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REVIEW ARTICLE

PHARMACOVIGILANCE BY ECG MONITORING: DETECTION OF CARDIAC ADVERSE DRUG REACTIONS AMONG DIFFERENT THERAPEUTIC CLASSES

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Abstract

Background: Drug-induced cardiovascular adverse drug reactions, including QT/QTc prolongation, conduction abnormalities, and arrhythmias, remain one of the major global safety challenges. Despite its simplicity and diagnostic value, the electrocardiogram is underutilized in real-world pharmacovigilance, particularly in outpatient and resource-limited settings. This review assesses the contribution of ECG monitoring to the detection of cardiac ADRs across major therapeutic classes.
Methods: This systematic review was conducted within the PECO framework. Detailed searches across MEDLINE/PubMed, EMBASE, Web of Science, Scopus, and grey literature sources were conducted. Eligible studies were trials involving human subjects receiving medications, with cardiac outcomes documented by ECG. Data extractions included ECG parameters related to the study drugs, demographic data, and clinical outcomes.
Results: In studies representing more than 1.7 million patients, ECG-detected cardiac ADRs occurred in about 1.06% of the exposed, with higher frequencies among psychotropic (1.8%) and chemotherapeutic agents (1.6%). The most frequent abnormality was QT/QTc prolongation, followed by conduction delays and arrhythmias. Automated EHR-based systems (NLP+RDI) showed high performance: sensitivity 93.8%, specificity 91.8%, and a reduction in manual review workload of approximately 75%. Demographic and clinical risk factors consistently identified as associated with higher ADR risk included older age, male sex, polypharmacy, and pre-existing cardiovascular disease.
Conclusion: ECG-based pharmacovigilance represents a robust and scalable approach toward cardiac ADR detection across diverse drug classes. Routine ECG monitoring, integrated with automated EHR-driven detection, offers a more sensitive, timely, and efficient approach to identifying ADRs, particularly in real-world, polypharmacy settings.
Keywords: Adverse drug reactions, cardiac, ECG, pharmacovigilance.

INTRODUCTION

Drug-induced cardiovascular adverse drug reactions are an important and potentially fatal global public health problem. Drug-induced changes in cardiac electrophysiology- such as QT interval prolongation, conduction delays, arrhythmias, or even sudden death due to torsades de pointes (TdP)-induced by several classes of drugs, including antimalarial, antibiotic, psychotropic, anti-arrhythmic, and oncologic agents, remain one of the most critical issues[1]. The regulatory withdrawal of drugs such as some antihistamines and prokinetics due to their pro-arrhythmia risks underscores the benefits of proactive cardiac safety testing[2].

The surface electrocardiogram (ECG) is a simple, non-invasive, and widely available tool for the assessment of cardiac electrical activity, whose advantages could be applied in pharmacovigilance; nevertheless, clinical practice substantially underuses ECG monitoring, especially in non-hospital and outpatient services[3]. A 2022 systematic review found that baseline ECG prior to high-risk QT-prolonging therapy was obtained in only about one-third of non-hospital patients, and

follow-up ECGs within 30 days were even less common, highlighting a very large chasm between recommended safety procedures and practice[3].

In contrast, data-rich methodologies based on large-scale ECG databases have recently revealed that several widely prescribed drugs, other than the classical "high risk" ones, are associated with QT prolongation and other conduction disturbances. For instance, a retrospective study of over a million standard 12-lead ECGs and thousands of continuous ECG recordings in the ICU showed 38 drugs associated with significant QT prolongation and 7 medications with confirmed risk in the constant monitoring studies[4,5]. This suggests that traditional risk estimates based on predefined lists may understate the overall incidence of drug-related cardiotoxicity. In addition, the risk is increased by polypharmacy, drug–drug interactions (DDIs), and patient comorbidities[6,7].

The paramecium of human studies revealed high variability in electrophysiological results due to DDIs affecting QT prolongation, underscoring the difficulty of predicting ADRs in real clinical settings[8]. On the other hand, retrospective monitoring of hospitalized patients has shown that drug-induced arrhythmias ≈, 1.08% are not rare, discovering that QT prolongation is one of the ECG-detectable abnormalities more frequently associated[9,10]. However, challenges persist. Most of the drug studies for potential cardiotoxicity exclude patients with comorbidities or on multiple other drugs, so they have limited applicability.

Differences in ECG acquisition methodology, variability in data reporting, and the lack of standardized follow-up (particularly in low-resource or community settings) also challenge uniform detection of adverse drug reactions (ADRs) (11–13). When such is the case, bringing ECG monitoring into pharmaco-vigilance systems is not a question of whether, but rather a matter of when. The integration of routine baseline and periodic ECG screening with big ECG data analysis and standardized reporting may enable health care to recognize subtle early electrop-hysiological abnormalities, single out suspect drugs (including new compounds), and intervene (dose reduction, therapeutic switch) without delay to avert potentially fatal arrhythmias and death[14-16].

The purpose of this review is therefore to collect available information on drug-induced cardiac ADRs detected using ECGs within and between therapeutic classes[17]. In this context, we would like: to introduce some more detailed discussion on common pathological ECG findings with drugs; introduce those therapeutic classes and drugs involved; offer insights into what real world ECG monitoring looks like and expose hidden gaps; examine caveats and challenges; and generate insights into where ECG monitoring could head into the future about safety monitoring in pharmacovigilance systems in particular, into resource-limited environments[18]. In this comprehensive overview, we therefore stress that ECG surveillance activity can now be viewed as the cornerstone of modern drug safety research and serves as an important tool for safeguarding the individual's cardiovascular system in the context of modern times of pharmagluttony[19,20].

METHODS

The review was conducted within the PECO framework. The population included human participants exposed to pharmaceutical agents. Exposure/Intervention included the use of one or more medications; Comparators included baseline ECGs or unexposed groups when available. Outcomes included ECG-confirmed cardiac adverse drug reactions such as QT/QTc prolongation, conduction abnormalities, arrhythmias, and related clinical events. Time covered changes from baseline to any follow-up ECG[15,21-23].

A priori protocol development included eligibility criteria, search strategy, data-extraction procedures, and risk-of-bias assessment; the protocol was registered in PROSPERO. A comprehensive search of PubMed, EMBASE, Web of Science, Scopus, and grey literature sources was performed using MeSH and keyword terms related to drug-induced ECG abnormalities. No limits were placed on study design or publication date. Searches followed PRISMA 2020 documentation standards. All citations were imported into reference-management software and deduplicated. Two independent reviewers screened titles/abstracts and assessed full texts using predefined criteria, with disagreements resolved by consensus[16,24]. Using a standardized form, data were extracted on study characteristics, population details, drug exposure, ECG parameters, cardiac/clinical outcomes, and potential risk modifiers. Quality assessment utilized the Cochrane Risk of Bias Tool for trials, Newcastle-Ottawa Scale for observational studies, and structured criteria for case reports/series[25]. A narrative synthesis was undertaken due to heterogeneity across drug classes and ECG methods; results were organized by therapeutic class. Meta-analysis was considered when methodological homogeneity allowed. Reporting followed PRISMA 2020 guidelines[26].

DISCUSSION

This review pooled data from studies including over 1.7 million patients. It showed that ECG-confirmed cardiac ADRs occur in about 1.06% of exposed individuals, therefore delineating a clinically relevant burden in real-world settings. Psychotropic drugs represented the leading class causing cardiac ADRs, at 1.8%, followed closely by chemotherapeutic agents, at 1.6%, suggesting both CNS-active and oncology drugs represent important classes deserving enhanced cardiovascular monitoring[27]. Of all ECG abnormalities reported, QT/QTc prolongation was the most common manifestation. At the same time, conduction delays and clinically significant arrhythmias were present less frequently but still stood out as essential safety concerns[28].

Moreover, developments in pharmacovigilance technologies were promising: automated systems that combined NLP and RDI exhibited sensitivity of 93.8% and specificity of 91.8%, while reducing the manual review workload by up to 75%[29]. These results indicate the value of AI-powered tools for improved identification and reporting of cardiac ADRs[30]. The

review also highlighted important patient-level risk factors, such as advanced age, male gender, polypharmacy, and pre-existing cardiovascular disease, significantly increasing susceptibility to drug-induced cardiac events[31]. Collectively, these results provide a comprehensive overview of epidemiology, drug classes of concern, diagnostic patterns, and technological advancements impacting cardiac ADR detection and management[32].

The conclusion that the original authors have reached is that ECG-based surveillance is an effective, feasible strategy for early detection of cardiac ADRs[33]. They recommend the routine integration of ECG monitoring, combined with automated EHR-based systems, into pharmacovigilance programs, especially for high-risk medications and populations[34].

Critical Analysis

a. Strengths of the article

The paper demonstrates several strengths that make it more scientifically sound and relevant to the discipline of pharmacovigilance. First, the article used a comprehensive and systematic search strategy consistent with the PRISMA recommendations, including searches in several key databases and grey literature[35]. By including a wide range of study designs clinical trials, observational research, and case series the review effectively captured real-world patterns of ECG-confirmed cardiac ADRs across diverse clinical contexts[36].

A second strength lies in the exceptionally large sample size, with over 1.7 million patients being represented[37]. It is such breadth that provides substantial statistical power and enables generalization across multiple health-care settings. The broad representation of clinical populations strengthens the applicability of reported ADR frequencies[38].

Third, the integration of automated detection systems, including NLP and RDI, into the review represents one of its major methodological assets[39]. These tools demonstrate high sensitivity and specificity, providing compelling evidence that AI-assisted ECG surveillance can augment traditional ADR reporting mechanisms[40].

Finally, the article provides clinically important insights into many therapeutic classes. In identifying patterns of cardiotoxicity among psychotropics, chemotherapeutics, antimalarials, and cardiovascular drugs, the review highlights the broad utility of routine ECG monitoring in the early detection of drug-induced electrophysiological disturbances[41,42].

b). Limitations and weaknesses

Nevertheless, several limitations are identified in this review. The studies included showed significant heterogeneity in ECG measurement methods, ADR definitions, follow-up duration, and quality of reporting[43]. This prevented complete quantitative pooling from being feasible and required a narrative synthesis, which generally entails a loss in statistical precision[44].

Additionally, pediatric populations and low-resource settings were underrepresented. Since most of the included studies were from adult cohorts and high-income countries, the generalizability of the findings to LMICs and vulnerable populations remains limited, especially in regions with constrained access to ECG[45]. Another limitation is the reliance on EHR quality for automated ADR detection. The reliability of NLP or algorithm-based systems could be compromised in settings where data entry may be incomplete or inconsistent[46]. This constrains the scalability of automated pharmacovigilance systems in facilities with weak digital infrastructure[47]. Finally, the review examined only electrophysiological abnormalities detectable by ECG[48]. ECG monitoring alone cannot capture structural, inflammatory, or metabolic cardiotoxic effects, and it thus appears that actual drug-induced cardiac injury is underestimated[49].

c. Comparison with existing literature

Generally, the results of this review are consistent with current evidence. The reported rate of ECG-confirmed ADRs, 1.06%, is thus consistent with previously published rates in extensive cohort studies of about 1.08% and thereby underlines the reliability of such prevalence estimates[45]. The findings regarding psychotropics and chemotherapeutics as the main contributors to QT prolongation and arrhythmias are well supported by evidence from established pharmacology literature, too, which long since has mentioned these classes of drugs as being at a high risk of electrophysiological toxicity.

Similarly, performance metrics for NLP-based detection systems parallel those from previous studies using EHRs to evaluate AI-enabled detection for conditions like agranulocytosis and rhabdomyolysis. Such convergence of evidence supports the growing role of automated analytics in advancing national and institutional pharmacovigilance systems. Equally, the risk modifiers identified-old age, male gender, polypharmacy, and pre-existing cardiovascular disease-are a reflection of established epidemiological trends within research in both cardiology and clinical pharmacology[49].

d. Overall contribution to pharmacovigilance

In all, the review represents a meaningful contribution to modern pharmacovigilance by showing how ECG monitoring can be used as a proactive tool for early detection of cardiotoxicity. The forward-looking review reflects global trends in digital health by integrating automated surveillance technologies with traditional methods of monitoring. The results also favour moving from reactive safety reporting to predictive and preventive monitoring, in cases involving high-risk conditions such as polypharmacy and drugs that prolong QT[49].

CONCLUSIONS

The review of ECG-based pharmacovigilance shows that systematic monitoring of drug-induced cardiac ADRs is possible and very relevant in daily clinical practice. Evidence from more than 1.7 million patients reveals that ECG-confirmed cardiac ADRs, such as QT/QTc prolongation, abnormalities of conduction, and arrhythmias, occur in a clinically relevant proportion of patients (≈1.06%) and are especially prevalent in psychotropic drug users (1.8%) and chemotherapeutic drug users (1.6%). These findings

indicate that proactive cardiac safety surveillance is necessary across therapeutic classes.

Importantly, it was also shown that the combination of automated systems using NLP and RDI increases sensitivity to 93.8% and specificity to 91.8%, while reducing the load for manual review by approximately 75%. This suggests that AI-assisted ECG monitoring may supplement conventional pharmacovigilance approaches by providing timely and effective detection of cardiotoxic events. Despite these advances, several gaps remain. Most studies emanate from high-income countries and adult populations, thereby limiting the generalizability of findings to low-resource settings and pediatric populations. In addition, ECG monitoring alone cannot detect structural, metabolic, or inflammatory cardiotoxicity and hence may be an underestimate of the actual burden of drug-induced cardiac injury. The heterogeneity in ECG measurement methods, reporting standards, and follow-up further limits comparability across studies.

Overall, the review provides a clear view of how ECG-based pharmacovigilance is a robust, scalable, and forward-thinking method for early detection of cardiac ADRs. Ensuring patient safety requires the inclusion of routine ECG monitoring in pharmacovigilance systems, especially for high-risk drugs and vulnerable populations, and the adjuvant use of digital health with AI-assisted analytics. Future studies must enhance the study of underrepresented populations, reporting harmonization, and the integration of ECG with other modalities to fully capture the cardiotoxicity spectrum. ECG monitoring has the potential to transform pharmacovigilance from reactive reporting to proactive, predictive, and patient-centred cardiac safety monitoring, especially when coupled with AI-driven tools.

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AUTHOR'S CONTRIBUTIONS

Said SS: conceptualization, literature survey, writing original draft, review, editing. **Simai B:** review, editing. **Okafor CJ:** writing original draft, review, editing, literature survey. **Rashid SS:** conceptualization, literature survey. **Mwadini AM:** writing original draft. **Hamisi HJ:** review, editing. **Obeagu EI:** writing original draft, literature survey, review, editing. Final manuscript was checked and approved by all authors.

DATA AVAILABILITY

The datasets generated or analyzed during this study are available from the corresponding author upon reasonable request.

CONFLICT OF INTEREST

None to declare.

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