ISSN: 0975-3583,0976-2833 VOL14, ISSUE01, 2023

Type: Original Research Article

A COMPARATIVE STUDY FOR EVALUATING THE FREQUENCY OF FALSE-POSITIVE DETECTION IN ELECTROCARDIOGRAM DEVICES IN COMPARISON TO CARDIOLOGIST DIAGNOSIS

Yogendra Singh[1], Sahil Mahajan[2], Salil Garg[2], Nitin Chandola[3*], Tanuj Bhatia[2], Richa Sharma[2], Basundhara Bansal[3]

[1]Department of Cardiology, Max Super-speciality Hospital, Dehradun, India
[2]Department of Cardiology, Shree Mahant Indresh Hospital, Dehradun, India
[3]Department of Research and Development, Sunfox Technologies, Dehradun, India

***Corresponding Author:**
Nitin Chandola,
Tech Lead, Sunfox Technologies Pvt. Ltd.
112, Nehru Colony Old Dharampur Road, Dehradun 248001, India
Tel.: 8192859437
E-mail: nitinchandola7@gmail.com

ABSTRACT

Electrocardiography is the most convenient and cost-effective method at the primary level of healthcare infrastructure to localize and diagnose Myocardial infarction, ischemic heart diseases, and numerous arrhythmias. The manufacturers of ECG machines provide computer-generated Interpretations. However, these machines have differences in implementing the algorithms, which cause the change in the diagnostic accuracy. Hence, the occurrence of False positives is the most commonly observed error that occurs during computer interpretation. This study aims to evaluate the differences observed in the computerized interpretation of ECG reports regarding the Cardiologist's diagnosis. The 12 lead ECG reports were collected from a 12-lead gold standard machine and a smartphone-based 12 lead ECG machine. The data of the 294 subjects out of 300 subjects were accessed from both ECG machines. The reports were evaluated by a Cardiologist based on the observational changes in the morphology of the ECG traces. The gold standard ECG machine was 92% sensitive, 47.9% specific and 26.43% accurate in correctly interpreting a normal ECG report concerning the diagnosis provided by a Cardiologist. Whereas the Smartphone-based 12 lead ECG was found to be 95.9% sensitive, 88.9% specific, and 86.2% accurate in detecting a normal ECG concerning the diagnosis provided by a Cardiologist. The ECG machine manufacturer's interpretation algorithm plays an important role in defining the accuracy of the ECG machine. The computerized interpretation is only an assisting tool for the clinicians and not an independent tool to be relied on while treating a patient during health emergencies and check-ups.

ISSN: 0975-3583,0976-2833 VOL14, ISSUE01, 2023

Keywords: Cardiovascular disease, Electrocardiography, Heart attack, Ischemic heart disease, Myocardial infarction

1. Introduction

Cardiovascular disease (CVD) is the key reason for mortality in India, and it is the leading cause of death worldwide.[1] Myocardial infarction (MI) and angina are major components of these CVDs. In electrocardiography (ECG), ST-T abnormalities, ST elevation, ST depression, and T wave inversions are early signs of Ischemia and MI.[2-4] These changes are only traceable in the 12 lead ECG reports and are classified as non-ST elevated myocardial infarction (NSTEMI) and ST elevated myocardial infarction (STEMI). The ECG machine nowadays can provide computerized interpretation for normal and abnormal cases. These devices are frequently used for Point of Care tests (POCTs) and rapid diagnosis at home and in places where conventional laboratory setups are not available. The paramedics claim to have experienced improved patient management in emergency conditions after using POCT devices.[5] A study shows that cardiology professionals are observing fewer constraints of resources by using these devices at POCT levels.[6,7] The studies using ECG reports on the detection of Acute Myocardial Infarction (AMI) showed that the specificity of the ECG interpretations is lower. Hence, it is very important to take symptoms into the consideration before interpreting AMI.[8,9]

It is observed that the single culprit artery occlusion increases the misinterpretation of the ECG's computerized interpretation algorithms. Whereas the multiple culprit artery occlusions have a more accurate computerized interpretation of ECG reports.[10] Inaccuracy and misinterpretation were also observed for computerized ECG interpretations of Gold Standard ECG machines when considered for clinical decision making.[11-13] The 12-lead ECG is the most studied tool that is recommended for pre-hospital management of AMI.[14-16] The mortality in AMI mostly occurs due to a lack of timely diagnosis, treatment and pre-hospital delays.[17,18] In the current scenarios, handheld, and smartphone-based ECG devices are used in pre-hospital management. The devices like Alivecor and other smartwatch-based ECGs claim to detect atrial fibrillation and can be a cost-effective and useful tool for consultation purposes only.[29,20]

False positives are the panic creators when it comes to medical devices. The false prediction by the computerized interpretation can mislead the diagnosis and can cause anxiety among the users of these devices. In this research article, we have addressed the occurrence of False positives by the computerized interpretation of two different ECG machines in comparison to the diagnosis given by the Cardiologist. In addition, we accessed the clinical profile of the patients with a history of MI and IHD. We aimed to find the reliability of the computer interpretation algorithms of the ECG machine that are used in hospitals and at POCTs utilizing statistical analysis.

ISSN: 0975-3583,0976-2833 VOL14, ISSUE01, 2023

2. Methods

2.1. Study design

In conducting this comparative study, the study design was developed with the approval of the ethical committee of Shri Mahant Indresh Hospital (SMIH), Dehradun, Uttarakhand, India. The study is the result of a collaborative effort by the faculty of the Department of Cardiology at SMIH. The study took place in the ECG laboratory of SMIH, and the study's design was divided into three parts. The duration of the study to screen the participants enrolled in it was 68 days.

2.1.1. Study instruments and measurements

A principal investigator (PI) executed the collection of the ECG reports with two different ECG machines, i.e., the available 12 lead gold standard ECG machine, Cardiart 9108 developed by BPL Medical Technologies, India, and a smartphone-based 12 lead Spandan ECG developed by Sunfox Technologies Pvt. Ltd., India. The acquisition of the ECGs was done by paramedic staff after a training session as the operating techniques of both ECG machines were different.

2.1.2. Data transfer from field to the study centre

The field data collectors and trial managers were asked to collect the consent forms, a case report format that contains age and gender, and clinical data like symptoms, cardiac history, and co-morbidities like diabetes and hypertension. The data was then logged and managed in the central data management system of the hospital.

2.1.3. ECG interpretations

A cardiologist was assigned to provide the clinical diagnosis for ECG reports by both the 12 lead Gold Standard ECG machine and the Smartphone-based 12 lead ECG machine. Abnormalities such as ST-T changes, Ventricular Premature Complex (VPC), STEMI, AMI, IHD or NSTEMI, Tachyarrhythmias, and Bradyarrhythmia are considered when categorizing cases as abnormal or normal.

2.2. Study objectives

The primary objective of this study was to determine the rate of false positives in the computerized interpretation of ECG machines with respect to the Cardiologist’s diagnosis. The ECG test was performed on the participants aged over 20 years in the ECG laboratory of SMIH, Dehradun. The secondary objectives were to understand the value of computerized ECG interpretation provided by different ECG machines in similar sample populations based on accuracy parameters and to evaluate the accuracy of a smartphone-based ECG machine with 12 lead Gold Standard ECG.

ISSN: 0975-3583,0976-2833 VOL14, ISSUE01, 2023

2.3. Inclusion and exclusion criteria

All the patients referred by the doctor for taking the ECG test in the ECG laboratory were eligible for enrollment in the study. People aged below 20 years were excluded from the study. ECG reports with underlying electrical disturbances and motion artifacts were also excluded.

2.4. Ethical considerations

The study was done after obtaining consent from the Head of the Department of Cardiology under the ethical considerations of SMIH, Dehradun, India. The study was initiated after obtaining consent from the Investigators, Cardiologists. Verbal and written consent were taken from each participant as per the declaration of Helsinki.

2.5. Sample size and sampling strategy

A sample size of 300 subjects was enrolled in the fixed time duration as per the protocols for the study but, due to exclusion criteria, a total of 294 subjects were eligible for the ECG test.

2.6. Study procedures

The study was carried out in two stages. The first stage was the collection of the consent forms from the participants in both verbal and written forms. The Case Report Format (CRF) set according to study protocols was filled out by the field data collectors and submitted to the PI. The CRF contained information on the history of diabetes, history of smoking, symptoms observed, pacemaker implantation, and history of coronary intervention. The CRF assisted the cardiologist to correctly diagnose the case. In the second stage, the 12 lead ECG was performed by the BPL Cardiart 1908 ECG machine, followed by the 12-lead ECG test by the Spandan smartphone-based ECG machine. Both the ECG machines were enabled for computerized interpretation and the printed reports were obtained. The Cardiologist was assigned to provide the diagnosis for both ECG reports. The computerized interpretations were not provided to the cardiologist as per the study protocols. A database was then created on a centralized server in which computer interpretation of the 12-lead gold standard ECG and Smartphone ECG were stored. The Cardiologist’s diagnosis was taken as the benchmark against which the false positives have been studied for both ECG machines.

2.7. Statistical analysis

Descriptive statistics were obtained for all the participants by developing the confusion matrix for interpretation of the 12-lead gold standard with the cardiologist's diagnosis and the 12-lead smartphone ECG with the cardiologist's diagnosis. Evaluation of the sensitivity, specificity, Negative Predictive Value (NPV), and Positive Predictive Value (PPV) was carried out for evaluating the false positives of ECG machines. The accuracy of the detection of normal cases correctly was also compared statistically.

ISSN: 0975-3583,0976-2833 VOL14, ISSUE01, 2023

3. Results

Among these enrolled participants, 6 cases were excluded as the participants didn't match the inclusion criteria.

3.1. Baseline Characteristics

Table 1 summarizes the baseline characteristics of the 294 participants of the study (mean age of 53.96 years, 29.9% females). Of these 294 participants, 13 (4.42%) patients were implanted with pacemakers, and 63 (21.4%) participants were implanted with stents. Whereas 73 (24.8%) participants had diabetes and 58 (19.7%) of the participants were in the habit of regular smoking. 220 (74.8%) participants had symptoms suggestive of CVDs.

Table 1: Participants characteristics in the study population and patients with and without Myocardial Infarction and Ischemic heart disease.

Variables	Number of participants
Total participants	300
Participants after exclusion	294
Participants with pacemakers	13
Participants with stents	63
Participants with a smoking habit	58
Participants with diabetes	73
Participants with chest pain, palpitations, syncope, and shortness of breath	220

3.2 Evaluation of the results

The evaluation criteria for the confusion matrix of the interpretation in comparison to the cardiologist diagnosis is shown in **Table 2**. for the Smartphone ECG machine and in **Table 3**. for 12 lead gold standard ECG machines.

Table 2: The decision-making criteria for the confusion matrix of smartphone-based ECG machine.

Cardiologist diagnosis	Smartphone ECG interpretation	Confusion Matrix
Normal	Normal	True Negative
Abnormal	Abnormal	True Positive
Normal	Abnormal	False Positive
Abnormal	Normal	Fales Negative

Table 3: The decision-making criteria for the confusion matrix of 12 lead gold standard-based ECG machines.

Cardiologist diagnosis	12 lead gold standard ECG interpretation	Confusion Matrix
Normal	Normal	True Negative

ISSN: 0975-3583,0976-2833 VOL14, ISSUE01, 2023

Abnormal	Abnormal	True Positive
Normal	Abnormal	False Positive
Abnormal	Normal	Fales Negative

Hence, there were 112 true positives, 90 false positives, 83 true negatives, and 9 false negatives detected for interpretation of the 12-lead gold standard ECG machine. Whereas 12-lead smartphone ECG machine was evaluated for 117 true positive cases, 19 false-positive cases, 153 true negative cases, and 5 cases of false negatives. Out of the 174 normal cases diagnosed by the cardiologist, only 46 cases were interpreted correctly by 12 lead gold standard ECG machine algorithms. Whereas 150 normal cases were interpreted correctly by a smartphone-based 12-lead ECG machine. **Table 4** shows the Matthews correlation coefficient of the machine for interpreting normal cases correctly.

Table 4: The correlation coefficient of ECG machines in comparison to Cardiologist diagnosis.

Correlation Coefficient (Matthews)	**Value**
Gold standard V/s Cardiologist	0.43025
Spandan v/s Cardiologist	0.8385

Hence, the 12-lead gold standard has been found to have a specificity of 47.9%, a sensitivity of 92.5%, a PPV of 55.44%, and an NPV of 90.21% as shown in (**Fig. 1)**. Whereas the Smartphone-based Spandan ECG was evaluated to have a sensitivity of 95.9%, and a specificity of 88.9%, the PPV and NPV were evaluated as 86.0% and 96.83% respectively, as shown in **(Fig. 2)**. The false positives in the 12-lead gold standard were 30.6%, and in smartphone ECG, false positives were recorded as 6.5%.

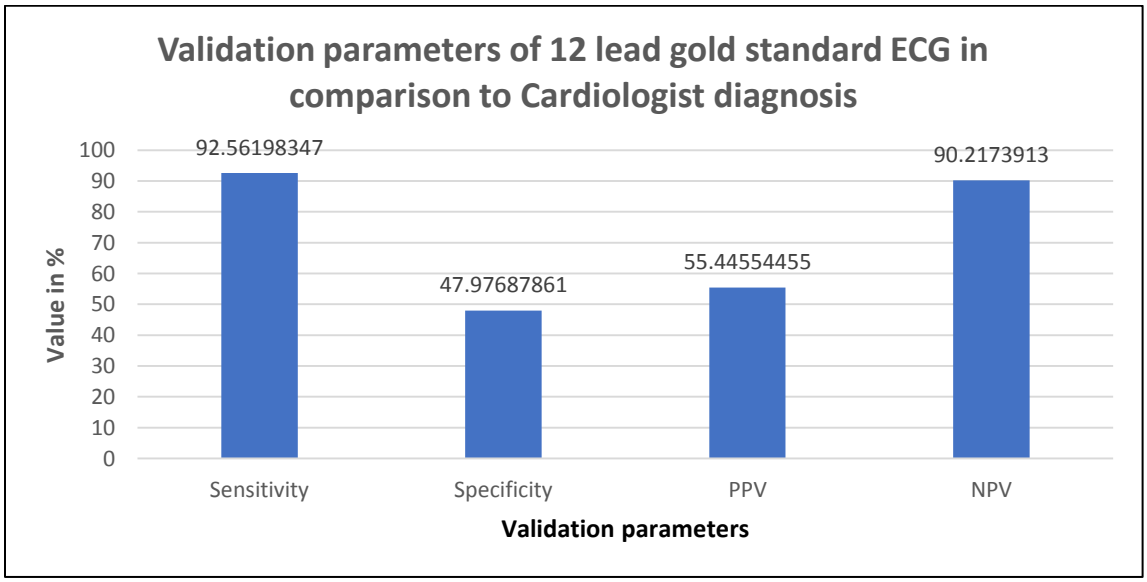

Fig. 1: Validation parameter for 12-lead gold standard ECG in comparison to the cardiologist diagnosis

ISSN: 0975-3583,0976-2833 VOL14, ISSUE01, 2023

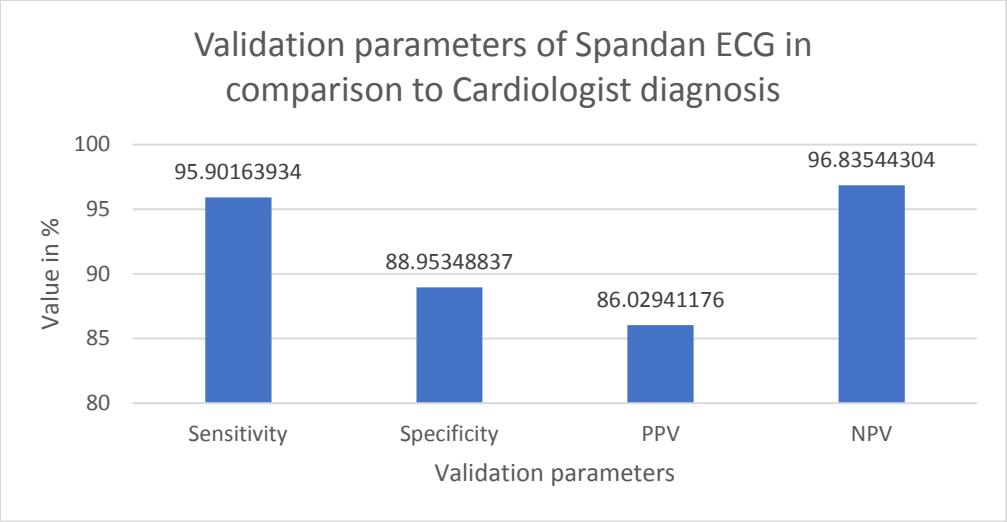

Fig. 2: Validation parameter for Spandan ECG in comparison to the cardiologist diagnosis

4. Discussion

The uneven results in a study on 974 subjects were observed, showing that ECG machines had low diagnostic values when used prior MI.[21] The sensitivity of ECG to detect MI was 38.0% and was 86.9% specific. The study found that the NPV and PPV are 84.0% and 43.6% respectively. ECG machine was also found to have low sensitivity for detection of Left Ventricular Hypertrophy (LVH) in Tanzanian women.[16] The diagnostic accuracy of ECG in detecting the MI using ST segment has poor specificity as the ST deviations are also seen in other conditions .[22] A study conducted on four different ECG machines suggested that portable ECGs can be inaccurate and uninterpretable at times.[23] The increase in specificity of 79.9% and decrease in specificity to 61.2% was observed when the ambulance ECG was considered in comparison to the ECG taken at the hospital. [24] The generated results from a multicentre study were compared with published study on diagnostic value of the ECG in detection of prior MI. This study was comparable based on the validation parameters. The study published gold standard ECG machines as 38% sensitive, 86.9% specific, NPV was 84.0% and PPV was 43.6%.[25] Hence, conventional electrocardiography machines were observed to interpret ECG reports with a high number of false positives as compared to the smartphone ECG machine. In comparison to the cardiologist's diagnosis, the smartphone-based 12-lead ECG was found to have fewer false positives in the computerized interpretation. The smartphone ECG algorithm works with an accuracy of 86.2% for detecting normal cases correctly. The 12-lead gold standard was 26.4% accurate in the interpretation of a normal case. Hence, the low false positives in the smartphone ECG device are the reliable parameter to support the fact that it can be used in POCTs and homecare applications. The smaller number of false positives ensures that the more unwanted panic will be reduced among the users of these devices. The ECG machines with the computerized interpretations are just an assistant tool to the cardiologist or physician and should not be considered as a standalone opinion for consultation and diagnosis.

ISSN: 0975-3583,0976-2833 VOL14, ISSUE01, 2023

5. Conclusion

The performance of computerized interpretation of ECG machines is dependent upon the kind of algorithms accessed and developed by the ECG machine manufacturer. The clinician must consider that no ECG machine can be accurate in different cases of use. Hence, for diagnostic accuracy, the performance of the 12-lead gold standard can be reliable; but, during POCT, the same machine can interpret most of the false positives, causing panic in the patient. Whereas the smartphone-based ECG machine shows more reliable outcomes for POCTs setups like ECG laboratories and health camps. The portable ECG machine has higher sensitivity. Hence, these machines can be used for the screening of large populations for coronary artery disease.

Declaration of competing interest

None of the authors have any conflicts of interest to declare.

Funding

The study was funded exclusively by the Sunfox Technologies Pvt. Ltd., The funding source had no role in the design, data collection, analysis or interpretation or writing up of the article.

Acknowledgement

Authors are thankful to Sunfox Technologies Pvt. Ltd., the manufacturers of Spandan ECG machine for providing organizational support to conduct the study.

References

[1] Benjamin EJ, Virani SS, Callaway CW, et al. Heart disease and stroke statistics—2018 update: a report from the American Heart Association. *Circulation.* 2018;137(12):e67-e492. https://dx.doi.org/10.1161/CIR.0000000000000558

[2] Ananthasubramaniam G, Ananthasubramaniam K. Stress electrocardiography testing in coronary artery disease: Is it time for its swan song or to redefine its role in the modern era?. *Ind Heart J*. 2022;74(2):81-85. https://doi.org/10.1016/j.ihj.2022.02.003

[3] Bednar MM, Harrigan EP, Anziano RJ, et al. The QT interval. *Prog Cardiovasc Dis*. 2001;43(5 Suppl 1):1-45. https://10.1053/pcad.2001.21469.

[4] Wang JJ, Pahlm O, Warren JW, et al. Criteria for ECG detection of acute myocardial ischemia: Sensitivity versus specificity. *J Electrocard*. 2018;51(6):S12-S17. https://doi.org/10.1016/j.jelectrocard.2018.08.018

[5] Welton NJ, McAleenan A, Thom HHZ, et al. Screening strategies for atrial fibrillation: a systematic review and cost-effectiveness analysis. *Health Technol Assess*. 2017;21(29). https://doi.org/10.3310/hta21290

[6] Dunlap D, Ding E, Abramo K, et al. Point-of-care testing, your cardiologist, and affairs of the heart. *Card Dig Health J.* 2021;2(6):331-335. https://doi.org/10.1016/j.cvdhj.2021.10.004

ISSN: 0975-3583,0976-2833 VOL14, ISSUE01, 2023

[7] Mostafa AA. Ding E, McManus DD, et al. Wearing your heart on your sleeve: the future of cardiac rhythm monitoring. *Current Card Rep.* 2019;21(12):1-11. https://doi.org/10.1007/s11886-019-1223-8

[8] Park JH, Moon SW, Kim TY, et al. Sensitivity, specificity, and predictive value of cardiac symptoms assessed by emergency medical services providers in the diagnosis of acute myocardial infarction: a multi-center observational study. *Clin Exp Emerg Med.* 2018;5(4):264. https://doi.org/10.15441%2Fceem.17.257

[9] Castelli WP, Garrison RJ, Wilson PWF, et al. Incidence of coronary heart disease and lipoprotein cholesterol levels: the Framingham Study. *JAMA.* 1986;256(20):2835-2838. https://doi.org/10.1001/jama.1986.03380200073024

[10] Kim S, Kim W, Kang GH, et al. Analysis of the accuracy of automatic electrocardiogram interpretation in ST-segment elevation myocardial infarction. *Clin Exp Emerg Med.* 2022;9(1):18. https://dx.doi.org/10.15441/ceem.21.163

[11] Ansari S, Farzaneh N, Duda M, et al. A review of automated methods for detection of myocardial ischemia and infarction using electrocardiogram and electronic health records. *IEEE Rev Biomed Eng.* 2017;10:264-298. https://dx.doi.org/10.1109/RBME.2017.2757953

[12] Vignesh BS, Paul JG, Kumaran S, et al. ECG in Acute MI-An early insight into the coronaries. *Ind Heart J.* 2018;70(Supp 2):S89. https://dx.doi.org/10.1016/j.ihj.2018.10.267

[13] Barbagelata A, Bethea CF, Severance HW, et al. Smartphone ECG for evaluation of ST-segment elevation myocardial infarction (STEMI): design of the ST LEUIS International Multicenter Study. J Electrocard. 2018;51(2):260-264. https://dx.doi.org/10.1016/j.jelectrocard.2017.10.011

[14] Morrison LJ, Brooks S, Sawadsky B, et al. Prehospital 12-lead electrocardiography impact on acute myocardial infarction treatment times and mortality: a systematic review. *Acad Emerg Medic*. 2021;13(1):84-89. https://dx.doi.org/10.1197/j.aem.2005.07.042

[15] Brainard AH, Raynovich W, Tandberg D, et al. The prehospital 12-lead electrocardiogram's effect on time to initiation of reperfusion therapy: a systematic review and meta-analysis of existing literature. *Americ J Emerg Med*. 2005;23(3):351-356. https://dx.doi.org/10.1016/j.ajem.2005.02.004

[16] Squire BT, Tamayo-Sarver JH, Rashi P, et al. Effect of prehospital cardiac catheterization lab activation on door-to-balloon time, mortality, and false-positive activation. *Prehospital Emerg Care*. 2014;18(1):1-8. https://dx.doi.org/10.3109/10903127.2013.836263

[17] O'Donnell D, Mancera M, Savory E, et al. The availability of prior ECGs improves paramedic accuracy in recognizing ST-segment elevation myocardial infarction. *J Electrocard*. 2015;48(1):93-98. https://dx.doi.org/10.1016/j.jelectrocard.2014.09.003

[18] Canto JG, Zalenski RJ, Ornato JP, et al. Use of emergency medical services in acute myocardial infarction and subsequent quality of care: observations from the National Registry of Myocardial Infarction 2. *Circulation.* 2002;106(24):3018-3023. https://doi.org/10.1161/01.cir.0000041246.20352.03

ISSN: 0975-3583,0976-2833 VOL14, ISSUE01, 2023

[19] Collins MC, Elliott EE, Stain NS, et al. A review of hand-held Electrocardiogram (ECG) recording devices. *Europ J Card Nur.* 2021;20(Supplement_1):zvab060.150. https://dx.doi.org/10.1093/eurjcn/zvab060.150

[20] Wong KC, Klimis H, Lowres N, et al. Diagnostic accuracy of handheld electrocardiogram devices in detecting atrial fibrillation in adults in community versus hospital settings: a systematic review and meta-analysis. *Heart.* 2020;106(16):1211-1217. https://dx.doi.org/10.1136/heartjnl-2020-3166

[21] Lobeek M, Badings E, Lenssen M, et al. Diagnostic value of the electrocardiogram in the assessment of prior myocardial infarction. *Netherlands Heart J*. 2021;29(3):142-150. https://dx.doi.org/10.1007/s12471-020-01515-w

[22] Coppola G, Carità P, Corrado E, et al. ST segment elevations: are always markersf acute myocardial infarction?. *Ind Heart J*. 2013;65(4):412-423. https://doi.org/10.1016/j.ihj.2013.06.013

[23] Mehta DD, Nazir NT, Trohman RG, et al. Perceptions and clinical accuracy compared to conventional cardiac monitoring. *J Electrocard.* 2015;48(4):710-716. https://dx.doi.org/10.1016/j.jelectrocard.2015.04.017

[24] Garvey JL, Zegre-Hemsey J, Gregg R, et al. Electrocardiographic diagnosis of ST segment elevation myocardial infarction: an evaluation of three automated interpretation algorithms. *J Electrocard*. 2016;49(5):728-732. https://dx.doi.org/10.1016/j.jelectrocard.2016.04.010

[25] Lobeek, Michelle, et al. Diagnostic value of the electrocardiogram in the assessment of prior myocardial infarction: *Netherlands Heart J.* 2021;29(3):142-150. https://dx.doi.org/10.1016/j.jelectrocard.2017.10.011