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Artificial Intelligence in Pharmacovigilance: A Comprehensive Review

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Abstract

Pharmacovigilance (PV) is a critical discipline dedicated to ensuring the safety of medicines throughout their lifecycle. The increasing volume of safety data generated from clinical trials, post-marketing surveillance, electronic health records, literature, and social media has created significant challenges for traditional pharmacovigilance systems. Manual processing, delayed reporting, and under-detection of adverse drug reactions (ADRs) limit the effectiveness of conventional approaches. Artificial Intelligence (AI), including machine learning (ML), deep learning (DL), and natural language processing (NLP), has emerged as a powerful solution to overcome these limitations. AI-driven techniques enable automated handling of individual case safety reports (ICSRs), early detection of safety signals, predictive risk assessment, and real-time drug safety monitoring. These technologies improve efficiency, accuracy, and consistency while reducing human workload and operational costs. This review presents a detailed overview of the role of artificial intelligence in pharmacovigilance, covering methodologies, applications, benefits, challenges, and future perspectives. The integration of AI into pharmacovigilance systems holds significant promise for enhancing patient safety and supporting regulatory decision-making.

Keywords: Pharmacovigilance, Artificial Intelligence, Machine Learning, Adverse Drug Reactions, Drug Safety

1. Introduction

Pharmacovigilance (PV) is defined as the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems. The primary aim of pharmacovigilance is to protect patient health and ensure that the benefit–risk balance of medicines remains favorable throughout their use. Individual Case Safety Reports (ICSRs) form the backbone of PV systems, providing essential information on suspected adverse drug reactions reported by healthcare professionals, patients, and pharmaceutical companies.

With the rapid expansion of healthcare systems and global drug usage, the volume of safety data has increased exponentially. Traditional pharmacovigilance methods rely heavily on manual review and statistical techniques, which are often time-consuming and limited in their ability to process large and

complex datasets. As a result, there is a growing need for innovative approaches that can enhance signal detection, improve efficiency, and support proactive safety surveillance.

Artificial intelligence (AI) has gained considerable attention in recent years as a transformative technology in healthcare. AI systems can analyze vast amounts of structured and unstructured data, identify hidden patterns, and generate actionable insights. In pharmacovigilance, AI has the potential to shift safety monitoring from a reactive model to a predictive and preventive framework, thereby improving patient safety and public health outcomes.

2. Materials and Methods

2.1 Literature Search Strategy

A comprehensive literature review was conducted using major scientific databases, including PubMed, Embase, Web of Science, and IEEE Xplore. Articles published from the year 2000 onwards and written in English were included in the review. Search terms included combinations of "artificial intelligence," "machine learning," "deep learning," "natural language processing," and "pharmacovigilance." Relevant review articles, original research papers, and conference proceedings were considered.

2.2 Study Selection and Evaluation

The selected studies were screened for relevance to pharmacovigilance applications of AI. Key evaluation criteria included the type of pharmacovigilance task addressed (signal detection, adverse event identification, data processing, or risk assessment), dataset characteristics, AI techniques used, and reported outcomes. Studies focusing on regulatory perspectives and real-world implementation were also included to provide a balanced overview.

2.3 Pharmacovigilance Databases

Several global databases support pharmacovigilance activities and AI-based analysis. VigiBase serves as the World Health Organization’s global database of reported adverse drug reactions. VigiAccess provides public access to VigiBase data, while VigiRank and VigiFlow support signal detection and ICSR management. These databases offer valuable resources for developing and validating AI models in pharmacovigilance.

3. Artificial Intelligence Techniques Used in Pharmacovigilance

3.1 Machine Learning Approaches

Machine learning algorithms are widely applied in pharmacovigilance for classification, prediction, and pattern recognition tasks. Supervised learning models use labeled datasets to identify ADRs and classify ICSRs. Unsupervised learning techniques explore unlabeled data to detect unknown safety signals and trends. Semi-supervised learning combines both approaches and is particularly useful when labeled data are limited.

3.2 Deep Learning

Deep learning models, such as neural networks, have demonstrated superior performance in handling complex and high-dimensional data. These models are increasingly used for signal detection, image analysis, and processing large pharmacovigilance datasets. Deep learning enhances the accuracy of safety assessments by capturing non-linear relationships within data.

3.3 Natural Language Processing

Natural language processing enables the extraction of relevant safety information from unstructured text sources, including clinical narratives, medical literature, and social media posts. NLP techniques facilitate automated identification of adverse events, drug names, and clinical outcomes, thereby improving the speed and efficiency of safety monitoring.

4. Applications of Artificial Intelligence in Pharmacovigilance

Artificial intelligence has diverse applications across pharmacovigilance activities. AI systems support automated case intake and processing, reducing manual effort and errors. Predictive models help identify high-risk patient populations and emerging safety concerns. AI is also used in signal detection and monitoring, drug–drug interaction analysis, and post-marketing surveillance.

The analysis of electronic health records and real-world evidence using AI provides valuable insights into drug safety in routine clinical practice. Additionally, AI-based tools can analyze social media data to capture patient-reported adverse events, complementing traditional reporting systems.

5. Benefits of Applying AI Techniques in Pharmacovigilance

The adoption of AI in pharmacovigilance offers several advantages, including faster detection of safety signals, improved data quality, reduced workload, and enhanced consistency in safety assessments. AI enables real-time monitoring of drug safety and supports proactive risk management. Techniques such as text mining, semantic searching, optical character recognition, and sentiment analysis further enhance the effectiveness of pharmacovigilance systems.

6. Challenges and Limitations

Despite its potential, the implementation of AI in pharmacovigilance faces several challenges. Data quality, lack of standardization, algorithm transparency, and interpretability remain major concerns. Regulatory acceptance and ethical issues related to data privacy and automation also require careful consideration. Addressing these challenges is essential to ensure reliable and responsible use of AI in drug safety monitoring.

7. Conclusion and Future Perspectives

Artificial intelligence represents a significant advancement in pharmacovigilance, offering innovative solutions to manage complex safety data and enhance drug safety monitoring. AI-based tools improve the detection of adverse drug reactions, support early signal identification, and enable proactive risk management. While challenges related to validation, transparency, and regulatory compliance persist, continued research and collaboration among regulators, industry, and academia will facilitate the sustainable integration of AI into pharmacovigilance systems. The future of pharmacovigilance lies in the balanced use of artificial intelligence and human expertise to ensure patient safety and public trust.

Declaration of Conflicting Interests

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