70% and 1.85%, respectively (Table 3).

Polypharmacy and multiple co-existing disease states were the predominant predisposing factors. The association

between polypharmacy and the number of ADRs was not statistically significant (chi-square=0.019; p=0.891) (Table 4). Withdrawal of the suspected drug was the principal management step, undertaken in 70.37% of reports, while additional treatment for the reaction was instituted in 59.26% and dose alteration was performed in 27.78% (Figure 4). The overall rate of ADR acceptance did not differ significantly across age groups (chi-square=2.930; p=0.403) (Table 5). Following drug

withdrawal or dose reduction, an improvement was observed in the majority of patients (83.33%), while 11.11% did not improve and the outcome could not be determined in 5.56% owing to loss to follow-up after discharge (Table 6).

Table 1: Distribution, incidence and type of adverse drug reactions.

Parameter	Category	Number of ADRs (%)	Additional detail
Sex	Male	30 (55.55)	20 patients; incidence 1.069/100 admissions
	Female	24 (44.44)	18 patients; incidence 0.851/100 admissions
	Total	54 (100)	38 patients; incidence 1.040/100 admissions
Reaction type	Type A (augmented)	48 (88.89)	Common 76%, infrequent 20%, rare 4%
	Type B (bizarre)	6 (11.11)	Common 71.42%, infrequent 14.28%, rare 14.28%

Total admissions during the study period=5192. Chi-square (ADR occurrence vs sex)=1.366; p=0.242 (not significant).

Table 2: Classes of drugs causing adverse drug reactions with their ATC codes.

Drug class	Representative ATC code	Number of ADRs	ADRs (%)
Antidiabetic	A10	11	19.29
Antibiotic	J01	7	12.28
NSAID	N02/M01	6	10.52
Antihypertensive	C07/C08/C09	5	8.77
Antiviral	J05	5	8.77
Statin	C10AA05	3	5.26
Anti-tubercular	J04	3	5.26
Anticancer	L01	3	5.26
Corticosteroid	H02AB	2	3.50
Antithyroid	H03AA01	2	3.50
Anti-inflammatory	M01AH05	1	1.75

Continued.

Drug class	Representative ATC code	Number of ADRs	ADRs (%)
Anticonvulsant	N03AX14	1	1.75
Antipsychotic	N05AH03	1	1.75

ATC: Anatomical Therapeutic Chemical classification; NSAID: non-steroidal anti-inflammatory drug.

Table 3: Causality and severity assessment of adverse drug reactions.

Assessment scale	Category	Number of ADRs	ADRs (%)
WHO-UMC causality	Certain	11	20.37
	Probable	42	77.78
	Possible	0	0.00
	Unlikely	1	1.85
Naranjo probability	Definite	7	12.96
	Probable	45	83.33
	Possible	1	1.85
	Unlikely	1	1.85
Hartwig severity	Mild	2	3.70
	Moderate	51	94.44
	Severe	1	1.85

WHO-UMC: World Health Organization-Uppsala Monitoring Centre.

Table 4: Influence of polypharmacy on adverse drug reactions.

Number of drugs	Number of ADRs	Patients with ADRs
≤5 drugs	48	33
>5 drugs	6	5

Chi-square=0.019; p=0.891 (no significant association between polypharmacy and ADRs).

Table 5: Acceptance of adverse drug reactions across age groups.

Age group (years)	Accepted	Not accepted	Total
18-30	6	3	9
31-45	5	2	7
46-60	33	5	38
Total	44	10	54

Chi-square=2.930; p=0.403 (no significant association between ADR acceptance and age group).

Table 6: Management and outcome of adverse drug reactions (n=54).

Category	Number of ADRs	ADRs (%)
Management action		
Drug withdrawn	38	70.37
Drug not withdrawn	16	29.63
Dose altered	15	27.78
ADR accepted	44	81.48
ADR not accepted	10	18.52
Additional treatment	32	59.26
No additional treatment	22	40.74
Outcome after de-challenge/dose alteration		
Improved	45	83.33
Unimproved	6	11.11
Unknown	3	5.56

Dose alteration and additional treatment are not mutually exclusive with drug withdrawal; a single reaction may fall

under more than one management action. Withdrawal status, acceptance status and additional-treatment status

are each mutually exclusive pairs summing to 54. Outcome was unknown in three reactions owing to loss to follow-up after discharge.

DISCUSSION

Adverse reactions leave their mark on both the patient in front of us and the system that treats them. A hospital that runs a sustained ADR programme gains more than a tally of events: it can gauge how safe its prescribing really is, follow incidence as it shifts over time, and keep its staff alert to the harms that medicines can cause. In our patients the reactions clustered, as expected, in adults who carried the usual risk markers, chiefly polypharmacy and a burden of coexisting illness.

Predictable, dose-related reactions dominated. Type A events made up 88.89% of the total against just 11.11% for type B, echoing what other groups have found when augmented reactions are the rule rather than the exception.⁹ Antidiabetic agents topped the list of culprits, with antibiotics close behind; metformin and insulin recurred among the former and ceftriaxone and azithromycin among the latter. Hospital series from similar settings report much the same cast of drugs.^{10,11}

The endocrine system bore the brunt of these reactions at 22.22%, and drug-induced hypoglycaemia stood out as the commonest single event. That is perhaps unsurprising: hypoglycaemia announces itself clinically and is confirmed at the bedside by a glucose reading, so it is unlikely to slip past unnoticed. The lesson is that quieter reactions may need deliberate searching, through symptoms and laboratory trends, if they are to be caught. Our causality profile, weighted heavily towards "probable" reactions, matches the pattern others have described.¹²

When an ADR is recognised, stopping or trimming the offending drug is usually the first move, and so it was here, with withdrawal recorded in 70.37% of reports. The literature points to age, sex, comorbidity, drug count and length of stay as risks for developing an ADR; in our cohort it was polypharmacy and multiple disease states that stood out most, a reflection of the fact that many reports came from the medicine wards, where patients rarely arrive with a single problem.¹³

The study is not without limits. Under-reporting shadows every spontaneous scheme and tempers how far the figures can be pushed. A handful of reactions also went unresolved on paper because the patient was discharged before de-challenge could be followed through. Even so, the data open a useful window onto the ADRs that arise in a tertiary care hospital.¹⁴

CONCLUSION

The reactions recorded together were mostly predictable, moderate in severity and, in principle, preventable, and they were propelled above all by polypharmacy and

coexisting illness. Antidiabetics and antibiotics were the drugs most often at fault, and the endocrine system the most frequent target. Keeping such harm in check will depend on disciplined spontaneous reporting, active pharmacovigilance and a steady effort to educate prescribers, so that the avoidable share of drug-related injury in tertiary care continues to shrink.

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