

Editorial



Revolutionizing Healthcare: The Future of Wearable Single-Lead ECG Monitoring System

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In recent years, there have been remarkable advancements in digital health technologies. Many individuals, including healthcare professionals, have adopted them into their daily lives. Among these innovations, electrocardiogram (ECG) monitoring devices, developed by various companies, are now being used in clinical settings. In response to the COVID-19 pandemic, the United States' Food and Drug Administration has permitted the sale of ECG products for remote monitoring by its guideline announced in 2020, further extending the guideline in 2023 to support the indefinite use of ECG and other non-invasive remote monitoring devices directly by patients.¹⁾ Similarly, in Korea, the Ministry of Food and Drug Safety is in the process of preparing the 'Preemptive Clinical and Approval Standards for Digital Health Devices' expected to be finalized by 2024.²⁾ Therefore, an increasing number of digital health devices are expected to be introduced into our daily lives and clinical practices within a next decade.

Among wearable ECG devices, the single lead ECG monitoring device has gained attention as it allows prolonged ECG monitoring with minimal discomfort and has emerged as a supplementary diagnostic tool to Holter monitoring. Understandably, it has begun to be employed as a telemonitoring device, even within hospital wards. However, for the potential substitution of the single ECG monitoring wearable device as a telemonitoring tool for patients admitted with acute conditions, comparative clinical trials against conventional equipment are considered essential.

In this issue of the journal, Kwon et al.³⁾ present a study comparing a novel telemonitoring system using a single-lead ECG patch to a conventional telemonitoring system in an inpatient setting. They reported that the novel telemonitoring system demonstrated excellent reliability and agreement in assessing ECG parameters compared to the conventional system, particularly in terms of intra-class correlation. Notably, the single-lead ECG patch significantly reduces signal loss compared to conventional methods due to the seamless wireless network facilitated by the dual connection configuration between the patch and neighboring gateways. Furthermore, the prevention of motion artifacts or poor electrode-to-skin contact has significantly reduced signal noise. While these results may be expected due to technological advancements, their significance is underscored by the well-designed research conducted in an inpatient setting, validating the effectiveness of the novel telemonitoring system.

Data Sharing Statement

The data generated in this study is available from the corresponding author upon reasonable request.

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Wearable ECG monitoring devices are expected to replace a significant portion of traditional telemonitoring systems. Although Kwon et al.³⁾ did not provide data on the cost-effectiveness of telemonitoring using wearable ECG patches in this study, it is expected to be more cost-effective than conventional systems and easily scalable in terms of the number of monitorable patients if necessary. Additionally, the advancement of wearable ECG monitoring devices can be linked to patient follow-up and treatment through remote monitoring. Especially at a time when the effectiveness of ECG screening for the general population is questionable, ECG monitoring in high-risk patients or remote monitoring in those already diagnosed with heart disease remains an important and evolving field.⁴⁾ Many countries have accumulated significant experience with remote monitoring, primarily focused on cardiac implantable electronic devices (CIEDs), which has been beneficial for patient care and prognosis.⁵⁾ However, in Korea, pilot projects for CIED remote monitoring are only just beginning.

Remote monitoring can be applied in various fields, extending beyond CIED monitoring. From a technological perspective, there are no longer significant hurdles to utilize digital health devices for remote monitoring. For example, utilizing single-lead ECG patches for remote monitoring simply requires the use of a personal smartphone as a gateway. It can be used for rhythm control in patients with atrial fibrillation, as well as for monitoring acute decompensation in those with heart failure, along with facilitating cardiac rehabilitation.^{6,7)} Nevertheless, there are several crucial aspects that need to be addressed. These include establishing adequate and reasonable legal and regulatory support, implementing appropriate pricing systems, and setting up decentralized clinical trial infrastructures to support new research for digital health devices.⁸⁻¹⁰⁾ As we navigate these challenges, leveraging the potential of remote monitoring with wearable ECG devices has the potential to revolutionize patient care and improve outcomes across diverse healthcare settings.

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