Artificial Intelligence-Assisted Pharmacovigilance for Adverse Drug Reaction Detection in Tertiary Care Hospitals: A Cross-Sectional Observational Study

Running Title

AI-Assisted Pharmacovigilance in ADR Detection

Authors and Affiliations

Rxxul Shxxxa ORCID: 00x0-00x2-45x7-11x3[1]*, Prxxxa Mxxxon ORCID: 00x0-00x1-87x5-66x4[2], Axxxit Vxxxma ORCID: 0x00-00x3-21x7-99x7[3]

[1]Department of Pharmacology, All India Institute of Medical Sciences, New Delhi, India
[2]Department of xxxxPharmacy, xxxxl College of Pharmaceutical Sciences, Bangalore Karnataka, India
[3]Department of Pharmacovigilance, Institute of Medical Sciences, Banaxxxxs Hxxxxu University, Vaxxxxasi, Uttar Pradesh, India

---

Corresponding Author

Dr. Rxxxl Sxxxma
Associate Professor
Department of Pharmacology
Axxxxx of Medical Sciences
New Delhi, India
Email: raXXXl.s@aiims.edu
Phone: +91-98xxxx10
ORCID ID: 0x00-00x2-45x7-1123

Abstract

Background

Pharmacovigilance plays a crucial role in identifying and preventing adverse drug reactions (ADRs). Traditional pharmacovigilance systems often suffer from

underreporting and delayed signal detection. Artificial intelligence (AI)-assisted systems may improve ADR identification and reporting efficiency.

Objective

To evaluate the effectiveness of AI-assisted pharmacovigilance tools in improving ADR detection and reporting in tertiary care hospitals.

Methods

A cross-sectional observational study was conducted across three tertiary care hospitals in India between January 2024 and December 2024. ADR reports generated using conventional spontaneous reporting methods were compared with reports identified using an AI-assisted pharmacovigilance screening system integrated with hospital electronic medical records. Data were analyzed using descriptive and inferential statistical methods.

Results

A total of 1,240 ADR cases were identified during the study period. The AI-assisted system detected 31.5% more ADRs compared to conventional reporting methods. Serious ADR identification improved significantly ($p<0.01$). The median time required for ADR signal identification decreased from 12 days to 4 days after AI implementation.

Conclusion

AI-assisted pharmacovigilance significantly improved ADR detection efficiency and timeliness in tertiary care hospitals. Integration of AI tools may strengthen pharmacovigilance systems and enhance patient safety.

Keywords

Pharmacovigilance; Adverse Drug Reaction; Artificial Intelligence; Drug Safety; Signal Detection; Clinical Research

---

Highlights

- AI-assisted pharmacovigilance improved ADR detection rates.
- Serious ADR identification significantly increased.
- AI reduced signal detection time in tertiary care settings.
- Integration with electronic health records enhanced reporting efficiency.
- AI may strengthen future pharmacovigilance systems.

Introduction

Pharmacovigilance is defined by the World Health Organization as the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other medicine-related problems. Pharmacovigilance systems are essential for ensuring drug safety after marketing approval and for protecting public health. Despite advancements in pharmacovigilance infrastructure globally, underreporting of adverse drug reactions (ADRs) remains a major challenge. Studies estimate that only 6–10% of ADRs are reported through conventional spontaneous reporting systems.[1]

The increasing complexity of healthcare systems, polypharmacy, and the emergence of novel therapeutics have highlighted the limitations of traditional pharmacovigilance methods. Delayed signal detection can result in prolonged patient exposure to potentially harmful drugs. Recent technological advances have introduced artificial intelligence (AI)-assisted systems capable of analyzing large healthcare datasets and identifying potential ADR signals more efficiently.[2]

Artificial intelligence techniques such as machine learning, natural language processing, and predictive analytics are increasingly being integrated into healthcare systems. These technologies can analyze electronic medical records, laboratory data, prescription patterns, and clinical narratives to identify possible ADRs. AI-assisted pharmacovigilance has shown promise in improving signal detection accuracy, reducing reporting delays, and enhancing pharmacovigilance workflows.[3]

However, evidence regarding the real-world implementation of AI-assisted pharmacovigilance systems in developing countries remains limited. India has one of the largest pharmacovigilance programs globally through the Pharmacovigilance Programme of India (PvPI), yet challenges such as underreporting and delayed reporting persist.[4]

The present study was conducted to evaluate the effectiveness of an AI-assisted pharmacovigilance system in improving ADR detection and reporting in tertiary care hospitals in India.

Materials and Methods

Study Design

A multicenter cross-sectional observational study was conducted.

Study Setting

The study was performed in three tertiary care teaching hospitals located in New Delhi, Karnataka, and Uttar Pradesh, India.

Study Duration

The study was conducted from January 2024 to December 2024.

Study Population

Hospitalized patients receiving at least one prescription medication during the study period were included.

Inclusion Criteria

- Patients aged ≥18 years
- Patients receiving prescription medications
- Availability of complete medical records

Exclusion Criteria

- Incomplete patient records
- Patients discharged within 24 hours
- Non-drug-related adverse events

AI-Assisted Pharmacovigilance System

The AI-assisted pharmacovigilance platform utilized machine learning algorithms integrated with hospital electronic medical record systems. The system screened laboratory abnormalities, medication histories, physician notes, and discharge summaries to identify potential ADRs.

Conventional ADR Reporting

Conventional pharmacovigilance relied on spontaneous ADR reporting by healthcare professionals through institutional pharmacovigilance forms.

Data Collection

Data collected included:

- Patient demographics
- Suspected medications
- ADR severity
- Organ system involvement
- Time to ADR detection
- Seriousness criteria

Causality Assessment

ADR causality was assessed using the WHO-UMC causality assessment scale.

Statistical Analysis

Data were analyzed using SPSS version 27. Continuous variables were expressed as mean ± standard deviation. Categorical variables were expressed as frequencies and percentages. Chi-square tests and independent t-tests were applied where appropriate. A p-value <0.05 was considered statistically significant.

Ethical Approval Statement

The study was conducted in accordance with the Declaration of Helsinki and approved by the Institutional Ethics Committee of All India Institute of Medical Sciences, New Delhi (Approval No: IEC/AIIMS/2023/245).

Informed Consent Statement

Written informed consent was obtained from all participants prior to study participation.

Clinical Trial Registration

Not applicable.

Results

Demographic Characteristics

A total of 1,240 ADR cases were identified during the study period. Among the affected patients, 52.4% were male and 47.6% were female. The mean patient age was 48.2 ± 15.7 years.

Table 1. Demographic Characteristics of Patients

Variable	Frequency (%)
Male	650 (52.4)
Female	590 (47.6)
Mean Age	48.2 ± 15.7 years

Variable	Frequency (%)
Serious ADRs	310 (25.0)
Non-serious ADRs	930 (75.0)

ADR Detection Comparison

The AI-assisted system detected 940 ADRs, whereas conventional spontaneous reporting identified 715 ADRs.

Table 2. Comparison of ADR Detection Methods

Detection Method	ADRs Identified
Conventional Reporting	715
AI-Assisted Detection	940
Increase in Detection	31.5%

Serious ADR Detection

The AI-assisted system identified significantly more serious ADRs compared with conventional methods ($p<0.01$).

Table 3. Serious ADR Detection

ADR Type	Conventional	AI-Assisted
Serious ADRs	180	310
Non-serious ADRs	535	630

Signal Detection Time

The median time required for ADR signal identification decreased from 12 days using conventional methods to 4 days using the AI-assisted system.

Discussion

The present study demonstrated that AI-assisted pharmacovigilance significantly improved ADR detection rates and reduced signal identification time in tertiary care hospitals. The findings are consistent with previous studies reporting enhanced pharmacovigilance efficiency using machine learning-based systems.[5]

One of the major strengths of AI-assisted systems is the ability to analyze large volumes of clinical data rapidly. Traditional spontaneous reporting systems depend heavily on healthcare professional engagement and are often associated with underreporting. AI-

assisted tools can continuously screen patient records and identify hidden safety signals that may otherwise remain undetected.[6]

The present study observed a 31.5% increase in ADR detection following implementation of the AI-assisted platform. Serious ADR detection also improved significantly. Early identification of serious ADRs is essential for minimizing patient harm and improving healthcare outcomes.

The reduction in signal detection time from 12 days to 4 days highlights the operational benefits of AI integration in pharmacovigilance workflows. Faster detection may facilitate earlier regulatory interventions and risk mitigation strategies.

Despite these advantages, AI-assisted pharmacovigilance systems have limitations. False-positive signals, data quality issues, and algorithm bias may affect performance. Human oversight remains essential for accurate causality assessment and regulatory decision-making.

The study had several limitations. It was conducted in selected tertiary care hospitals and may not represent smaller healthcare institutions. Additionally, long-term cost-effectiveness analyses were not performed.

Future research should focus on multicenter implementation studies, algorithm optimization, and integration of AI tools into national pharmacovigilance programs.

Conclusion

AI-assisted pharmacovigilance systems significantly improved ADR detection rates and reduced reporting delays in tertiary care hospitals. Integration of AI technologies into pharmacovigilance workflows may strengthen drug safety surveillance and improve patient safety outcomes. Continued regulatory guidance and human oversight remain essential for successful implementation.

Author Contributions (CRediT Taxonomy)

Contribution Area	Author Initials
Conceptualization	RS, PM
Methodology	RS, AV
Data Collection	PM, AV
Formal Analysis	RS
Writing – Original Draft	RS
Writing – Review & Editing	PM, AV
Supervision	RS

Contribution Area	Author Initials
Funding Acquisition	Not Applicable

Funding Statement

The authors received no external funding for this study.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

The datasets generated during the current study are available from the corresponding author upon reasonable request.

AI Disclosure Statement

The authors used ChatGPT only for language editing and grammar refinement. The authors reviewed and approved all manuscript content and take full responsibility for the scientific accuracy of the manuscript.

Publication Ethics Statement

The authors confirm that this manuscript is original, has not been published previously, and is not under consideration elsewhere. All ethical standards and publication guidelines were followed.

Acknowledgments

The authors acknowledge the support provided by participating hospitals and pharmacovigilance staff involved in data collection.

References

1. Hazell L, Shakir SA. Under-reporting of adverse drug reactions: a systematic review. Drug Saf. 2006;29(5):385-396. doi:10.2165/00002018-200629050-00003. PMID:16689555.

2. Bate A, Evans SJ. Quantitative signal detection using spontaneous ADR reporting. Pharmacoepidemiol Drug Saf. 2009;18(6):427-436. doi:10.1002/pds.1742. PMID:19358218.

3. Harpaz R, DuMouchel W, Shah NH, Madigan D, Ryan P, Friedman C. Novel data-mining methodologies for adverse drug event discovery and analysis. Clin Pharmacol Ther. 2012;91(6):1010-1021. doi:10.1038/clpt.2012.50. PMID:22549283.

4. Kalaiselvan V, Kumar P, Mishra P, Singh GN. System of adverse drug reactions reporting: what, where, how, and whom to report? Indian J Crit Care Med. 2015;19(9):564-566. doi:10.4103/0972-5229.164807. PMID:26430368.

5. Segal ES, Valette J, Oster L, et al. Machine learning in pharmacovigilance: opportunities and challenges. Drug Saf. 2020;43(12):1275-1287. doi:10.1007/s40264-020-00980-8.

6. Zhao J, Henriksson A, Asker L, Boström H. Detecting adverse drug events using machine learning methods. J Biomed Inform. 2015;56:38-48. doi:10.1016/j.jbi.2015.05.004. PMID:25976469.

Figure Legends

Figure 1

Workflow of AI-assisted pharmacovigilance system for ADR detection.

Figure 2

Comparison of ADR detection rates between conventional and AI-assisted systems.

Supplementary Material

Supplementary Appendix 1: ADR Data Collection Form
Supplementary Appendix 2: WHO-UMC Causality Assessment Scale

Pre-Submission Checklist

Requirement	Completed
Structured Abstract Included	☑
Vancouver References Checked	☑
Ethical Approval Included	☑
COI Statement Included	☑
Data Availability Statement Included	☑
AI Disclosure Included	☑
ORCID IDs Included	☑
Reporting Checklist Uploaded	☑
Author Contributions Included	☑