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Original Research Article

Assessment of adverse drug reactions and intravenous incompatibilities in a tertiary care teaching hospital

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ABSTRACT

Background: Adverse drug reactions (ADRs) and intravenous (i.v.) incompatibilities are significant concerns in clinical practice due to their potential to compromise patient safety and treatment efficacy. This study aimed to evaluate the prevalence, types, and consequences of ADRs and i.v. incompatibilities in prescriptions from tertiary care hospitals. The study also aimed to identify the most frequently implicated drugs and conditions associated with these issues and suggest recommendations for improving prescribing practices.
Methods: A prospective observational study was conducted over one year in a tertiary care hospital. Data were collected from 1000 patients across various age groups and genders in tertiary care settings. Detailed demographic information, prescribing patterns of high-risk medications, department-specific distribution, i.v. incompatibilities, and specific ADRs were analyzed. The assessment criteria included adherence to STGs, identification of deviations, and analysis of potential consequences.
Results: The study revealed a significant prevalence of unacceptable deviations from standard treatment guidelines, particularly with medications such as pantoprazole and rabeprazole with domperidone. High-risk medications like anticoagulants, antiplatelets, insulin, chemotherapeutic agents, opioids, and corticosteroids were frequently prescribed, with notable department-specific variations. I.v. incompatibilities were common with chemotherapeutic agents and insulin, while specific ADRs were associated with chemotherapeutic agents, insulin, anticoagulants, and corticosteroids.
Conclusions: The findings highlight the need for improved prescribing practices and strict adherence to guidelines, especially for high-risk medications. Implementation of targeted interventions, enhanced training for healthcare providers, utilization of electronic systems, robust pharmacovigilance programs, patient education, and department-specific protocols are recommended to enhance patient safety and treatment outcomes in tertiary care settings.

Keywords: Adverse drug reactions, High-risk medications, Intravenous incompatibilities, Medication safety, Patient safety

INTRODUCTION

Adverse drug reactions (ADRs) and Intravenous (IV) incompatibilities are critical issues in healthcare settings, particularly in tertiary care hospitals where the complexity of patient cases and treatments are higher.[1,2] ADRs refer to any unintended and harmful reaction to a drug that occurs at normal doses used for prophylaxis, diagnosis, or therapy.[3] I.v. incompatibilities occur when two or more substances react adversely when mixed or administered together, leading to reduced drug efficacy, precipitation, or toxic effects.[4]

High-risk medications, which often have narrow therapeutic indices and complex pharmacokinetics, are more prone to causing ADRs and i.v. incompatibilities.[5]

These issues can lead to severe patient harm, increased hospital stays, and higher healthcare costs.[6] Understanding the prevalence, types, and implications of ADRs and i.v. incompatibilities is essential for developing strategies to mitigate these risks and improve patient safety.[7,8]

This study aimed to evaluate the prevalence and types of ADRs and i.v. incompatibilities in prescriptions from tertiary care hospitals across India. By identifying common drugs and conditions associated with these issues, the study seeks to provide recommendations for improving prescribing practices and enhancing medication safety.[9]

METHODS

Study design

A prospective observational study carried out at Sri Ramakrishna Hospital, a multi-specialty tertiary care teaching institution located in Coimbatore, Tamil Nadu, India. The investigation spanned a duration of six months, beginning in September 2023 and concluding in February 2024. The study aimed to assess the patterns, prevalence, and clinical significance of adverse drug reactions (ADRs) and intravenous (i.v.) incompatibilities, particularly among patients receiving high-risk medications.

Participants were selected based on predefined inclusion and exclusion criteria to ensure the relevance and reliability of data. Patients of both sexes and all age groups, who were either admitted to or consulted in departments such as general medicine, cardiology, intensive care unit (ICU), surgery, pediatrics, and obstetrics and gynecology, were considered for enrolment. To be included in the study, patients must have been prescribed at least one medication during their course of treatment and must have willingly provided written informed consent after being briefed on the purpose and procedures of the study.

Patients who were critically ill and incapable of giving consent, those with incomplete or insufficient medical records, and individuals who declined to participate were excluded from the analysis. This selection process was designed to capture a wide spectrum of prescribing practices and patient profiles while maintaining ethical and methodological rigor.

Study procedure

Data collection was carried out by a trained team of pharmacists and clinical pharmacologists under the supervision of faculty from the department of pharmacy practice. Each patient who met the inclusion criteria was enrolled after obtaining informed consent. Clinical data were collected using a structured case documentation form that included demographic details, diagnosis, comorbidities, and complete prescription information such as drug name, dosage, frequency, route of administration, and duration of therapy.

Particular focus was given to prescriptions involving high-risk medications, including but not limited to anticoagulants, antiplatelets, insulin, chemotherapeutic agents, opioids, and corticosteroids. Patients were monitored for any adverse drug reactions (ADRs) during the hospital stay or follow-up visits. Identified ADRs were assessed for type, severity, and causality using the WHO-UMC causality assessment scale.

In addition to ADRs, intravenous (i.v.) drug combinations were evaluated for potential incompatibilities. I.v. admixtures were physically inspected for signs of precipitation, color change, crystallization, or separation. Compatibility was further verified using standard reference sources such as Micromedex and Trissel's Handbook on Injectable Drugs. Clinical relevance and outcomes of any incompatibility identified were documented.

The collected data were periodically reviewed to ensure completeness and consistency. Observations were recorded in real time to minimize recall bias and ensure accurate reporting of events. All findings were de-identified and coded prior to analysis to maintain patient confidentiality.

Ethical Approval

The study protocol was reviewed and approved by the institutional ethical committee of Sri Ramakrishna Hospital, Coimbatore. Prior to the initiation of the study, the purpose, procedures, and confidentiality aspects were clearly explained to all participants. Written informed consent was obtained from each participant before inclusion in the study, and all ethical principles outlined in the Declaration of Helsinki were strictly followed.

Statistical analysis

All collected data were entered into Microsoft Excel and verified for accuracy before analysis. Descriptive statistics were used to summarize the data. Categorical variables such as gender distribution, types of adverse drug reactions, and intravenous incompatibilities were expressed as frequencies and percentages. The analysis focused on identifying the most commonly involved high-risk medications, the departments where they were prescribed, and their associated ADRs or i.v. incompatibilities. Due to the observational nature of the study, no inferential statistical tests were applied. The results were interpreted to highlight patterns, trends, and areas requiring intervention to improve medication safety.

RESULTS

The study reveals a significant prevalence of ADRs and i.v. incompatibilities in tertiary care hospitals. ADRs and i.v. incompatibilities can lead to serious patient safety issues, including prolonged hospital stays, increased healthcare costs, and, in severe cases, life-threatening

conditions. Pantoprazole and the combination of rabeprazole+domperidone were among the most frequently implicated drugs in ADRs and i.v. incompatibilities.[10-12] These drugs are commonly prescribed for gastrointestinal conditions but are associated with a high risk of adverse reactions and interactions, particularly when not used according to guidelines.[13] Upper respiratory tract infections and hypertension were common conditions linked to these deviations, highlighting the need for targeted interventions in these areas.[14,15] The study included 1000 patients, with a nearly even distribution between males (54%) and females (46%). The majority of patients were in the age groups of 18-35 years (25%), 36-50 years (30%), and 51-65 years (27%). Only a small percentage were under 18 years (5%) and over 65 years (13%) (Table 1).

Table 1: Demographic characteristics of the study population.

Demographic variables	Number of patients	Percentage
Total patients	1000	100
Gender		
Male	540	54
Female	460	46
Age group (years)		
<18	50	5
18-35	250	25
36-50	300	30
51-65	270	27
>65	130	13

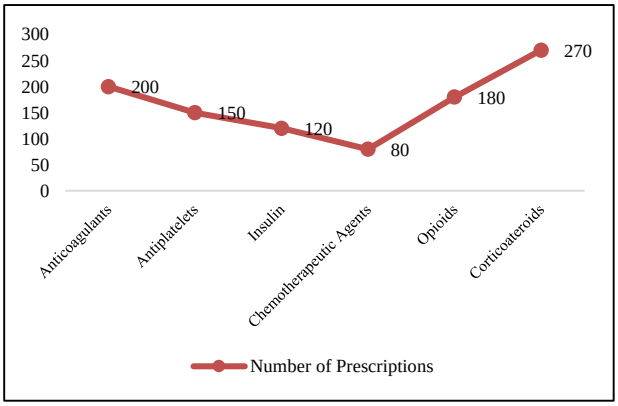

Figure 1: Prescribing pattern of high-risk medications.

High-risk medications were prescribed as anticoagulants (20%), antiplatelets (15%), insulin (12%), chemotherapeutic agents (8%), opioids (18%), and corticosteroids (27%). Corticosteroids had the highest prescription rate, followed by anticoagulants and opioids (Figure 1). I.v. incompatibilities were most frequent with chemotherapeutic agents (50%) and insulin (20.8%). Anticoagulants and corticosteroids also had notable rates of incompatibility (15% and 13%) respectively (Figure 2).

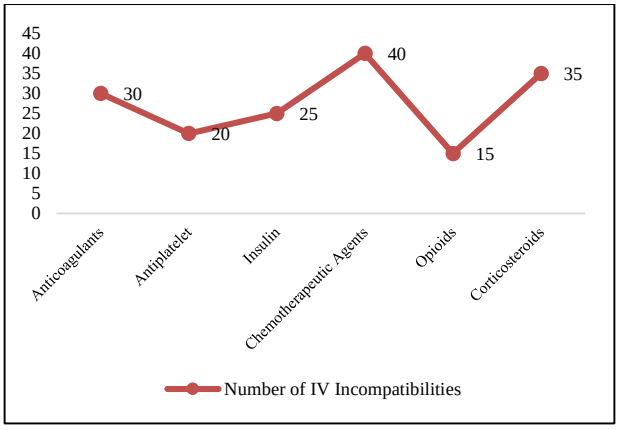

Figure 02: I.v. Incompatibilities of high-risk medications.

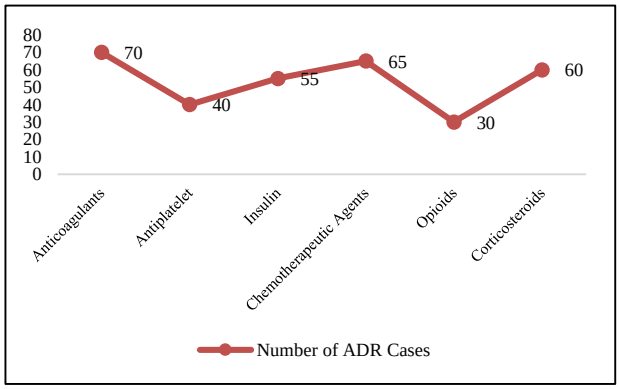

Figure 3: Adverse drug reactions associated with high-risk medications.

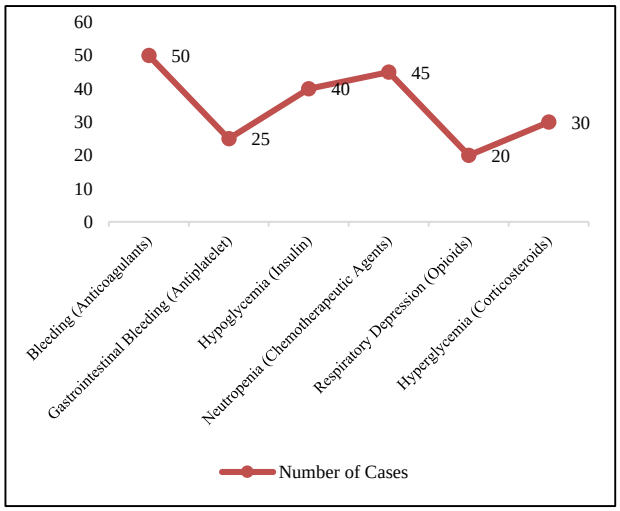

Figure 4: Specific adverse drug reactions of high-risk medications.

ADRs were most commonly associated with chemotherapeutic agents (81.3%) and insulin (45.8%). Significant ADRs were also reported for anticoagulants (35%) and corticosteroids (22.2%) (Figure 3). Specific ADRs included bleeding (71.4%) and gastrointestinal bleeding (62.5%) for anticoagulants and antiplatelets,

respectively. Hypoglycemia was a common ADR for insulin (72.7%), while neutropenia was prevalent with chemotherapeutic agents (69.2%). Respiratory depression (66.7%) was notable with opioids, and hyperglycemia (50.0%) with corticosteroids (Figure 4).

DISCUSSION

This study provides a comprehensive analysis of the prescribing patterns, adverse drug reactions (ADRs), and intravenous (IV) incompatibilities associated with high-risk medications in a tertiary care hospital.[16] The findings underscore the critical need for enhanced prescribing practices, stringent adherence to standard treatment guidelines (STGs), and proactive management of medication-related risks to improve patient safety and treatment outcomes.[17]

The study included 1000 patients with a balanced gender distribution (54% male and 46% female) and a diverse age range. The majority of patients were aged between 18 and 65 years, with only a small percentage being under 18 years or over 65 years. This demographic distribution supports the generalizability of the findings across different patient groups and highlights the importance of age- and gender-specific considerations in prescribing practices.[18]

High-risk medications, including anticoagulants, antiplatelets, insulin, chemotherapeutic agents, opioids, and corticosteroids, were prescribed frequently. Corticosteroids had the highest prescription rate (27%), followed by anticoagulants (20%) and opioids (18%). This high prescription rate reflects the reliance on these medications for managing various clinical conditions but also underscores the need for careful monitoring to mitigate associated risks.[19,20] The frequent use of corticosteroids is particularly concerning given their well-documented potential for causing significant adverse effects, such as hyperglycemia, immunosuppression, and osteoporosis. Similarly, the widespread use of anticoagulants and antiplatelets necessitates vigilant monitoring for bleeding complications, while the use of opioids demands careful assessment to prevent respiratory depression and dependence.[21] The distribution of high-risk medications varied significantly across different hospital departments, reflecting the specific therapeutic needs of each specialty.[22] For instance, anticoagulants and antiplatelets were predominantly prescribed in the cardiology department, insulin in endocrinology, chemotherapeutic agents in oncology, opioids in surgery, and corticosteroids in rheumatology.[23]

This departmental distribution highlights the importance of developing targeted interventions and guidelines tailored to the specific needs and risks associated with each department.[24] For example, cardiology departments should focus on protocols for safely managing anticoagulants and antiplatelets, while oncology departments need stringent guidelines for handling chemotherapeutic agents to minimize ADRs and i.v. incompatibilities.[25]

I.v. incompatibilities were identified in 221 cases (46.5%), with chemotherapeutic agents (50%) and insulin (20.8%) being the most commonly implicated. These incompatibilities can lead to serious complications, including precipitation, loss of drug efficacy, and increased risk of infections. The high rate of i.v. incompatibilities with chemotherapeutic agents underscores the complex nature of chemotherapy administration, which often involves multiple drugs with narrow therapeutic indices.[26] To address this, hospitals should implement compatibility checkers and protocols for i.v. administration to prevent adverse outcomes.[27] Additionally, regular training sessions for healthcare providers on recognizing and managing i.v. incompatibilities are essential to enhance patient safety.[28]

ADRs were identified in 254 cases (53.5%), with chemotherapeutic agents (81.3%) and insulin (45.8%) being the most frequently associated medications. Common ADRs included gastrointestinal disturbances, allergic reactions, electrolyte imbalances, and central nervous system effects. The high incidence of ADRs with chemotherapeutic agents highlights the need for proactive pharmacovigilance and patient monitoring to detect and manage these reactions promptly.[29] Given the potentially severe consequences of ADRs, healthcare providers must be vigilant in monitoring patients, especially those receiving high-risk medications, and be prepared to take immediate action to mitigate adverse effects.[30]

Specific ADRs included bleeding (71.4%) and gastrointestinal bleeding (62.5%) for anticoagulants and antiplatelets, respectively. Hypoglycemia was a common ADR for insulin (72.7%), while neutropenia was prevalent with chemotherapeutic agents (69.2%). Respiratory depression was notable with opioids (66.7%), and hyperglycemia with corticosteroids (50.0%). These findings highlight the critical need for individualized patient assessments and monitoring plans tailored to the specific risks associated with each high-risk medication.[31] For example, patients on anticoagulants and antiplatelets should be regularly monitored for signs of bleeding, while those on insulin should have their blood glucose levels closely tracked to prevent hypoglycemia. Similarly, patients receiving chemotherapeutic agents require regular blood tests to monitor for neutropenia, and those on opioids should be assessed for respiratory depression.[32]

Recommendations for improving prescribing practices

Based on the findings of this study, several recommendations can be made to improve prescribing practices and minimize the risks associated with high-risk medications:

Enhanced training and education

Regular training sessions for healthcare providers on safe prescribing practices, identification and management of ADRs, and recognition of i.v. incompatibilities are essential.[33] These sessions should include updates on the

latest guidelines and protocols to ensure healthcare providers are well-informed.

Strict adherence to guidelines

Hospitals should enforce policies that mandate adherence to STGs and conduct regular audits to ensure compliance. Penalties for non-compliance and incentives for adherence can help enforce these policies effectively.[34]

Utilization of electronic systems

Implementing electronic prescribing systems with built-in drug interaction and i.v. compatibility checkers can help identify potential ADRs and i.v. incompatibilities in real-time, allowing for immediate corrective actions.[35]

Pharmacovigilance programs

Establishing robust pharmacovigilance programs to monitor and manage ADRs effectively. These programs can help in early detection, reporting, and mitigation of ADRs, thereby improving patient outcomes.[36]

Patient education

Educating patients about the risks associated with high-risk medications and the importance of reporting any adverse effects promptly can help in early identification and management of ADRs.[37]

Department-specific protocols

Developing and implementing department-specific protocols to address the unique prescribing patterns and challenges associated with high-risk medications.[38] This can ensure that each department has tailored guidelines to minimize risks and improve patient safety.[39]

The study has several limitations, including its observational nature, which may introduce reporting biases. Additionally, the study was conducted in selected tertiary care hospitals, which may limit the generalizability of the findings to other settings. The reliance on prescription records also means that undocumented ADRs or i.v. incompatibilities may have been missed.

Future research should focus on multi-center studies to validate the findings and develop standardized protocols for managing high-risk medications. Integrating advanced technologies, such as AI-driven drug interaction checkers, can further enhance real-time decision-making and patient safety. Additionally, longitudinal studies could provide insights into the long-term impact of improved prescribing practices on patient outcomes and healthcare costs.

CONCLUSION

The study highlighted the significant impact of high-risk medications on patient safety and the critical need for improved prescribing practices, adherence to guidelines, and proactive management of medication-related risks. By implementing the recommended interventions, healthcare institutions can significantly reduce the prevalence of ADRs and i.v. incompatibilities, thereby enhancing patient safety and treatment outcomes. These findings provide valuable insights for healthcare providers and policymakers aiming to improve medication safety in tertiary care settings.

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