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Assessment of diagnostic accuracy of SanketLife – A wireless, pocket-sized ECG biosensor, in comparison to standard 12 lead ECG in the detection of cardiovascular diseases in a tertiary care setting

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ABSTRACT

Background: The SanketLife is a low cost, portable, pocket sized 12 lead ECG mechanised by SanketLife app running on compatible iOS and Android phones that connect wirelessly via Bluetooth technology to the device.

Objective: The current study was conducted to assess the diagnostic accuracy of SanketLife ECG in comparison to standard 12 lead ECG (GE-2000) in detection of cardiovascular diseases.

Research design and methods: This was a prospective diagnostic test accuracy trial conducted in outpatient settings of a tertiary cardiac care centre in India. A total of 100 patients, attended cardiology OPD, were included in the study. Consecutive ECGs were taken by 12 lead standard ECG as well as by SanketLife ECG. Diagnostic accuracy variables such as sensitivity, specificity, negative and positive predictive value, negative and positive likelihood ratios were estimated. Ethical permission was taken from the Institutional ethical committee.

Results & conclusion: The analysis showed a high degree of agreement and accuracy of SanketLife in detecting major cardiovascular conditions (Major Minnesota codes) such as Left and right bundle branch block, ST-segment elevation and ST-segment depression, AV conduction block. SanketLife showed high sensitivity (98.15%) and specificity (100%) in diagnosing major cardiovascular conditions.

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1. Background

1.1. Cardiovascular diseases in India

The age-standardized cardiovascular disease mortality rate in India is higher than the global average (272 vs 235 per 100,000 population) [1]. It is not only the high incidence rate of cardiovascular diseases in the Indian population, but they also get affected at

a younger age. Cardiovascular diseases manifest in Indian population on an average a decade earlier than western countries and impact working age group substantially in terms of deaths and morbidity [2,3].

The magnitude of the financial burden of Cardiovascular diseases in India is also enormous. According to a health economics study, hospitalizations with CVD resulted in 12% higher odds of incurring catastrophic spending and 37% greater odds of falling into poverty in India in comparison to communicable diseases [4].

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1.2. Delay in care and field triage

High incidence rate along with poor outcome indicates failure of

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the preventive measure at all levels from primary to tertiary in preventing cardiovascular mortality and morbidity. It is not only the sedentary lifestyle, inappropriate diet, the high prevalence of diabetes and hypertension but also poor management of acute cardiac events such as myocardial infarction, which set back efforts towards reducing premature mortality associated with CVDs.

According to a multi-centre study [5] conducted in Punjab (India), 42% of all patients presenting with STEMI (ST-elevation myocardial infarction) at five different tertiary cardiac care centres were late by more than 6 h because of the pre-hospital delay. Delay was significantly associated with factors such as being elderly, rural residence and illiteracy. Recognizing symptoms as cardiac in origin, hospital as first medical contact, pre-hospital ECG was associated with shorter delays. Another study [6] by Ong Me advocated out of hospital ECG and transmission to higher centres as the best practice for chest pain management. This study estimated a significant reduction in the door to balloon times in patients with acute STEMI with the help of out of hospital 12 lead ECG recording and transmission. A tertiary care hospital-based study [7] in Srinagar estimated that 44.7% of acute STEMI reported late to the hospital because of misdiagnosis by local healthcare providers. Rural residence, referral, and transport delay were among other important reasons.

S. Mehta et al. in his article [8] discussed seven system barriers in the management of acute STEMI in low- and middle-income countries especially in the context of India. Unavailability of low-cost ECG machines, lack of training of general physicians in its interpretation, risk stratification/triage at the primary level, the transmission of vitals and ECG findings to the corresponding tertiary care centres were highlighted with other reasons such as lack of insurance. Use of telemedicine, cheap ECG, empowering general physicians by training and continuous medical education (CME) should be the part of the broader strategy to improve the overall outcome of patients.

A meta-analysis [9] in its findings concluded that pre-hospital triage and telemedicine are associated with a nearly halved time to treatment in STEMI. Other studies in India [10] and outside [11] has shown significant improvement in the management of patients with MI by a well-coordinated healthcare system, where timely triage at periphery results in better outcomes.

1.3. SanketLife role as a biosensor in early detection of myocardial infarction

Biosensors along with artificial intelligence and machine learning have been projected for long as the future of cardiac care [12]. Marjan Gusev in his article [13] presented the framework of using ECG as a biosensor in as heart attack alerting system. This system consisted of a small portable ECG biosensor placed at the patient's body and an application installed in the smartphone, which can receive ECG signals and transmit them to the data centre and also a web application on the cloud. The data centre can detect any abnormal heart activity, while the cloud-based application can convey it to the doctors in charge of providing 24-h medical services. Another similar article [14] also described the detection of heart attack by using a wearable ECG sensor and a mobile phone. SanketLife ECG works on similar line as a biosensor in the detection of electrical abnormalities and communicating those to the data centre through an application installed in the smartphone.

1.4. Rationale of the study

According to Guyatt and colleagues, "Diagnostic technology should be disseminated only if they are less expensive, produce fewer untoward effects, at least as accurate as existing technologies,

eliminate the need for other diagnostic interventions, without loss of accuracy or lead to the institution of effective therapy".

It is evident that portable, low cost 12 lead ECG can be very helpful in the triage of patients with chest pain in peripheral areas. In countries like India, where more than half of the population lives in villages, far from the tertiary care centres, cheap ECG along with telemedicine will be a boon for millions of people. The current study was done to assess the diagnostic accuracy SanketLife device against standard 12 lead ECG.

1.5. Aim and objective

Primary Objective of the study was to establish diagnostic accuracy of SanketLife (A portable, wireless 12 lead ECG) against standard 12 lead ECG in the detection of cardiovascular diseases in a tertiary outpatient care setting.

2. Research design and methods

This was a prospective diagnostic accuracy trial, where participants underwent for both type of ECG (a standard 12 lead ECG as well as SanketLife) consecutively. The primary objective of the study was to ascertain the diagnostic accuracy and reliability of the SanketLife ECG in comparison to standard 12 lead ECG. Randomization of subjects was not done. The study was conducted in a tertiary care setting.

A total of 100 patients was included in the study at a tertiary care setting. Though [15] it was convenient sampling but according to a study nomogram calculates a sample size of 91 at sensitivity of 0.97, prevalence of 0.25 and absolute precision of 0.07. A sample size of 100 has Patients included in the study either came to the cardiac tertiary care centre with symptoms suggestive of cardiovascular disease or have a history of it. All patients who were referred for 12 lead standard ECG, also got their consecutive ECG done with SanketLife. (Fig. 1) ECG reports were stored at the company's cloud. ECG data were retrieved, once the sample size was reached. All reports were coded according to the Minnesota coding protocol.

ECG variables namely Heart Rate, PR, QRSD, QT & QTc were monitored, displayed and saved in our system and compared against certain heart abnormalities visual against traditional 12 LEAD ECG machine.

2.1. Quality control and quality assurance procedures

The clinical trial is conducted (Data management, documentation and reporting) in compliance with the protocol, ICH GCP guidelines and in line with other regulatory protocols. The ICH GCP guideline was developed with the consideration of the current good clinical practices of the European Union and countries like Japan, and the United States, Australia, Canada, the Nordic countries and the World Health Organization (WHO).

2.2. SanketLife ECG device

SanketLife is an ECG monitor which is pocket-able, leadless and can support up to 12 lead. The proposed device is mechanised by a SanketLife app running on compatible iOS and Android phones that connect wirelessly via Bluetooth technology to the device. The 12 lead ECG can be measured anytime, anywhere and the reports can be easily downloaded and instantly shared with the healthcare professional for immediate clinical advice. The ECG reports are also saved in the cloud for future reference. The device mainly consists of electronics such as sensors, comparators, filters and, Bluetooth chip.

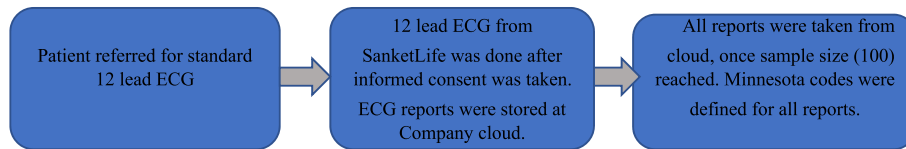


Fig. 1. Study design.

2.3. Statistical analysis

Following end, outcomes were calculated for SanketLife in comparison to standard 12 lead ECG (GE 2000) for all Minnesota codes (disease conditions) separately.

1. Specificity and sensitivity
2. Positive and negative predictive value
3. Positive and the negative likelihood ratio
4. Disease prevalence

2.4. Inclusion criteria

1. Male or female subjects aged 18 years or more, willing and able to give informed consent.
2. Diagnosed with required disease/severity/symptoms, any specific assessment criteria for these, or be in good health
3. Participants have clinically acceptable laboratory and ECG done at the same time and place along with SanketLife ECG

2.5. Exclusion criteria

1. Significant renal or hepatic impairment and scheduled elective surgery or other procedures
2. Terminally ill and any other significant disease or disorder which, in the opinion of the Investigator, may either put the participants at risk because of participation in the study, or may influence the result of the study, or the participant's ability to participate in the study.

2.6. Ethical considerations and participant's confidentiality

Ethical permission was taken from the institutional ethics committee of Shri Jayadeva Institute of Cardiology, Bangalore. Confidentiality of participants was maintained by de-identifying personal identifiers and only anonymized data were used in the analysis. All data and related information were stored securely and only accessible to trial staff and principal investigator. Written informed consent was taken from all patients before participating in the study.

3. Results: data analysis

The total sample size on which analysis conducted, was 91 because of the poor quality of reports. All subjects were male with a mean age of 52.02 years (SD: 14.04) and median of 55. Age of subjects ranges from 24 to 91 years. Matching was done between Minnesota codes assigned to ECG findings of SanketLife and standard 12 lead ECG. Individual codes (a few cases had more than one code) were matched.

Abnormal Q waves (Minnesota code:1-1-6) were infrequent and reported in only one case by both types of ECGs. (Table 1) Left axis deviation was reported in two cases with 100% matching of results.

In Minnesota code 3 (High amplitude R waves) similar findings were reported by SanketLife as of standard 12 lead ECG in 9 cases. Though in 2 cases, where 12 lead ECG shows normal R waves, SanketLife showed high amplitude R waves.

ST depression (4-1-1, 4-1-2, 4-4) was reported in 22 ECGs by the standard as well as SanketLife with mismatching in two ECGs where 12 lead standard ECG was normal while SanketLife found ST junction depression (Code 4-4). Out of 32 cases, the pattern of T waves were similar in 29 cases in both type of ECGs. Atrio-ventricular defects and ventricular block were reported in 9 cases with 100% matching. ST-segment elevation and Hyperacute T waves also reported by both type of ECGs among 23 cases with 100% matching. In Minnesota coding category 8 (Arrhythmia), there is a total of 11 cases. There was a lack of agreement in both the cases of atrial premature beats and four cases of premature ventricular beats.

3.1. Major and minor ECG abnormalities (Table 2)

Minnesota coding has been extensively used in population studies of ECG abnormalities and trials. Several studies classified ECG finding into major and minor abnormalities by using Minnesota code.

According to a Chinese study [16], major abnormalities have included Minnesota codes as 1-1, 1-2, 4-1, 4-2, 5-1, 5-2, 6-1, 6-2, 7-1, 7-2, 7-4, 8-1 and 8-3 and minor abnormalities were defined as ECGs without any major abnormality and Minnesota codes 1-3, 2-1, 2-2, 3-1, 3-2, 4-3, 5-3, 6-3, 9-1. Belgian interuniversity research on Nutrition and Health (BIRNH) study [17] classified ECG findings into major and minor.

3.2. Estimation of diagnostic accuracy

Sensitivity, specificity, positive and negative predictive value, the positive and negative likelihood ratio for SanketLife ECG in comparison to standard 12 lead ECG was calculated for major and ischaemic ECG findings. (Table 3) Overall findings have combinations such as only major code, only minor code and both major and minor codes together. For the analysis purpose, in cases where both major and minor codes were reported together, only major codes were considered. Minor codes and time variant ECG findings such as atrial and ventricular premature beats were not taken into account for matching. Out of total 91 subjects, 53 major codes were accurately detected by SanketLife.

4. Discussion

Since the time of large room size ECG machines to portable pocket-size ECG devices, electrocardiography has undergone dramatic changes. These transformations helped in minimizing the time period of 'event to intervention' drastically in cardiac emergencies.

The primary objective of the current study was to assess the diagnostic accuracy of SanketLife ECG with respect to gold standard a 12 lead ECG (GEE2000). Ninety-one patients, with both the ECGs has done, were included in the final analysis. ECG findings were

Table 1
ECG (Standard and SanketLife) findings (Minnesota code wise).

| ECG findings | Number Of subjects | Minnesota coding (SanketLife) | Minnesota coding (12 lead standard) | Matching Comment |
|---|--------------------|-------------------------------|--|------------------|
| Q waves (Code:1) | | | | |
| Small Initial R wave in V1 and V2 lead | 1 | 1-1-6 | 1-1-6 | Yes |
| Axis deviation (2) | | | | |
| Left | 2 | 2-1 | 2-1 | Yes |
| High Amplitude R waves (3) | | | | |
| Left type | 8 | 3-1 | 3-1 | Yes |
| Left type | 2 | 3-1 | Normal | No |
| Right type | 1 | 3-2 | 3-2 | Yes |
| ST depression (4) | | | | |
| STJ depression \geq 2.0 mm and ST segment horizontal or downward sloping in any of leads I, aVL, or V6 | 8 | 4-1-1 | 4-1-1 | Yes |
| STJ depression \geq 1.0 mm but < 2.0 mm, and ST segment horizontal or downward sloping in any of leads I, aVL, or V6. | 2 | 4-1-2 | 4-1-2 | Yes |
| STJ depression \geq 1.0 mm but < 2.0 mm, and ST segment horizontal or downward sloping in any of leads I, aVL, or V6 | 10 | 4-4 | 4-4 | Yes |
| STJ depression \geq 1.0 mm and ST segment upward sloping or Ushaped, in 2 any of leads I, aVL, or V6. | 2 | 4-4 | No upward sloping ST segment | No |
| T wave negativity (5) | | | | |
| Negative T-wave in Lead I, II & V5 V6 | 27 | 5-2 | 5-2 | Yes |
| Flat T wave in V1 and Positive T wave in V2 | 2 | 5-3 | 5-3 | Yes |
| Flat T wave in V1 and Positive T wave in V2 | 2 | 5-3 | 1.Negative T wave in V1 & Flat T wave in V2 2. Normal R wave 3 | No |
| | 1 | No 5-3 | 5-3 | No |
| AV conduction defect (6) | | | | |
| Wenckebach's Phenomenon (P-R interval increasing from beat to beat until QRS and T dropped) | 3 | 6-2-3 | 6-2-3 | Yes |
| Ventricular blocks (7) | | | | |
| Left bundle branch block | 2 | 7-1-1 | 7-1-1 | Yes |
| Right bundle branch block | 2 | 7-2-1 | 7-2-1 | Yes |
| Intraventricular conduction delay | 2 | 7-4 | 7-4 | Yes |
| Arrhythmias (8) | | | | |
| Atrial or junctional premature beats | 1 | 8-1-1 | Normal | No |
| Atrial or junctional premature beats | 1 | Normal | 8-1-1 | No |
| Ventricular premature beats | 3 | 8-1-2 | 8-1-2 | Yes |
| Ventricular premature beats | 5 | 8-1-2 | Normal | No |
| Atrial fibrillation (Persistent) | 1 | 8-3-1 | 8-3-1 | Yes |
| Low QRS amplitude (9-1) | 1 | 9-1 | 9-1 | Yes |
| ST segment elevation (9-2) | 16 | 9-2 | 9-2 | Yes |
| Hyperacute T wave (9-5) | 7 | 9-5 | 9-5 | Yes |
| Normal ECGs | 10 | Normal | Normal | Yes |

classified according to Minnesota codes by an electrophysiologist. Prevalence of ECG abnormalities (Minnesota codes) was calculated. Among major abnormalities, T wave inversion was the most common finding followed by ST depression and frequent premature beats. An epidemiological study [18], which pooled data from four Belgian populationbased studies, estimated prevalence of ECG abnormalities and found ST depression, T wave inversion as the most prevalent ECG abnormalities.

4.1. ST depression and T wave inversion

Minnesota code 4 and 5 represents ST depression and T wave inversion respectively. According to a follow-up study [19] Code 4-1, 4-2, 5-1 and 5-2 were classified as major ECG abnormalities while Code 4-3, 4-4, 5-3 and 5-4 were defined as minor. In our analysis, 10 ECGs reported code 4-1. SanketLife identified similar code in all these subjects. The 4-3 code was reported in 12 subjects by standard 12 lead ECG, among them SanketLife reported it in 10 subjects. Major findings were captured with great accuracy by SanketLife. All

27 subjects with the major category of T wave inversion (5-2), were correctly diagnosed by SanketLife. Among the other 5 subjects two were identified with minor ECG abnormality (5-3) by both types of ECGs. One case reported 5-3 code in SanketLife ECG and not in 12 lead standard ECG, while two subjects reported in standard 12 lead ECG, were not reported by SanketLife. Overall major ECG abnormalities were reported by SanketLife with 100% accuracy.

4.2. AV conduction defects and ventricular defects

Among 9 subjects, AV conduction and ventricular defects (Minnesota Code 6 and code 7) were detected by SanketLife as well as by standard 12 lead ECG.

4.3. Arrhythmias

A single case of atrial fibrillation (Minnesota code: 8-3-1) was accurately detected by SanketLife. SanketLife reported ventricular premature beats in 7 cases while standard 12 lead ECG in 3 out of 7.

Table 2
Distribution of Minnesota codes in sample subjects.

| Type of ECG abnormalities | Minnesota Code | Prevalence N (%) |
|---|----------------|------------------|
| Major ECG abnormalities | | |
| ST depression | IV1-2 | 10 (10.9) |
| T wave inversion | V 1-2 | 26 (28.5) |
| Complete or second-degree AV block | VI 1-2 | 3 (3.3) |
| Complete left or right bundle branch block | VII 1-2 | 4 (4.4) |
| Frequent premature beats | VIII 1 | 10 (10.9) |
| Atrial fibrillation | VIII 3 | 1 (1.1) |
| Minor ECG abnormalities | | |
| Borderline Q wave | I 3 | 0 (0) |
| Left or right axis deviation | II 2 | 0 (0) |
| QRS high voltage | III 1-2 | 11 (12.1) |
| Borderline ST segment depression | IV 3 | 0 (0.0) |
| T wave flattening | V 3 | 7 (5.5) |
| QRS low voltage | IX 1 | 1 (1.1) |
| Myocardial ischaemia (Ischaemic ECG) | | |
| Presence of Q/QS patterns | I 1-3 | 1 (1.1) |
| Significant or borderline ST segment depression | IV1-3 | 10 (10.9) |
| Deep or moderate T wave inversion | V 1-3 | 31 (34.1) |
| Evidence of complete left bundle branch block | VII 1 | 2 (2.2) |

Table 3
Diagnostic accuracy parameters of SanketLife.

| ECG type | | Positive | SanketLife ECG | | Total |
|----------------------|----------|----------|----------------|--|-------|
| | | | Negative | | |
| 12 lead standard ECG | Positive | 53 | 1 | | 54 |
| | Negative | 0 | 37 | | 37 |
| | Total | 53 | 38 | | 91 |

Sensitivity: 98.15%.

Specificity: 100%.

Positive predictive value: 100%.

Negative predictive value: 97.36%.

Positive likelihood ratio: -

Negative likelihood ratio: 0.02.

There was discordance between two types of ECGs in identifying atrial and ventricular premature beats. A comparative study [20] of 60-s standard ECG vs 24-h Holter monitoring in the detection of ventricular arrhythmias reported that ventricular ectopic beats were present in 17% of standard ECG against 90% of the Holter monitoring among 100 patients admitted for definite acute myocardial infarction. This study concluded standard ECG as an insensitive method for the diagnosis of ventricular arrhythmia. Time is also an important function in the diagnosis of ventricular ectopic. Time-variant nature of these findings is a plausible explanation for the discrepancy between standard ECG and SanketLife in the diagnosis of atrial and ventricular premature beats.

4.4. Miscellaneous (Minnesota code 9)

SanketLife ECG correctly diagnosed miscellaneous ECG abnormalities including low QRS amplitude (Minnesota code (MC): 9-1), ST segment elevation (MC:9-2) and hyperacute T waves (MC:9-5). Ten ECGs were classified as normal by both standard and SanketLife ECG.

5. Conclusion

SanketLife has identified all major ECG abnormalities in high agreement with standard 12 lead ECG. SanketLife has shown high sensitivity in detecting significant abnormalities. Discordance was reported in identifying minor ECG abnormalities and time-dependent atrial and ventricular premature beats where continuous monitoring is a better method.

High sensitivity (True positive) and specificity of SanketLife in identifying electrical cardiac abnormalities, its portability coupled with real-time transmission and low cost makes it a suitable candidate for the emergency as well as outpatient based cardiac care in clinical and community settings.

Declaration of competing interest

None.

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