

Opinion Paper

Artificial intelligence-based novel wearables for non-invasive point-of-care assessment of high sensitivity cardiac troponins in patients with acute coronary syndrome

 Krishna Mohan Surapaneni

Departments of Biochemistry & Medical Education, Panimalar Medical College Hospital & Research Institute, Chennai, India

Abstract

The timely and accurate diagnosis of acute coronary syndrome (ACS) is essential for improving patient outcomes, as delayed treatment can result in irreversible myocardial damage and increased mortality. Many studies investigated the feasibility and efficacy of artificial intelligence (AI)-based wearable technologies for the non-invasive, point-of-care assessment of high-sensitivity cardiac troponins (hs-cTn), a critical biomarker for myocardial injury. These wearables combine advanced biosensors with machine learning algorithms to deliver real-time, accurate hs-cTn measurements, enabling faster and more effective clinical decision-making. Clinical trials reveal that AI-powered wearables achieve diagnostic accuracy comparable to traditional laboratory assays while significantly reducing diagnostic time and resource burden. Additionally, their portability and cost-effectiveness make them suitable for diverse healthcare settings, including remote and resource-limited environments. This opinion paper seeks to elaborate on the insights gained from this study, emphasizing the transformative potential of AI-driven wearables in enhancing ACS diagnosis, streamlining patient care, and reducing strain on healthcare systems.

Keywords: Artificial intelligence, machine learning, non-invasive diagnostics, point-of-care testing, wearable technology

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Acute coronary syndrome (ACS) is one of the leading causes of death globally. Rapid advancements in healthcare technology have made rapid detection and treatment more effective [1]. However, the incidences of out-of-hospital deaths are still at alarming levels. With the facility of point-of-care (POC) assessment, we can drastically bring down these concerning numbers. Timely diagnosis allows for prompt interventions, reduces long-term complications, and enhances overall patient outcomes.

Cardiac biomarkers, including high-sensitivity cardiac troponins (hs-cTn), are essential for the early detection and diagnosis of ACS. Creatine kinase-MB, myoglobin, and troponins serve as indicators of myocardial damage, with troponins being highly specific markers. High-sensitivity troponin assays, a significant advancement, enable the detection of even minor cardiac in-

juries, facilitating early intervention and improved patient outcomes. Serial testing of hs-cTn levels helps assess changes over time, aiding in risk stratification. The precision and specificity of these assays, coupled with their ability to rule out ACS, have transformed clinical approaches, providing a valuable tool for timely and accurate diagnosis in cardiovascular care.

However, traditional laboratory-based testing faces challenges in achieving early detection, particularly in cases like ACS, where timeliness is critical. The emergence of artificial intelligence (AI)-based wearable devices offers a transformative approach to non-invasive, POC diagnostics for ACS. These smart wearables leverage AI algorithms to analyze biosignals and biomarkers in real time, providing immediate insights into cardiac health [2]. By enabling the continuous monitoring of

Address for correspondence: Krishna Mohan Surapaneni, PhD., MHPE. Departments of Biochemistry & Medical Education, Panimalar Medical College Hospital & Research Institute, Chennai, India

Phone: +0919789099989 **E-mail:** krishnamohan.surapaneni@gmail.com **ORCID:** 0000-0002-5204-5708

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high-sensitivity cardiac troponin (hs-cTn) levels, these devices could facilitate the early detection of myocardial injury, even in asymptomatic individuals or those at high risk of ACS.

A pioneering study was conducted by Sengupta et al. [3] on the effectiveness of a wrist-worn transdermal infrared spectrophotometric sensor (transdermal-ISS) and a machine learning algorithm to predict elevated high-sensitivity cardiac troponin-I (hs-cTnI) levels in ACS patients. The study, encompassing 238 patients across five sites, demonstrates the clinical feasibility of this innovative method, showcasing high sensitivity and specificity in predicting elevated hs-cTnI levels. This breakthrough holds promise for rapid, bloodless biomarker diagnosis in real-world settings, potentially revolutionizing point-of-care assessments for acute myocardial infarction and facilitating efficient triaging of patients with suspected ACS (Fig. 1).

Discussion

The discussions surrounding this novel but nascent approach are currently focused on its potential applications and the ongoing testing required for future clinical trials. There is an ongoing United States study enrolling participants to assess the device's value in emergency rooms, with prospects of extending its use to chest pain units, urgent care settings, and even ambulances by trained paramedics, eliminating the need for blood draws [4]. In addition to wrist wearables, more wear-

ables, such as skin patches and other sensors, can also be developed with transparent algorithms. These innovations offer diverse options for continuous monitoring and early detection of high-sensitivity cardiac troponins in patients with ACS.

Another study by Li et al. [5] confirms that Mindray's hs-cTnI using CLIA (Chemiluminescence Immunoassay), a laboratory-based assay, is precise, sensitive, and specific in measuring cardiac troponin, making it a valuable diagnostic tool for myocardial infarction. Its comparable performance to the ARCHITECT hs-cTnI assay suggests it could be a reliable alternative, offering clinicians confidence in accurate diagnoses [6]. This positive outcome may influence healthcare practices, stimulate further research, and impact regulatory considerations for cardiac troponin assays. While the study extensively discusses the analytical and diagnostic performance of the hs-cTnI (CLIA) assay, it does not explicitly address the crucial need for early detection of acute coronary syndrome (ACS). Timely identification of ACS is vital for prompt intervention and improved patient outcomes.

While the potential of these technologies is significant, their impact on laboratory medicine must also be considered. In many countries, medical biochemists play a central role in managing POC devices, including their procurement, verification, and quality control [7]. The introduction of AI-based wearables into clinical practice could significantly alter these responsibilities. Laboratory medicine specialists might need

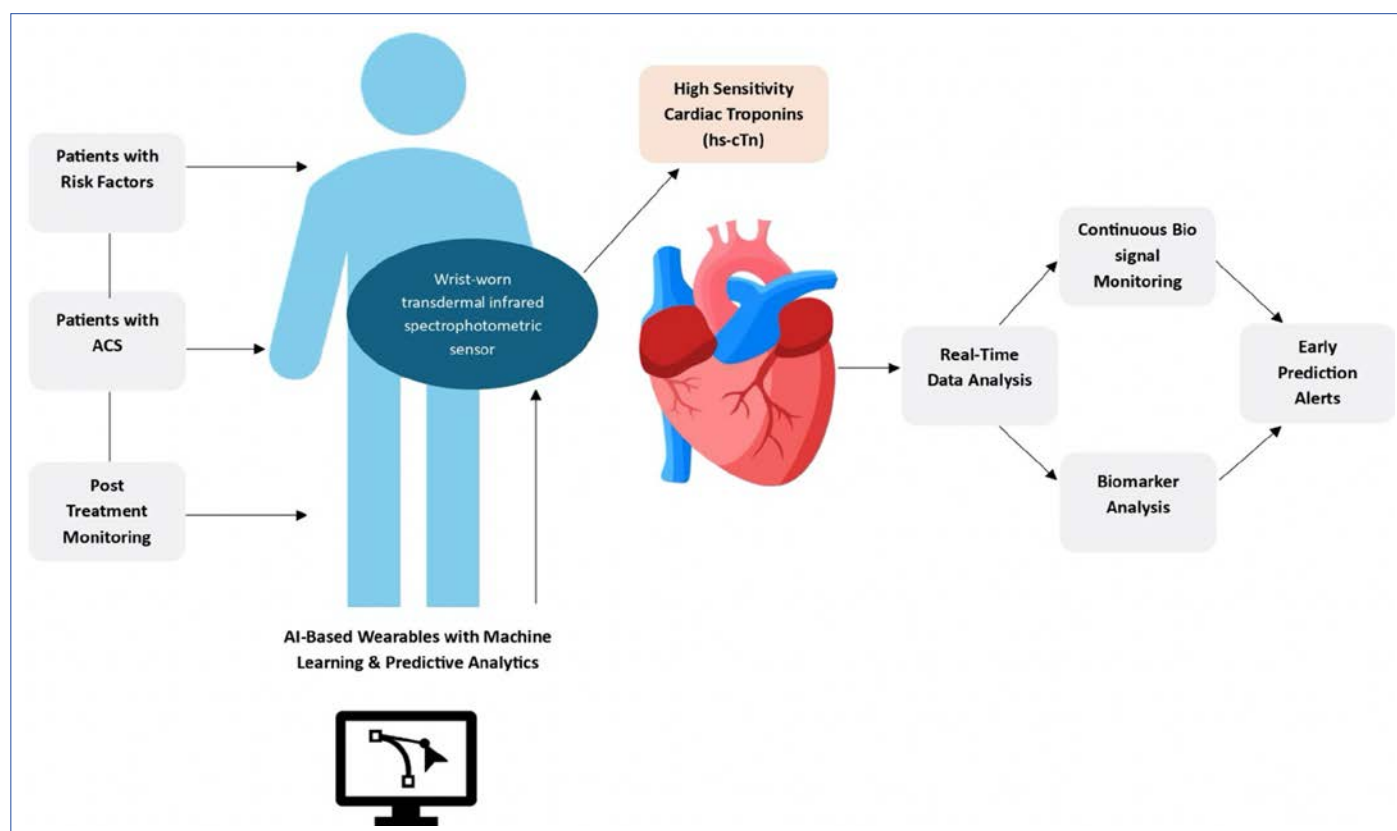


Figure 1. Illustration of how AI-based point-of-care testing wearables such as wrist-worn transdermal infrared spectrophotometric sensor (transdermal-ISS) helps in predicting elevated high-sensitivity cardiac troponin-I (hs-cTnI) levels.

ACS: Acute coronary syndrome.

Table 1. Comparison of lab-based and AI-based detection of cardiac biomarkers

Aspect	Lab-based detection	AI-based detection (transdermal-ISS)
Accuracy	Gold standard with high accuracy and reliability	High sensitivity and specificity demonstrated in clinical settings
Invasiveness	Requires blood sample collection	Non-invasive; uses a wrist-worn sensor
Time to results	Typically requires several hours for processing	Rapid, real-time predictions
Point-of-care utility	Limited by need for specialized lab infrastructure	Portable and suitable for bedside or out-of-hospital use
Scalability	Limited by equipment and trained personnel	Highly scalable with minimal hardware requirements
Cost efficiency	High costs due to reagents, equipment, and labor	Potential for lower costs over time with widespread adoption
Patient comfort	May cause discomfort due to blood draw	Comfortable and non-invasive for patients
Application in remote areas	Challenging due to infrastructure requirements	Feasible with minimal infrastructure
Real-time monitoring	Not feasible for continuous monitoring	Enables continuous or repeat assessments over time

to adapt their expertise to include oversight of these novel devices, from validating AI algorithms to ensuring the accuracy of data generated by wearables [8].

Methodologically, laboratory-based hs-cTn assays benefit from well-established protocols for calibration, quality control, and standardization, ensuring consistent results across diverse patient populations and settings. In contrast, wearable devices face challenges such as variations in skin properties (e.g., pigmentation, hydration, and thickness), environmental factors (e.g., temperature and movement artifacts), and signal processing limitations [9]. A comparison of both methods is given in Table 1. To address these challenges, robust testing of wearables in real-world scenarios is essential. For example, longitudinal studies could compare hs-cTnI trends obtained via wearables and laboratory assays under identical clinical conditions, assessing concordance and reliability.

Practical examples of implementation can further highlight the feasibility and integration of wearable technologies into the healthcare system. For instance, in pre-hospital settings such as ambulances or urgent care centers, wearables could provide real-time troponin trends, enabling paramedics to stratify ACS risk before reaching the hospital. However, seamless data integration with centralized laboratory systems is crucial to ensure continuity of care. A standardized reporting framework, where wearable-generated data can be directly compared or correlated with laboratory assay results, would facilitate such integration and support clinical decision-making [10].

The challenges highlighted, including cost, accessibility, and the need for clinical validation, merit deeper analysis. For instance, cost-effectiveness studies should evaluate whether wearables reduce overall healthcare expenses by minimizing hospital admissions, reducing emergency department congestion, and preventing unnecessary invasive procedures [11]. To overcome accessibility barriers, especially in resource-limited settings, partnerships with governmental health programs or subsidized models could promote equitable adoption. Regarding valida-

tion, multicenter trials across diverse populations should assess the wearables' sensitivity and specificity against laboratory assays to ensure global applicability and reliability [12].

Finally, addressing regulatory and operational considerations is paramount. Unlike laboratory assays, wearable devices operate under conditions where data quality can be influenced by user adherence and device variability [13]. Regulatory agencies such as the FDA or EMA should collaborate with developers to establish robust standards for wearable validation, ensuring safety, efficacy, and reproducibility. Furthermore, laboratory professionals, such as medical biochemists, must play a key role in developing protocols for periodic calibration, data verification, and integration into existing diagnostic workflows [14]. This collaboration would bridge the gap between wearable technology and traditional laboratory medicine, ensuring complementary use rather than competition. By integrating a direct comparison, technical specifics, practical use cases, and actionable strategies, this letter can offer a balanced and scientifically robust perspective that fosters meaningful dialogue within the academic and clinical communities.

Conclusion

AI-powered wearable technologies represent a groundbreaking shift in diagnosing and managing acute coronary syndrome (ACS). By providing rapid, non-invasive, and real-time insights into high-sensitivity cardiac troponin (hs-cTn) levels, these innovations have the potential to redefine point-of-care diagnostics, particularly in pre-hospital and remote settings. They promise not only faster triaging and earlier interventions but also improved accessibility for patients who might otherwise face barriers to traditional laboratory testing.

The road ahead involves translating these promising technologies into clinical practice. Future efforts should prioritize large-scale validation across diverse populations, ensuring reliability and inclusivity. Beyond clinical accuracy, addressing practical

challenges like cost, user adoption, and system integration will be key to their success. Collaboration between regulatory bodies, healthcare providers, and technology developers will be critical to establishing standards that ensure safety and efficacy. With continued innovation and careful implementation, AI-based wearables could bridge critical gaps in ACS care, offering a scalable solution that aligns with the demands of modern healthcare systems. Their integration has the potential to not only enhance clinical workflows but also alleviate pressure on emergency departments, ultimately advancing the future of cardiovascular care.

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