ORIGINAL RESEARCH

Cross-Sectional Study to Find Out the Prevalence of Cardiovascular Diseases Through Detection of ECG Abnormalities in Undiagnosed Population Using a Handheld ECG Device, SanketLife Pro Plus

ITRA SINGH*, RAHUL RASTOGI†, NEHA RASTOGI†, ASHISH SAINI‡, OJASAVI NIRAV#

ABSTRACT

Background: In India, cardiovascular diseases (CVDs) are now the main cause of sudden death. Statistics on prevalence or nationally representative surveillance statistics, however, are lacking. **Aim:** The objective of this cross-sectional study was to assess the ECG findings in general OPD patients not yet diagnosed with any CVD using SanketLife Pro Plus handheld ECG device. **Materials and methods:** The study data was extracted from a free ECG test camp, which was organized in the common OPD waiting area at Indraprastha Apollo Hospitals in New Delhi. Of the 100 persons screened, 78% had sinus rhythm and 13% had tachycardia. Apart from these, no other major findings were detected in the study population. One percent ST depression and 4% T-wave inversions were the significant findings of concern, suggestive of myocardial ischemia or infarction, especially in the undiagnosed population. **Conclusion:** Considering the sample size, even at a 1% incidence of major ECG abnormalities, the outcome is indicative of a possible underlying danger, which is avoidable with early detection and thorough awareness. A mass ECG screening along with collection of relevant data and appropriate research design may help to identify the population at risk. Besides the ECG screening, a stroke risk assessment should be done and prophylaxis must be given to the individuals who have been diagnosed with CVDs.

Keywords: Handheld ECG device, ECG abnormalities, undiagnosed patients, Agatsa SanketLife Pro Plus

The Global Burden of Disease study estimated the age-standardized cardiovascular disease (CVD) death rate as 272 per 1,00,000 people in India, which is higher than the global average of 235 per 1,00,000 people. Premature mortality in terms of years of life lost because of CVDs in India has increased by 59%, from 23.2 million in 1990 to 37 million in 2010. Early age of onset, high case fatality rate and rapid progress are some features particular to CVD in India[1]. Clinical and autopsy studies have repeatedly shown a predominating, common pathophysiology in Western populations, showing that the most frequent pathologic substrate is coronary heart disease (CHD) and that the most frequent electrophysiological mechanism of sudden cardiac death is ventricular fibrillation[2]. High CVD mortality in the South Asian region and India can be attributed to 4 factors, including lack of policies related to social determinants of CVD for control of primordial risk factors such as smoking, smokeless tobacco, alcohol, physical inactivity, and unhealthy diet; poor-quality preventive management, low availability and substandard acute CHD management and lack of appropriate long-term care of these patients and absent cardiovascular rehabilitative and secondary prevention programs[3]. ECGs are unquestionably capable of detecting disease that can be missed by-medical history and physical examination[4]. It has been proposed that latent

*Clinical Research Associate and Medical Content Writer
†Founder
‡Product Specialist and ECG Analyst
#Senior Product Specialist
Agatsa Software Pvt. Ltd., Noida, Uttar Pradesh, India
Address for correspondence
Dr Itra Singh
Clinical Research Associate and Medical Content Writer
Agatsa Software Pvt. Ltd., Sector 59, B-01, Noida - 201301, Uttar Pradesh, India
E-mail: Itra.singh@agatsa.com; itrasingh11@gmail.com

cardiovascular illness can be found by electrocardiogram (ECG) screening in asymptomatic subjects. However, for many populations, including asymptomatic middle-aged (sedentary) persons, ECG screening alone may not be sufficient[5]. But, this has been proposed as a way of reducing the burden of the disease by detecting people who would benefit from prophylactic anticoagulation therapy before the onset of symptoms[6]. Advancements in technology have made it possible to use a range of methods to assist the screening for sudden cardiac death utilizing both medically prescribed equipment and consumer electronic devices capable of detecting AF[7].

MATERIALS AND METHODS

This is a cross-sectional, time-bound study conducted during a free health check-up camp at Indraprastha Apollo Hospitals, from 16th May to 23rd May, 2023 at New Delhi. A dedicated booth for free ECG screening was set up in the common OPD waiting area. The camp is a periodical program by Agatsa Software Pvt. Ltd. in collaboration with Indraprastha Apollo Hospitals, New Delhi, aimed at generating all-round awareness on health using cardiac health patient education material and the SanketLife Pro Plus ECG device demonstration as the mass awareness module. During the camp, participants were screened with the help of a handheld ECG device "SanketLife". The data collection team comprised of 6 members including one ECG analyst and 5 volunteers to organize and conduct the ECG recordings at the booth. Patients were given 2 minutes to sit down and get their bodies into stable physical condition before the data collection. Individuals diagnosed with any disease such as orthopedic concerns, fever and infection were included. Patients with diagnosed CVD were excluded from the study.

After the information was gathered, those who came to the booth had their ECGs taken. A total of 100 individuals participated in the study. All the participants signed a written informed consent form. Their identities were kept confidential. Necessary permissions were taken from the administration to perform the ECG screening at the venue.

ECG screening was conducted free of cost. Participants who had noteworthy findings were referred right away to the cardiologists available at the hospital.

Inclusion Criteria

All the subjects including all genders between 18 to 60 years were included. The subjects were self-reported, who visited the health camp and were ready to participate in the study.

Exclusion Criteria

Patients above 60 were excluded as the touch-based device gives more vibrations due to skin aging and shaking of limbs. Though the device has connection points for DB15 cable, this feature was not used because of the limited resources at that point of time. Portable ECG devices must be used with DB15 lead wires for better reports in persons aged 60 years and older. Those who were under the observation of a cardiologist were also excluded as we were targeting undiagnosed population.

Statistical Analysis

The selected participants were above 18 years of age visiting different OPD for different problems were recruited and had no symptom of CVD. Patients with CVDs were not selected for study. The ECG was performed by ECG technicians and reports were analyzed by Cardiologists of Apollo Hospitals who are empanelled with Agatsa. The average mean and percentage of the ECG abnormalities were calculated to check the prevalence of silent symptoms of cardiac dysfunction, which had not manifested by then.

SanketLife Pro Plus: Device Specifications

The device is a 12-lead portable ECG device, which is able to collect 12-lead ECGs both by touch and by lead. To convert a touch-based device into a conventional lead-based ECG machine, a switch-sy converter with the help of a 3.5 mm jack can be attached to the device. User's mobile phone and the Pro Plus ECG device are connected through Bluetooth. The reports are generated in an application called SanketLife. This device has 3 sensors, 8 placements that record 8-lead ECGs, i.e., lead 1, lead 2 and others are V1 to V6; hence, the remaining 4 leads, i.e., lead 3, AVR, AVL and AVF, are automated leads that are generated through artificial intelligence. This device can record up to 300 ECGs without changing the batteries. The battery is a CR-2032 coin-cell battery. It is a CDSCO, ISO approved device.



RESULT

Out of the 100 participants who voluntarily participated in the study, significant cardiac findings on the ECG were found only in 7 participants (Table 1). Among the participants screened, most of the study participants were of age group 30 to 60 years. Out of them, 86% participants were male and 14% were female. Seventy-eight percent participants had sinus rhythm; 9% had bradycardia and 13% had tachycardia. Minor ECG abnormalities such as borderline Q-wave, left or right axis deviation, QRS high/low voltage, borderline ST-segment depression, premature beats, were also detected but their prevalence was not conclusive because of insufficient data in context of masses. The significance of these findings will depend on the patient's individual medical history and other factors for example, ST-segment depression is more likely to be a sign of myocardial ischemia in an older patient with coronary artery disease.

Table 1. ECG Findings in the Study Population

ECG findings	No. of patients
Sinus rhythm	78
Sinus bradycardia	9
Sinus tachycardia	13
Total	**100**
Major ECG abnormalities	
ST depression	1
T-wave inversion	4
Complete or second-degree AV block	0
Complete left or right bundle branch block	1
Frequent premature beats	1
Atrial fibrillation	0
Minor ECG abnormalities	
Borderline Q-wave	2
Left or right axis deviation	1
QRS high voltage	4
Borderline ST-segment depression	0
T-wave flattening	0
QRS low voltage	2
Myocardial ischemia (Ischemic ECG)	
Presence of Q/QS patterns	0
Significant or borderline ST-segment depression	1
Deep or moderate T-wave inversion	2
Evidence of complete left bundle branch block	2

DISCUSSION

ST depression even at 1% identification and T-wave inversion at 4% are the most concerning findings, as these can be signs of incidents that may lead to sudden cardiac death for ex-myocardial ischemia or infarction, especially in undiagnosed population. Such cases increase the burden of cardiac emergencies in resource-crunched settings.

The complete left bundle branch block (LBBB) is a significant finding, which was seen in a 49-year-old man who was accompanying a patient and visited the ECG camp (Fig. 1). He had hypertension for the past 20 years. Undiagnosed and untreated LBBB can result in sudden cardiac death caused by acute heart failure. He was referred to the cardiologist for further investigations and medical management.

A systematic review of studies on CVD in Asian Indians from January 1969 to October 2012 revealed that the prevalence in urban areas was 2.5% to 12.6% and 1.4% to 4.6% in rural areas. The overall prevalence of CVD in South Indian population has been estimated to be 11%, a 10-fold increase as compared to the prevalence in urban India in the 1970s[8-10]. A previous study conducted in Delhi found the prevalence of CHD to be 14.8% in urban areas[11].

Cardiovascular risk factors such as hypertension, hypercholesterolemia, low high-density lipoprotein cholesterol, hypertriglyceridemia and tobacco use are highly prevalent in the urban Indian middle class. There is low awareness, treatment and control of hypertension and hypercholesterolemia in patients with diabetes[12].

All these findings and data from old records point towards a mass screening of ECG along with other biochemical parameters for diseases prevalence and severity prediction.

SanketLife Pro Plus portable ECG gadget proved successful in assessing the prevalence of cardiac-related diseases in the general population. It offers a comprehensive ECG, is simple to use for home monitoring as well as in a clinical setting to obtain a rapid ECG at the clinician's workstation, and is therefore helpful in making clinical decisions.

CONCLUSION

Enhancing ECG interpretation skills and raising knowledge of the AF guidelines may result in an increase in AF screening[13]. Even at 1% rate, if we consider the sample size, the result indicate an underlying silent potential threat, which is completely

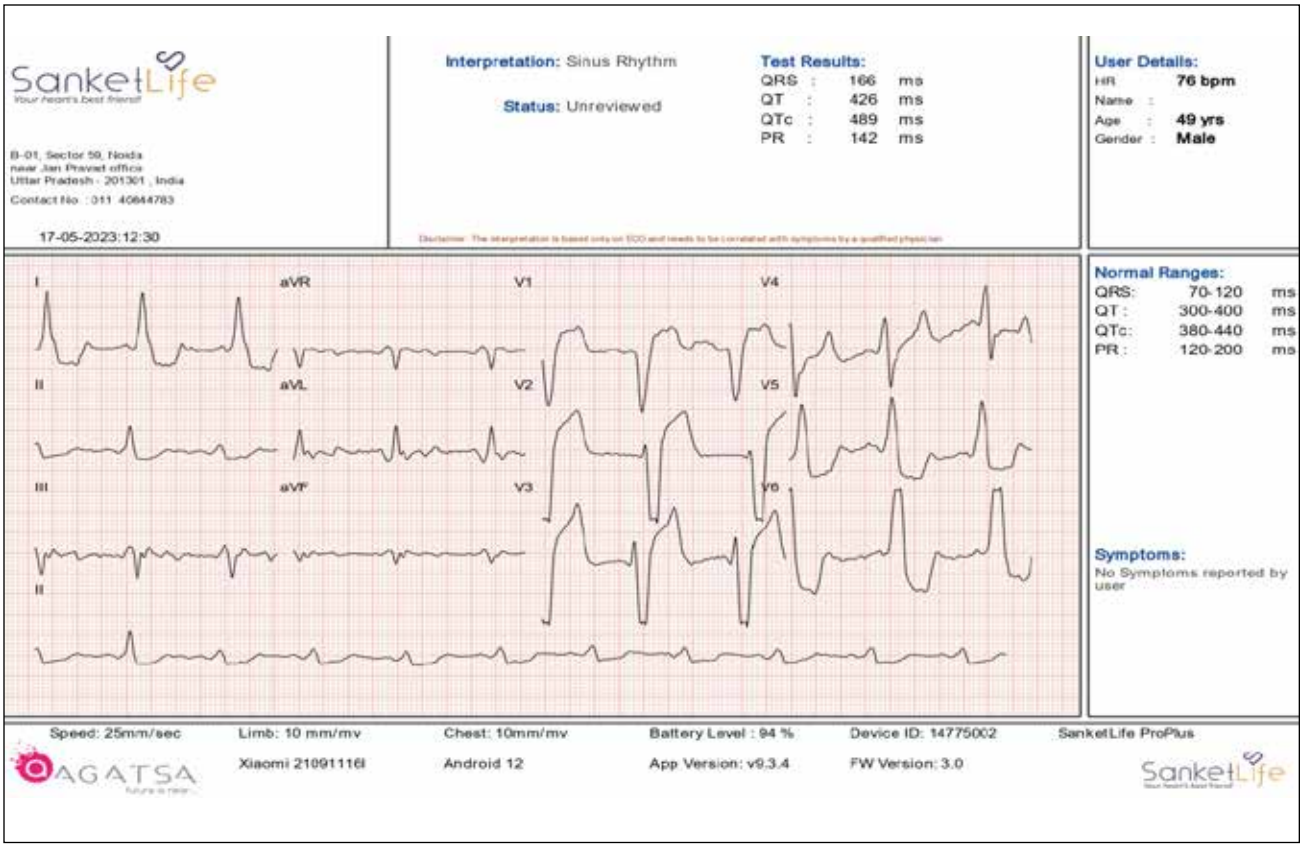


Figure 1. ECG report of 49-year-old man generated by CDSCO, ISO approved device, SanketLife Pro Plus, showing abnormalities such as left bundle branch block, ST elevation wide QRS complexes.

avoidable with timely diagnosis and proper awareness. Though the complete demographic information and pathophysiological profile of the participants was not available. Since the above described findings were obtained only by taking 12-lead ECG.

More studies including demographic information, anthropometric assessment and complication assessments are advisable to extract reliable results in undiagnosed sections of society. A mass ECG screening campaign along with proper data collection and relevant research design is much needed to identify those who are unaware but are at risk. Stroke risk assessment should be performed and prophylaxis for example statins, must be provided to those diagnosed with a heart disease to prevent the emerging outbreak of cardiac emergencies.

Acknowledgment

Special thanks to the study participants and Agatsa Software Pvt. Ltd, Noida, UP, India for their support in conducting this study.

Conflict of Interest

None.

REFERENCES

1. Prabhakaran D, Jeemon P, Roy A. Cardiovascular diseases in India. Circulation. 2016;133(16):1605-20.
2. Tereshchenko LG. Electrocardiogram as a screening tool in the general population: a strategic review. J Electrocardiol. 2013;46(6):553-6.
3. Gupta R, Mohan I, Narula J. Trends in coronary heart disease epidemiology in India. Ann Glob Heal. 2016;82(2):307-15.
4. Webster G, Carberry T, Berger S. Screening for prevention of sudden death in the young. Curr Opin Cardiol. 2020;35(1):80-6.
5. Orchard JJ, Neubeck L, Orchard JW, Puranik R, Raju H, Freedman B, et al. ECG-based cardiac screening programs: legal, ethical, and logistical considerations. Heart Rhythm. 2019;16(10):1584-91.
6. Moran PS, Flattery MJ, Teljeur C, Ryan M, Smith SM. Effectiveness of systematic screening for the detection of atrial fibrillation. Cochrane Database Syst Rev. 2013;(4):CD009586.
7. Roger VL. Epidemiology of heart failure. Circ Res. 2021;128(10):1421-34.
8. Shrivastava U, Misra A, Mohan V, Unnikrishnan R, Bachani D. Obesity, diabetes and cardiovascular diseases in India: public health challenges. Curr Diabetes Rev. 2016;13(1):65-80.

9. Rao M, Xavier D, Devi P, Sigamani A, Faruqui A, Gupta R, et al. Prevalence, treatments and outcomes of coronary artery disease in Indians: a systematic review. Indian Heart J. 2015;67(4):302-10.
10. Mohan V, Deepa R, Shanthi Rani S, Premalatha G. Prevalence of coronary artery disease and its relationship to lipids in a selected population in South India. J Am Coll Cardiol. 2001;38(3):682-7.
11. Huffman MD, Prabhakaran D, Osmond C, Fall CHD, Tandon N, Lakshmy R, et al. Incidence of cardiovascular risk factors in an Indian urban cohort. J Am Coll Cardiol. 2011;57(17):1765-74.
12. Gupta A, Gupta R, Sharma KK, Lodha S, Achari V, Asirvatham AJ, et al. Prevalence of diabetes and cardiovascular risk factors in middle-class urban participants in India. BMJ Open Diabetes Res Care. 2014;2(1):e000048.
13. Wong KC, Kok C, Marschner S, Usherwood T, Chow CK. Screening for atrial fibrillation and other arrhythmias in primary care. BMC Fam Pract. 2020;21(1):79.

■■■■

Subfebrile Fever: An Early Indicator of Peripartum Infection in Prolonged Rupture of Membranes

Peripartum subfebrile fever in women with prolonged rupture of membranes (ROM) >12 hours is associated with adverse maternal and neonatal outcomes, including increased rates of endometritis, surgical site infections, neonatal intensive care admission and neonatal fever, according to a study published in the *American Journal of Obstetrics & Gynecology*[1].

This retrospective cohort study enrolled 1,796 women who were admitted to a tertiary university-affiliated hospital from July 2021 to May 2023. Inclusion criteria were singleton term pregnancies, ROM >12 hours and maximal body temperature of 37.9°C. The study focused on assessing the endometritis rate, the primary study outcome, in women with prolonged ROM and subfebrile fever (37.5-37.9°C) compared to those with normal body temperature (<37.5°C). Two latency period groups, ROM of 12 to 18 hours (n = 687) and ROM >18 hours (n = 1,109), were analyzed. Intravenous ampicillin was administered to women with ROM >18 hours for group B streptococcus prophylaxis. Chorioamniotic-membrane swabs were obtained in cases of prolonged ROM (>18 hours).

In both latency groups, women with subfebrile fever had higher rates of endometritis, surgical site infections, neonatal intensive care admission and neonatal fever. In the ROM 12 to 18 hours group, the respiratory distress syndrome rates were higher among women with subfebrile fever compared to those with normal body temperature. In the ROM >18 hours group, significantly greater numbers of Enterobacteriaceae isolates were detected on chorioamniotic-membrane cultures, among those who were subfebrile (22%) than with normal intrapartum temperature (11%).

It is evident from the results that women with subfebrile fever and prolonged ROM experience greater maternal and neonatal morbidity compared to those with normal body temperature. They suggest that subfebrile fever may serve as an early indicator of peripartum infection as evidenced by higher rates of endometritis and surgical site infections in women with ROM >12 hours who had subfebrile fever. Hence, women with subfebrile fever should be monitored for signs of infection. The potential benefits of antibiotic treatment in reducing maternal and neonatal morbidity should be taken into consideration in such situations.

Reference

1. Shqara RA, et al. 98 Is subfebrile fever during prolonged ROM (>12 hours) related to infectious outcomes? Am J Obstet Gynecol. 2024;230(1 Suppl):S71-72.