Detection of Arrhythmia and Auscultation Assistance through Screening Device': A Clinical Study by Larkai Healthcare Pvt. Ltd.

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Abstract: *Larkai Healthcare Pvt. Ltd. (hereinafter referred to as 'the Company') is an Eastern-India-based start-up Company established on the 1st day of January 2020. Larkai adheres to the traditional business model which aims to accomplish the benchmark in the biomedical instrumentation market of India assuring affordable healthcare facilities. The Company's efforts to provide innovative and high-quality cardiac diagnostic/ monitoring products that are accurate and convenient to operate. The Company's pivotal and crucially developed product i. e., the 'Heart and Lungs Screening Device is created with the fundament of detecting ailments relating to the human organs, heart and lungs. To specify, the said device can well detect heart arrhythmias such as Tachycardia and Bradycardia. For visualization of the findings, the device depicts a real-time graph of heart and lungs auscultation along with amplified and noise-reduced sound. To brief a little on the mechanism of the Company's 'Heart and Lungs screening device', the said device is structured as a stainless-steel electrode. The unique software designed in the device analyses the BPM data collected by such electrode thereby identifying episodes of abnormal heartbeats suggestive of Arrhythmia. The device is developed to generate an electrocardiogram (ECG) waveform similar to a single-lead electrocardiogram, which provides a classification of the waveform as sinus rhythm (SR) that may either be high rate or low heart rate or may even be inconclusive in appearance. The present paper aims to provide a detailed analysis and understanding of the aptitudes of said features along with elucidation of testing and validation.*

Keywords: Healthcare, Arrhythmia, Heart, ECG, PCG, Clinical data

1. Introduction

'Cardiac Arrhythmia' or Heart Arrhythmia is a medical condition wherein the heart bit is found to be of an irregular pattern. Heart arrhythmia is commonly known as a heart rhythm problem which occurs when the electrical signals coordinating with the heart's beats do not work properly. Because of the incorrect signals, the heart beats too quickly (tachycardia), too slowly (bradycardia), or irregularly.

The symptoms of Heart Arrhythmia are usually fast or slow heartbeat, skipping beats, dizziness, pain in the chest, gasping breath, and sweating. However, most often than not Heart Arrhythmias are found to be asymptomatic in nature, or say, people, fail to note the symptoms. Hence, the majority of the population with arrhythmia is unaware of carrying the ailment. This reason in itself is enough to substantiate the cause of research on Arrhythmia. The increase in the risk of stroke has contributed to the necessity to research in this domain. This again has led to research on effective pharmacologic treatments to minimize stroke risk along with demand in the market for consumer devices to detect arrhythmia both in clinical as well as a non-clinical sphere for the sake of common people.

In view of the above situation, Larkai Healthcare Pvt. Ltd. has developed the above-said device to contribute to the emerging needs of healthcare at present. The 'Heart and lungs screening device' provides detection of Arrhythmia by identifying periods of irregular heartbeats by using electronic signals combines with a typical algorithm. The data produced is basically in line of ECG, specifically a single-lead ECG.

ECG- based Detection

Technical and Feature Description:

1) Firstly, the electrical activity of the heart is captured by a 3.5mm Jack connected with a Dry lead electrode.
2) Then, a 3.5mm Jack is connected with an ECG sensor which is an integrated signal conditioning chip with an operating voltage of 3.3V. It is designed to extract, amplify, and filter small biopotential signals in the presence of noisy conditions, such as those created by motion or remote electrode placement.
3) The signal is then passed through 2.7 V 8-Channel 10-Bit A/D Converters with Serial Peripheral Interface (SPI).
4) A/D Converters send data to the Microprocessor following the Serial Peripheral Interface (SPI) protocol.
5) A microprocessor (usually an ARM Cortex-A Series) runs an operating system to process the ECG signal.
6) The data is processed using wavelet Analysis and pattern recognition systems using python algorithms to detect cardiac abnormalities.
7) The data are sent to a 7-inch LCD-based display for interpretation.
8) A portable thermal printer can be connected to the Microprocessor to print the ECG graph.

PCG and Lungs Auscultation Assistance

Technical and Feature Description:
1) Firstly, the Lungs' sound signals are captured by a piezoelectric sensor or piezoelectric transducer.
2) Thereafter, the signal passes through low harmonic distortion and low noise operational amplifiers.
3) Then, Audio codecs which is a type of audio data

converters that encode analog audio as digital signals and decode digital audio back into analog.

4) A microprocessor (usually an ARM Cortex-A Series) runs an operating system to process the audio signal.
5) The operating system in the microprocessor processes the algorithm based on pattern recognition systems and analyzes the data to give screening data on lungs abnormalities.
6) The data are sent to a 7-inch LCD-based display for interpretation.
7) A portable thermal printer can be connected to the Microprocessor to print the sound graph.

Pre-Clinical Development
The pre-clinical stage was very crucial. The researchers of the Company have strategized different situations so as to formulate the mechanism for years.

Prior to clinical testing, the study was thoroughly conducted to develop the ECG-based detection algorithm and to evaluate algorithm performance across conditions where the patient is in a stable environment and comfortable sitting. Such studies used to be performed on 516 control subjects out of which 90 subjects used to report arrhythmia.

Since ECG is electrical pulse sensitive and the device electrodes are placed on the thumb, the electrodes can be moved to the chest to take the data in case of cuts/burns or bruises on the thumb. After the ECG data has been recorded one can place the piezo sound sensor on the chest and thorax for real-time auscultation of the heart and lungs as required. Thereafter the real-time auscultation gets graphically represented on the screen.

Clinical Validation

Experiment Design

The Company conducted research and experiments to validate the device's capacity as detailed hereunder:

1) Generate an ECG waveform similar to a Single Lead ECG from a standard 12-lead ECG and
2) Use a rhythm classification algorithm to classify this single lead ECG as either SR or Arrhythmia.
3) Compare the arrhythmia identified by larkai's device with arrhythmia identified by the 12-lead ECG device and calculate accuracy, sensitivity, and specificity.
4) Provide auscultation assistance to the physician and validate its overall quality through the physician's interpretation

Clinical Validation Study:
A clinical validation study was performed in April 2021 by a team of experienced researchers to validate the performance of the ECG and also to conduct the quality validation of auscultation. The study's primary endpoints were first, to find the sensitivity and specificity of the device to detect arrhythmia and SR. Secondly, understanding the level of quality of auscultation sound produced by the device through physicians' interpretation. The protocol was approved by a team of interventional cardiologists and Doctors. Besides the consent of the subjects to participate

before enrollment was confirmed through the informed consent form (ICF). Further, all relevant materials prior to subject enrolment were also noted and taken on record.

The study participants enrolled, constituted of subjects both with known cases of arrhythmia as well as with no known cardiac rhythm abnormalities. The participants were asked to record single lead ECGs using the Company's screening device and then recorded 12-lead ECGs using an FDA-cleared clinical device respectively. Participants were duly assisted with the device by experts while taking the data. In case there happened an event of any irregularity in the test due to any issues, the test was repeated from the beginning.

While calculating the accuracy, sensitivity, and specificity the following parameters were considered:

1) If the gold standard 12-lead ECG and Larkai's screening device both detect arrhythmia it's a true positive (TP).
2) If the gold standard 12-lead ECG and Larkai's screening device both detect sinus rhythm (SR) it's a true negative (TN).
3) If the gold standard 12-lead ECG detects arrhythmia and Larkai's screening device detects sinus rhythm (SR) it's a False Negative (FN).
4) If the gold standard 12-lead ECG detects sinus rhythm (SR) and Larkai's screening device detects arrhythmia it's a False Positive (FP).

Table 1: Data of TN, TP, FN, and FP

Parameter	Value
TN	417
TP	90
FN	2
FP	3

The results in lieu of considered parameters are represented hereunder:

Table 2: Accuracy, Sensitivity, and Specificity Results

Parameter	Value
Sensitivity	90/92 (97.8%)
Specificity	417/420 (99.2%)
Accuracy	507/512 (99.02%)

2. Results

The experiment was conducted through minute supervision of experts and the functioning of the device was noted carefully.

The study enrolled a total of 516 subjects out of which 512 met the eligibility criteria. The result showed that 415 had normal sinus rhythm, 88 had tachycardia and 8 had bradycardia.

The ECG results showed an accuracy of 99.02%. The ECG is capable of pre-screening the above-mentioned disease without facing any difficulty.

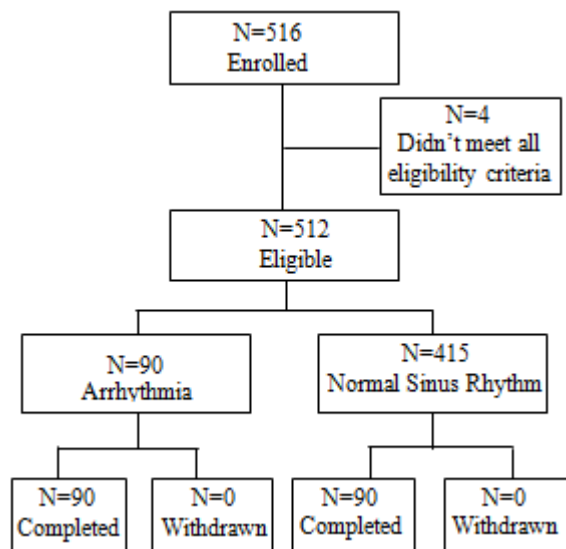The result from the experiment is pictorially represented below for ease of reference:

Diagram 3: Representation of final result

However, for the PCG results, we have identified a scope of improvement in the occurrence of noise while capturing the PCG sounds. This breach can be improved further by putting effort to cancel the peripheral noises that the device is capturing from external sources.

Nevertheless, it is observed that the device is pretty capable of pre-screening heart diseases with the help of ECG and PCG results and the algorithms.

3. Conclusions

Larkai Healthcare Pvt. Ltd. 's 'Heart and Lungs screening device' helps in the early screening of arrhythmia in the heart. It enables the detection of irregular heart rhythms and helps the physician in better auscultation with real-time graphical support. It not only helps physicians or medical professionals but may also help layman and common people to determine the health of their heart with a bit of instruction or guidance on the same.

The said device has been tested and compared with the gold standard 12-lead ECG where the device has an accuracy of 99.02%, has a sensitivity of 97.8%, and a specificity of 99.2%.

The testing has been conducted over a period of 30 days on 512 individuals (Ongoing) under the supervision of *Dr. Rusheekanta Mohanta* (a Cardiologist at Heartmate Institute of Cardiovascular Science and Research, Orissa) and is validated against a gold standard 12 Lead Electrocardiogram (ECG) machine for the accuracy of its ECG features along with doctors' interpretation for the Phonocardiogram/ Heart sound features.

The study was conducted through expert supervision for a considerable time. As elucidated above, the comfort and concern of participants were given utmost priority while the experiment was conducted. The participants were thoroughly instructed, guided, and assisted along with providing basic education on cardiac health.

Following are the propositions from the validation study:

1) The ECG has got validated with 99% accuracy.
2) Sound recording is found to have 90-95% clarity without much noise.
3) Phonocardiogram (PCG) heart sound trials are 90% normal, with a moderate amount of noise that needs to be controlled.

In fine, it is pertinent to mention that Larkai Healthcare Pvt. Ltd. 's 'Heart and Lungs Screening Device" is an affordable, portable, and lightweight device that can be used in places without electricity, or even without internet connectivity, and in remote areas where the 12-lead ECG device shall not be very handy to use or is unavailable. It can also act as a support to physicians and doctors in the auscultation of heart and lungs sound with enhanced and amplified audio with real-time graphs. Last but not the least, it is apposite to mention that the said device and the research is pivotal around the cause of contributing to the healthcare system of India and educating the mass on cardiac health. This many fold cause seems possible to be gratified through Larkai's affordable and convenient mobile device.