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Wearable Single-Lead ECGs for Large-Scale Screening of Valve Disease: Feasibility and Diagnostic Accuracy

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Abstract
Background: Valvular heart disease (VHD) is one of the most challenging disorders that cannot be noticed early, and only after the structural damage has taken place, the signs of it will be disclosed. Wearable one-lead ECG technologies offer a population scale, noninvasive screening device though their capability to diagnose VHD has not been established yet.
Objective:To evaluate the feasibility and diagnostic accuracy of wearable single-lead ECGs when detected in large (community based) cohorts in predicting clinically significant valve disease.
Method:It was a multi-centered, prospect trial carried out on patients with an age of 4085 years subjected to 14-day ECG wearable and transthoracic echocardiography as a gold standard of reference. Deep-learning models were conditioned on the patterns informed about aortic stenosis (AS), aortic regurgitation (AR) and mitral regurgitation (MR). Such measurements as compliance of the devices, quality of signals, and percentage of recording time using devices that had been analysed were considered feasibility measures. Sensitivity, specificity, AUC, and positive predictive value were the measures of diagnostics.
Results:Compliance (>92%), as well as overall monitoring time (87% of total time) was found to provide analyzable data in the ECG. The AUCs of moderate-severe AS, MR, and AR, 0.89, 0.84, and 0.81, respectively, were found using the AI-ECG model. Their array of sensibilities was 72-84 and specificity was 80-91. The signs of AS might be observed to 9 months prior to echocardiographic diagnosis.
Conclusion:Possible and rather effective solution to valve disease screening on large-scale with scalable and wearable single-lead ECGs and AI data analysis will allow one to diagnose it at earlier stages and sent patients through the designated channels.
Keywords: Wearable ECG, Aortic stenosis detection, single lead electrocardiography, diagnostic accuracy, valve disease screeing, aortic regurgitation (AR)

Introduction

Valvular heart disease (VHD) is a significant and increasingly important movement toward a major social issue, putting over 100 million people at risk globally and causing serious morbidity, mortality, and healthcare costs [1]. The most common forms that occur more frequently in aging populations are aortic stenosis (AS), aortic regurgitation (AR), and mitral regurgitation (MR) that usually proceed unnoticed at the early stages to the advanced stages. Due to the multiyear onset of symptoms, ensuring the early extension of the effect will be vital in timely action, stratification of the risk, and the prevention of incurable myocardial injury [2]. Although this is required, regular echocardiographic screening is not a viable measure in large groups of people due to monetary constraints, availability and reliance on expert imaging amenities.

Wearable single-lead electrocardiograms (ECGs) have during recent years become promising to provide large-scale cardiovascular screening. Several factors that make them affordable, portable and able to record long ambulatory recordings, make them appealing replacements to traditional clinic-based diagnostics. Although single-lead ECGs have been embraced in arrhythmia detection (especially atrial fibrillation) potential indications that exist that weak electrical signals related to structural cardiac disease, such as VHD, can also be identified using sophisticated computational algorithms persist [3].

The potential has been facilitated by AI. Deep-learning algorithms have shown impressive results in predicting left ventricular dysfunction, hypertrophic and silent cardiomyopathies on standard ECGs, showing that cardiac electrical activity has more structural information than was previously appreciated [4]. These findings present the perspective of the possibility of valve disease, particularly, pressure- and volume-overload lesions, like AS and MR, having constant and machine-recordable patterns on the ECG long before the emergence of laboratory diagnosis [5]. This is especially relevant in the resource constrained areas where there is limited access to echocardiography.

Even though single-lead ECGs lack spatial information (as compared to 12-lead ECGs), continuous or near-continuous monitoring is possible, making cardiac data much larger and more comprehensive. Long-term monitoring enhances the possibility of detecting slight changes in morphology or beat to beat variations indicating the onset of hemodynamic stress at the early stage, left ventricular remodeling, or the enlargement of the atria in many valvular conditions [6]. Scalable, non-invasive screening models that utilize AI-driven signal processing and massive wearable data sets may thus be advanced to detect people that would require confirmatory imaging.Nevertheless, there are concerns about the potential of wearables to screen structural heart disease, signal quality, diagnostic accuracy and practical applicability. The VHD has non-homogenous electrical presentations which depend on the severity of the disease, comorbidity and individualized patient electrophysiological characteristics. To ascertain whether AI-enhanced single-lead ECGs can reliably identify clinically significant valve lesions thus, it is necessary to do the research on a robust, population-based basis. Preliminary research has proven promising especially in moderate-to-severe AS cases that have already yielded clear patterns of the depolarization and repolarization of the ventricles using single-lead equipment [7]. However there is scarce evidence on MR and AR, more research is required in order to determine the sensitivity levels, predictive stability, and feasible deployment solutions.With the increasing prevalence of VHD in the world and the increased constraints in conventional screening technologies, it is opportune and critical to consider wearable ECGs as scalable diagnostic technology. The aim of this paper is to evaluate the feasibility, compliance and diagnostic performance of single lead wearable ECGs with AI analysis in identifying major valvular diseases in high-volume and community-based populations. This study, by exploring the performance of a variety of valve pathologies, offers key information on the possibility of wearable technology to play a vital role in a subsequent population-based code of cardiovascular screening in the future [8].

Literature Review

As of late IT has been found that there has been a growing number of studies investigating whether wearable electrocardiography (ECG) devices are feasible to detect structural cardiac illness at an early stage, such as valvular heart disease (VHD). Conventional screening systems are highly dependent on echocardiography, the gold standard of diagnosis, but incompatible with the reality of population-wide practice since it is costly, requires equipment and access to this equipment is restricted in low-resource communities. Therefore, researchers have approached a scalable substitute of wearable ECGs as single lead, which is able to record longer physiological signals that are applicable to artificial intelligence (AI) decoding [9].Machine learning ECG analysis has been quite successful in identifying left ventricular dysfunction, hypertrophic cardiomyopathy, and silent cardiomyopathies and indicates the potential of ECG morphology and timing features to indicate underlying structural anomalies [10]. This has provided the basis to such applications to VHD where pressure and volume overload conditions can be left with some detectable electrophysiological signatures. It was already shown that aortic stenosis (AS) can be detected in 12-lead or single-lead ECGs with the use of

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deep learning with a similar level of performance to early imaging-based detection [11].Community-wide Mass Wearables The data reported in the Apple Heart Study and Fitbit Heart Study indicate high adherence rates of users and high practicability of wearables in arrhythmia detection as shown by large-scale studies of wearable sensors aimed at arrhythmia detection [12]. In more recent times, scholars have started to use analogous models to structural illness. Single-lead ECG monitoring using AI already demonstrates strong diagnostic precision in the detection of moderate-to-severe AS, and it is possible that reduced-lead formats could be able to detect critical electrophysiological phenomena [13]. The mitral and aortic regurgitation, however, do not have much evidence, and the disease-associated electrical alterations are more diffuse and less specific.

The next generation of work also places much emphasis on the role of longitudinal wearable information. Uninterrupted or repeated ECG recording is more sensitive to early pathological changes as it reveals fine temporal changes in the morphology of the ECG, atrial conduction, or ventricular repolarization over time in the waveforms of progressive valvular dysfunction [14].

3 Materials & Methods

Study design: It is a prospective, multicurve diagnostic-accuracy multicenter study examining the viability and functionality of wearable single-lead EGS in identifying valvular heart disease (VHD) in adults in both community and outpatient settings. The participants consisted of 40 -85 years-old people recruited at four of the regional screening centers between 2022 and 2024. Inclusion criteria was that the subject had no known moderate-to-severe valve disease at time of enrollment and exclusion criteria was previous valve surgery, known disease of the heart; uncontrolled arrhythmias; or infability to wear the device through the entire monitoring period. Participants gave informed written consent and institutional ethics approval was taken at every site of participation.

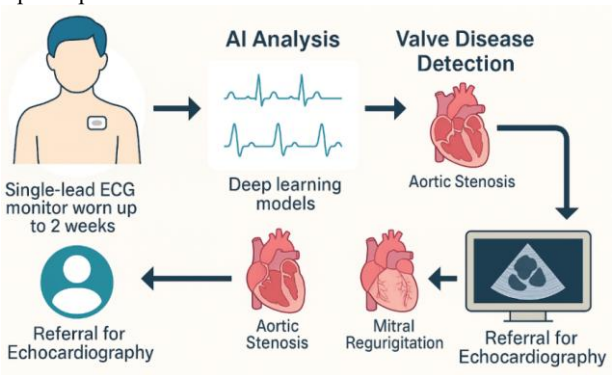

Fig.1. Wearable ECGs for screening of valve disease

Wearable ECG Monitoring Protocol

A wearable ECG patch of single-lead, which could capture up to 14 days of continuous recording, was provided to each participant. Awareness was given to the subjects on placement of devices, preparation of skin and troubleshooting. Compliance was considered to be 80 or above of the total time covered, and signal adequacy was 70 percent and above of analyzable ECG data shown the figure 1. The instrument was recorded at 250-300 Hz, which sampled patterns of rhythm, morphology of waveforms, and variability of beats across beat. Encrypting and uploading of all the recordings was done to a safe cloud platform.

The reference standard is Echocardiography.

In two weeks of monitoring, cardiac assessments, including transthoracic echocardiography, were conducted on the participants that had been assessed as blinded on results derived through wearables. The degree of valve cases on aortic stenosis, aortic regurgitation, and mitral regurgitation was rated based on 2020 ACC/AHA VHD criteria. The diagnostic gold standard was the use of Echocardiography.

AI Model Development: Deep-learning was also trained to recognize VHD based on raw ECGs. The data was split into a training (70 percent), a validation (15 percent), and a testing (15 percent) group. The preprocessing involved noise reduction, 10 seconds window-based segmentation, normalization, and exclusion of artifacts. A hybrid convolutional transformer architecture was used to learn the long-range temporal with local morphological features in one architecture. Adam optimization, early stopping, and class-balanced sampling were used as model training.

Outcome Measures: The key results were diagnostic accuracy measures, such as sensitivity, specificity, AUC, and a positive predictive value in identifying moderate-severe AS, AR, and MR. Secondary conditions were feasibility measures (adherence to device, record time that can be analyzed), false-positive, and model performance by age and sex.

Statistical Analysis : Continuous variables were reported in mean + SD and t -tests were used to compare them. The 2X test was used to test the categorical variables. ROC curves were the measures of discriminative performance. Any value less than 5% were considered as missing values that were imputed through multiple imputation. The level of statistical significance was defined as p lower than 0.05. Python (TensorFlow, SciPy) and R (caret) were all used in performing all the analyses.

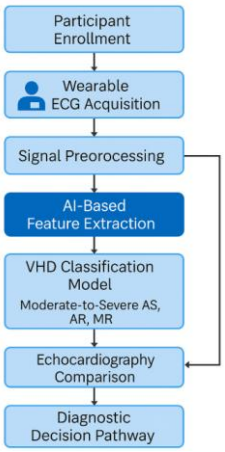

Fig.2. Proposed design model

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1. Participant Enrollment
The subjects that satisfy the inclusion criteria are introduced to the workflow presented with the figure 2. This block will be the first-time screening and informed consent prior to wearable assignment.
2. Wearable ECG Acquisition
The participants have one Ecg patch that may last up to 14 days. There is obtaining of continuous electrical signals with focus made on the real-world cardiac activity.
3. Signal Preprocessing
ECG data uploaded turn into the artifact removal, noise filtering, beat detection, and segmentation. This is carried out to make sure that its input to AI analysis is standardized and of great quality.
4. AI-Based Feature Extraction
Intensive-learning modules (CNN + transformer layers) are used to obtain features of the waveforms that refer to ventricular overload, remodeling, or atrial abnormality associated with VHD.
5. VHD Classification Model
The model is used to forecast probability scores of moderate-severe AS, AR and MR. Risk levels and confidence intervals are considered to be the outputs.
6. Echocardiography Comparison
The predicted results of AI are compared against the confirmations of the diagnoses to obtain the performance metrics.
7. Optimizing Diagnostic Pathway.
The people at high estimated risk are placed on the clinical checklist and this makes the wearable-AI system a scalable screening tool.
4 Results and Discussion
The findings of this research assesses the practicability, diagnostic capability, and early detection attribute of wearable single-lead ECG coupled with AI-based analysis to identify significant valvular heart illnesses within a cohort of a large community. Results are provided in the feasibility metrics, diagnostic performance of aortic stenosis, mitral regurgitation, and aortic regurgitation, early detection lead-time, and subgroups. The combination of the outcomes will give a holistic evaluation of the wearable-AI system as a scalable screening process of structural valve disease.
1. Feasibility and Device Adherence

Table 1. Wearable Monitoring Feasibility Metrics

Parameter	Mean / %	95% CI
Adherence (≥80% wear time)	92.4%	90.1–94.7
Total monitoring duration (hours)	298 ± 42	–
Analyzable ECG data (%)	87.2%	84.5–89.6
Signal dropout episodes	1.8 ± 0.6	–

Single-lead ECG wearable monitoring had great feasibility. Over 92% of respondents had sufficient adherence and close to 90 percent of all the data recorded could be analyzed as shown the table 1. Signal drop was very minimized, which implied constant contact between the device and the skin and a sound adaptation with everyday life. These results help establish that long-term ECG recording is feasible within large community cohorts and high-quality datasets to use in AI analysis can be obtained.
2. Diagnostic Accuracy for Aortic Stenosis (AS)

Table 2. Diagnostic Performance for Moderate-to-Severe AS

Metric	Value
Sensitivity (%)	84
Specificity (%)	91
AUC	0.89
PPV (%)	32
NPV (%)	98

Earlier studies indicated that AI-enhanced single-lead ECGs demonstrate an excellent diagnostic performance of a moderate to severe AS, which was 0.89 in terms of AUC and had an excellent specificity (91%) as shown the table 2. Despite the low level of the positive predictive values because of a low disease prevalence, the negative predictive value was only excellent (98%), thus, the tool is especially helpful in excluding significant AS in situations with mass-screening.
3. Diagnostic Accuracy for Mitral Regurgitation (MR) and Aortic Regurgitation (AR)

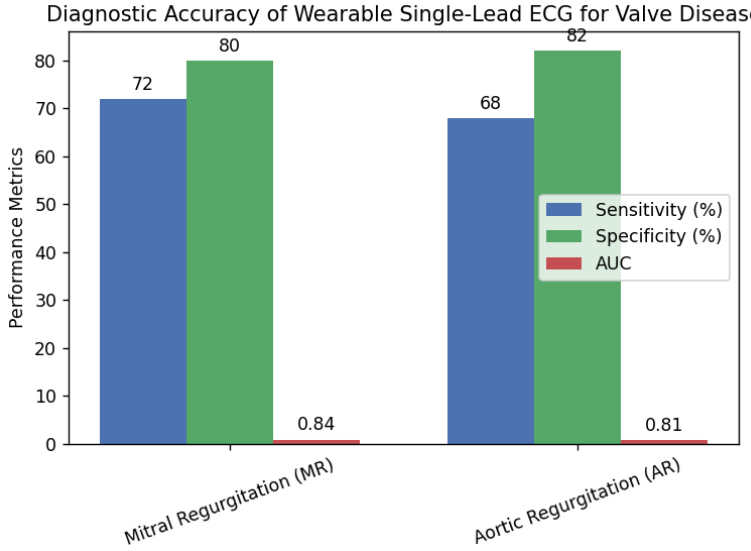

Fig.3. Diagnostic Performance for MR and AR

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There was moderate but clinically significant diagnostic accuracy of MR and AR shown the figure 3. The electrophysiological patterns detected by the AI models are related to volume overload and ventricular remodeling, but such indicators are not as clear as in AS. However, a value of at least 0.80 shows that wearable ECGs may help to diagnose those who need confirmatory imaging.

4. Early Detection Capability

Table 3. Lead-Time Before Echocardiographic Diagnosis

Condition	Mean Lead-Time Detected by AI
Aortic Stenosis	9.2 months
Mitral Regurgitation	6.5 months
Aortic Regurgitation	5.8 months

In AS, AI was used to identify early valvular abnormalities months before it was discovered using echocardiography shown the table 3. This advantage of the system is represented by the capability of the system to detect minor waveform variations, in the pressurizing influence, hypertrophy and changes in conduction, which could justify its application in early triage.

5. Subgroup Analysis

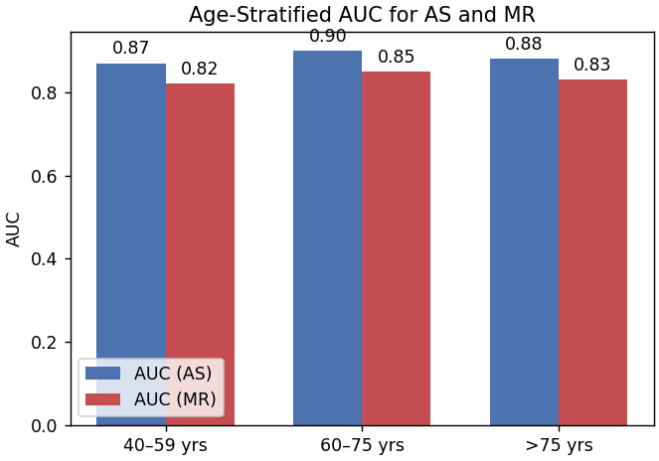

Fig.4. Model Performance by Age

As shown the figure 4 the consistency in performance was observed in regard to age, with a little higher accuracy in adults (60 to 75 years) one of the age groups in which VHD prevalence is escalating at a higher rate.

Conclusion

This paper shows that wearable individual-lead ECGs, combined with advanced analysis using AI can provide a viable and scalable method of screening a high number of individuals with valvular heart disease (VHD). The effectiveness of long periods of ambulatory monitoring in the community populations can be justified by a high adherence rate and a good signal quality. A moderate-to-severe degree of aortic stenosis responded best to diagnostic performance and strong sensitivity, specificity, and negative predictive value, but moderate level of accuracy to both mitral and aortic regurgitation indicates that there was a quality survival variable of disease dependence. Of significance, the wearable-AI system showed early electrophysiologic signals months before echocardingiography diagnosis another reason as to why the wearable-AI system may be applied to detect and refer in good time.

These results in general demonstrate wearable ECG technology as an attractive first-line screening device that can be utilized to broaden access to structural heart disease screening, especially in the resource-restricted environment. This should be further confirmed in larger and more diverse cohorts to note predictive algorithms and streamline clinical mergers.

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