The application of novel digital intelligent device in the assessment of cardiac function in patients with arrhythmia

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Abstract: Acoustic electrocardiography (ACG) is a new non-invasive test that combines the visualization of traditional ECG waveforms and heart-generated sound waveforms to jointly assess cardiac function and cardiac pathology. However, traditional ACG equipment is limited by technology and suffers from problems such as inconvenience and inaccuracy. In recent years, with the development of artificial intelligence technology, some newly developed wearable single-lead ACG devices have appeared, which have applications in the fields of heart failure and coronary heart disease. In order to further clarify the efficacy of this new ACG device for cardiac function assessment in irregular ECG and heart sound waveforms, this study will be validated in patients with arrhythmia, ROC curves show better evaluation of EMAT and EMAT% for HFrEF.

1. INTRODUCTION

Acoustic cardiography (ACG) is a new non-invasive cardiac monitoring technique that combines the features of traditional phonocardiography (PCG) and electrocardiography (ECG). It is capable of accurately identifying and analyzing different types of heart sounds, heart murmurs, and prosthetic valve sounds, and assessing the overall functional status of the heart by monitoring changes in left heart function [1].

ACG devices require highly sensitive heart sound transducers and conventional ECG leads capable of recording the mechanical (heart sounds) and electrophysiological activity (ECG waveforms) of the heart during systole and diastole (Fig. 1). By analyzing the heart sound signals, it is possible to differentiate between the first heart sound(S1), the second heart sound(S2), and any other heart sound or murmur present, allowing for further assessment of the patient's condition.

However, conventional ACG devices have several problems:

1) Traditional ACG devices are bulky and inconvenient, requiring complex equipment and power support, limiting their portability and usefulness in clinical and routine monitoring.

2) Conventional devices may lack accuracy in acquiring and analyzing heart sounds and ECG signals, and may be subject to external interference when acquiring heart sounds and ECG signals

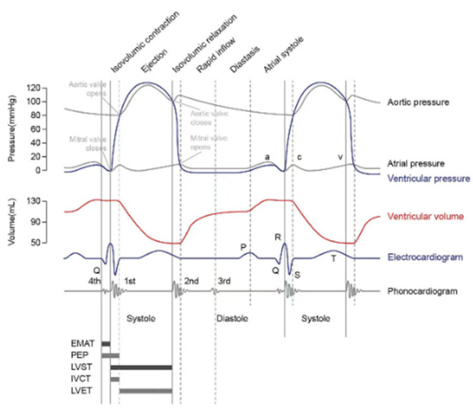

Fig. 1. ACG Basic Principle Diagram (figure from Wikipedia)

ACG is wearable, low-cost, and high-quality signals, making it particularly suitable for remote home monitoring, outpatient clinics, and community-based rapid screening of patients with paroxysmal arrhythmias.

Therefore, in recent years, there has been new heart sound electrocardiographic equipment research in China, this acoustic Signals we used were captured using the WENXIN® device (Wenxin Tech. Fuzhou, China). The device has received approval from the Chinese National Medical Products Administration (NMPA). Compared with traditional ACG, the device focuses on developing deep learning-based algorithms for r-peak detection by constructing a new model combining CNN and LSTM algorithms. The proposed model consists of two 1D-CNN layers, each followed by an average pooling layer. These 1D layers will extract high-dimensional spatial features

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from the input ECG signal and downsample to reduce the dimensionality of the hidden output. A 1D U-Net model is also used to recognize the ECG images. The traditional U-Net model encoder-decoder structure and the 2-layer per block convolution structure are retained, while the convolutional, maximum pooling, and upper convolutional layers are all changed to one-dimensional, and the number of filters in each convolutional layer is adjusted to better extract spatial features from the one-dimensional signal. It is robust to noise while maintaining an efficient and accurate recognition decision [2]. In this paper, a preliminary validation of the efficacy of this new ACG device for the assessment of cardiac function will be carried out in the case of patients with cardiac arrhythmia, to explore whether the new ACG has clinical utility.

Previous studies have shown that the prolongation of electromechanical activation time (EMAT) values measured by conventional ACG is strongly correlated with the decline in cardiac systolic function, which is of clinical value in the judgment of assessing the severity and progression of diseases such as heart failure due to severe arrhythmias [3]. We will study the correlation between EMAT and its normalized values measured by the new ACG and cardiac function in patients with arrhythmia to demonstrate the better monitoring performance and generalizability of the new ACG device with artificial intelligence-based modifications [4].

2. Methods

2.1. Subject of the study

Patients with arrhythmia admitted to the First Affiliated Hospital of Nanjing Medical University between 1 November 2022 and 9 March 2024 were selected for the study. Life-threatening acute and serious diseases, loss of consciousness, anterior chest deformity, psychiatric diseases, and obesity were excluded. All patients gave informed consent. This prospective study was approved by the Ethics Committee of the First Affiliated Hospital of Nanjing Medical University (2020-SRFA-301).

2.2. Methods of study

Patients' general information was collected using the hospital's electronic case system after enrolment. This included demographic information: age, gender, height, weight, BMI, and whether there was a combination of hypertension, diabetes, coronary heart disease, and other diseases; as well as relevant tests and examinations: blood biochemistry, troponin T(TNT), N-terminal pro-B-type natriuretic peptide (NT-proBNP), echocardiography (Philips Electrophysiology, Netherlands), 12-lead electrocardiogram(Seer Light, General Motors, USA), and other clinical examinations, which required the fitting of a single-lead smart cardiac ACG device, with the main detection indexes of EMAT and EMAT% (EMAT%=EMAT/ dominant RR interval).

The device used in this study was a new wearable ACG recorder (model: HR-0536), which is capable of simultaneous monitoring and digital acquisition of ECG and heart sound signals, and consists of a main unit, a USB charging cable, disposable ECG electrodes, and its accompanying mobile application, "Wenxin" APP (firmware version: V1.0).

Operation s (Fig. 2)*:*

1) Recorder main unit and disposable electrode patches
2) Remove the center protective film.
3) Fasten the patch to the device
4) Remove the clear protective film on the back of the patch
5) Switch on the main unit
6) Paste it 2.5cm from the left edge of the sternum to the fourth rib in the left midclavicular line

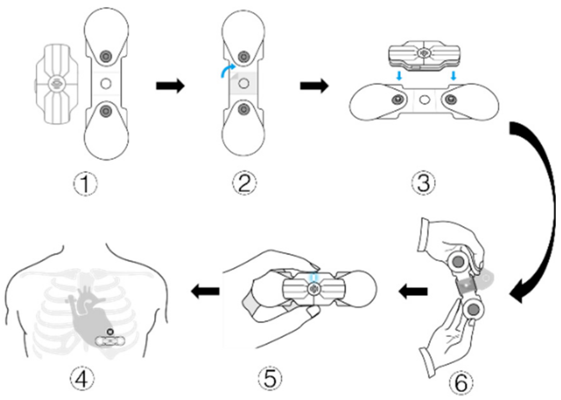


Fig. 2. Wearing process flow diagram (figure from wenxintech)

After opening the "Wenxin" APP and logging in to your account, you can connect to the ACG recorder via Bluetooth and upload the digitized signals to the cloud database for back-end analysis and archiving. With the help of AI automatic analysis software developed by Artificial Intelligence, the device can automatically identify P and QRS waves and annotate them in real-time. The analysis results can be returned to the mobile application. (Fig.3)

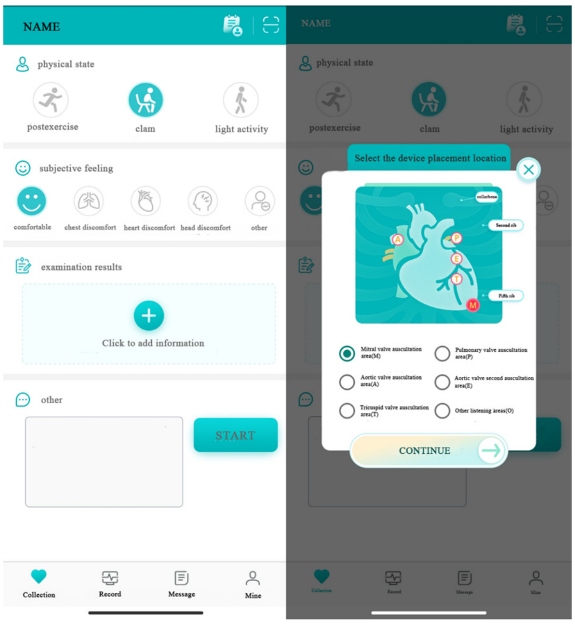


Fig. 3. APP interface

2.3. Statistical Analysis

Analyses were performed using GraphPad Prism8, SPSSV26.0, and Origin2021 software, and all statistics were expressed as measurements by mean ± standard deviation, and group comparisons were performed by paired t-test. Continuous variables of patients' basic data were analyzed by descriptive analysis, and the underlying prevalence and symptoms were analyzed by Fisher exact test, and P<0.01 was considered as statistically significant difference.

3. RESULT

3.1. Basic information

A total of 42 patients were enrolled in this study, including 21 males and 21 females, with a male-to-female ratio of 1:1 (Table 1).

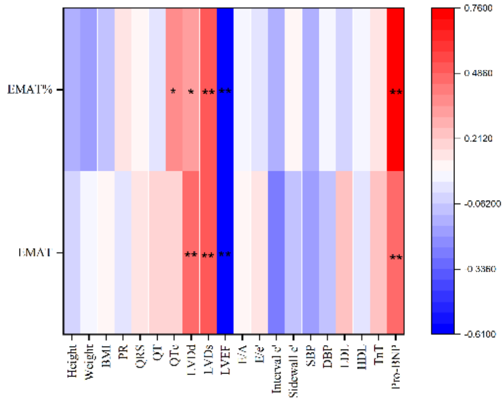
Table 1 General condition of the enrolled patients

	Male(*n*=21)	Female(*n*=21)
Age	61.52±15.46	49.76±19.26
Height (m)	1.71±0.06	1.62±0.07
Weight (kg)	68.93±10.15	62.44±6.80
BMI (kg/m^2)	23.72±3.43	23.62±3.74
heart rate (/min)	79.00±23.25	75.67±15.47
Systolic blood pressure (mmHg)	117.43±14.34	118.10±13.52
Diastolic blood pressure (mmHg)	72.95±13.13	72.76±11.14
Hypertension [n(%)]	8(38.10%)	3(14.30%)
Diabetes [n(%)]	1(4.80%)	2(9.50%)
Coronary heart disease [n(%)]	5(23.80%)	0(0.00%)
Premature atrial contractions [n(%)]	12(57.10%)	14(66.70%)
Premature ventricular contractions [n(%)]	18(85.70%)	20(95.20%)
Atrial fibrillation [n(%)]	4(19.00%)	1(4.80%)

3.2. Data correlation analysis

To further evaluate the correlation between heart sound and ECG detection indicators and cardiac indicators, we integrated and processed the relevant data, and in order to display the data results more intuitively, we drew a heat map through Origin software (Fig.4)

As can be seen from the figure, there is a correlation between EMAT/EMAT% and both of the two most classical indices of cardiac function, LVEF and NT-proBNP (p<0.01), and there is a significant correlation. Considering that LVEF = [(end-diastolic volume - end-systolic volume) / end-diastolic volume] × 100% and that there is a certain ratio between left ventricular diameter (LVD) and ventricular volume, LVD was not included in the analysis for the time being.



Note: LVEF = left ventricular ejection fraction; LVDd=left ventricular end-diastolic dimension; LVDs =left ventricular end-systolic dimension; SBP=systolic blood pressure; DBP=diastole blood pressure; LDL=low density lipoprotein; HDL=high density lipoprotein

*: At the 0.05 level (two-tailed), the correlation is significant.

**: At the 0.01 level (two-tailed), the correlation is significant.

Fig. 4. Pearson correlation analysis heat map

4. Comparison of the relationship between ACG indexes and cardiac function indices LVEF and NT-proBNP

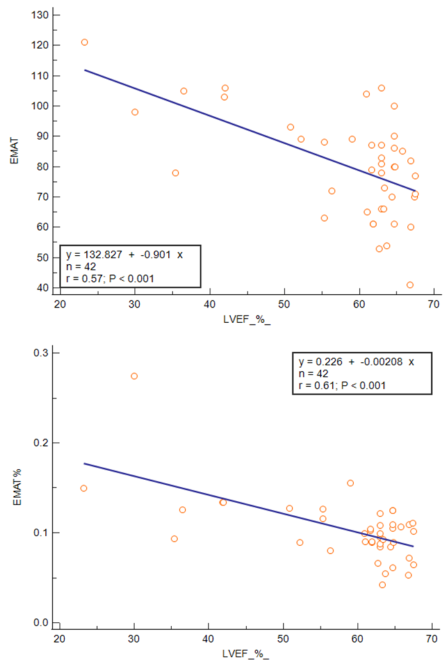


Fig.5. LVEF-related scatterplots and regression equations

First, we verified the relationship between cardiac function index LVEF and heart sound electrocardiogram indicators EMAT and EMAT%, and performed linear regression analysis of the data, and we found that there was significant statistical significance for both groups of indicators (p<0.01). The regression model showed strong explanatory power, and the coefficient of determination R^2 of EMAT was 0.327, while the coefficient of determination of EMAT% R^2 was 0.369. (Fig.5).

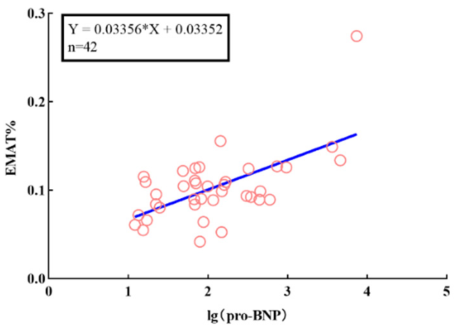


Fig.6. NT-proBNP-related scatterplots and regression equations

Secondly, the association of NT-proBNP, an indicator of cardiac function, with EMAT and EMAT%, an indicator of heart sound electrocardiogram, was verified and the data were analyzed by linear regression analysis, and it was found that NT-proBNP had a statistically significant relationship with EMAT% ($p<0.01$) whereas there was not much statistical significance after the linear regression analysis with EMAT ($p=0.05$). The coefficient of determination R^2 of EMAT in the regression model was 0.178 while that of EMAT% was 0.551, which has strong explanatory power. (Figure 6)

5. Evaluation of the efficacy of LVEF for cardiac function

To visually demonstrate the assessment performance of the model for evaluating patients with heart failure, this study plotted the subject operating characteristic curves (ROCs) for EMAT and EMAT% in patients with heart failure diagnosed by elevated NT-proBNP (NT-proBNP ≥300 pg/mL) and in patients with HFrEF(heart failure with reduced ejection fraction (LVEF <50%))as measured by echocardiography [5] (Figs. 7-8).

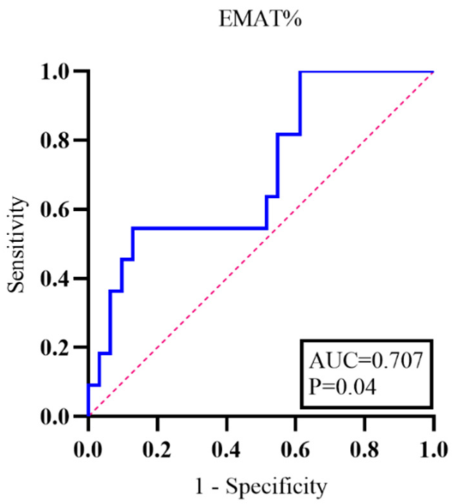


Fig.7 NT-proBNP-related ROC curve

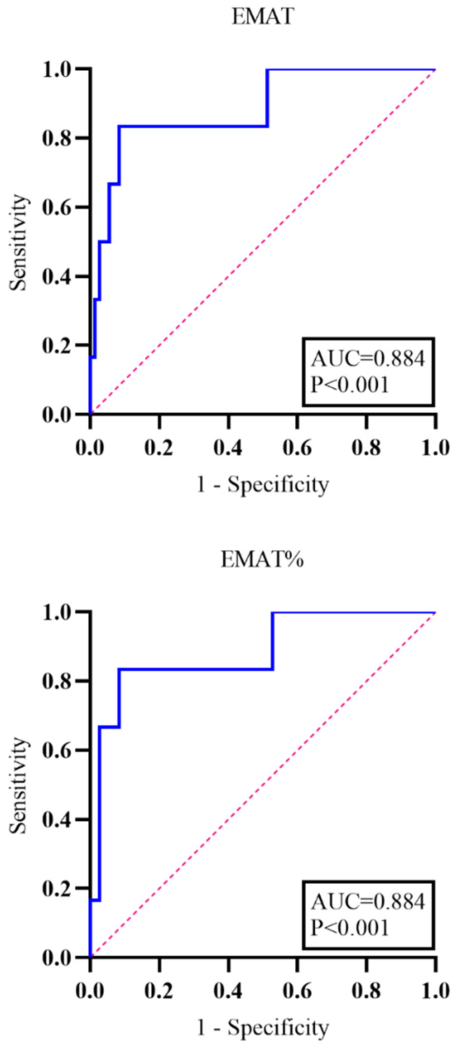


Fig.8. LVEF-related ROC curves

The area under the ROC curve was 0.884 for LVEF and 0.707 for NT-proBNP, indicating that the ACG device has high accuracy and reliability in assessing cardiac function and diagnosing cardiac insufficiency and has high predictive power, especially for HFrEF.

6. DISCUSSION

At the 2020 European Society of Cardiology (ESC) Congress, many authoritative experts agreed that AI is playing a revolutionary driving role in the frontier field of cardiovascular medicine, which will not only reshape the diagnostic standards of cardiovascular disease but also have great significance for achieving the precise formulation of individualized treatment plans [6]. Breakthrough research results of AI are emerging at an unprecedented rate [7]. By intelligently analyzing the meticulous ECG signals of arrhythmia patients, researchers and clinicians can more accurately determine the stage of the disease, predict the course of the disease, and formulate more targeted and personalized treatment strategies accordingly.

The aim of this study was to validate a new wearable device for assessing cardiac function in patients by EMAT and EMAT%, which has been suggested in the literature to be negatively correlated with LVEF and positively correlated with NT-proBNP [8].Our results show that the new wearable single-lead ACG device was validated in this study, showing high efficacy in all cases, with an area under the ROC curve greater than 0.7, a result that highlights the device's accuracy, convenience, and innovation in the assessment of cardiac function. While traditional EMAT and EMAT% measurements usually require complex equipment and specialized operations, the new wearable device simplifies the measurement process and provides real-time results, making cardiac function assessment more convenient and practical.

The great plan of "Healthy China 2030" programmed "clearly states that people's health should be the ultimate goal of economic development and political system reform", and explicitly identifies prevention of diseases and prolongation of life expectancy as the two main goals. The new wearable device will increase the feasibility and popularity of cardiac function assessment for arrhythmia patients due to its convenience and innovation. By using the device, doctors and clinicians can more conveniently and efficiently assess the heart's systolic function and pumping capacity in primary hospitals, especially for the initial assessment of cardiac function in patients with arrhythmia. This is important for early screening, treatment planning and dynamic assessment of heart disease.

It is worth noting that there are some limitations in this study, such as the small sample size, the lack of interference resistance of the device itself and the limitations of the study design. Future studies can further expand the sample size, consider more influencing factors and compare with other traditional measurements to further validate the reliability and effectiveness of novel wearable devices in cardiac function assessment, while continuously improving the algorithms and models in an effort to obtain the best efficacy. In addition, this study lacked a separate study on HFmrEF (heart failure with mildly reduced ejection fraction (LVEF of 41-49%)) and only analyzed the classic 50% threshold, and subsequent studies need to further analyze the classification of HFmrEF according to guidelines.

In summary, the results of this study indicate that the new wearable ACG device is able to assess patients' cardiac function conditions more quickly and conveniently, with a high degree of consistency with traditional methods. The convenience and innovation of this device provides new possibilities for cardiac function assessment and is expected to be widely used in clinical practice.

7. CONCLUSION

1. This new ACG device makes it easier to assess heart function, detect abnormal changes, and help doctors detect cardiac risks.

2. By utilizing cardiac acoustic-electrical devices, we can extend the benefits of cardiac function assessment to the community and grassroots level, due to their non-invasive nature.

3. Wearable ACG devices are important for the diagnosis and management of patients with cardiac arrhythmias, helping to detect signs of deterioration in cardiac function at an early stage, adjusting personalized treatment plans, and improving treatment outcomes.

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