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ANALYSIS OF ADVERSE DRUG REACTIONS IN SURGICAL PATIENTS IN A TERTIARY CARE TEACHING HOSPITAL

Pharmacology

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ABSTRACT

Aim-To study adverse drug reactions (ADRs) occurring in hospitalized patients of the General Surgery department of a tertiary care teaching hospital.

OBJECTIVES

1. To determine the incidence of adverse drug reactions among hospitalized surgical patients.
2. To assess the causality of reported ADRs using the WHO–UMC causality assessment scale.
3. To evaluate the severity of ADRs using the Hartwig and Siegel severity assessment scale.
4. To assess the preventability of ADRs using the Thornton preventability scale.

Material and methods - The present study was Aim to conducted analysis of adverse drug reactionsin the Department of General Surgery of a tertiary care teaching hospital. The study was carried out in collaboration with the Department of Pharmacology, which functions as the Adverse Drug Reaction Monitoring Centre (AMC) under the Pharmacovigilance Programme of India (PvPI). The study was conducted over a period of 12 months following approval from the Institutional Ethics Committee (IEC). The hospital is a tertiary care referral center catering to patients from urban as well as rural areas and provides comprehensive surgical care including emergency and elective procedure. **Result – Conclusion-** The present study demonstrates that adverse drug reactions constitute a significant and clinically important burden in hospitalized surgical patientsThese findings collectively emphasize the importance of active pharmacovigilance surveillance, rational prescribing, and targeted antibiotic stewardship in surgical departments. Integration of structured pharmacovigilance programs into routine clinical practice, supported by interdepartmental collaboration between Pharmacology and Surgery, can substantially reduce preventable drug-related morbidity and improve patient safety outcomes in tertiary care settings.

KEYWORDS

ADR , SSI , ANTIBIOTIC ,RATIONAL USE

INTRODUCTIONS-

Adverse drug reactions (ADRs) are a major concern in contemporary clinical practice and represent a significant cause of patient morbidity, prolonged hospitalization, and increased healthcare costs. The World Health Organization (WHO) defines an adverse drug reaction as "a response to a drug which is noxious and unintended and occurs at doses normally used in humans for prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function" (1).

Globally, ADRs account for approximately 5–10% of hospital admissions and are among the leading causes of in-hospital complications and preventable patient harm (2). Recent systematic reviews have demonstrated that a substantial proportion of ADRs—ranging from 30% to 50%—are preventable, highlighting deficiencies in rational prescribing, drug monitoring, and pharmacovigilance practices (3). In addition to increasing morbidity, ADRs significantly impair patients' quality of life and place an economic burden on already strained healthcare systems (4).

Among hospitalized populations, surgical patients constitute a distinct high-risk group owing to the complexity of perioperative drug therapy, rapid therapeutic changes, and physiological stress associated with surgery and anesthesia (5).

Antimicrobial agents, particularly antibiotics, are consistently reported as one of the most frequent causes of ADRs in surgical wards. Their widespread use for both prophylactic and therapeutic purposes increases the risk of allergic reactions, gastrointestinal disturbances, hepatotoxicity, nephrotoxicity, and cutaneous manifestations (6)

In India, the true burden of ADRs is likely underestimated due to underreporting despite the establishment of the Pharmacovigilance Programme of India (PvPI). Data specifically focusing on ADRs in surgical inpatients remain limited, especially from tertiary care teaching hospitals that manage complex surgical cases and serve as referral centers (7).

AIM AND OBJECTIVES

OBJECTIVES

1. To determine the incidence of adverse drug reactions among hospitalized surgical patients.
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3. To evaluate the severity of ADRs using the Hartwig and Siegel severity assessment scale.
4. To assess the preventability of ADRs using the Thornton preventability scale.

MATERIAL NND METHODS

The study was conducted over a period of 12 months following approval from the Institutional Ethics Committee (IEC). The hospital is a tertiary care referral center catering to patients from urban as well as rural areas and provides comprehensive surgical care including emergency and elective procedures.The study was conducted in accordance with the ethical principles of the Declaration of Helsinki and institutional guidelines for biomedical research involving human participants.The study population consisted of patients admitted to the General Surgery wards of the tertiary care teaching hospital during the study period.

All hospitalized patients who received at least one medication during their hospital stay were considered eligible for screening for possible adverse drug reactions.

INCLUSION CRITERIA

- Patients admitted to the General Surgery department during the study period.
- Patients receiving one or more medications during hospitalization.
- Patients of either gender and all adult age groups (≥18 years).
- Patients who developed suspected adverse drug reactions during hospital stay.

EXCLUSION CRITERIA

- Patients admitted for less than 24 hours.

- Patients admitted primarily due to intentional or accidental drug poisoning/overdose.
- Patients with known drug abuse or substance dependence.
- Patients unwilling to provide informed consent.

RESULT AND OBSERVATION-

Table 1 Demographic profile of study population (n = 85)

Variable	Category	Frequency (n)	Percentage (%)
Age (years)	18–30	18	21.2
	31–50	34	40.0
	51–70	23	27.1
	>70	10	11.7
Sex	Male	48	56.5
	Female	37	43.5

Table 2 Distribution of primary diagnosis

Diagnosis	Frequency (n)	Percentage (%)
Cholelithiasis	18	21.2
Perforation peritonitis	17	20.0
Blunt abdominal trauma	15	17.6
Acute appendicitis	12	14.1
Incarcerated hernia	10	11.8
Intestinal obstruction	7	8.2
Others (Breast lump, Thyroid nodule)	6	7.1

Table 3. Distribution of surgical procedures performed

Surgery	Frequency (n)	Percentage (%)
Exploratory laparotomy	28	32.9
Cholecystectomy	18	21.2
Appendectomy	12	14.1
Hernia repair	10	11.8
Bowel resection	9	10.6
Others (Breast surgery, Thyroidectomy)	8	9.4

Table 4. Clinical pattern of ADRs

ADR Type	Frequency (n)	Percentage (%)
Maculopapular rash	19	22.4
Post-operative nausea and vomiting	16	18.8
Diarrhea	13	15.3
Gastritis / epigastric pain	11	12.9
Acute kidney injury (AKI)	9	10.6
Bleeding manifestations	6	7.1
Others	11	12.9

Table 5. Drug classes responsible for ADRs

Drug Class	Frequency (n)	Percentage (%)
Antibiotics	39	45.9
NSAIDs	14	16.5
Opioids	12	14.1
Antiemetics	8	9.4
PPIs	7	8.2
Anticoagulants	5	5.9

Causality assessment of ADRs

Category	Frequency (n)	Percentage (%)
Probable	47	55.3
Possible	34	40.0
Certain	4	4.7

Table 7. Severity of ADRs

Category	Frequency (n)	Percentage (%)
Mild	51	60.0
Moderate	26	30.6
Severe	8	9.4

Table 8. Preventability of ADRs

Category	Frequency (n)	Percentage (%)
Not preventable	52	61.2
Probably preventable	25	29.4
Definitely preventable	8	9.4

DISCUSSION

A total of 85 patients with suspected ADRs were identified and systematically evaluated for incidence, causality, severity, and preventability using validated pharmacovigilance tools.

Demographic Characteristics

In the present study, the mean age of patients experiencing ADRs was 44.8 ± 13.2 years, with the majority (40.0%) belonging to the 31–50 years age group. A slight male predominance was noted, with males accounting for 56.5% of ADR cases. The slight male predominance observed in the present study is consistent with findings from Shamna et al., who reported a male-to-female ratio of approximately 1.3:1 among patients with ADRs in a hospital-based pharmacovigilance study (8). . (Table 1)

Clinical Profile and Surgical Procedures

The distribution of primary diagnoses among patients experiencing adverse drug reactions is presented in Table 2. Cholelithiasis (21.2%) was the most common diagnosis, followed closely by perforation peritonitis (20.0%) and blunt abdominal trauma (17.6%). The predominance of abdominal surgical conditions suggests that patients requiring intensive perioperative pharmacotherapy, including antibiotics, analgesics, and supportive medications, may be at a relatively higher risk of developing ADRs. Additionally, the presence of ADRs across diverse surgical diagnoses highlights the multifactorial nature of drug-related adverse events in the surgical setting. (Table -2)

Exploratory laparotomy (32.9%) was the most commonly performed surgical procedure, followed by cholecystectomy (21.2%). The predominance of major abdominal procedures aligns with published evidence linking complex perioperative drug regimens with increased ADR burden (9). Importantly, the occurrence of ADRs even in relatively minor procedures such as hernia repair and appendectomy underscores that drug-related adverse events in surgical patients are not exclusively a function of operative complexity, but are influenced by the totality of pharmacotherapeutic exposure, including pre-existing medications, anesthetic agents, and post-operative analgesics. (Table 3)

Pattern of Adverse Drug Reactions

Maculopapular rash (22.4%) was the most frequently reported ADR, followed by post-operative nausea and vomiting (18.8%), diarrhea (15.3%), and gastritis or epigastric pain (12.9%). The predominance of cutaneous and gastrointestinal manifestations is in agreement with findings from multiple published studies. Davies et al. reported that skin reactions and gastrointestinal disturbances collectively accounted for nearly 50% of all hospital-acquired ADRs, attributing this pattern to the widespread use of antibiotics, NSAIDs, and opioids (10). Shamna et al. similarly identified cutaneous reactions and gastrointestinal disturbances as the two most prevalent ADR types in their prospective surveillance study, with antibiotics as the primary causative drug class . (8)

The occurrence of clinically significant ADRs such as acute kidney injury (10.6%) and bleeding manifestations (7.1%) merits special consideration. AKI in the surgical setting may be attributable to nephrotoxic antibiotics such as aminoglycosides, as well as NSAIDs and perioperative contrast agents. Bleeding manifestations were predominantly associated with anticoagulant use. Bakri and Jaly reported analogous findings in their multicenter study, noting that nephrotoxic and hematological ADRs, although relatively infrequent, contribute disproportionately to prolonged hospitalization and morbidity in surgical patients (11). The diversity of ADR types observed in the present study reflects the complexity of perioperative drug exposure and reinforces the necessity of active pharmacovigilance surveillance in surgical departments. (table -4)
Drug Classes Implicated in ADRs

Antibiotics emerged as the most frequently implicated drug class, accounting for 45.9% of all ADRs in the present study, followed by NSAIDs (16.5%), opioids (14.1%), antiemetics (9.4%), proton pump inhibitors (8.2%), and anticoagulants (5.9%). This finding is consistent with a broad body of published evidence. Shegena et al., in a systematic review and meta-analysis encompassing over 20 hospital-based pharmacovigilance studies, reported that antimicrobial agents accounted for 30–50% of all reported ADRs in hospitalized patients, with beta-lactams and cephalosporins being the most commonly implicated individual agents (12). The high proportion of antibiotic-associated ADRs is not unexpected, given their routine use for both surgical site infection prophylaxis and empirical treatment of postoperative infections.

In contrast to the present findings, certain international studies have reported higher proportions of cardiovascular drug-related ADRs in surgical inpatients, likely reflecting differences in patient demographics and the prevalence of preexisting cardiac comorbidities (10). The relatively lower burden of cardiovascular drug-related ADRs in the present cohort may reflect the younger age distribution of the study population and the elective and emergency abdominal surgical focus. (Table 5)

Causality Assessment (WHO–UMC Scale)

Using the WHO–UMC causality assessment scale, the majority of ADRs were classified as probable (55.3%), followed by possible (40.0%), and certain (4.7%). These findings are in close agreement with published literature from Indian tertiary care settings. Kalaiselvan et al., in a large-scale analysis of causality assessment data submitted to the Pharmacovigilance Programme of India (PvPI), reported that approximately 45–55% of ADRs were categorized as probable and 30–40% as possible, with only a small fraction classified as certain (13).

The substantial proportion of "possible" ADRs in the present study reflects the influence of underlying surgical conditions, concomitant medications, and comorbidities, which complicate definitive causal attribution. This underlines the importance of systematic use of validated causality tools to improve the scientific rigor of ADR reporting and the reliability of pharmacovigilance data. (Table- 6)

Severity Assessment (Hartwig and Siegel Scale)

The Hartwig and Siegel severity assessment scale revealed that the majority of ADRs were mild (60.0%), with moderate reactions accounting for 30.6% and severe ADRs comprising 9.4% of cases. This distribution is broadly comparable to findings reported in other hospital-based ADR studies. Davies et al. reported that mild-to-moderate ADRs collectively account for 80–90% of all ADRs in hospitalized patients, with severe reactions typically observed in a small minority of cases (10). Similarly, Shamna et al. reported that severe ADRs constituted approximately 8–10% of total ADRs in their prospective study, a proportion closely aligned with the present findings (8).

However, certain studies have reported higher proportions of moderate and severe ADRs. Alomar noted that severe ADRs may constitute up to 20% of total ADRs in studies employing broader severity definitions or including mixed medical–surgical populations with greater comorbidity burden (14). The relatively lower prevalence of severe ADRs in the present study may partly reflect the active surveillance methodology employed, which facilitated early detection and prompt management of ADRs before clinical escalation. Furthermore, the predominance of antimicrobial-related cutaneous reactions and gastrointestinal disturbances — which are generally mild to moderate in nature — may have contributed to the lower severity distribution observed.

Despite the predominance of mild reactions, the presence of severe ADRs such as acute kidney injury and bleeding manifestations carries important clinical implications. These reactions necessitated prompt pharmacological intervention, drug discontinuation, or supportive care, and likely contributed to prolonged hospitalization in affected patients. The findings reinforce the importance of close monitoring of renal function in patients receiving nephrotoxic medications and of coagulation parameters in those on anticoagulant therapy, particularly in the perioperative period (11). (Table 7)

Preventability Assessment (Thornton Scale)

Preventability assessment using the Thornton scale revealed that 61.2% of ADRs were not preventable, 29.4% were probably preventable, and 9.4% were definitely preventable. These findings are consistent with data from published meta-analyses and prospective studies. Inácio and Cavaco, in a systematic review of preventable ADRs in hospitalized patients, reported a pooled preventability estimate of approximately 29%, indicating that nearly one-third of all ADRs could potentially be avoided with optimal prescribing and monitoring practices (15). A similar distribution was reported by Oscanoa et al., who found that preventable ADRs constituted approximately 25–35% of total ADRs across multiple hospital-based study settings (16).

The proportion of definitely preventable ADRs (9.4%) in the present study is particularly significant from a clinical and public health perspective. These reactions were attributable to identifiable factors such as inappropriate drug selection, dosing errors, failure to account for known drug interactions, and inadequate clinical monitoring. Studies conducted in Indian tertiary care surgical settings have demonstrated that targeted interventions by clinical pharmacologists and pharmacovigilance teams can significantly reduce the prevalence of preventable ADRs, particularly those related to antibiotic use and polypharmacy (17)

Notably, certain international studies have reported higher proportions of preventable ADRs compared to the present study. Hakkarainen et al. reported preventability rates of up to 50% in studies employing more stringent criteria that included medication errors and near-miss events within their definitions (18). The combined burden of definitely and probably preventable ADRs in the present study (38.8%) nonetheless underscores that a substantial proportion of drug-related harm in surgical patients remains avoidable and should be targeted through systemic quality improvement measures, including prescribing audits, clinical pharmacology training, and structured pharmacovigilance programs.

Implications for Pharmacovigilance and Clinical Practice

The findings of the present study have several important implications for clinical practice and pharmacovigilance in surgical settings. The high burden of antibiotic-associated ADRs underscores the need for robust antibiotic stewardship programs in surgical departments, with particular emphasis on rational use of broad-spectrum agents, appropriate duration of prophylactic therapy, and early de-escalation based on microbiological culture data. The substantial proportion of probably and definitely preventable ADRs highlights actionable targets for reducing drug-related harm through prescribing audits, educational interventions, and structured monitoring protocols (12, 15).

Active surveillance methodology, as employed in the present study, has been demonstrated to detect significantly more ADRs than passive reporting alone. Lopez-Gonzalez et al. reported that spontaneous ADR reporting captures only 6–10% of actual ADR events in clinical settings, with underreporting being especially pronounced in surgical departments due to attribution bias and competing clinical priorities [19]. The integration of pharmacovigilance activities into routine surgical ward rounds — as facilitated by the collaboration between the Department of Pharmacology and the Department of General Surgery in the present study — represents a model approach to strengthening ADR detection and reporting in resource-limited settings, and is aligned with the objectives of the Pharmacovigilance Programme of India (PvPI)(17).

The systematic use of validated assessment tools — the WHO–UMC causality scale, the Hartwig and Siegel severity scale, and the Thornton preventability scale — adds scientific rigor to ADR evaluation and facilitates meaningful comparison with published literature (13.16) . These tools also provide a standardized framework for communicating ADR data to clinicians, regulators, and pharmacovigilance authorities, thereby supporting improved medication safety culture in hospital settings.

Limitations of the Study

The present study has several limitations that should be acknowledged. First, the study was conducted in a single tertiary care teaching hospital, which may limit the generalizability of findings to other healthcare settings, including community hospitals and primary care facilities. Second, the consecutive sampling technique, while appropriate for a prospective surveillance study, may not fully capture the true incidence of ADRs if some reactions were mild and went unrecognized despite active monitoring. Third, the practical inability to perform rechallenge in hospitalized patients restricted the proportion of ADRs classifiable as "certain" on the WHO–UMC scale, which may have influenced the causality distribution. Fourth, ADR outcomes with delayed onset after hospital discharge may not have been captured within the study period. Future multi-center studies with longer follow-up durations and larger sample sizes are warranted to provide more robust estimates of ADR incidence and to characterize risk factors for severe and preventable ADRs in Indian surgical patients.

CONCLUSION

The present study demonstrates that adverse drug reactions constitute a significant and clinically important burden in hospitalized surgical patients. Antibiotics were the most frequently implicated drug class, accounting for nearly half of all reported ADRs, followed by NSAIDs and opioids. Cutaneous and gastrointestinal manifestations were the predominant reaction types, while clinically serious events such as acute kidney injury and bleeding were also observed, underscoring the need for vigilant perioperative monitoring.

On causality assessment, the majority of ADRs were classified as probable, reflecting a consistent temporal relationship between drug exposure and the adverse event. Most reactions were mild in severity; however, a notable proportion were moderate to severe, necessitating drug withdrawal or active therapeutic intervention. Preventability assessment revealed that nearly 39% of ADRs were either probably or definitely preventable, highlighting tangible deficiencies in prescribing practices, drug monitoring, and adherence to treatment protocols.

These findings collectively emphasize the importance of active pharmacovigilance surveillance, rational prescribing, and targeted antibiotic stewardship in surgical departments. Integration of structured pharmacovigilance programs into routine clinical practice, supported by interdepartmental collaboration between Pharmacology and Surgery, can substantially reduce preventable drug-related morbidity and improve patient safety outcomes in tertiary care settings.

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