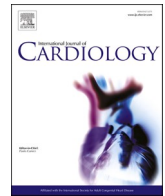




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Short communication

Layman electrocardiographic screening using smartphone-based multiple-lead ECG device in school children

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ABSTRACT

Background: Pre-participation ECG screening of large populations has a significant socioeconomic impact. Technological progress now allows for high-tech-low-cost ECG screening using validated smartphone-based devices capable of guiding to the correct performance of a 12-lead ECG by layman with no medical background. **Methods:** We enrolled 728 (364, 52% males) individuals, aged 12–13 years who underwent ECG screening with a smartphone 12-lead ECG during school hours by layman volunteers. Correct electrodes placement was provided by a validated image-processing algorithm by the smartphone camera in the App. ECG interpretation was via a telecardiology platform and alterations classified following current standards.

Results: A total of 741 ECGs were recorded, of which 13(2%) were technically not interpretable. Mean PR, QRS and QTc were: 145 ± 22 , 85 ± 19 and 387 ± 57 msec. No QTc prolongation was observed. Mean QRS axis was 15° ; 26 (4%) patients presented an rBBB. T-wave inversion from V1-V3 was present in 145 (21%) subjects. Twenty-one(3%) patients were referred to second level examination: deep Q-waves in inferior leads in 12(1.6%), ventricular ectopics in 5(0.7%), anterior T-waves inversions V1-V4 in 3(0.4%); extreme right axis deviation in 1 (0.3%). Second line investigations did not provide any definitive diagnosis. Total project costs (material equipment and human cost) was 14.460€, 19.51€ per individual. The potential net saving with respect to current pre-participation screening cost was 19%.

Conclusions: Layman 12-lead Smartphone-ECG population screening proved feasible and effective, with a rate of non-interpretable ECG of <5%. Potential cost-saving in ECG screening and recording was 19%, providing an appealing opportunity when large campaigns should be addressed also in developing countries.

Most cardiovascular conditions responsible for sudden cardiac death (SCD) in young population are clinically silent and unlikely to be suspected or diagnosed on the basis of spontaneous symptoms [1]. The Italian screening program has shown that ECG, in addition to history and physical examination, has a substantial incremental value for identifying asymptomatic individuals who have potentially lethal heart disorders [1]. However, screening of large populations has a significant socioeconomic impact, estimated to be € 45/individual, of which around 18% are related to nurse, infrastructure, consumables and ECG device costs [2–4]. Technological progress now allows for low-cost ECG screening using validated smartphone-based devices [5,6] capable of guiding to the correct performance of a 12-lead ECG by a volunteer with

no medical background [7]. We therefore took this opportunity to perform a feasibility study of layman smartphone-based ECG screening on school children aged 13–14 years and to evaluate its cost-effectiveness, in collaboration with the local cardiology unit.

Between March and June 2019 a total of 728 (364, 52% males) individuals, aged 12–13 years was screened as part of the project ‘In the heart of the city’ in collaboration with 13 volunteers from Croce Rossa Italiana and Misericordia di Firenze. Screening sessions were carried out during school hours in the gyms of 5 Tertiary Schools in Florence, Italy. Each individual underwent a 12-lead ECG with D-Heart smartphone ECG by a volunteer with a predefined smartphone dedicated to the project [5,6]. Correct electrodes placement and ECG quality was

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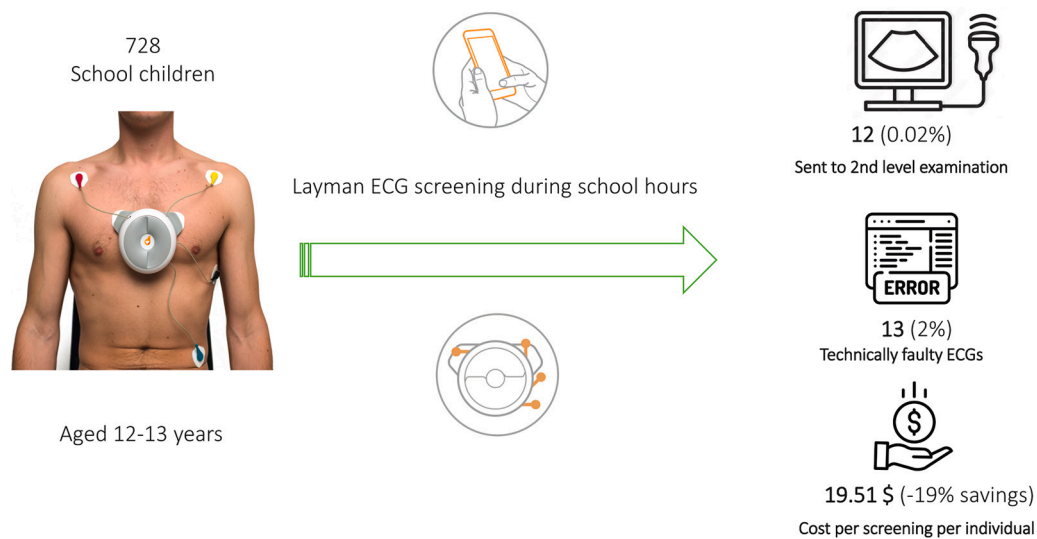


Fig. 1. Feasibility of Layman ECG screening in school children using smartphone based technologies.

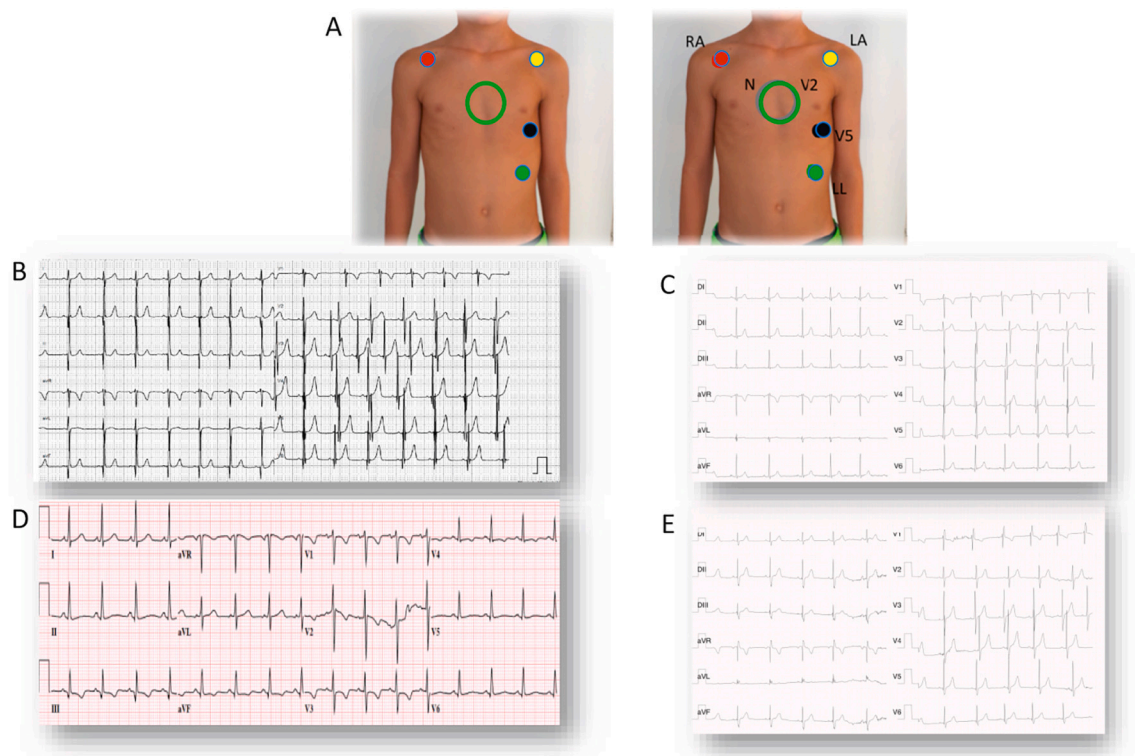


Fig. 2. Electrode placement algorithm and ECG tracings.

Panel A shows the identification by the smartphone camera of the correct electrodes placement on the chest of the screened school children. In panel B, a 12-lead ECG showing inferior deep Q waves is shown. Panel C presents a normal tracing of 13 years old boy. In panel D, a tracing of a 13 years old girl is shown, showing persistent T wave inversion in anterior leads, that qualified the individual for an echocardiography. Panel E represents an incomplete right bundle branch block in a 12 years old boy.

provided by the previously validated image-processing algorithm to the correct electrode placement by the smartphone camera in the D-Heart App [7]. ECG recording length was 12 s, interpretation was provided within 1 week by three cardiologists via a telecardiology platform. ECG alterations were classified following current standards [8].

A total of 741 ECGs were recorded, of which 13 (2%) were technically not interpretable. Specifically, 8 contained movement artifacts, 2 a missing lead and 3 were incorrectly saved (Fig. 1).

Of the 728 children examined, 15 (2%) had a history of asthma, 3

were affected by coeliac disease and 1 presented dextrocardia. ECG showed sinus rhythm in 526 and sinus arrhythmia in 202 (28%) of them. Mean PR, QRS and QTc were respectively: 145 ± 22 , 85 ± 19 and 387 ± 57 msec. No QTc prolongation was observed. Mean QRS axis was 15° and 26 (4%) patients presented an incomplete right bundle branch block. The pattern 'juvenile T wave inversion', with T wave inversion from V1-V3, was present in 145 (21%) subjects. A total of 21 (3%) patients was referred to second level examination. Main reasons were: deep Q waves in inferior leads in 12 (1.6%), ventricular ectopics in 5

(0.7%), anterior T waves inversions from V1 to V4 in 3 (0.4%) and extreme right axis deviation in 1 (0.3%) (Fig. 2). Second line investigations did not show any definitive diagnosis and 8 (1%) referred children are currently in follow-up.

Total project costs consisted in material equipment cost (328 € for the ecg device, 100 € for the electrodes, 400 € for a medium quality smartphone) and human cost (19 € for each tele-cardiology report by the National Health Service cardiologists), resulting in a total of 14.460 €, i. e. 19.51 € per individual. Considering only the ECG recording and interpretation aspect, the net saving compared to standard pre-participation screening programs was 19% (24.08 € vs 19.51 €).

The present pilot study shows the feasibility of layman 12-lead ECG population screening using novel smartphone based technologies. To our knowledge, this is the first attempt to use smartphone guided 12-lead ECG acquisition technologies to offer cost effective pre-participation population screening, since previous experiences relied on single-lead ECGs [9,10]. The proposed approach proved effective, providing good quality 12-lead tracings for the correct identification of abnormalities with a rate of non-interpretable ECG of <5%. A total of 2% of patients were referred to second line investigation. Interpretation of ECG related abnormalities in the pre-adolescent phase is challenging and might lead to false positive. This is partly explained by the different level of transition toward 'adulthood' of the heart between age 12–14. However, current literature of large screening addressing the same age range report a similar rate of second line investigations. Specifically, mass screening of school children by using an ECG resulted in 2.7% of Japanese students addressed to additional evaluation and testing [11]. In 2006 to 2007, 400 healthy children were screened at The Children's Hospital of Philadelphia using a personal medical questionnaire, physical examination, ECG, and echocardiography and ten individuals (2.5%) were found to have potentially serious conditions [12]. Lastly, screening of more >4000 children using an ECG-based system at the Children's Hospital of Philadelphia identified 5%–7% of the children who needed a second line investigation with a positive rate of 0.7% for true significant conditions from this ECG-based screening [13].

Current proposed approach might be an appealing cost-saving strategy, since it can potentially reduce the cost of ECG recording and interpretation by 19%. Given the global shortage of health personnel, such remote high-technology-low-cost strategy, employing health volunteers can be of primary importance in developing countries, where access to facilities is challenging and specialists are few. Criticisms that cite a lack of infrastructure to perform ECG screening fail to recognize that facilities, equipment, and infrastructure might already exist. An ECG could be appended to existing well-child visits or to large-scale school screening events. Although an entirely new system does not need to be created, further, large scale studies evaluating technical and logistic aspects should be performed in order to understand its applicability and potential advantages on a regional or national level.

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