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Short communication

Cardiovascular screening in low-income settings using a novel 4-lead smartphone-based electrocardiograph (D-Heart®)☆

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ABSTRACT

Background: MHealth technologies are revolutionizing cardiovascular medicine. However, a low-cost, user-friendly smartphone-based electrocardiograph is still lacking. D-Heart® is a portable device that enables the acquisition of the ECG on multiple leads which streams via Bluetooth to any smartphone. Because of the potential impact of this technology in low-income settings, we determined the accuracy of D-Heart® tracings in the stratification of ECG morphological abnormalities, compared with 12-lead ECGs.
Methods: Consecutive African patients referred to the Ziguinchor Regional Hospital (Senegal) were enrolled (n = 117; 69 males, age 39 ± 11 years). D-Heart® recordings (3 peripheral leads plus V5) were obtained immediately followed by 12 lead ECGs and were assessed blindly by 2 independent observers. Global burden of ECG abnormalities was defined by a semi-quantitative score based on the sum of 9 criteria, identifying four classes of increasing severity.
Results: D-Heart® and 12-lead ECG tracings were respectively classified as: normal: 72 (61%) vs 69 (59%); mildly abnormal: 42 (36%) vs 45 (38%); moderately abnormal: 3 (3%) vs 3 (3%). None had markedly abnormal tracings. Cohen's weighted kappa (k_w) test demonstrated a concordance of 0,952 ($p < 0,001$, agreement 98,72%). Concordance was high as well for the Romhilt–Estes score ($k_w = 0,893$; $p < 0,001$ agreement 97,35%). PR and QRS intervals comparison with Bland-Altman method showed good accuracy for D-Heart® measurements (95% limit of agreement ±20 ms for PR and ±10 ms for QRS).
Conclusions: D-Heart® proved effective and accurate stratification of ECG abnormalities comparable to the 12-lead electrocardiographs, thereby opening new perspectives for low-cost community cardiovascular screening programs in low-income settings.

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1. Introduction

Mobile health (mHealth) technologies are revolutionizing the practice of cardiovascular medicine. The global diffusion of smartphone devices is producing profound changes in diagnostics, as much relevant data could now be generated locally by the patient rather than centrally by providers [1]. While high-income countries remain at the forefront of developing the latest mobile technologies used in healthcare, the rate of penetration of such technologies in low- and middle-income countries has recently exceeded that of their wealthier neighbors [2]. In general,

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low- and middle-income countries have major restrictions on their healthcare capacities due to the lack of infrastructures, human resources and logistics. Smartphone technology may overcome several of these limitations by providing an easy and affordable access to accurate diagnostic and monitoring methods [2].

The importance of non-communicable diseases – and especially of cardiovascular related morbidity and mortality [3,4] – is rising steeply in low-income countries, unmasking new unmet needs for risk assessment and early diagnosis [5]. In such setting, widespread availability of accurate ECG screening would represent a major step in the right direction [6,7]. However, a low-cost, user-friendly smartphone-based electrocardiograph, enabling the acquisition of multiple lead electrocardiograms (ECG) with a reliability comparable to the standard ECG, is still lacking. D-Heart® electrocardiograph has been recently developed with this specific aim, both for iOS and Android operative systems, enabling the acquisition of surface electrical signals through 5 electrodes, capturing 3 peripheral and 1 precordial lead (V5), and their transmission to the smartphone via Bluetooth technology (Fig. 1).

Because of the potential impact of such technology in low-income countries, we performed a validation study of D-Heart® in a community hospital in Senegal, comparing the accuracy of D-Heart® tracings for the stratification of ECG morphological abnormalities compared with a standard 12-lead technique.

2. Methods

2.1. Study population

Consecutive patients referred at the Ziguinchor Regional Hospital (Senegal) for routine medical evaluation at Radiology, Medicine and Surgical Departments were enrolled from January to February 2016. The study was undertaken in the setting of the cooperation program set by the Center for International Cooperation and Development (CICOPS) of the University of Pavia, Italy.

2.2. ECGs acquisition

D-Heart® and 12-lead recordings were subsequently obtained (within 2–5 min) in each subject. Severity of ECG abnormalities was defined by a semi-quantitative score based on the sum of 9 criteria (based on reference 8): abnormal cardiac rhythm, QRS duration ≥ 100 ms, Romhilt–Estes (R-E) score ≥ 5, fascicular block and/or bundle-branch block, ST-T abnormalities, ST-T segment elevation ≥ 0.2 mV, prolonged QTc interval, pathological Q waves and absence of normal Q wave. Four ECG groups were identified: normal (0 criteria); mildly abnormal (1–3 criteria); moderately abnormal (4–6 criteria); markedly abnormal (7–9 criteria).

ECGs from D-heart® were assessed by two independent observers (J.I. and N.M.) that categorized in a separate database the ECG abnormalities, whereas two other independent observers (A.F. and M.T.) analyzed the tracings from standard electrocardiograph.

2.3. D-Heart® smartphone electrocardiograph technology

The D-Heart® device was conceptualized by N.M. and N.B. as a device for electrocardiographic screening in low income settings. It's is constituted by a battery-powered device for ECG measurement on multiple leads (3 peripherals and one precordial (V5)) connected through the use of Bluetooth low energy to a smartphone. The device was created for the electrocardiographic measurement allowing the user to perform a measurement of up to 8 leads. The front end is constituted by 3 Sigma Delta modulators able to sample the ECG signal and then filter the signal in a digital way. The module Bluetooth Low Energy is able to send data to the smartphone or Tablet deputy to the ECG signal display, whereas Lithium battery ensures the functionality during measurement. The actual components of the device offer a manufacturing price of <35 $ per unit.

The sample was described by means of the usual descriptive statistics: for continuous variables by mean, standard deviation or median and interquartile range, when appropriate and for categorical variables by proportions. The concordance between D-Heart® and standard 12 lead electrocardiographs was assessed by:

- the weighted k_w-Cohen index, with its relative significance, taking as the endpoint variable the ECG group;
- the Bland-Altman method, with a 95% confidence level, for the PR and QRS interval measurements. Since differences between the two measurements did not follow a normal distribution, a non-parametric approach (median value and 2.5^ and 97.5^ percentiles) was used to determine the limits of agreement.

p values were two-sided and considered significant at the 0.05 level. All analyses were performed using SPSS/for Windows, version 20.

3. Results

The study enrolled 117 patients of African origin (69 males, mean age 39 ± 11 years) with a mean blood pressure of 119 ± 21/78 ± 9 mm Hg. Eight (7%) patients had a diagnosis of hypertension, whereas

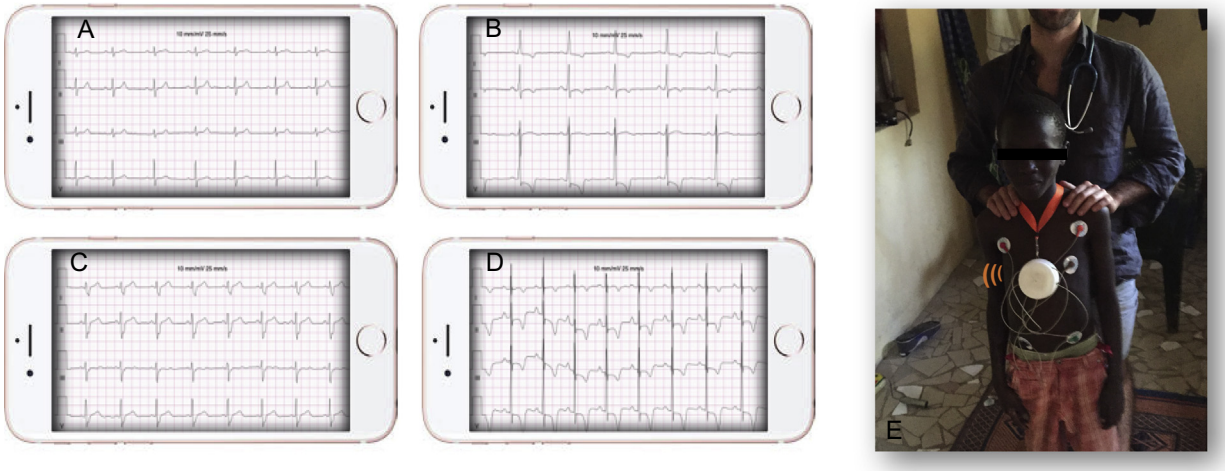

Fig. 1. D-Heart system configuration. Panels A, B, C and D represent different ECGs from D-Heart as displayed on the smartphone. Panel E shows a pediatric patient wearing D-Heart Device.

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5 (4%) presented a history of coronary artery disease. D-Heart® and Twelve-lead ECG tracings were respectively classified as: normal: 72 (61%) vs 69 (59%); mildly abnormal ECG: 42 (36%) vs 45 (38%); moderately abnormal ECG: 3 (3%) vs 3 (3%).

Agreement was obtained in 116/117 (99%) cases with D-Heart tracings and in 115/117 cases with 12-lead ECGs. When there was disagreement, ECGs, both from D-Heart and standard 12 lead electrocardiograph, were adjudicated by an independent observer (I.O.). Weighted Cohen's kappa (k_w) test showed a concordance of 0,952 ($p < 0{,}001$) with an agreement of 98,72% between the two techniques. Thus, while the 12-lead ECG was – as expected - more sensitive for mild abnormalities, there was a 100% concordance for the moderately abnormal tracings.

Of note, concordance was also high for the Romhilt–Estes score ($k_w = 0{,}893$; $p < 0{,}001$). Comparison of PR and QRS intervals (Bland-Altman method, non-parametric approach) showed excellent concordance for D-Heart® measurements (95% limit of agreement −20 to +20 ms for PR and −10 to +10 ms for QRS).

4. Discussion

Cardiovascular diseases (CVD) are an emerging threat to populations of low-income countries. It is estimated that, in 2013, CVD accounted for >40% of all causes of death in sub-Saharan Africa [9]. Concomitantly, these areas are affected by dramatic shortage of health professionals who are mainly concentrated in urban areas, while 60% of the patients still live in rural settings [6]. In a country such as Cameroon, there is one cardiologist every 50,000 inhabitants, compared with the EU standard of 1 every 500 [10]. Telemedicine is an appealing alternative to direct access to medical structures, by providing easy and affordable access to specialist care and reducing the need for rural patients to travel for health-related issues [11].

Additionally, telemedicine may play a pivotal role in reducing healthcare costs in low-income settings, for both the patients and the hospital facilities, including a >70% cost reduction in the setting of obstetrics and cardiology services [12]. Lastly, telemedicine opens the possibility for international cross-border services, aimed at managing and reporting the enormous amount of data acquired, as well as at linking global (remote) experts with local health workers [11].

Several smartphone based electrocardiographs are commercially available, such as AliveCor or Cardiosecur, but both are mostly intended for rhythm analysis rather than morphological interpretation, thus unsuitable for electrocardiographic population screening in low income settings. In the present study, the potential role of the D-Heart® device was evaluated in the only hospital present in Casamance, the Southern region of Senegal. The cardiology center at Ziguinchor Regional Hospital serves a region expanding on a total surface of 28,350 km^2. Basic health services to the population are delivered via 8 Community Health Centers and 12 Service Pharmacies. Although D-Heart allows immediate and on site interpretation of the electrocardiogram and therefore is not solely intended for telemedicine purposes, its potential for telemedicine is obvious and relevant. The present device validation study might lay the foundation for future telemedical screening protocols aimed to improve the appropriateness and efficacy of referral to specialized medical care. Potential benefits range from early diagnosis of acute heart conditions to screening of high-risk populations, to remote monitoring of known chronic conditions.

Despite the many ways in which telemedicine may transform healthcare for the better, mHealth faces a number of major challenges. Specifically, the validation of novel technologies represents a critical step in our understanding of whether they can substitute or implement current used methodologies [13–15]. With this aim, we assessed the accuracy of the D-Heart® electrocardiograph, demonstrating that tracings obtained from smartphones may compare favorably with the current gold standard 12-lead in identifying ECG abnormalities. D-Heart was originally conceived based on the evidence that a system with 5 electrodes (3 peripheral leads plus V5), had a 95% sensitivity compared with a 12-lead tracings in conventional recordings [16]. However, since the 12-lead ECG was found to be more sensitive in identifying minor ECG abnormalities, we decided to improve the clinical accuracy of D-Heart. Particularly, since the 3 mildly abnormal tracings mislabeled by D-Heart® were misclassified because of the lack of specificity for Left Ventricular Hypertrophy (LVH) Criteria we decided to derive the augmented leads (aVL, aVF and aVR) and insert an additional precordial electrode (V2) to explore more reliably the anterior territories of the heart and enable the correct identification of LVH.

Of note, the present study was based on a low-risk patient cohort, with limited prevalence of abnormal tracings, as would be expected in a young community-based African population.

5. Conclusions

D-Heart® ECGs proved accurate, allowing a stratification of ECG abnormalities comparable to the standard 12-lead ECG in a low-income setting. Novel smartphone-based techniques open promising perspectives for low-cost cardiovascular screening programs. Further studies are clearly needed to assess if these theoretical advantages are supported by patient-centered outcomes and positive cost-benefit analysis.

Conflict of interest

Niccolò Maurizi and Nicolò Briante are the co-founders of the social innovative start-up D-Heart.

Acknowledgments

Essential contribution to the development of the hardware and software of D-Heart device was given by Niccolò Maurizi, Nicolò Briante.

Screening procedures in Senegal have been carried out by Niccolò Maurizi, Alessandro Faragli, Jacopo F. Imberti, Fulvio Avvantaggiato and Gian Battista Parigi.

Patients were enrolled from Amadou Sall and Abibou Cisse outpatient clinics (Dept. of Radiology, Medicine and Surgery of Regional Hospital of Ziguichor, Casamance, Senegal).

Data analysis was carried out by Niccolò Maurizi, Alessandro Faragli, Jacopo Imberti, Iacopo Olivotto, Mattia Targetti and Katia Baldini.

Statistical support was provided by Biostatistic Department of the University of Pavia, particularly by Francesca Gigli Berzolari and Paola Borrelli.

Manuscript conceptualization and writing has been provided by Niccolò Maurizi, Iacopo Olivotto, Franco Cecchi, Niccolò Marchionni and Stefano Perlini.

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Feasibility of cardiovascular screening in low-income settings using smartphone-based technologies

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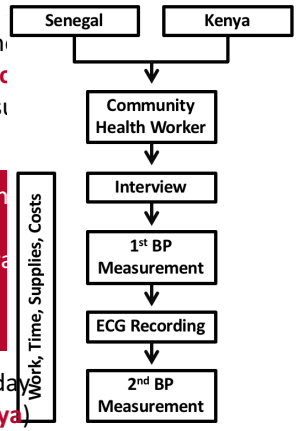
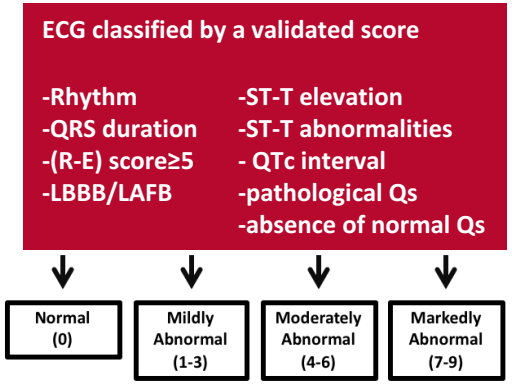
Introduction. Mobile health (**m-Health**) technologies revolutionizing cardiovascular (CV) medicine. However, m than 80% of heart disease related deaths occur in **lo income settings**, that are unable to take advantage of su innovations for healthcare awareness and prevention.

Purpose. To assess the feasibility of a pilot CV screen campaign with smartphone based m-health devices:
-D-Heart®, a validated low-cost 8-lead electrocardiogra (199€)
-iHealth® blood pressure (BP) recorder (~70€)

Methods. A total of 231 patients were enrolled in a two-da screening at 4 rural dispensaries, 2 in Kitui District (**Kenya**) and 2 in Ziguinchor District (**Senegal**).





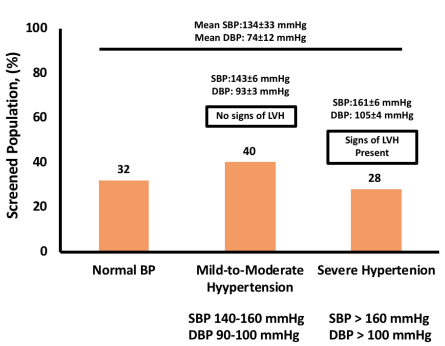


Figure 1. Blood Pressure mesaurment results

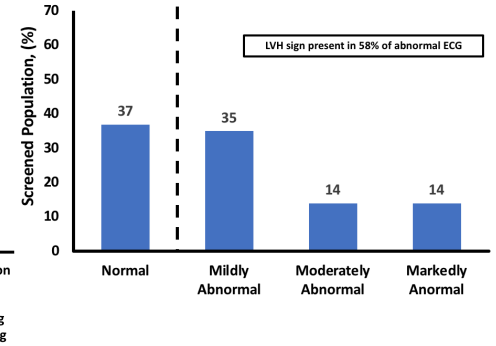


Figure 2. ECG Screening results

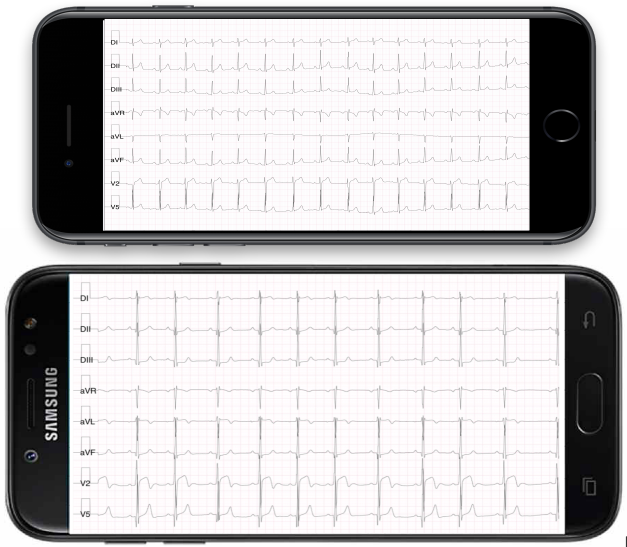


Figure 3. Samples of D-Heart ECGs recorded

Results. Clinical characteristics of the 231 patients are summarized in **Table 1, Figure 1 and Figure 2.**

Table 1. Baseline characteristics of the screened population

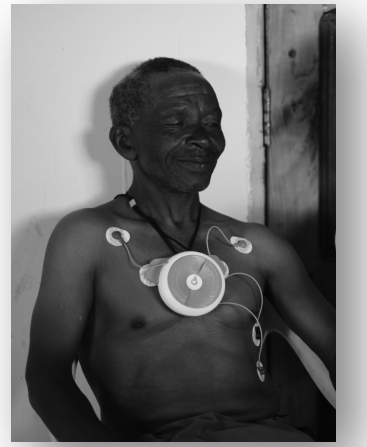
	Overall	Men	Women	p
Demographics				
Population – N, (%)	231	121 (52)	110 (48)	
Age	36±21	41±17	32±12	<0.01
BMI	24±2.9	22.3±1.5	27.2±1.1	<0.01
CV risk Factors				
Smoking Hx – N, (%)	78 (34)	60 (50)	18 (16)	<0.01
Alcohol (>2.5 U/day) – N, (%)	92 (40%)	67 (55)	37 (33)	<0.01
HTN Hx – N, (%)	11(5)	5 (4)	6 (5)	ns
Diabetes Mellitus	15	7 (6)	8 (7)	ns
Previous AMI	3 (1)	2 (2)	1 (1)	ns

71% never had BP measured before

91% never had ECG recording before

Cost-Effectiveness Analysis. Taking into account:
-device price
-consumables
-salaries
-USB solar powered technology
-visit time (6±2 minutes).

€1.10/patient
- **€0.80 for community health worker**
- **€0.30 for consumables**



Conclusions. D-Heart® ECG screening combined with smartphone BP measurement proved **efficient** and **cost-effective**. This should encourage to develop low-cost/high-technology community-based CV screening programmes in low-income settings.

Disclosures. Dr. Fumagalli was awarded a research grant from D-Heart Srl in December 2017

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SHORT REPORT

Use of Smartphone-operated ECG for home ECG surveillance in COVID-19 patients

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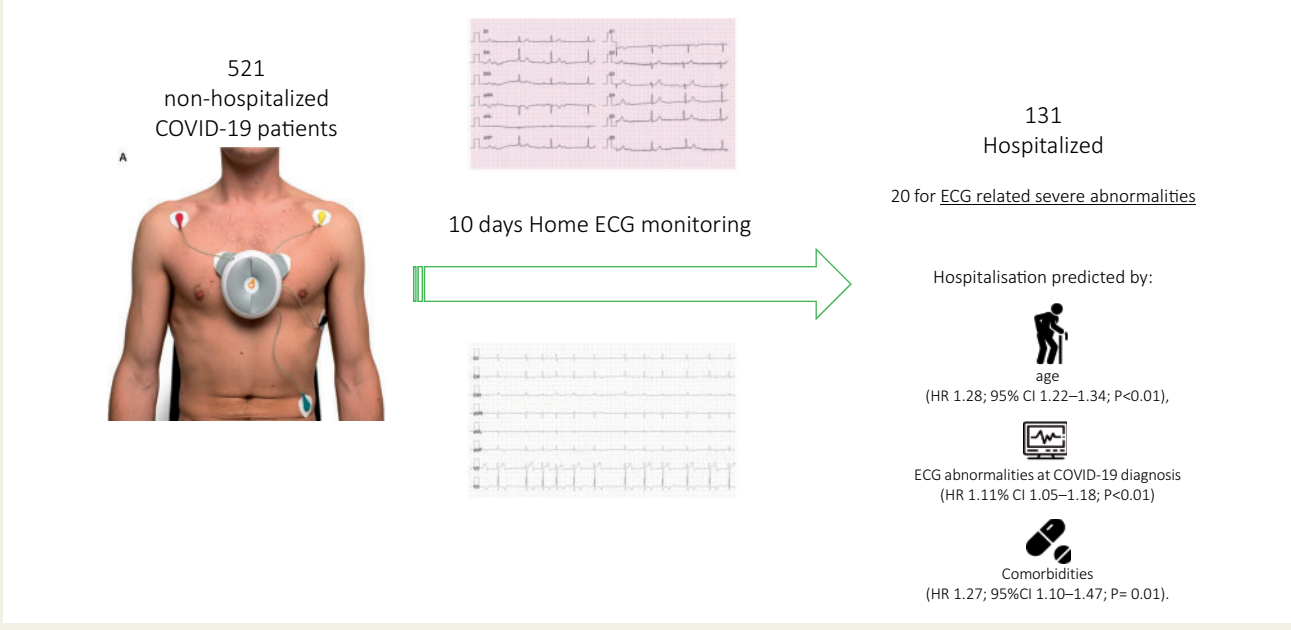
Keywords Telecardiology • COVID-19 • ECG • Screening



Graphical abstract

Current COVID-19 pandemic is challenging hospital capacity and healthcare workers. In such setting, it is imperative to properly select stable COVID-19 patients to be treated at home. Therefore, empowering family physicians and their patients with accurate and portable home diagnostic devices, including electrocardiogram (ECG) devices and oximeters, to early identifies those with evolutive potential becomes a priority.[1] However, limited data exist on the role of ECG as home monitoring tool for COVID-19 stable patient.[2]

We evaluated the use of a portable 8/12 leads Smartphone-operated ECG device for self-home ECG recording, the prevalence of ECG abnormalities, and predictors of short-term hospitalization in COVID-19 patients treated at home.

From March to October 2020, we provided 21 family physicians with a previously validated portable hospital-grade 8/12-Lead Smartphone-operated ECG device (D-Heart, sampling frequency 640 Hertz) [2] approved for homecare to enable ECG recording of

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COVID-19 infected non-hospitalized patients (positive nasal-swab PCR). First ECG was operated by the patient at home with the supervision of the family physician, than the device was left to the patients to record at least one ECG at Day 4 of infection or whenever a cardiac symptom was present for the first 10 days of infection. Included patients had the ability to properly use smartphone's basic functions. Patients were instructed to record a 12-lead ECG in case of ischaemia-related symptoms; in all other cases, an 8-Lead ECG was performed (including DI, DII, DIII, aVR, aVL, aVF, V2, and V5). Electrocardiogram recording length was 12 s, interpretation was performed by three cardiologists via a telecardiology platform 24/7 within 15 min from ECG arrival. ECG alterations were classified following current standards.[3] QT interval was measured manually in lead II and V5 for each ECG: mean value was used for QTc calculation, corrected with Bazzett formula.[4]

A total of 521 patients was enrolled: median age at COVID-19 diagnosis was 61 (28–74) years and 323 (62%) were male. Three-hundred thirty-eight (65%) patients had at least one co-morbidity, of whom 198 (38%) had hypertension, 93 (18%) presented pre-existing cardiac conditions (31 previous myocardial infarction, 43 chronic heart failure, 19 severe valvular disease). Thirty-four (7%) patients were excluded from the study for insufficient ECG quality (21 for ECG non-interpretability for excessive ECG noise, 6 resulted not able to properly operate the device despite initial enrolment, 7 because of incompatible smartphones).

Electrocardiogram was recorded for 487 patients (total of 1256 ECGs, 2.5 per-patient): mean PR interval was 159 (145–188) ms, QRS 85 (71–101) ms, QTc 419 (402–448) ms. Ninety-two (19%) patients presented an abnormal baseline ECG: pathologic ST-T alterations in 58, right bundle branch block in 22, Left bundle branch block in 21, 1st degree-atrioventricular block in 19, and atrial fibrillation in 17 patients.

During the 10 days of study time, 131 (27%) patients were hospitalized: 89(68%) for dyspnoea and desaturation, 22(17%) for severe diarrhea, and 20 (15%) following ECG diagnosed abnormalities: 9 new onset Atrial Fibrillation/Flutter, 6 new-onset Right Bundle branch block, 3 acute coronary syndromes, 2 high degree atrioventricular-block (*Figure 1*). Of the 131 patients hospitalized, 42 (32%) presented an abnormal ECG at study enrolment. Predictors of hospitalization at multivariable analysis were age [hazard ratio (HR) 1.28, 95% confidence interval (CI) 1.22–1.34; $P < 0.01$], presence of any ECG abnormalities at infection diagnosis (HR 1.11%, 95% CI 1.05–1.18; $P < 0.01$), and presence of any co-morbidities (HR 1.27, 95% CI 1.10–1.47; $P = 0.01$).

A subgroup of 323/487 patients underwent Hydroxychloroquine/Azithromycin therapy (400–500 mg respectively, during March–May 2020). At Day 4 of combined therapy, ECG interval durations did not significantly change [PR 152 (137–190), QRS 88 (68–104) ms, QTc 428 (408–453) ms; (Wilcoxon-signed rank-test, $P > 0.05$)]. However, 21 (7%) patients prolonged the QTc interval significantly from

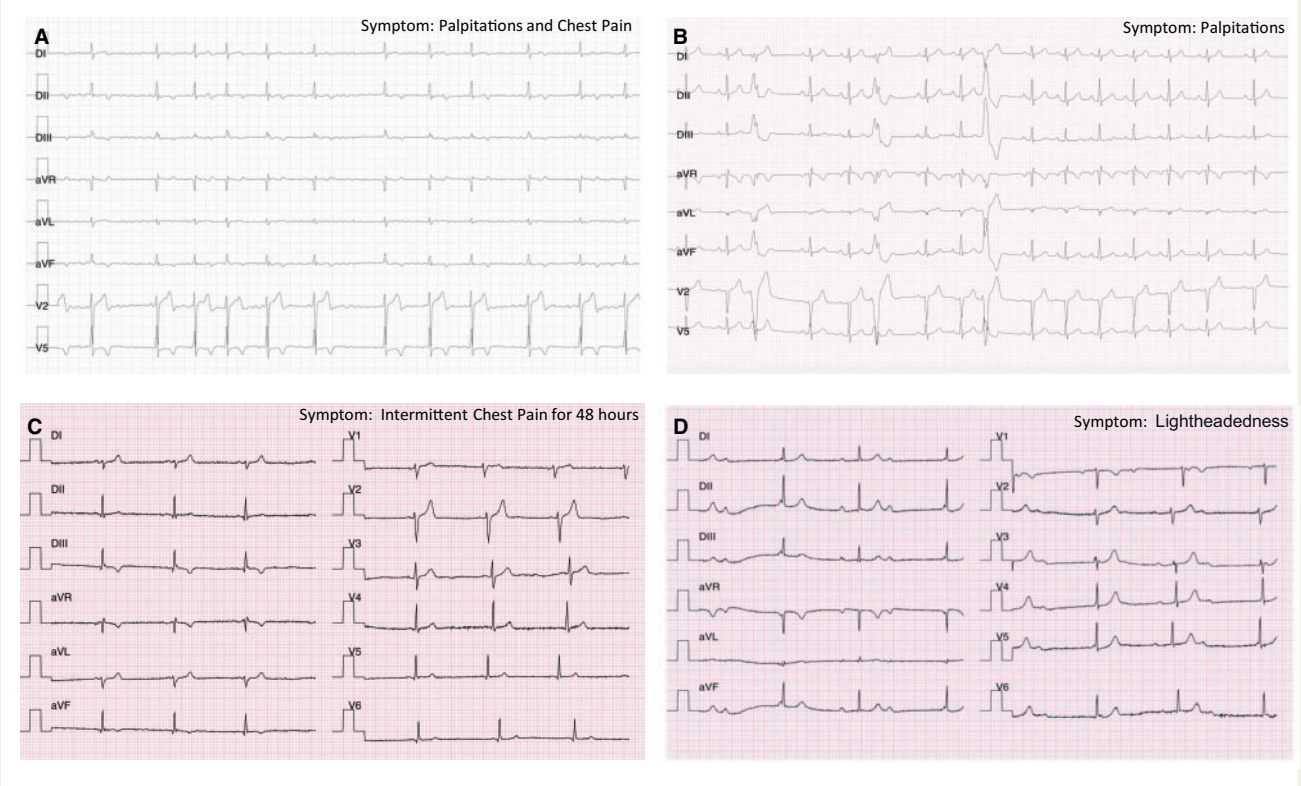

Figure 1 Self-recorded ECGs with a 8/12 lead smartphone-operated ECG device. In panel A, an 8-lead ECG of a 56 years old man with no previous cardiovascular history showed new-onset Atrial Fibrillation and infero-lateral repolarization abnormalities; the patient has been subsequently diagnosed with COVID-19 related myocarditis. In panel B, an 8-lead ECG of a 68 y/o woman complaining of palpitations is presented; the trace shows multifocal PVCs. Panel C shows a 12-lead ECG from a 75 years old man, with multiple cardiovascular risk factors with inferior repolarization abnormalities; the man was subsequently diagnosed with subacute inferior myocardial infarction. Panel D presents a 12-lead ECG of a 71 yearsold man with a high degree atrioventricular block.

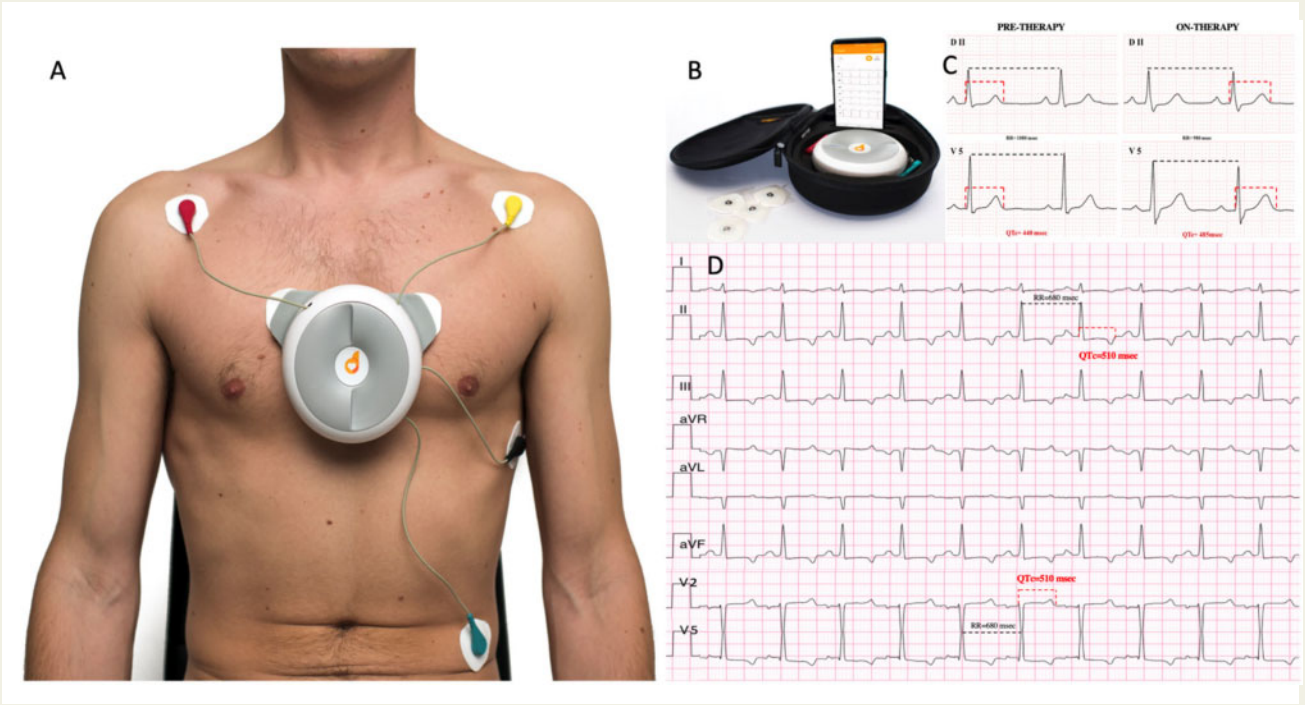

Figure 2 Multiple Lead Smartphone ECG device for self surveillance in non-hospitalized COVID-19 patients. In *panel A*, the 8/12 lead smartphone ECG device on a patient. In *panel B*, the homecare kit is displayed. In *panel C*, two ECGs pre therapy and after 4 days with Hydroxycholoroquine and Azytrhomicin are displayed: prolongation of QT interval of 45 msec. *Panel D* shows an ECG with a QTc of 510 msec after 4 days of Azytrhomicin and Hydroxycholoroquine therapy.

baseline, with a median increase of 41 [34–87 interquartile range (Wilcoxon-signed rank-test) $P < 0.05$]. Of these, nine (3%) developed QTc > 500 ms prompting treatment discontinuation (*Figure 2*). Of note, three had prior myocardial infarction.

As the coronavirus pandemic is radically transforming our health-care systems, it is crucial to preserve hospital capacity by empowering family physician and their patients with appropriate tools to early identify those with a worse short-term clinical deterioration.

We report, here, that home ECG monitoring of non-hospitalized COVID-19 patients can identifies disease-related cardiac complications and that the presence of ECG alterations at COVID-19 diagnosis independently predicts, together with age and co-morbidities, the risk of short-term hospitalization in the first 10 days of the disease. Moreover, outpatient QTc monitoring was feasible, identifying in 3% of patients who underwent during the first pandemic the no longer encouraged Hydroxychloroquine/Azithromycin therapy a significant QTc prolongation.

Electrocardiogram may help stratify patients not only by revealing acute changes, such as ST-segment/T-wave abnormalities or possible new arrhythmias/conduction disorders but also by showing chronic abnormalities suggesting an underlying cardiac disease, already been associated with worse COVID-19 prognosis,[1] but also identifies those with a worse short-term clinical outcome.

No previous study, however, assessed the performance of smartphone ECG devices in the setting of home monitoring of patients with stable COVID-19. Smartwatches and other smartphone ECG devices, despite being extremely portable, easy to use, and ideal for simple arrhythmias assessment,[5,6] might not be adequate to complete evaluation of patients with complex ECG alterations, as ST/T changes, where all precordial leads should be available.[3]

Evidences are emerging suggesting a potential role of multiparametric tele-monitoring for stable COVD-19, but whether this should be regularly performed or be limited to specific subgroups of patients should still be clarified. Further studies are needed addressing its impact on outcome on a population scale.

Conflict of interest: N.M. is a co-founder of social-vocation start-up D-Heart srl. The other authors have no conflict of interest to declare.

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Feasibility of a Combined Mobile-Health Electrocardiographic and Rapid Diagnostic Test Screening for Chagas-Related Cardiac Alterations

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Abstract: Background: Chronic Chagas cardiomyopathy (CChC) is the most common cause of death related to Chagas disease (CD). The aim of this study was to assess the feasibility of a combined rapid diagnostic test (RDT) and electrocardiographic (ECG) screening in a remote rural village of the Bolivian Chaco, with a high prevalence of CChC. Methods: Consecutive healthy volunteers > 15 years were enrolled in the community of Palmarito (municipality of Gutierrez, Santa Cruz Department, Bolivia) in February 2019. All patients performed an RDT with Chagas Stat-Pak® (CSP, Chembio Diagnostic System, Medford, NY, USA) and an ECG by D-Heart® technology, a low-cost, user-friendly smartphone-based 8-lead Bluetooth ECG. RDTs were read locally while ECGs were sent to a cardiology clinic which transmitted reports within 24 h from recording. Results: Among 140 people (54 men, median age 38(interquartile range 23–54) years), 98 (70%) were positive for *Trypanosoma cruzi* infection, with a linear, age-dependent, increasing trend ($p < 0.001$). Twenty-five (18%) individuals showed ECG abnormalities compatible with CD. Prevalence of ECG abnormalities was higher in infected individuals and was associated with higher systolic blood pressure and smoking. Following screening, 22 (16%) individuals underwent clinical evaluation and chest X-ray and two were referred for further evaluation. At multivariate analysis, positive CSP results (OR = 4.75, 95%CI 1.08–20.96, $p = 0.039$) and smoking (OR = 4.20, 95%CI 1.18–14.92, $p = 0.027$) were independent predictors of ECG abnormalities. Overall cost for screening implementation was <10 $. Conclusions: Combined mobile-Health and RDTs was a reliable and effective low-cost strategy to identify patients at high risk of disease needing cardiologic assessment suggesting potential future applications.

Keywords: Chagas disease; Chagas Stat-Pak; chronic Chagas cardiomyopathy; mHealth; telemedicine; seroprevalence; Bolivia; Chaco

1. Introduction

Chagas disease (CD), caused by infection with the protozoan parasite *Trypanosoma cruzi*, is the neglected tropical disease exerting the highest burden in most Latin American countries, with 8 million persons chronically infected and approximately 200,000 new cases

each year [1]. It is transmitted to humans through the feces of infected hematophagous triatomine insects in areas in which the disease is endemic and, occasionally, by non-vectorial mechanisms such as blood transfusion, organ transplants, or vertically from mother-to-child [2].

Three clinical stages of CD have been described: the acute phase, typically asymptomatic and short-lasting, followed by a chronic long-acting phase that may span for decades without showing any symptoms associated to the infection (indeterminate stage), and the determinate phase. Approximately 40% of chronically infected individuals progress to either advanced cardiac and/or digestive tract forms characterized by high morbidity and mortality, if left untreated [2].

Despite progress in vector control [3,4], a timely and accurate diagnosis remains a major obstacle to start treatment. Still today, early accessing to presently available drugs is a major issue. It is estimated that current chemotherapies only reach 1% of infected individuals [1,5].

Communities with intense transmission remain, especially in the Bolivian Gran Chaco (estimated infection rate at 4% per year) [3,4]. Cardiac involvement, i.e., Chagas Cardiomyopathy (CChC), is the main cause of death [2,5,6]. The early signs of Chagas cardiomyopathy are typically conduction system abnormalities, most commonly right bundle branch block (RBBB), often progressing to bifascicular blocks. Later manifestations include left ventricular systolic dysfunction, apical aneurysms, high-degree atrioventricular block, and sustained and non-sustained ventricular tachycardia [6–8]. Of note, sudden cardiac death may occur at any moment, including early phases. Therefore, early recognition of cardiac involvement through cost-effective screening efforts becomes a priority in areas with high endemic burden. As patients with CD, compared to non-CD subjects, have almost a three-fold higher prevalence of electrocardiogram (ECG) alterations, ECG coupled with a rapid diagnostic test (RDT) screening can be a reasonable first-line approach. However, limited resources, lack of trained personnel and infrastructures in highly endemic areas, challenge the implementation of such programs. Smartphone technology, with its' computational power, applied to telemedicine may overcome several of these limitations by providing an easy and affordable access to accurate diagnostic methods [9–11].

The aim of this study was to understand the potential impact and sustainability of a mHealth ECG screening program, coupled with an RDT test, in remote rural villages of the Bolivian Chaco with the help of a validated smartphone-based ECG (D-Heart®). The present device allows low-cost ECG screening campaigns by community health workers and offers the possibility of Remote ECG interpretation by expert physicians.

2. Materials and Methods

2.1. Study Population and Settings

The study was carried out in Palmarito Community (municipality of Gutierrez, Santa Cruz Department; 19°49′ S; 63°48′ W, Bolivian Chaco Region), in February 2019. In this region, estimated seroprevalence of Chagas Disease is 50% in the general population, but can be as high as 70% in individuals aged >15 years [3,4]. The nearest secondary level Hospital is located 80 km far away (Hospital Municipal de Camiri). All individuals $\geq$ 15 years old were invited to participate to the study. Overall, 653 inhabitants live in Palmarito, of whom 402 people $\geq$ 15 years old. A representative sample of 140 healthy volunteers were consecutively enrolled, taking into account the age group distribution. Demographic data was recorded, and a brief clinical history, focused on common cardiovascular risk factors and manifestations, was obtained through a standardized questionnaire. Height and weight were recorded and body mass index (BMI) calculated. All participants underwent blood pressure (BP) measurement, by trained personnel, before performing electrocardiographic and serological screening; those with elevated systolic (SBP $\geq$ 140 mmHg) and/or diastolic blood pressure (DBP $\geq$ 90 mmHg) had a second measurement.

2.2. ECG Screening and Referral Path

For each participant, an ECG was recorded using D-Heart® electrocardiograph. D-Heart® is a CE marked multiple lead smartphone-based ECG device (DI, DII, DIII, aVR, aVL, aVF peripheral leads V2 and V5 precordial leads) specifically designed for ECG screening in low-income settings by non-medical personnel [10,11]. The device is manufactured by the social-vocation start-up D-Heart, an Italian-based company. The device weighs less than 194 g and is extremely portable. If operated by non-health professionals it can register an 8-lead ECG, whereas in the health professionals setting standard 12-lead ECG can be acquired. The module Bluetooth Low Energy streams the ECG data to the smartphone in a medically certified App that enables in loco reading of the tracings or Telecardiology Reporting via web-based Telecardiology Platform. The actual components of the device offer a manufacturing price of 90$ per unit.

ECG tracings were acquired with D-Heart Smartphone ECG device during the on-site screening activities and were sent daily to the Cardiomyopathy Unit, Careggi Hospital, Florence, Italy where they were read with D-Heart Telecardiology Platform within 24 h by two staff physicians, N.M and C.F., blinded for subjects' *T.cruzi* infection status. Each ECG was recorded with a dedicated smartphone protected by a code known by the Community Health Worker. An abnormal ECG suggestive of CChC was defined as an ECG with (i) ventricular conduction defects: complete right BBB (RBBB), left anterior fascicular block, left posterior fascicular block, left bundle branch block, or bifascicular block; (ii) any degree of atrioventricular block; (iii) rhythm disturbances: atrial fibrillation/flutter, junctional rhythm, sinus bradycardia with heart rate < 50 beats/min, or complex ventricular ectopy; (iv) other: pathologic Q waves, fragmented QRS, low QRS voltage [6,7,12]. Other findings, such as incomplete RBBB, atrial ectopy, nonspecific ST-T wave changes, right or left ventricular hypertrophy were considered nonspecific for CChC and were not included in our definition of CChC-related ECG abnormality. Reports were sent back daily to the Community Health Center in Palmarito.

2.3. T. cruzi Infection Screening Chagas Stat-Pak® Assay

After ECG testing, all patients during the onsite screening activities performed a Chagas Stat-Pak® (CSP) (Chembio Diagnostic System, Medford, NY, USA), an immunochromatographic, qualitative, rapid diagnostic test (RDT), which uses a combination of antigens for the detection of IgG antibodies to *T. cruzi*, in use as standard tool for Chagas disease screening by the Chagas National Program since 2005. Blood samples were obtained by finger-prick and the result read after 15 min, according to the manufacturer's instructions. During previous studies, carried out in the same highly endemic area of the Bolivian Chaco, CSP yielded excellent performance in comparison with the conventional serology, with sensitivity, specificity, positive predictive value and negative predictive value up to 100%, 99.3%, 99.5%, and 100%, respectively [13,14].

2.4. Sustainability and Cost of a mHealth Screening Campaign

Financial feasibility models were built to project the overall cost of our screening campaign. A total of two analyses were performed: the first model would include start-up and operative costs related to human resources, consumables (RDT kits, electrodes, disinfection kits), non-consumable devices (D-Heart®, compatible smartphone, blood pressure cuff, and internet connection) and logistics; the second one would comprise only consumables and human resources for screening continuation.

2.5. Statistical Analysis

Statistical analysis of the data was performed with STATA 11.0 (StataCorp, College Statio, TX, USA). Frequencies and percentages with 95% confidence intervals (CI) for categorical variables, means and medians and interquantile ranges (IQR) for continuous variables were calculated. T-Student test or Mann–Whitney test were used to compare continuous variables. Chi-square test, or Fisher's exact test, when appropriate, were used

to investigate the association between positive CSP test with ECG abnormalities, individual risk factors and demographic data. Multivariate logistic regression was performed including age, sex and all the variables significantly associated to ECG abnormalities at univariate analysis. Results were considered significant when the p-value ≤ 0.05.

2.6. Ethics Statement

The study was realized in agreement with the Ministry of Health of the Plurinational State of Bolivia (Convenio Ministerio de Salud y Deportes, Estado Plurinacional de Bolivia/Cátedra de Enfermedades Infecciosas, Universidad de Florencia, Italia), the Servicio Departamental de Salud (SEDES) of Santa Cruz and with the support of the Guaraní political organization (Asamblea del Pueblo Guaraní). The study was approved by a local Ethic Committee and a written informed consent was obtained by each enrolled participant (or by a parent or a legal guardian, if minor).

3. Results

3.1. Baseline Characteristics

Of the 140 subjects included in the study, 54 (39%) were men, with a median age of 38 (interquanrtile range 23–54) from 15 to 85 years old. Twenty-four (17%) had family history for cardiovascular diseases and 11 (8%) of sudden unexpected death. Cardiovascular risk profile was generally low, with only five (4%) individuals affected by Type 2 diabetes mellitus, two (1%) with known dyslipidemia and median BMI was 24 kg/m2 (22–27). Palpitations were reported by 39 (28%) patients, whereas chest pain was the most common complaint, present in 82 (59%) patients. History of loss of consciousness was present in 14% of patients (Table 1)

Table 1. Characteristics of the surveyed population in a rural community of the Bolivian Chaco by *T. cruzi* infection status.

	Total (***n*** **= 140)**	**Chagas Stat Pak®**		***p*-Values**
		Negative (***n*** **= 42)**	**Positive** (***n*** **= 98)**	
Sex				
Male	54 (39%)	22 (41%)	32 (59%)	
Female	86 (61%)	20 (23%)	66 (77%)	0.028 *
Age	38.5 (23–54)	20 (17–30)	45 (33–62)	<0.001 #
Range	15–85	15–75	15–85	
15–20 yo	34	23 (68%)	11 (32%)	
21–49 yo	63	17 (27%)	46 (73%)	
≥50 yo	43	2 (5%)	41 (95%)	<0.001 §
SBP (mmHg)	111 ± 16	110 ± 15	117 ± 13	0.010 °
DBP (mmHg)	69 ± 10	67 ± 8	70 ± 10	0.048 °

Legend: IQR: interquartile range; yo: year-old; SBP: systolic blood pressure; DBP: diastolic blood pressure; * Pearson's chi-squared test; # Mann–Whitney test; § linear regression; ° *t*-Student test.

No one had been screened with an ECG or for *T. cruzi* before the study enrolment.

3.2. Outcome of Combined T. cruzi and ECG Screening

Community screening was carried out in 6 days. RDTs were read locally, and results recorded, while ECGs were sent to the Florence Cardiomyopathy Unit and analyzed within 24 h (average response time: 9 ± 1 h). No ECG recording was lost, and all patients with positive ECG and RDT results combined were actively referred to further evaluation.

Overall, 98 (70%) subjects were screened positive for *T.cruzi* infection with CSP (Table 2). *T. cruzi* seroreactive people were significantly older than uninfected ones ($p < 0.001$), with a linear, age-dependent, increasing trend ($p < 0.001$). Ten subjects (7%; 51 to 85 years) had elevated BP values: four had arterial hypertension at two successive measures, and

six had isolated systolic hypertension (SBP $\geq$ 140 mmHg, DBP < 90 mmHg). Of note, only two were aware of their condition. Mean SBP and BDP values were slightly—but significantly—higher in CSP-positive group than in non-reactive people (Table 2).

Table 2. Electrocardiographic findings in *T. cruzi* infected and uninfected population of a rural community of the Bolivian Chaco.

	Total (*n* = 140)	**Chagas Stat Pak®**	
		Negative (*n* = 42)	**Positive (*n* = 98)**
Normal	115 (82%)	39 (93%)	76 (78%)
Any CD-related abnormality	25 (18%)	3 (7%)	22 (22%)
Bundle Branch Blocks			
Complete right BBB	6 (4%)	0	6 (6%)
Left anterior fascicular block	2 (1%)	0	2 (2%)
Atrioventricular Blocks			
I degree atrioventricular block	3 (2%)	1 (2%)	2 (2%)
Rhythm disturbances			
Sinus bradycardia	3 (2%)	1 (2%)	2 (2%)
Complex ventricular ectopies	2 (1%)	0	2 (2%)
Other			
Pathologic Q waves	2 (1%)	0	2 (2%)
Fragmented QRS	5 (4%)	1 (2%)	4 (4%)
Low QRS voltage	2 (1%)	0	2 (2%)
Heart rate (bpm) (±SD)	70 ± 10	73 ± 12	69 ± 9
PR interval (ms) (±SD)	156 ± 21	156 ± 16	159 ± 22
QTc interval (ms) (±SD)	410 ± 24	408 ± 25	411 ± 23

Legend: CD: Chagas disease; BBB: bundle branch blocks; AVB: atrioventricular block; bpm: beats per minute; ms: milliseconds; SD: standard deviation.

None of the study participants had performed an ECG test prior to enrolment. A total of 115 (82%) subjects had a normal ECG, while 25/140 (18%) showed ECG abnormalities, compatible with CD, and prevalence was higher in CSP positive individuals (22% vs. 7%, $p = 0.03$). No differences were described for PR and QTc intervals duration. ECG abnormalities included Bundle Branch Blocks ($n = 8$), 1st Degree Atrioventricular blocks ($n = 3$), rhythm disturbances ($n = 5$), pathologic Q waves ($n = 2$), fragmented QRS ($n = 5$), and low QRS voltage ($n = 2$) (Table 2). ECG abnormalities were directly associated with higher systolic blood pressure (117 ± 13 vs 110 ± 15, $p = 0.017$) and smoking habit (48 vs 26%, $p = 0.030$) (Table 3). Age- and sex-adjusted multivariate analysis confirmed the association of ECG abnormalities with CSP-positive results (OR: 4.75, 95%CI 1.08–20.96, $p = 0.039$) and smoking habit (OR: 4.20, 95%CI 1.18–14.92, $p = 0.027$).

Table 3. Characteristics and cardiovascular risk factors of the surveyed population in a rural community of the Bolivian Chaco, by D-Heart® result.

	Total (n = 140)	D-Heart® ECG		p-Value
		Normal (n = 115)	Any Abnormality (n = 25)	
Sex				
Male	54 (39%)	44 (38%)	10 (40%)	0.871 *
Age				
Median (IQR)	38 (22–54)	37 (20–53)	40 (31–59)	0.92 #
Range	15–85	15–85	16–83	
Chagas Stat Pak®				
Negative	42	39 (34%)	3 (12%)	
Positive	98	76 (66%)	22 (88%)	0.032 ^
CV risk factors				
Family history of CV diseases	24 (17%)	22 (19%)	2 (8%)	0.247 ^
Family history of sudden death	11 (8%)	11 (10%)	0	0.211 ^
Positive Smoking History	42 (30%)	30 (26%)	12 (48%)	0.030 *
Dyslipidaemia	2 (1%)	1 (0.9%)	1 (4%)	0.326 ^
Diabetes	5 (4%)	4 (3.5%)	1 (4%)	0.632 ^
History of leg oedema	54 (39%)	41 (36%)	13 (52%)	0.128 *
Loss of consciousness	20 (14%)	16 (14%)	4 (16%)	0.757 ^
History of Palpitations	39 (28%)	33 (29%)	6 (24%)	0.635 *
History of Chest pain	82 (59%)	66 (57.4%)	16 (64%)	0.543 *
BMI (IQR)	24 (22–27)	24 (22–27)	24 (22–28)	0.389 #
SBP (mmHg)	111 ± 16	110 ± 15	117 ± 13	0.017 °

Legend: CV: Cardiovascular Disease; IQR: Interquartile range; BMI: Body Mass Index; SBP: Systolic Blood Pressure. * Pearson's chi-squared test; # Mann–Whitney test; ^ Fisher's exact test; ° t-Student test

3.3. Medical Referral, Feasibility of Current Screening Strategy, and Cost Analysis

Twenty-two patients with a positive CSP testing and possible CD-related ECG abnormalities were recalled from Palmarito Community and referred to the second level Camiri Hospital, where physical examination and chest X-ray were performed. All 22 patients had CD diagnosis confirmed by Chagatest Lisado ELISA (Wiener Laboratories, Rosario, Argentina), performed at the "Elvira Wunderlich" Health Center, Santa Cruz, Bolivia. Of these, two patients had cardiomegaly on the chest X-ray and were referred to further third level examinations. The first person was a 45-year old man, active smoker with history of chest pain; his ECG showed sinus bradycardia with a RBBB. The second person was a 59-year old woman, with history of palpitations, leg edema, chest pain, and loss of consciousness; at ECG, a RBBB and low voltages were present (Figure 1A–C). People with positive CSP, but normal ECG findings, were referred to the Chagas National Program for serological confirmation and possible benznidazole treatment, and managed according to their guidelines [15].

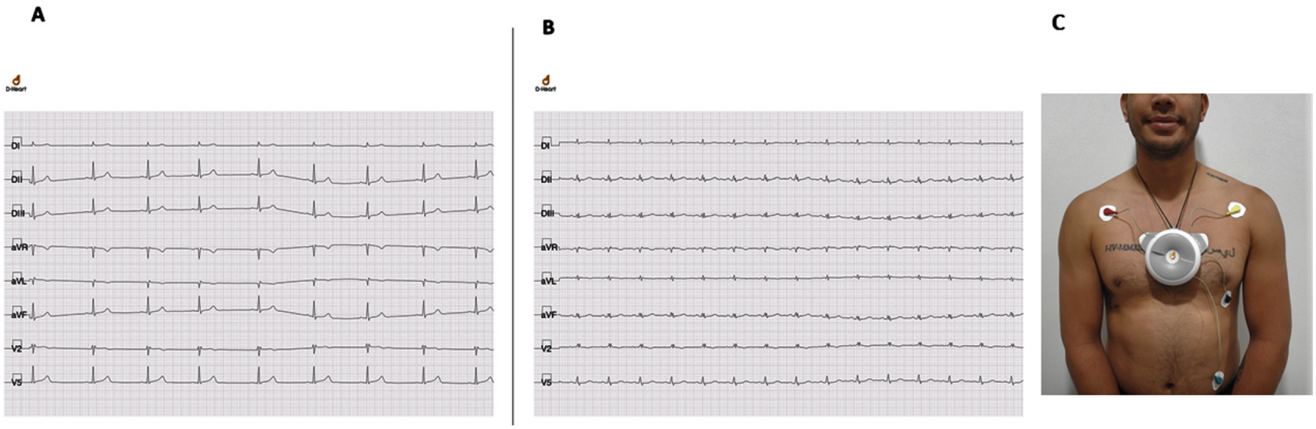

Figure 1. ECG samples of patients referred to further second level examinations and Smartphone ECG device used in the screening activities. (**A**) 45-year old man, active smoker with history of chest pain; his ECG showed sinus bradycardia with a RBBB; (**B**) 59-year old woman, with history of palpitations, leg oedema, chest pain and loss of consciousness; at ECG, a RBBB and low voltages were present. (**C**) Patient during screening activities with D-Heart Smartphone ECG device operating. The D-Heart device can record either 8- or 12-lead ECGs. In the 8-lead setting, DI, DII, and DIII leads are directly measured, as well as precordial unipolar leads V2 and V5. Augmented leads aVR, aVL, and aVF are calculated by definition. In the 12-lead settings, the unipolar electrode in V5 is sequentially placed in V6, V4, V3, V1 position to acquire all the precordial recordings.

Two models for cost effectiveness analysis were developed. The first one, comprising start-up and operative costs, is summarized in Table 4. For a 6-day screening for a community of 150 inhabitants, the overall start-up amount was projected to 4.82$/patient and to 8.23$/patient when operative costs (i.e., on-site nurse and healthcare assistant with remote physician on call) were included. For the second model, intended to predict cost of screening continuation, an average of 5.13$/patient was estimated.

Table 4. RDT and ECG screening model for 150 Individuals for a 6-day screening.

Start Up Cost				
	Item	**Cost/Unit**	**Units Needed**	**Total Cost ($)**
Consumables	D-Heart	280	1	280
	Smartphone	200	1	200
	Electrodes	0.12	150	18
	Blood Pressure Cuff	20	1	20
	Rdt	1	150	150
	Disinfection Kit	2	5	10
	Data Plan (Sim Card) 10 GB for 30 Days	40	1	40
Operative Costs	Nurse	100	1	100
	Healthcare Assistant	60	1	60
	Remote Physician	330	1	330
	Transportation (200 Km)	11	6	66

4. Discussion

In this study, we evaluated the feasibility of a combined mobile-health electrocardiographic and rapid diagnostic test screening for Chagas-related cardiac alterations in a in a low-income setting, hyperendemic for CD. Subjects screened with ECG were also tested for the presence of *T.cruzi* antibodies, by an easy-to-use RDT.

In the surveyed community, seroprevalence for *T. cruzi* was 70%, and its distribution by age-class was consistent with previously reported data from this [3,4].

More than one in five patients with CSP positive serology showed ECG abnormalities compatible with CChC (n = 22/98, 22%), in line with the estimate that 20–30% of infected individuals eventually develop heart disease. The most common findings were ventricular conduction defects, including RBBB and left anterior fascicular block. Moreover, we observed a number of ECG with fragmented QRS, considered as a predictor of arrhythmic events in patients with ischemic and non-ischemic cardiomyopathy, previously reported to be highly prevalent among patients with advanced CChC [6,7]. Other abnormalities included AVB and rhythmic disturbances, which are typical CChC manifestations, and low QRS voltage, which has been previously identified as a strong predictor of the risk of death from cardiac causes in CD patients [12].

Notably, 2 of the 22 individuals with positive ECG and CSP were referred for further medical evaluation: in both cases, ECG showed at least two alterations and chest X-ray was abnormal. Multiple ECG abnormalities have already been described as highly prevalent in patients with signs of dilated cardiomyopathy at echocardiogram [12].

Overall, our observations strongly emphasize the potential application of mHealth technology and telemedicine, together with RDT, to improve access to diagnosis and treatment for CD and CChC in remote areas of the rural Bolivian Chaco. In fact, although a pilot study, simultaneous screening by CSP and D-Heart electrocardiograph resulted feasible, with a cost/patient < 10$ to start up.

The combined, on-field use of RDT and ECG in large-scale screening campaigns could play a pivotal role within a more comprehensive strategy against CD. Early diagnosis of CD is of paramount importance to start treatment before symptoms progress. In remote regions, easy-to-use RDTs, which use whole blood from digital puncture as sample, would ease access to CD diagnosis, allowing timely treatment.

Recently, the use of combined RDTs was shown to be a reliable and accurate alternative to conventional serological assays in order to achieve a conclusive CD diagnosis, in settings where equipped labs and trained personnel are not available [13].

The role of antitrypanosomal treatment in adult patients with established CChC remains controversial. So far, the only published placebo-controlled trial in adults with advanced CChC concluded that benznidazole treatment did not affect the clinical progression of Chagas cardiomyopathy, but important methodological bias has been raised [16,17]. Ideally, etiological treatment should be offered timely in adult patients with chronic Chagas disease before established cardiac damage requires more aggressive management [18,19]. Furthermore, recently published studies support benznidazole use in standard treatment in addition to new alternative regimens for short-course and combination treatments [20].

Screening campaigns that result in early therapy inception are, however, successful as long as effective vector control activities can be achieved, and intensive care be delivered to individuals in need.

As a case in point, in 2013, blanket insecticide application was shown to decrease the force of infection in the Bolivian Chaco, though active transmission remained [3,21,22]. Moreover, several pharmacological and non-pharmacological interventions are currently available and have been increasingly used in CChC patients with the intention of preventing or delaying complications [23].

As part of the study protocol, ECG recordings were sent to Florence for analysis. It is tempting to hypothesize that, should combined (ECG and RDTs) screening programs be further implemented, ECGs could be seamlessly transmitted to local cardiologists or community physicians with the intention to monitor individuals through time and create electrocardiographic and serologic 'profiles' to detect conversion (Figure 2A,B).

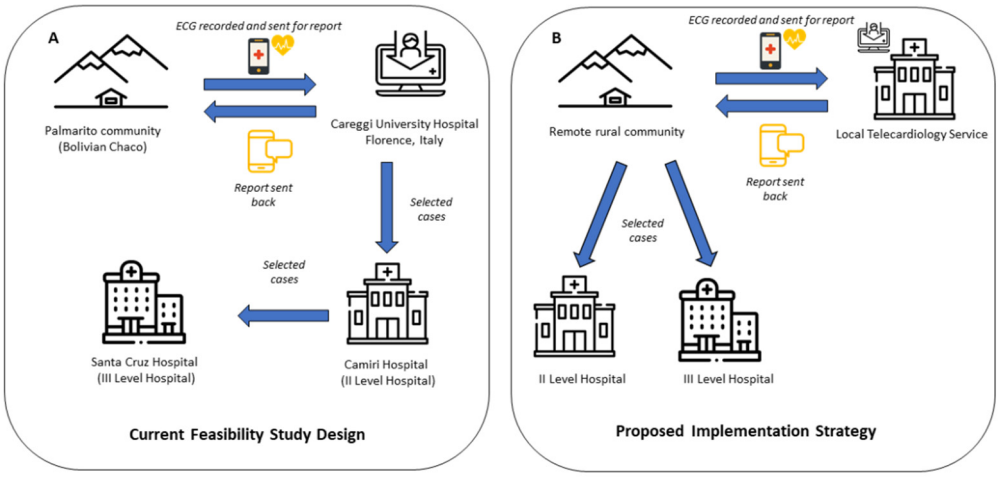

Figure 2. Current Study Design and Proposed on site implementation strategy. (**A**) Current study design is summarized. Specifically, patients are screened on site, in a community of the Bolivian Chaco. ECGs are sent to Telecardiology Service in Careggi University Hospital, Italy and reports are back on site; in case of need, patients with a pathologic ECG were recalled back in the community and referred to the nearest second level Hospital in Camiri (distance 80 km). Patients requiring higher level of care were further referred to a III level Hospital in Santa Cruz (distance 250 km). (**B**) Proposed implementation strategy is described. Patients are screened on site and ECGs are sent to a local telecardiology service; in case of need, patients with a pathologic ECG are recalled back in the community and referred to a second or third level Hospital, according to their condition.

Finally, pocket echocardiography integrated mHealth device assessments are now under scrutiny for potential applications in resource-limited settings. In a randomized trial enrolling 253 patients at a tertiary care center in Bangalore, India, patients who were randomly allocated to a m-health clinic for valvular and structural heart disease, as opposed to standard of care, were associated with shorter time to definitive therapy [24].

In this scenario, adding such instruments to CD screening would allow to reduce lag from infection to diagnosis, increase access to therapy and improve outcomes in patients with signs compatible with early cardiomyopathy, thus limiting disease progression and morbidity.

Ultimately, our effort may focus on bringing high-tech instruments at low-cost for effective remote screening therefore allowing for appropriate and timely diagnosis.

The study has limitations. The healthy volunteers were not randomly selected, but consecutively enrolled in the Health Centre. Severely ill community residents may have been unable to report to the health Centre for evaluation. Moreover, screening for CD was made on a single RDT, namely, CSP assay, which is in use as standard tool for Chagas disease screening by the Chagas National Program since 2005 and showed an excellent performance in the same geographical area [13,14]. Only people with potential CD-related ECG abnormalities (n = 22) were referred to a secondary level hospital for further investigations, including serology confirmation by ELISA testing. People with positive CSP, but normal ECG findings, were referred to the Chagas National Program for serological confirmation and were offered benznidazole treatment, but such data were not collected, being beyond the objective of the study.

5. Conclusions

Early diagnosis of CD and CChC is of paramount importance to provide access to targeted therapy (currently <1% of all seropositive subjects) and maximize treatment benefits. Combined mHealth and RDTs may prove reliable and effective low-cost strategies, especially in rural, highly endemic environments like the Bolivian Chaco, to identify patients at high risk of disease and in need of further cardiologic assessment. Further

studies are clearly needed to assess if these theoretical advantages are supported by patient-centered outcomes and positive cost–benefit analysis.

Author Contributions: Conceptualization, M.S. (Michele Spinicci), C.F., N.M., M.R., I.O. and A.B.; methodology, M.S. (Michele Spinicci), C.F., N.M., M.R., I.O. and A.B.; validation, H.G., R.V., M.S. (Marianne Strohmeyer), I.O. and A.B.; formal analysis, M.S. (Michele Spinicci), C.F. and N.M.; investigation, E.G., M.R. and V.P.; resources, N.M., H.G., M.S. (Marianne Strohmeyer), V.P. and R.V.; data curation, M.S. (Michele Spinicci), C.F., N.M., V.P. and E.G.; writing—original draft preparation, M.S. (Michele Spinicci), C.F. and N.M.; writing—review and editing, M.S. (Michele Spinicci), C.F., N.M., I.O. and A.B.; supervision, H.G., R.V., I.O. and A.B. All authors have read and agreed to the published version of the manuscript.

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Institutional Review Board Statement: The study was conducted according to the guidelines of the Declaration of Helsinki, and approved by a local Ethics Committee (Colegio Médico de Santa Cruz, TDEM CITE No. 008/2018).

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The data presented in this study are available on request from the corresponding author.

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Conflicts of Interest: N.M. owns shares of the social vocation start-up D-Heart srl. The other authors declare no conflicts of interest. The funders had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript; or in the decision to publish the results.

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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-partecipation 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 iRBB. 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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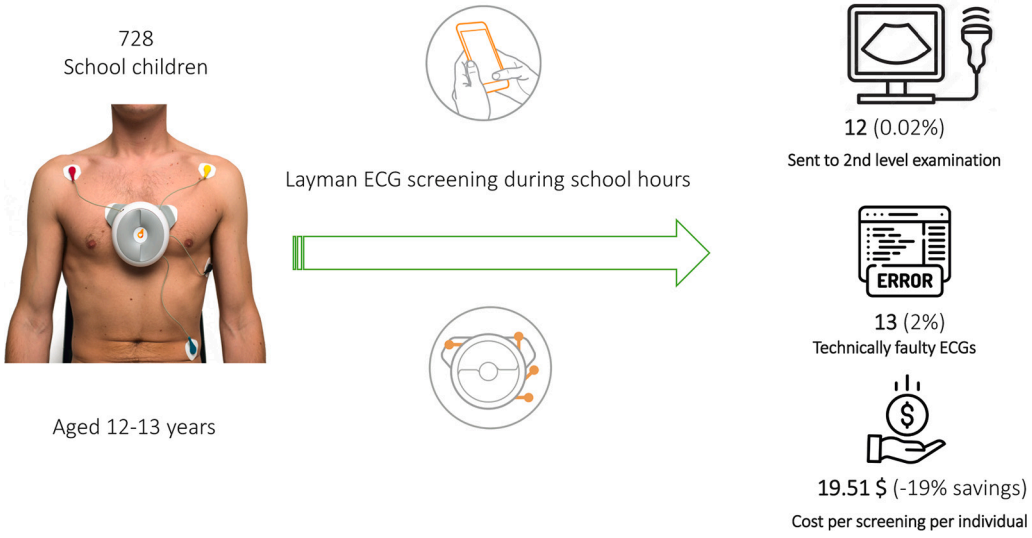

Fig. 1. Feasability of Layman ECG screening in school children using smartphone based technologies.

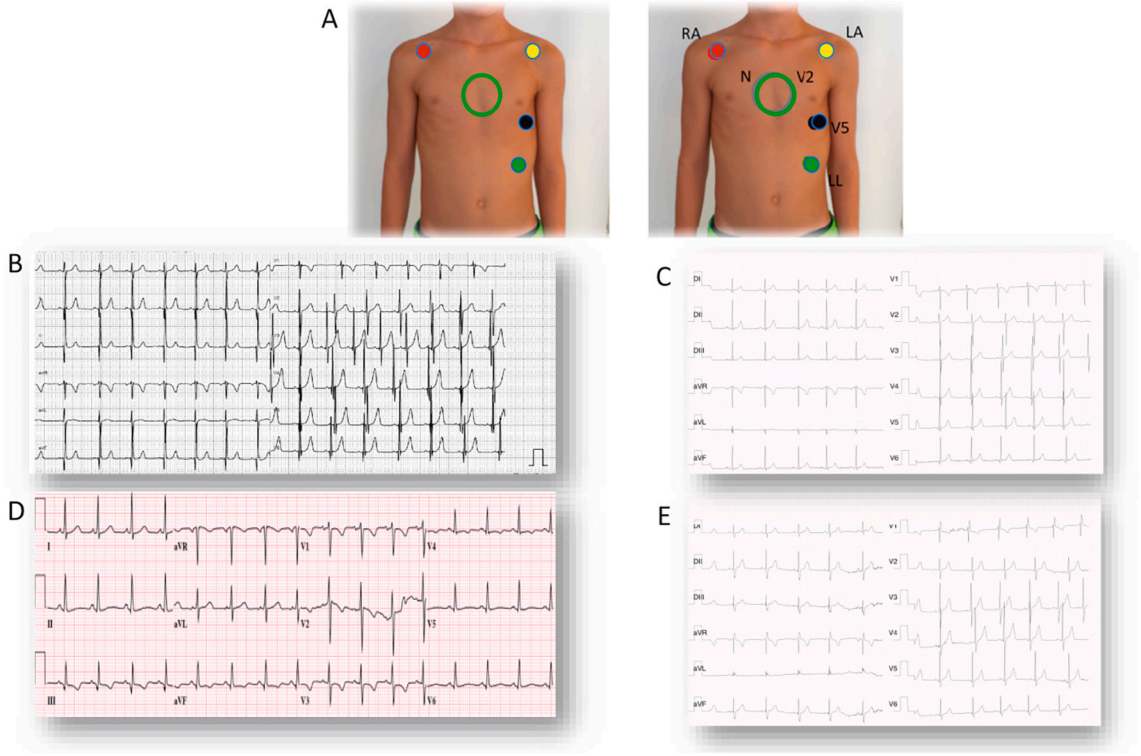

Fig. 2. Electrode placement algorythm and ECG tracings.
Panel A shows the identification by the smartphone camera of the correct electrodes placement on the chest of the screened school children. In panel B, a 12-lead ECG showing inferior deep Q waves is shown. Panel C presents a normal tracing of 13 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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Letters to the Editor

Feasibility of Using the Metaverse as Telecardiology Platform: Remote Follow-up of a Patient With Vasospastic Angina

To the Editor:

Since the metaverse was introduced, there have been ongoing discussions regarding its potential impact on health care.[1] Being an interactive virtual environment using augmented reality (AR) and virtual reality (VR), the metaverse can be also conceived as a potential telemedicine platform. As its use for medical purposes has not been investigated yet, we evaluated the feasibility of performing a telecardiology consultation, combining the use of the metaverse with telemedical devices.[2]

A digital consultation room was created inside the Aimedis (Venlo, Limburg, The Netherlands) metaverse platform (General Data Protection Regulation [GDPR]-compliant, Conformite Europeenne [CE] medical device). Patient and doctor were given secured login access account to interact with virtual avatars and Oculus Quest-2 (Menlo Park, CA) VR headsets. Integration of the portable D-Heart (Genoa, Liguria, Italy) smartphone-based 12-lead electrocardiography device was performed in the virtual room.[3]

A 30-year-old obese male patient presented for resolved recurrent episodes of cardiac chest pain at rest, without

Figure 1. The first cardiology consultation in the metaverse via avatar-based patient-doctor interaction. (**A**) The doctor interprets using an avatar in real time the electrocardiogram (ECG) derived from the smartphone device that is directly integrated to the metaverse consultation room. (**B**) Via avatars, the doctor discusses the symptoms in real time with the patient and shares the diagnosis based on the ECG and medical history.

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electrocardiographic (ECG) abnormalities, normal laboratory tests and echocardiography. Coronary angiogram excluded the presence of coronary artery disease and showed partial (50% to 70%) constriction of the right coronary artery (RCA) to acetylcholine, suggesting a diagnosis of possible vasospastic angina. As no ECGs were available during the angina episodes, the patient was discharged under treatment with diltiazem and instructed to use the metaverse platform, coupled with the smartphone ECG, device in case of symptoms.

At day 10 from discharge, the patient experienced palpitations and general discomfort. He logged into the metaverse in which the cardiologist was available. The anamnesis of the episode was collected, and he was instructed to autorecord and share the 12-lead ECG, blood pressure (BP), and oxygen saturation (Fig. 1; Video 1, view video online). Although clinical and ECG data were reassuring and consistent with anxiety (comparable ECG, BP 135/93 mm Hg, oxygen saturation 97%), the cardiologist recommended an evaluation in the emergency department. Hospital workup results, including laboratory analysis and 12-lead ECG, were consistent with the diagnosis provided during the metaverse consultation.

The current remote virtual consultation of a young patient with possible vasospastic angina, supported by clinical and ECG parameters, showed the feasibility of combining metaverse AR-VR with existing telemedicine innovations to empower decentralized medical care.[2,3] As the adoption and diffusion of the metaverse is predicted to increase exponentially,[1] its potential use as certified medical platform interconnecting diverse telemedicine innovations might overcome 1 of the limiting factors of telemedicine diffusion: that is, the need to adopt different platforms with specific technological needs for different purposes.[4] Further studies are needed to understand whether the use of the metaverse as a telemedical platform can be cost effective and diagnostically relevant.

Ethics Statement

Written informed consent has been obtained from the participants included in the study.

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Disclosures

Dr Maurizi and Nicolo Briante are shareholders of the social-vocation startup D-Heart Biomedical Company. Dr Kaldasch is a shareholder and chief executive officer of the Aimedis B.V. The other authors have no conflicts of interest to disclose.

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Supplementary Material

To access the supplementary material accompanying this article, visit the online version of the Canadian Journal of Cardiology at www.onlinecjc.ca and at https://doi.org/10.1016/j.cjca.2022.07.020.

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Validation of a multiple-lead smartphone-based electrocardiograph with automated lead placement for layman use in patients with hypertrophic cardiomyopathy

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ABSTRACT

Background: A smartphone 12-Lead ECG that enables layman ECG screening is still lacking. We aimed to validate D-Heart ECG device, a smartphone 8/12 Lead electrocardiograph with an image processing algorithm to guide secure electrode placement by non-professional users.

Methods: One-hundred-fourty-five patients with HCM were enrolled. Two uncovered chest images were acquired using the smartphone camera. An image with virtual electrodes placement by imaging processing algorithm software was compared to the 'gold standard' electrode placement by a doctor. D-Heart 8 and 12-Lead ECG were obtained, immediately followed by 12-lead ECGs and were assessed by 2 independent observers. Burden of ECG abnormalities was defined by a score based on the sum of 9 criteria, identifying four classes of increasing severity.

Results: A total of 87(60%) patients presented a normal/mildly abnormal ECG, whereas 58(40%) had moderate or severe ECG alteration. Eight(6%) patients had ≥1 misplaced electrode. D-Heart 8-Lead and 12-lead ECGs concordance according to Cohen's weighted kappa test was 0,948 ($p < 0,001$, agreement of 97.93%). Concordance was high for the Romhilt–Estes score ($k_w = 0,912$; $p < 0.01$). Concordance between D-Heart 12-Lead ECG and standard 12-Lead ECG was perfect ($k_w = 1$). PR and QRS intervals measurements comparison with Bland-Altman method showed good accuracy (95% limit of agreement ±18 ms for PR and ± 9 ms for QRS).

Conclusions: D-Heart 8/12-Lead ECGs proved accurate, allowing an assessment of ECG abnormalities comparable to the standard 12-lead ECG in patients with HCM. The image processing algorithm provided accurate electrode placement, standardizing exam quality, potentially opening perspectives for layman ECG screening campaigns.

Digital health and telemedicine flourished during the recent pandemic and modified the traditional physical way of patient-doctor interaction by using digital means and the Internet [1]. The global diffusion of smartphone devices is producing profound changes in diagnostics, as much relevant data may now be generated locally by the patient rather than centrally by providers [1,2]. Although the standard 12-Lead electrocardiogram (ECG) is a cost-effective, valuable and non-invasive test, most machines are complex, relatively expensive and require the supervision by healthcare professional. Moreover, up to 15% of out of hospital ECGs may present technical errors like limb lead switching, abnormal voltage standardization and improper precordial lead placement [3,4]. Several intuitive, accurate and validated smartphone ECG devices are available on the market, but none has been designed or approved to operate as a standard 12-Lead ECG in the hand

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of layman users [5,6]. These aspects become relevant for large screening campaigns, in resource-limited settings or in vast and low populated regions, where local health center often is the first point of contact [2].

D-Heart 8/12 Lead ECG is a multiple lead ECG device that a dedicated App is able to record, display and store ECG tracings. Correct ECG execution is guided by an image processing algorithm that uses the smartphone camera, to minimize errors by layman patients. Users frame their own chest with the smartphone and the image processing algorithm displays the correct anatomical electrode location by recognizing patient's shoulders and other anatomical landmarks [7].

In the presented study, we aim to validate the D-Heart 8/12-Lead ECG device and automatic electrode placement software, as compared to the standard 12-Lead ECG in patients with hypertrophic cardiomyopathy (HCM), the most common inherited heart disease, characterized by severe ECG abnormalities [8]. ECG is considered to be an excellent tool for screening and monitoring in these patients [8] and is even more sensitive than ultrasonography in the identification of affected family members [9].

Methods

Consecutive patients with a diagnosis of HCM referred for outpatient evaluation at a referral national institution for cardiomyopathies were enrolled. All patients were older than 18 years old. Patients with paced ventricular rhythm at the time of the ECG were excluded from the study. Informed written consent for the study participation and the publication of the images was acquired for each patient. The study was approved by the local ethics committee (Comitato Etico Area Vasta Centro Toscano, *protocol number SPE 16.211*).

D-Heart 8/12 lead ECG device and app

The D-Heart 8/12 Lead ECG device was conceptualized as a device for electrocardiographic screening in resource limited settings. It is constituted by a battery-powered device for ECG measurement on multiple leads (three peripherals and two precordials (V2 and V5)) connected through the use of Bluetooth low energy to a smartphone with a dedicated App (Fig. 1). The device was created for the electrocardiographic measurement allowing the user to perform standard 8-Leads setting (arrhythmias diagnosis or monitoring) and/or in 12-Lead ECG setting. In the latter, the standard 8-Lead ECG is coupled with the sequential asynchronous recording of 6 s ECG from each precordial position (V6, V4, V3 and V1) by V5 electrode misplacement (Fig. 1). The front end is constituted by 3 Sigma Delta modulators able to sample the ECG signal and then filter the signal in a digital way. The module Bluetooth Low Energy is able to send data to the smartphone or Tablet deputy to the ECG signal display, whereas Lithium battery ensures the functionality during measurement.

The dedicated App, for iOs and Android systems, contain an image processing algorithm that uses the smartphone camera to guide the correct electrode placement on the patient's chest. Once the user frames its own chest with the smartphone, the algorithm identifies and displays the electrodes' theoretical location by recognizing patient's shoulders and other anatomical landmarks. The user, by mirroring his/her image user can proceed to electrode placement (Fig. 1).

Electrode placement performance test

The image processing software performances were validated in the study population. For each patient, two uncovered chest images were acquired using the smartphone camera. No image was acquired from a previous database or contained previously created elements. The first image was processed and virtual electrodes automatically placed by D-Heart App with the imaging processing algorithm software. The second image was stored in a database and virtual electrodes were placed on the chest picture by a trained doctor, blinded to the image processing algorithm results. The two chest images were than compared for assessment of the accuracy of the software in the placement of electrodes,

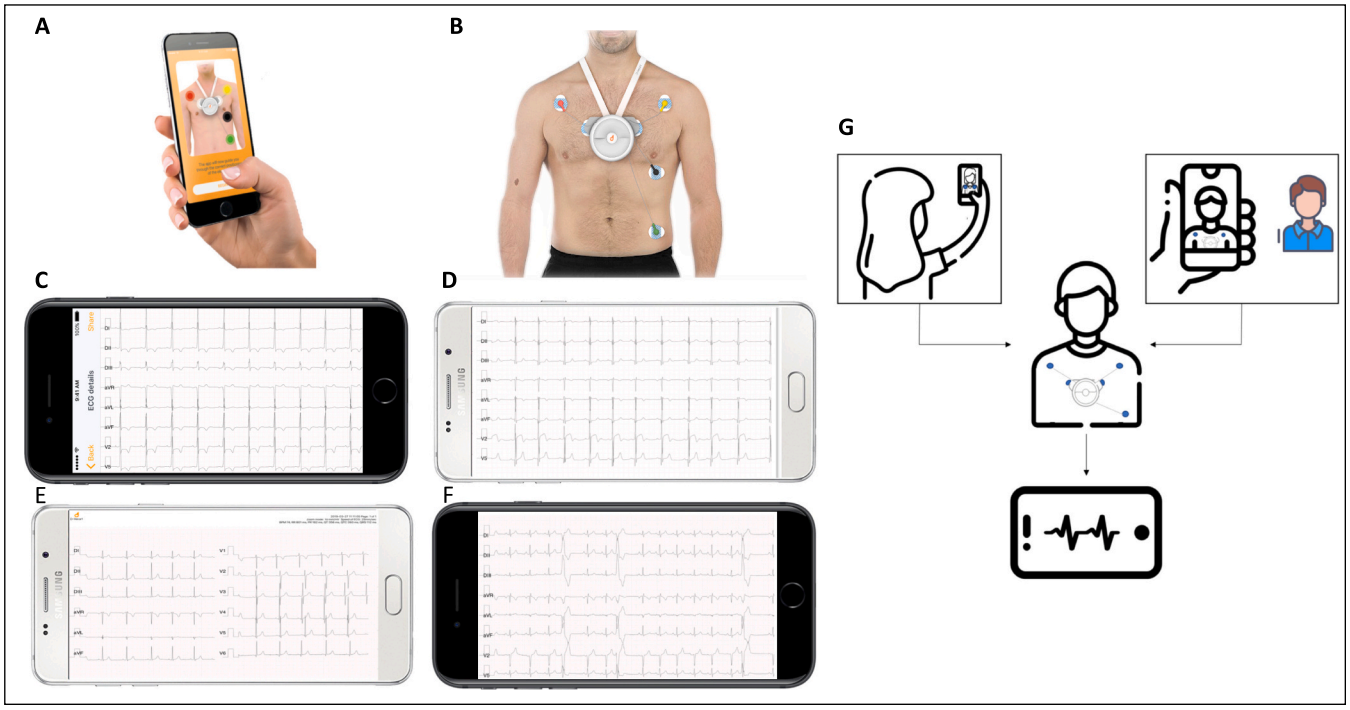

Fig. 1. Multiple Leads Smartphone ECG for layman use.
In Panel A the dedicated App with the electrode placement algorythm is shown. Panel B displays the portable ECG device hardware worn by a patient (circular device with central button). Panel C, D, E and F shows ECG 8 and 12 lead ECG acquired during the study of patients with HCM. Panel G show function of the D-Heart App ECG device: image processing algorythm indicated electrodes placement (bottom right and bottom left), the user wears the ECG device and the ECG is shown on the smartphone.

assuming the doctor electrode placement as the 'gold standard'. Particular attention was dedicated to women, who were instructed to place the electrodes under the breast tissue for V3, V4 and V5 position. For peripheral electrodes (RA, LA, LL) an error within ±3 cm was considered to be acceptable, whereas for precordial electrodes (V1, V2, V3, V4, V5 and V6) an error within ±2 cm was considered satisfactory.

ECGs acquisition

D-Heart 8/12 Lead ECGs and standard 12-lead recordings were subsequently obtained (within 2–5 min) in each subject. Electrode placement performed by the image processing algorithm was used and consumable electrodes were employed. Standard 12-Lead ECG used for the comparison and used as the 'gold standard' was MyCardioPad 12-Lead (Esaote SpA). Severity of ECG abnormalities was defined by a previously validated semi-quantitative score based on the sum of 9 criteria (based on reference 10) by each reader: abnormal cardiac rhythm, QRS duration ≥100 ms, *Romhilt-Estes Score* (R-E) score ≥ 5, fascicular block and/or bundle-branch block, ST-T abnormalities, ST-T segment elevation ≥0.2 mV, prolonged QTc interval, pathological Q waves and absence of normal Q wave. Four ECG group were identified: normal (0 criteria); mildly abnormal (1–3 criteria); moderately abnormal (4–6 criteria); markedly abnormal (7–9 criteria). ECGs from D-heart were assessed by two independent observers (J.I. and C.F.) that categorized in a separate database the ECG abnormalities, whereas two other independent observers (A.F. and N.M.) analyzed the tracings from standard electrocardiograph. PR and QRS intervals were measured manually on printed ECGs by two independent observers (J.I. and C.F.).

Statistics

The primary objective was to determine the concordance between the accuracy of D-Heart 8-L and 12-L ECG readings with respective standard ambulatory 12-L ECG readings.

To obtain a level of tolerance β (probability of judging the measurements incorrectly discordant) equal to 0.99 with a first type error of 0.05, at least 110 cases were required. Considering a possible 20% drop out, a total of at least 145 patients were recruited.

The sample was described by means of the usual descriptive statistics: for continuous variables by mean, standard deviation or median and interquartile range, when appropriate and for categorical variables by proportions. The concordance between electrode placement algorithm and doctor's placement was assessed by the weighted k_w-Cohen index, with its relative significance, taking as the endpoint variable the doctor's placement.

The concordance between D-Heart 8 and 12 Lead ECG readings and the standard 12 lead ECG readings was assessed by:

- the weighted k_w -Cohen index, with its relative significance, taking as the endpoint variable the ECG group;
- the Bland-Altman method, with a 95% confidence level, for the PR and QRS interval measurements. Since differences between the two measurements did not follow a normal distribution, a non-parametric approach (median value and 2.5^ and 97.5^ percentiles) was used to determine the limits of agreement.

P values were two-sided and considered significant at the 0.05 level. All analyses were performed using SPSS/for Windows, version 20.

Results

Clinical and echocardiographic profile

The 145 consecutive HCM study patients were 51 ± 16 years old, and 90 (62%) were males. Mean BMI was 23 ± 4 (19 to 28) kg/m2, 125 patients were asymptomatic or had mild symptoms (86%, in NYHA class I-II), 41 (28%) had LV outflow obstruction >30 mmHg at rest and 32 (22%) had atrial fibrillation (AF) (Table 1). Syncope had occurred in 13 (9%) and 19 (13%) had a history of non-sustained ventricular tachycardia (NSVT). Mean Left atrial (LA) diameter was 40 ± 6 mm, with a mean Left Ventricular ejection fraction (LV EF) of 65 ± 9%. Maximal LV thickness was 23 ± 5 mm, and was ≥30 mm in 12 (8%). (Table 1).

Table 1
Clinical characteristics of the 145 HCM patients stratified per severity of ECG abnormalities.

	Variable	Total Cohort (*n* = 145)	Normal / Mildly Abnormal ECG (*n* = 87)	Moderately / Severely Abnormal ECG (*n* = 58)	
Medical History					
	Age (years)	51 ± 16	46 ± 18	52 ± 14	p = 0.03
	Male sex (n)	90 (62%)	52 (59%)	38 (65%)	*p* = 0.45
	NYHA I - II	125 (86%)	80 (92%)	45 (78%)	*p* = 0.02
	NYHA III -IV	20 (14%)	7 (8%)	13 (22%)	p < 0.01
	LVOT Gradient >30 mmHg (n)	41 (28%)	18 (21%)	23 (40%)	p < 0.01
	Syncope (n)	13 (9%)	5 (6%)	8 (14%)	*p* = 0.05
	Non sustained VT (n)	19 (13%)	9 (10%)	10 (17%)	*p* = 0.21
	Myectomy (n)	22 (15%)	4 (5%)	18 (31%)	p < 0.01
	Alcohol Septal Ablation (n)	6 (4%)	2 (3%)	4 (5%)	*p* = 0.78
	Atrial Fibrillation (n)	32 (22%)	11 (13%)	21 (36%)	p < 0.01
Echocardiography					
	LA diameter (mm)	40 ± 6	38 ± 9	43 ± 5	p < 0.01
	EF (%)	65 ± 9	65 ± 9	63 ± 11	*p* = 0.55
	Maximal LV thickness (mm)	23 ± 5	22 ± 6	24 ± 3	*p* = 0.31
	LV thickness ≥ 30 mm (n)	12 (8%)	4 (5%)	8 (14%)	p < 0.01
	Restrictive diastolic pattern (n)	6 (4%)	4 (5%)	2 (3%)	*p* = 0.67

Abbreviations: LVOT = left ventricular outflow tract; VT = ventricular tachycardia on ambulatory ECG; ICD = implantable cardioverter defibrillator; LA = left atrium; LV = left ventricle; EF = ejection fraction; LV = left ventricle; NYHA = New York heart association

A total of 87 (60%) patients presented a normal/mildly abnormal ECG, whereas 58 (40%) had moderate or severe ECG alterations based on the pre-defined score. Patients with abnormal ECG were older (52 ± 14 vs 46 ± 18 years, $p = 0.03$), more symptomatic (13 (22%) vs 7 (8%) in NYHA III-IV, $p < 0.01$) and presented a more severe cardiomyopathy phenotype: they were more frequently obstructive (23 (40%) vs 18 (21%), $p < 0.01$) with a more dilated LA (43 ± 5 vs 38 ± 9 mm, $p < 0.01$) and underwent more frequently septal reduction procedures (18 (31%) vs 4 (5%) for myectomy, $p < 0.01$) (Table 1).

Electrode placement algorithm performance

Electrode placement algorithm was operated in all study patients and an output was given in 145/145 cases. Median placement error for the image processing software was on horizontal and vertical axis

respectively: 0.3 [0.1–1] cm and 0.8 [0.5–1.5] cm for RA; 0.9 [0.9–1.5] cm and 1 [0.5–1] cm for LA; 0.8 [0.5–1] cm and 0.7 [0.3–1] cm for LL; 0.8 [0.5–1] cm and 1 [0.5–1.5] cm for V1; 1 [0.2–1.3] cm and 0.2 [0.1–0.5] cm for V2; 0.8 [0.5–1] cm and 0.8 [0.5–1] cm for V3; 0.4 [0.1–1] cm and 0.5 [0.4–0.8] cm for V4; 0.6[0.3–1] cm and 0.4 [0.2–1] cm for V5; 0.4 [0.3–1] cm and 0.9 [0.8–1.2] cm for V6 (Table 2, Fig. 2).

Eight (6%) patients had at least 1 electrode misplaced 1 isolated RA misplacement, 3 isolated V1 misplacement, 2 combined V4 and V6 misplacement, 1 combined V1, RA, LL misplacementand 1 case with RA, LL, V4 and V5 misplacement (Table 2, Fig. 2). Of these, 7 were females and 5/7 with BMI > 24 (mean BMI 27 ± 2 kg/m2). The one male patient with at least one electrode misplaced, had a normal BMI.

Weighted Cohen's kappa (k_w) test showed a concordance of 0,902 (p ⟨0,001) with an agreement of 93.88% between the two techniques.

D-Heart 8-Lead ECG and Standard 12-Lead ECG

Agreement between readers was obtained in 144/145 (99%) cases with D-Heart tracings and in 143/145 (99%) cases with 12-lead ECGs. When there was disagreement, ECGs, both from D-Heart and standard 12 lead electrocardiograph, were adjudicated by an independent observer (M.T.).

D-Heart 8-Lead and 12-lead ECG tracings were respectively classified as: normal: 9 (6%) vs 9 (6%); mildly abnormal: 75 (52%) vs 78 (54%); moderately abnormal: 50 (35%) vs 48 (33%) and severely abnormal 10 (7%) vs 10 (7%). Weighted Cohen's kappa (k_w) test showed a concordance of 0,948 ($p < 0{,}001$) with an agreement of 97.93% between the two techniques (Fig. 3).

Mean PR and QRS interval measurements from D-Heart tracings and 12 Lead Electrocardiograph were 168 ± 31 ms vs 173 ± 33 and 104 ± 32 ms vs 108 ± 29 ms respectively. Of note, concordance was also high for the *Romhilt-Estes Score* ($k_w = 0{,}912$; $p < 0.01$). Comparison of PR and QRS intervals (Bland-Altman method, non-parametric approach) showed excellent concordance for D-Heart® measurements (95% limit of agreement −18 to +18 ms for PR and − 9 to +9 ms for QRS) (Fig. 4). No misclassification of 1st degree AV block or bundle branch block occurred.

D-Heart 12-Lead ECG and Standard 12-Lead ECG

Agreement between readers was obtained in 143/145 (99%) cases with D-Heart tracings and in 143/145 (99%) cases with 12-lead ECGs.

D-Heart and 12 standard 12-lead ECG tracings were respectively classified as: normal: 9 (6%) vs 9 (6%); mildly abnormal: 78 (54%) vs 78 (54%); moderately abnormal: 48 (33%) vs 48 (33%) and severely abnormal 10 (7%) vs 10 (7%), with a 100% agreement between the two techniques. Of note, concordance was also high for the *Romhilt-Estes Score* ($k_w = 0{,}967$; $p < 0.01$). (Fig. 3).

Table 2
Electrode placement algorythm performance: median errors in placement and number of electrodes misplaced.

	Horizontal axis (cm)	Vertical axis (cm)	Number of electrodes displaced
RA	0.3 [0.1–1] (0–2.5)	0.8 [0.5–1.5] (0–2.5)	2/144 (1.4%)
LA	0.9 [0.9–1.5] (0–2)	1 [0.5–1.0] (0–2)	0
LL	0.8 [0.5–1] (0–2)	0.7 [0.3–1] (0–2)	2/144 (1.4%)
V1	0.8 [0.5–1] (0–2)	1 [0.5–1.5] (0–2)	4/144 (2.8%)
V2	1.0 [0.2–1.3] (0–2)	0.2 [0.1–0.5] (0–2.5)	0
V3	0.8 [0.5–1] (0–2)	0.8 [0.5–1] (0–2)	0
V4	0.4 [0.1–1] (0–2)	0.5 [0.4–0.8] (0–2)	3/144 (2.1%)
V5	0.6 [0.3–1] (0–2)	0.4 [0.2–1] (0–2)	1/144 (0.7%)
V6	0.4 [0.3–1] (0–2.5)	0.9 [0.8–1.2] (0–1.5)	2/144 (1.4%)

Abbreviations: RA: Right Arm; LA: Left Arm; LL: Left Leg.

Mean PR and QRS interval measurements from D-Heart tracings and 12 Lead Electrocardiograph were 170 ± 28 ms vs 173 ± 33 and 104 ± 28 ms vs 108 ± 29 ms respectively. Concordance was also high for the *Romhilt–Estes score* ($k_w = 0{,}952$; $p < 0.01$). Comparison of PR and QRS intervals (Bland-Altman method, non-parametric approach) showed excellent concordance for D-Heart® measurements (95% limit of agreement −20 to +20 ms for PR and − 10 to +10 ms for QRS) (Fig. 4). No misclassification of 1st degree AV block or bundle branch block occurred.

Discussion

Despite the many ways in which telemedicine is transforming healthcare, mHealth faces a number of major challenges. Specifically, the validation of novel technologies represents a critical step in our understanding of whether they can substitute or implement current methodologies [11,12]. With this aim, we assessed the accuracy of the D-Heart 8/12-Lead electrocardiograph, demonstrating that tracings obtained from smartphones may compare favorably with the current gold standard 12-lead in identifying ECG abnormalities.

D-Heart 8/12-Lead ECG device was designed to address the specific need of enabling the performance of multiple lead tracings by layman users. Enabling volunteers with no medical background to perform a correct recording of a 12-lead ECG might expand the use of such exam beyond the hospital settings. Large, low-cost/high-tech ECG screening campaign in resource-limited settings can be designed and implemented as well as and promote early diagnoses in community-based and homecare settings [9,13–15]. Such approach has already been tested in other field of healthcare, such as ophthalmology [16,17], showing impressing results in terms of reliability and cost-effectiveness. One of the main limiting factor to the diffusion of multiple lead ECG screening was the need of trained personnel not only for the interpretation of the tracings but as well for the correct recording of the exam [3]. Up to 15% of the ECGs performed in extra-hospital setting may presents technical errors such as limb lead switching or improper precordial lead placement [4]. Therefore, a process to standardize the correct recording of an exam becomes a priority. The automatic electrode placement algorithm by the smartphone camera has been designed to overcome this limit. By using an image-processing technology present in commercial smartphones, it identifies crucial anatomical landmarks on the patient's chest to guide the user to the correct identification of the electrodes location. The algorithm proved effective with an acceptable average error: ultimately, only 8% of the patients had one or more electrodes misplaced, to a degree that did not compromise the overall adjudication of ECG abnormalities. To our knowledge, van Dam et al. were the only to apply image processing to a dedicated multisensory static camera for the correct electrode positioning during electrophysiology procedure [18]. Despite encouraging preliminary results, the extension of such technique to routine and out of hospital ECG screening is unfeasible. The novel concept that an image processing technology may be used to guide a noninvasive clinical procedure has potential implications for other fields of healthcare [19]. Further work should be done regarding the analysis of female thorax, since 7/8 patients with at least an electrode misplaced were females. Specifically they mostly presented with an increased BMI and challenges in the identification was more pronounced in women with significant breast mass. Despite a dedicated sub-analysis could not be performed in the present investigation, a current ongoing sub-project, using artificial intelligence model is currently investigating the present aspect. Moreover, in the present study, extreme phenotypes were underrepresented, since mean BMI was normal and no patients with a BMI > 30 kg/m2 were enrolled. Such limitations should be addressed before utilization of such device in mass screening campaigns. D-Heart ECG device uses Mason-Likar ECG disposition for seek of simplicity of ECG recording. In this system, chest electrodes are placed in the standard positions, but limb electrodes are transposed to the torso to reduce movement artefacts. Right and left arm electrodes are placed

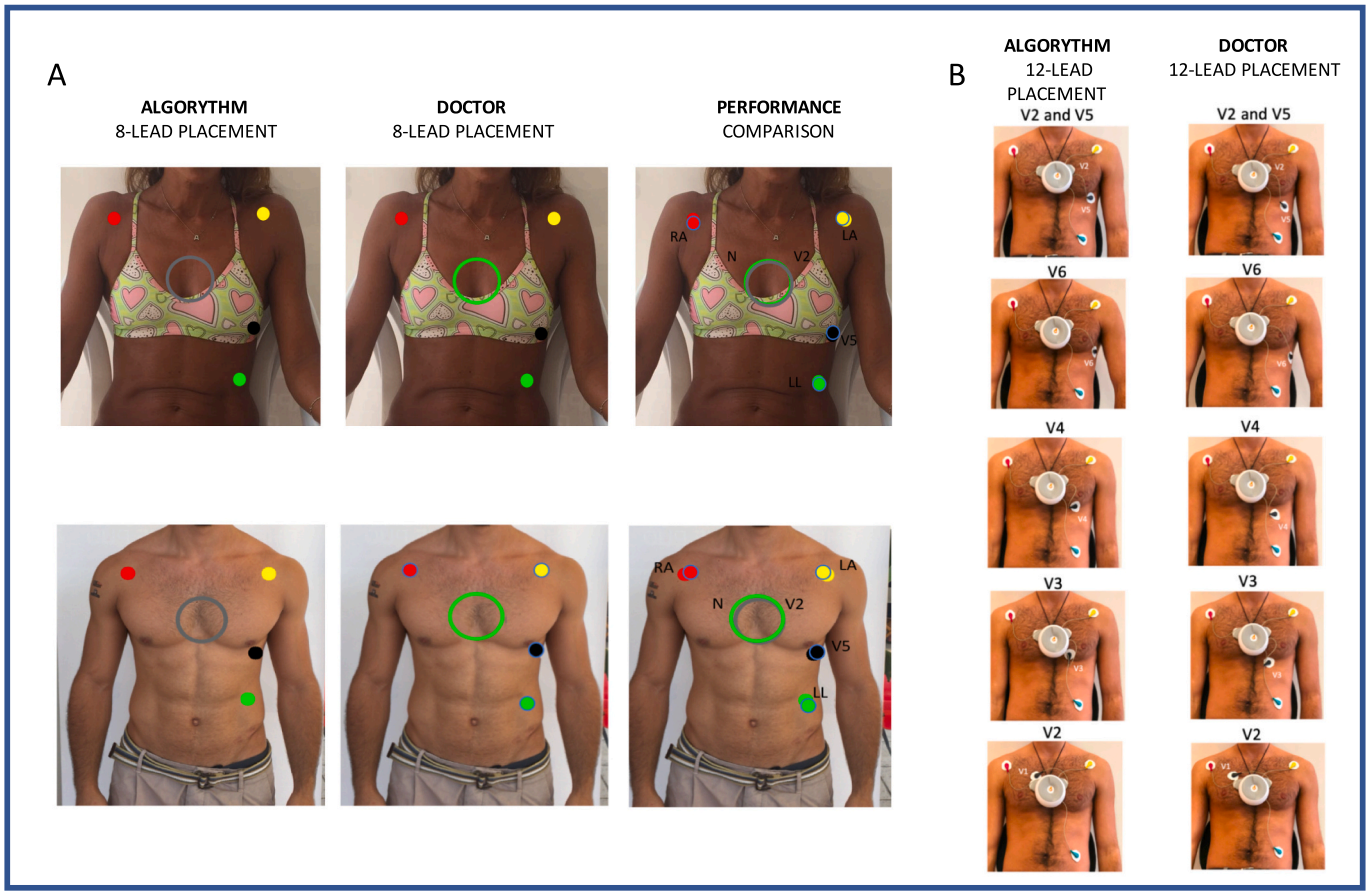

Fig. 2. Image processing electrode placement algorithm performance evaluation.
Panel A shows the performance of the algorithm in the detection of the 8-lead setting. Automatic algorithm's placement, doctor's placement and their comparison are represented.
Panel B represents the performance of the algorithm in the detection of the 12-lead setting. Automatic algorithm's placement and doctor's placement are shown for each precordial electrodes.
Abbreviations: RA: Right Arm; LA: Left Arm; LL: Left Leg; N: neutral or mass electrode.

in the infraclavicular fossae, medial to the deltoid muscle, 2 cm below the lower border of the clavicle. Right and left leg electrodes are kept in the anterior axillary line, halfway between costal margin and iliac crest (Fig. 1). Right lower electrode serves as the ground as in standard 12 lead ECG. This lead system is routinely used for treadmill testing, as well as for real time ST segment monitoring during hospital surveillance. As a result of the electrode positioning, Q waves in the inferior leads may be masked and there is mild right ward shift in the QRS axis. However, none of this characteristics were observed in the present study and no ECG in the 12-lead ECG group was misclassified in different class of abnormalities.

The disease chosen for validation of our algorithm deserves a mention, in view of its characteristic and challenging ECG abnormalities observed in HCM patients, often associated with prognostic implications. Since HCM is the most common cause of sudden death in young athletes, the possibility to screen ample populations employing non-professional personnel appears highly desirable and cost-effective. In our cohort, 40% of patients presented moderate to severe ECG alterations. They were on average older, more symptomatic, more frequently obstructive and with a more dilated left atrium, thereby reflecting a more severe cardiomyopathy phenotype [8]. D-Heart 8/12 Lead ECG proved accurate, allowing stratification of ECG abnormalities comparable to the standard 12-lead ECG also in the identification of LVH. A total of 3 ECGs, were misclassified by D-Heart in the 8-Lead setting, while the 12 lead system showed optimal concordance with the standard 12-Lead Electrocardiograph measurements of PR and QRS interval, with minor differences, below the sensitivity of manual measurement in clinical practice.

Several other smartphone-based electrocardiographs are commercially available, including AliveCor or Cardiosecur [20,21]. They are mostly intended for rhythm analysis and recommended as a screening tool for atrial fibrillation (AF) in high-risk population or to monitor recurrences post AF ablation procedure [22]. Such products are characterized by an extreme usability and have extensively validated for rhythm analysis [23]. Although such devices may be used as a more accessible 'interim' screening tool for arrhythmias (including detection of symptomatic episodes), they cannot replace the 12-Lead ECG in population screening that allows also a morphological assessment. Conversely, the present study represents the validation of a 12-lead ECG mHealth devices allowing layman data acquisition, to potentially promote large and cost-effective screening campaigns. The latter have been historically limited, particularly in the US and Canada, by logistical and economic aspects that can be potentially overcome by validated low-cost/high-tech mHealth devices.

Further studies now are clearly needed to assess if these theoretical advantages are supported by patient-centered outcomes and positive cost-benefit analysis.

Conclusions

D-Heart 8/12-Lead ECGs proved accurate, allowing a stratification of ECG abnormalities comparable to the standard 12-lead ECG in a patient

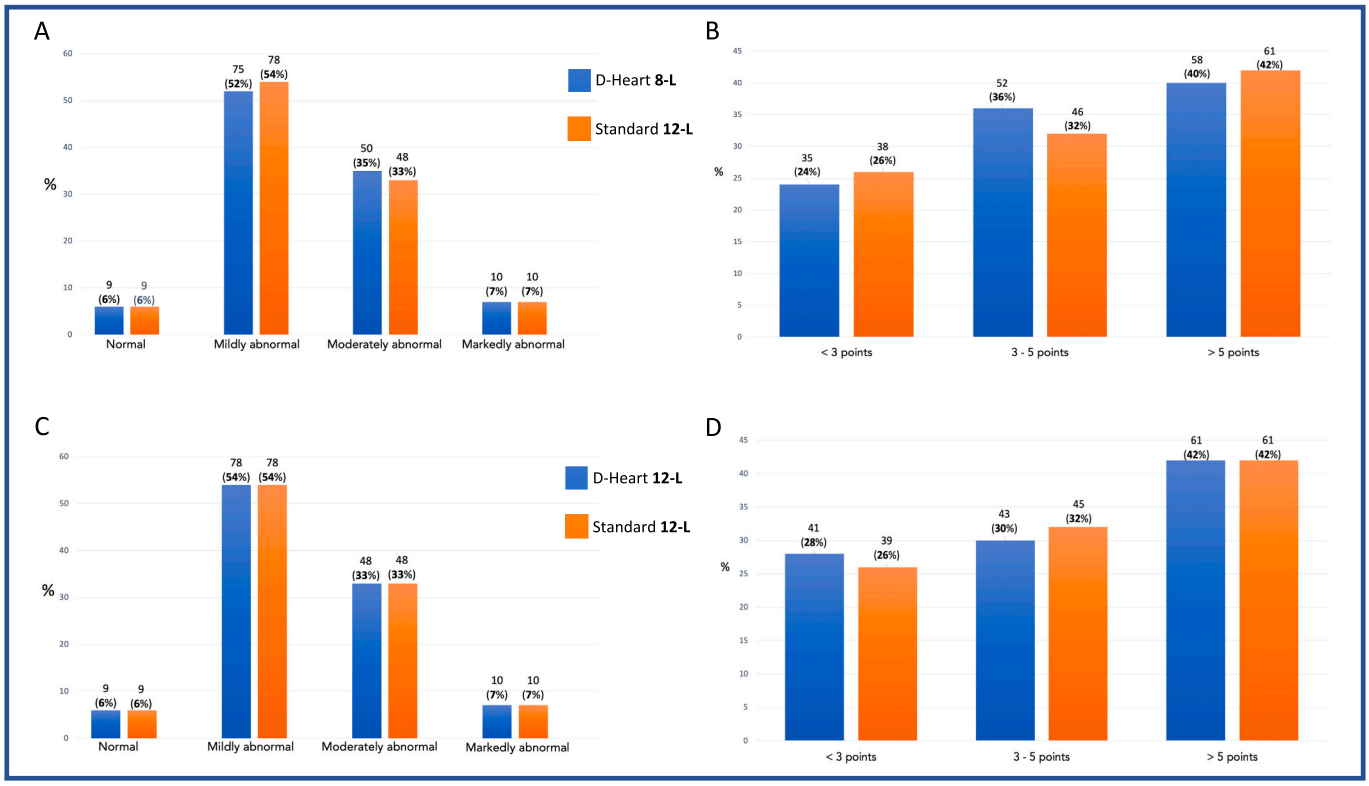

Fig. 3. Severity of ECG abnormalities and Rohmlit-Estes score of ECG recorded with D-Heart device and Standard Ambulatory ECG.
In Panel A and B, comparison results between D-Heart 8-Lead ECG and standard 12-Lead ECG in ECG abnormalities and Romhilt-Estes Score are represented. Panel C and D shows comparison results between D-Heart 12-Lead ECG and standard 12-Lead ECG in grading ECG abnormalities and Romhilt-Estes Score.

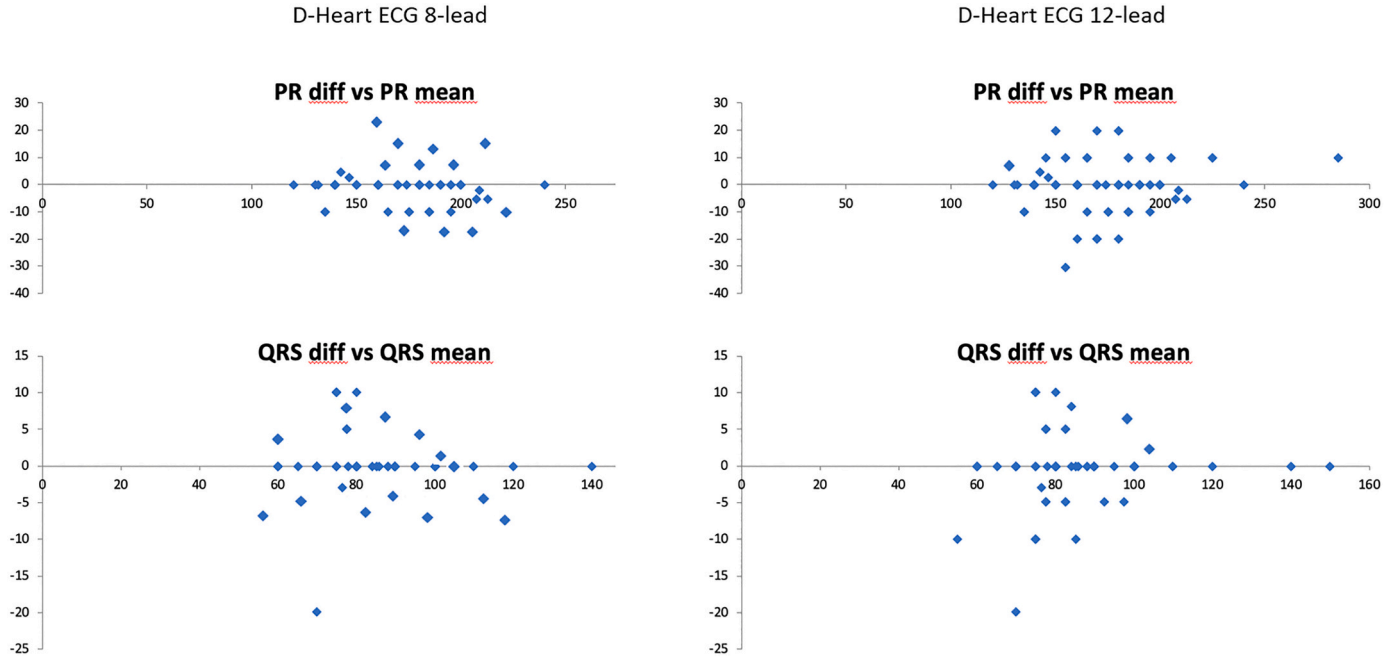

Fig. 4. Bland-Altmann plotting of PR and QRS intervals measurement differences between D-Heart 8 and 12 Lead ECG and standard 12 Lead ECG.
Bland-Altmann plot for PR (top) and QRS (bottom) differences are shown.

with HCM, characterized by high prevalence of abnormal ECGs. The image processing algorithm guided the users to accurate electrode placement, standardizing the exam quality. Novel smartphone-based techniques open promising perspectives for low-cost cardiovascular screening programs. Further studies are clearly needed to assess whether such technologies would have patient-centered outcomes and positive cost-benefit analysis.

Author contribution

NM, CF, AF, MT were involved in patient enrollment, data acquisition and analysis. NM, FC, NM, IO were responsible for project design. IS, HL were involved in the statistical analysis. PM, OM, IO, FC, NM gave critical revision to the manuscript.

Data availability

Data would be available upon acceptable request to the corresponding author.

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Les dispositifs intelligents et l'IA en cardiologie peuvent-ils améliorer la pratique clinique?

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Le monitorage à distance devient de plus en plus populaire parmi les praticiens de la santé pour le diagnostic et la surveillance des maladies cardiaques. Plusieurs dispositifs «intelligents» et connectés aux smartphones ont été développés et validés durant ces dernières années, mais leur utilisation clinique est toujours limitée. Bien que les progrès de l'intelligence artificielle (IA) soient en train de révolutionner plusieurs domaines, l'impact que ces innovations pourront avoir dans le monde médical est toujours inconnu. Le but de cet article est de passer en revue les principaux dispositifs disponibles et de comprendre les applications actuelles de l'IA en cardiologie, afin de mieux saisir dans quelle mesure ils sont susceptibles de transformer notre pratique clinique quotidienne.

Can smart devices and AI in cardiology improve clinical practice?

Remote monitoring is becoming increasingly popular among healthcare professionals and patients for diagnosing and treating heart disease. Several smart devices connected to smartphones have been developed and validated in recent years, but their clinical use is still limited. Significant advances in the field of artificial intelligence (AI) are also revolutionizing several fields, yet the impact that these innovations could have on routine clinical practice is still unknown. We review the evidence and uses of the main smart devices currently available as well as the latest applications of AI in the field of cardiology, with the aim to ultimately evaluate the potential of this technology to transform modern clinical practice.

INTRODUCTION

La santé digitale et la télémédecine ont fleuri pendant la pandémie récente et modifié la façon traditionnelle d'interaction physique entre le patient et le médecin par l'utilisation de moyens digitaux et internet. La surveillance à distance et ambulatoire devient de plus en plus populaire parmi les praticiens de la santé et les patients pour la surveillance et le diagnostic continus à long terme des maladies cardiaques.[1] Les progrès sur les plans du matériel et du logiciel ont conduit au développement de nouveaux dispositifs à la fois pratiques et abordables, permettant la surveillance des populations vulnérables depuis le confort de leur domicile, tout en fournissant des alertes critiques pour les événements nécessitant une attention médicale rapide ou une hospitalisation.[2] Alors que la technologie est devenue essentielle à la médecine cardiovasculaire et que l'intelligence artificielle (IA) ouvre des possibilités dans plusieurs domaines, la contribution de cette technologie à l'amélioration de la pratique quotidienne est inconnue de la plupart des cliniciens. Dans cet article, nous examinons les preuves actuelles concernant les appareils digitaux et l'IA en cardiologie et voyons comment et quand ils peuvent nous aider dans la façon dont nous traitons les patients.

QUELS SONT LES DISPOSITIFS «INTELLIGENTS» ET POURQUOI SONT-ILS UTILISÉS?

Les cardiologues utilisent de plus en plus la technologie pour fournir des solutions de diagnostic et de suivi à distance, en partie grâce à des dispositifs implantables ou portables. Ces derniers permettent la détection précoce d'événements physiologiques critiques, donnant aux patients plus de temps pour demander une aide médicale.[2]

La plupart des preuves dans la littérature sont liées à des dispositifs connectés à un smartphone, capables de générer et parfois d'interpréter un ECG professionnel.[1] Ces dispositifs peuvent être divisés en capteurs portables (wearable) ayant le potentiel de fournir des informations de surveillance et de diagnostic critiques des paramètres physiologiques, et en dispositifs capables d'enregistrer un ECG professionnel sur demande.

De nombreux dispositifs portables ont été introduits pour la surveillance cardiaque à distance et à long terme, mais parmi eux, les montres connectées sont les plus étudiées et validées. La technologie utilisée est la photopléthysmographie (PPG), qui utilise des faisceaux lumineux pour détecter les changements de volume sanguin passant par le poignet. L'intervalle «pic à pic» entre les pulsations peut être interprété comme l'intervalle R-R cardiaque, [3] et si incorporé à un algorithme, il peut détecter la fibrillation auriculaire (FA) (**figure 1**). L'Apple Watch, comparée aux enregistreurs sous-cutanés implantables, a démontré une sensibilité de 87% et une spécificité de 97% pour identifier les patients atteints de FA silencieuse.[4] La montre Google a aussi des performances similaires, avec une

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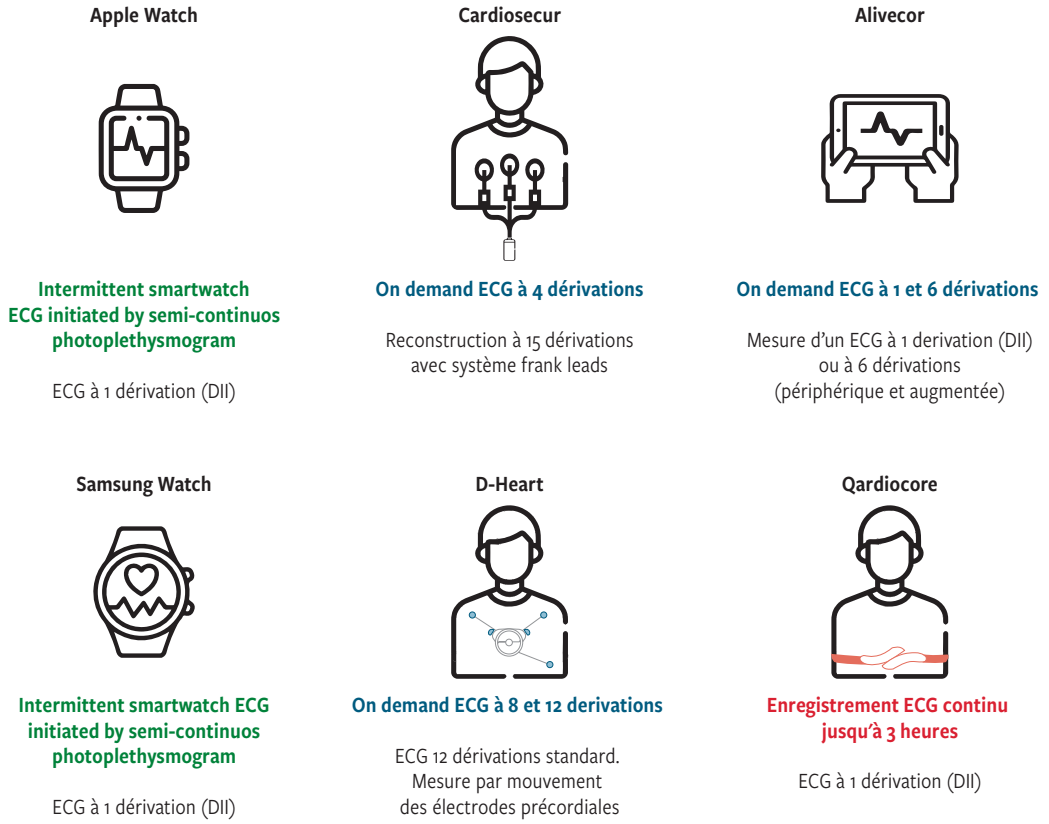
FIG 1 **Caractéristiques techniques des dispositifs ECG pour smartphone**

La figure présente les dispositifs validés et disponibles sur le marché suisse.



sensibilité de 88% et une spécificité de 81% dans l'identification des patients atteints de FA silencieuse (**figure 2**).[5] Ces preuves ont conduit à la recommandation de la Société européenne de cardiologie de proposer ces dispositifs pour le dépistage de la FA (classe d'évidence I, niveau B).[6]

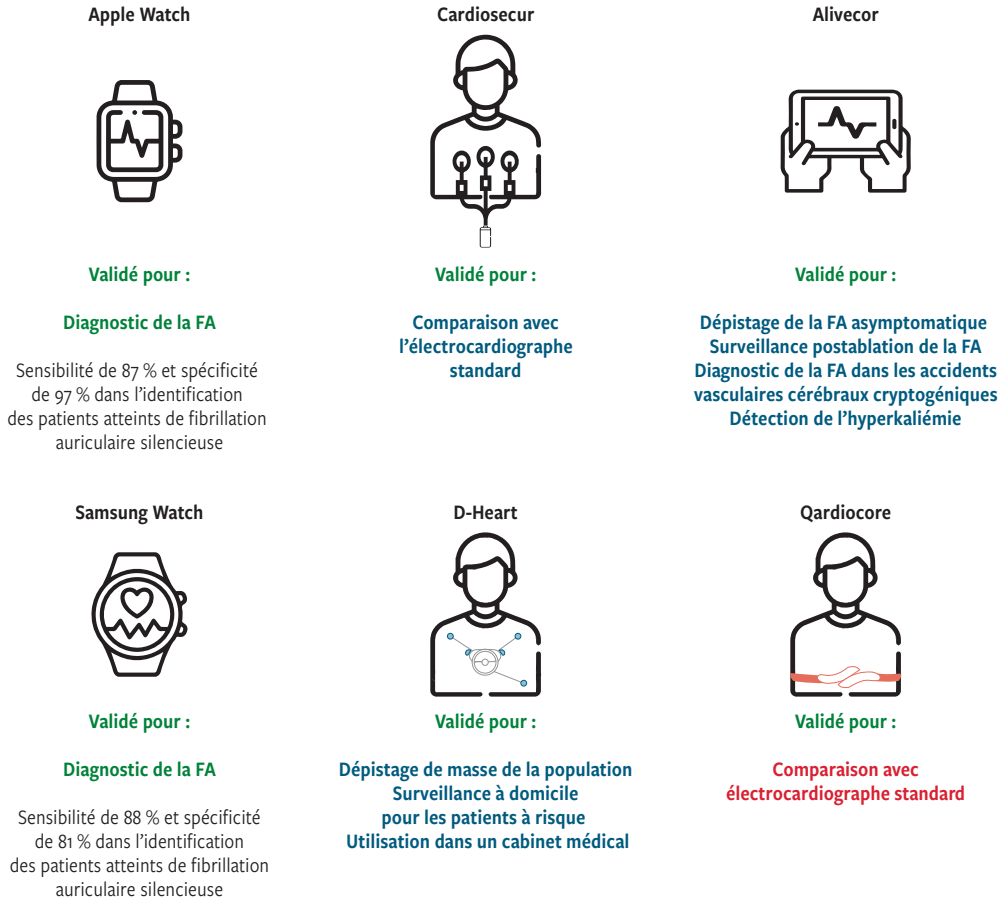
Une autre classe de dispositifs est capable d'enregistrer un ECG professionnel sur demande avec l'aide d'un smartphone. Parmi ceux-ci, Alivecor est un ECG portable capable d'enregistrer un tracé à 1 ou 6 dérivations en utilisant les doigts ou le contact de certaines parties du corps.[7] Il a été validé pour le dépistage de la FA asymptomatique, [7] la surveillance post-ablation d'une FA, [8] le diagnostic de la FA dans les accidents vasculaires cérébraux cryptogéniques[9] et la détection automatique de l'hyperkaliémie.[10] D-Heart est un ECG professionnel basé sur un smartphone capable d'enregistrer un tracé à 8 ou 12 dérivations à l'aide d'électrodes standards (**figure 1**). L'application guide l'utilisateur au placement correct des électrodes sur le thorax grâce à un algorithme d'«image processing» (traitement d'image) lié à la caméra du smartphone.[11] Il a été validé pour le dépistage ECG de masse d'une population saine et de patients avec maladies cardiaques, [11-13] la surveillance à domicile des patients à risque[14] cardiaque et l'utilisation dans un cabinet médical (**figure 2**).[15]

Cardiosecur est un ECG de smartphone à 4 dérivations utilisant des électrodes standards qui permet de reconstruire un ECG à 15 dérivations (en utilisant la méthode de Frank), tandis que Qardiocore est un ECG à 1 dérivation capable de surveillance continue (**figure 1**). Il n'existe aucune validation de cas d'utilisation, ces dispositifs ont seulement été validés en termes de précision par rapport à l'ECG standard à 12 dérivations (**figure 2**).

Enfin, l'introduction de métavers en médecine cardiovasculaire, qui représente la convergence d'un environnement virtuel en ligne immersif interconnecté dans lequel les participants interagiront avec du contenu 3D et des avatars, a été proposée.[16] Le «CardioVerse» a le potentiel d'améliorer la pratique médicale de multiples façons. En premier lieu, en tant que plateforme de télémédecine universelle, mais aussi pour entraîner les patients à la réalité virtuelle ainsi que pour aider les cardiologues interventionnels dans la planification des interventions grâce à la visualisation 3D augmentée des structures cardiaques (**figure 3**).[16] Récemment, un essai de faisabilité a été réalisé concernant l'utilisation de métavers en tant que plateforme de télécardiologie pour le diagnostic précoce et la surveillance des patients cardiaques,[17] permettant l'identification d'un patient atteint d'angine de Prinzmetal. De plus, via un programme d'entraînement en réalité virtuelle dédié dans le métavers, des patients présentant une claustrophobie limitante ont pu effectuer pour la première fois une résonance magnétique cardiaque.[18] Cependant, malgré l'enthousiasme mondial concernant le métavers, ses applications en matière de soins de santé et de médecine cardiovasculaire sont encore limitées à quelques projets et des données

FIG 2 **Indication d'utilisation clinique des dispositifs ECG pour smartphone**

La figure présente les dispositifs actuellement disponibles sur le marché suisse.



supplémentaires sont nécessaires pour calibrer sa mise en pratique clinique.[19]

L'INTELLIGENCE ARTIFICIELLE PEUT-ELLE AIDER LE CARDIOLOGUE?

L'IA fait usage de l'ingénierie et de l'informatique pour produire une intelligence qui simule ou complémente l'intelligence humaine. L'apprentissage automatique (machine learning (ML)) représente pour sa part le cerveau de l'IA, avec le développement d'algorithmes qui exploitent les données et s'améliorent automatiquement avec l'expérience.[20]

Quant au deep learning (DL), il s'agit d'une technique d'apprentissage automatique spécifique, basée sur des réseaux de neurones artificiels entraînés à large échelle (**figure 4**).[21] La puissance de l'IA réside dans sa capacité à extraire des informations utiles de données complexes et potentiellement massives, parfois bien au-delà de ce qui est possible pour les cliniciens humains. Grâce à cette capacité, l'IA a le potentiel d'aider les cliniciens dans le diagnostic, le traitement et la prévention des maladies. Ci-après, nous présentons un résumé des applications récentes de l'IA à l'échocardiographie et à la détection et évaluation de la maladie coronarienne.

IA ET MALADIE CORONARIENNE

Bien qu'il existe divers exemples d'application de l'IA dans le domaine de la maladie coronarienne (MC), cette partie va se concentrer sur les applications récentes de l'IA et, en particulier, sur deux modalités d'imagerie coronarienne: la coronarographie invasive (ICA) et la tomodensitométrie (CT) cardiaque.

L'ICA reste l'investigation «gold standard» pour l'évaluation de la MC. Lors d'une ICA, le cardiologue procède généralement à une évaluation visuelle de la sévérité anatomique d'une sténose coronarienne. Cependant, ces évaluations visuelles sont sujettes à une importante variabilité inter et même intraopérateur,[22] motivant ainsi le développement de la coronarographie quantitative (QCA) pour une quantification plus précise et reproductible du degré de sténose.[22] La segmentation des artères coronaires à partir des images d'ICA est la première étape clé de la QCA. À cet égard, plusieurs études ont proposé des méthodes robustes pour la segmentation des artères coronaires en utilisant des modèles de DL,[23,24] qui est également capable de localiser, segmenter et calculer le pourcentage de sténoses,[25] et même de détecter le type de lésion.[26] Plus récemment, la faisabilité de la détection en temps réel des sténoses coronariennes a même été démontrée.[27]

FIG 3 Applications actuelles du «CardioVerse» en pratique clinique

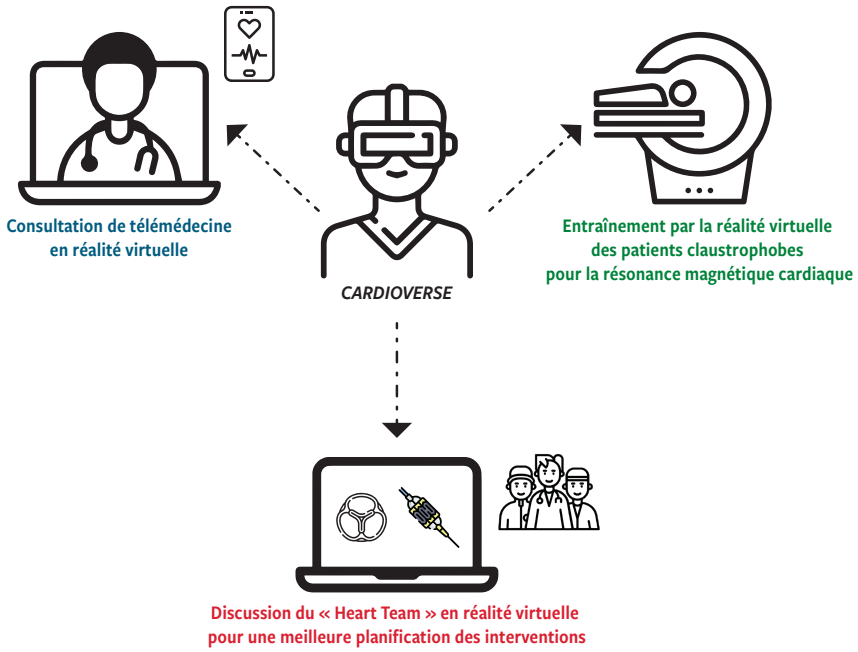
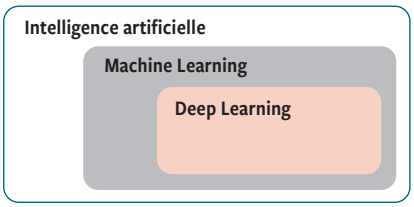


FIG 4 Aperçu de l'intelligence artificielle



Cependant, l'évaluation anatomique n'est pas la seule utilisée dans l'appréciation d'une sténose; les mesures hémodynamiques jouent un rôle important dans l'évaluation des sténoses anatomiquement intermédiaires, comme la fraction de réserve de débit (Fractional Flow Reserve: FFR). Dans cette optique, un algorithme de ML a démontré sa capacité à classifier la FFR (≤ 0,80 vs > 0,80), basé sur des caractéristiques cliniques et angiographiques calculées depuis les images d'ICA.[28]

En outre, nous avons récemment publié la première étude démontrant la capacité du DL à prédire la survenue d'un infarctus depuis les images d'ICA. En utilisant une cohorte de patients ayant subi une ICA pour un infarctus, chez qui une ICA antérieure avait été réalisée dans les 5 ans, notre modèle de DL a surpassé l'évaluation visuelle humaine et les paramètres angiographiques établis (par exemple, diamètre de la sténose) dans la prédiction de la lésion responsable de l'infarctus futur (**figure 5**).[29-31]

Les applications de l'IA dans le domaine du CT coronaire sont déjà relativement avancées. Une approche de ML pour la quantification rapide et automatisée du score de calcification des artères coronaires (CAC) à partir du CT sans contraste a donné des résultats prometteurs.[32] De plus, des études, intégrant les données CAC avec d'autres variables cliniques en utilisant un modèle de ML, ont aussi démontré une valeur ajoutée dans la stratification du risque coronaire.[33,34] Une étude a également présenté un algorithme de DL capable de générer automatiquement des mesures du tissu adipeux épicardique (EAT) (un marqueur pronostique dans la MC) en moins de 30 secondes.[35]

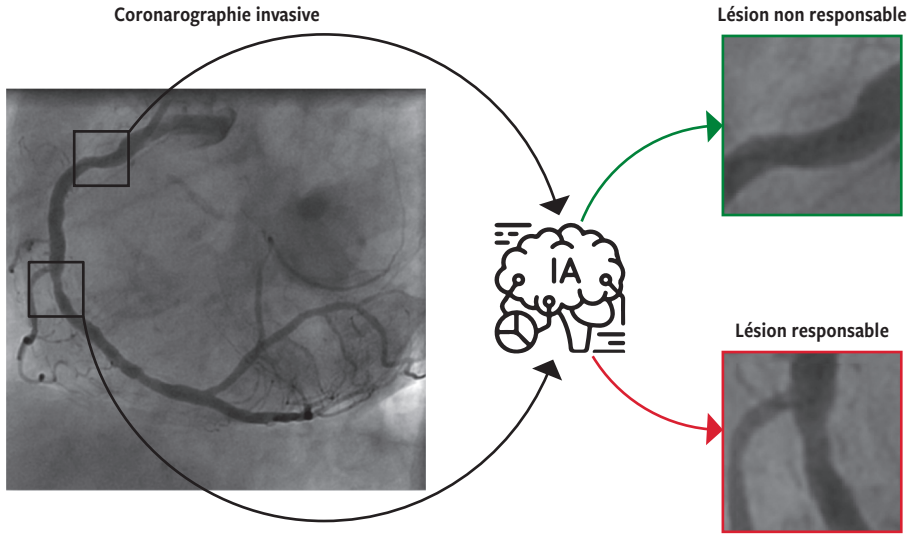
L'IA a également été employée pour stratifier le risque des plaques athérosclérotiques, en utilisant un grand nombre de caractéristiques du CT coronaire avec contraste (CTCA). Un modèle de ML a réussi à identifier des lésions athérosclérotiques à risque, avec une performance surpassant l'évaluation visuelle.[36] Un modèle de ML a également été capable de prédire des événements indésirables en combinant les données cliniques et du CCTA.[37]

Au-delà de l'évaluation coronaire, l'IA a récemment été appliquée afin de détecter et quantifier du tissu adipeux péricoronaire (PCAT) (marqueur de l'inflammation coronaire), et prédire le risque de survenue d'un événement cardiovasculaire.[38] De plus, comme avec l'ICA, l'IA a été également utilisée pour prédire la présence d'une lésion hémodynamiquement significative (tel que décrit plus haut),[39] et même la lésion coupable dans une cohorte de patients présentant un syndrome coronarien aigu évalué par CTCA.[40]

IA ET ÉCHOCARDIOGRAPHIE

L'échographie cardiaque (EC) est la modalité d'imagerie de première ligne pour le dépistage et la surveillance des cardiopathies et valvulopathies. Des outils d'IA ont été développés pour optimiser l'acquisition d'images ou en automatiser l'interprétation, concernant les fonctions systolique et dias-

FIG 5 IA pour prédire la lésion responsable d'un infarctus à partir de la coronarographie



tolique et la présence de cardiomyopathie ou de valvulopathie. L'interprétation de l'EC dépend fortement de la qualité des images acquises et de l'expérience de l'opérateur. Des logiciels basés sur le DL proposent une aide pendant l'acquisition pour optimiser la qualité de l'examen.[41] Lorsqu'utilisée par un personnel médical non spécialisé en cardiologie, la qualité d'image guidée par l'IA a été jugée comme étant de qualité diagnostique dans > 90% des cas.[41] La fraction d'éjection ventriculaire gauche (FEVG) est estimée ou calculée en traçant manuellement le bord de l'endocarde en systole et en diastole, avec une possible variabilité inter et intraobservateur. Le calcul automatisé de la FEVG par un algorithme de ML a montré moins de variabilité, avec une bonne correspondance avec la FEVG déterminée par trois cardiologues (r = 0,95 (p < 0,001; IC: 0,938-0,960)).[42] De multiples paramètres échocardiographiques sont intégrés dans un algorithme diagnostique de la dysfonction diastolique (DD) et des pressions de remplissage élevées. Or, la corrélation avec les mesures invasives des pressions de remplissage n'est que modeste.[43] Des modèles de «Deep Neural Network» ont identifié des phénotypes de patients à risque de DD, avec une meilleure corrélation aux pressions de remplissage.[44] Enfin, un modèle de DL a pu identifier des valvulopathies mitrale et aortique avec une haute précision sur classification et analyse automatiques de vues d'EC et des flux valvulaires (AUC > 0,88).[45] L'utilisation de l'IA en EC est en plein essor, et déjà utilisé sous forme de logiciels commercialisés pour l'acquisition et l'analyse d'images. La force de l'IA naît de la capacité d'analyse des pixels supérieure à l'œil. De futurs modèles d'IA pourraient faire un apprentissage non supervisé des EC, permettant à l'algorithme de déterminer seul les critères diagnostiques importants.

CONCLUSION

Notre pratique clinique est de plus en plus liée à l'utilisation des dernières avancées. Les dispositifs diagnostiques basés sur des smartphones ont démontré la possibilité d'améliorer l'identification de certaines arythmies fréquentes et asymptomatiques, [7-9] ainsi que la possibilité de réaliser des ECG professionnels plus rapidement et dans un milieu non hospitalier.[11-15] Quant à l'IA, elle a le potentiel de révolutionner le domaine du diagnostic de la maladie coronarienne (MC). Son utilisation lors d'une coronarographie va permettre prochainement un traitement plus rapide et plus efficace. De plus, les technologies de l'IA peuvent aider à la prévention de la MC en identifiant les patients ou les lésions à haut risque, particulièrement en utilisant les images du CT coronaire.

Bien que les avantages de l'IA et des dispositifs «intelligents» dans le domaine médical soient encore en cours d'évaluation et qu'il faille davantage valider et interpréter les fonctionnements des algorithmes utilisés par l'IA, il est clair que cette technologie a le potentiel de transformer la manière dont nous diagnostiquons, traitons et prévenons les maladies cardiovasculaires.

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IMPLICATIONS PRATIQUES

- Les dispositifs diagnostiques basés sur des smartphones ont démontré la possibilité d'améliorer l'identification de certaines arythmies fréquentes et asymptomatiques, ainsi que de réaliser des ECG professionnels plus rapidement et dans un milieu non hospitalier.
- L'intelligence artificielle (IA) a le potentiel de révolutionner le domaine du diagnostic de la maladie coronarienne (MC).
- Son utilisation lors d'une coronarographie va permettre prochainement un traitement plus rapide et plus efficace.
- De plus, les technologies de l'IA peuvent aider à la prévention de la MC en identifiant les patients ou les lésions à haut risque, particulièrement en utilisant les images du CT coronaire.

STRATÉGIE DE RECHERCHE DANS *PUBMED*

Une recherche systématique a été effectuée sur PubMed avec les mots-clés suivants: 'Digital ECG devices', 'Smartwatch', 'Artificial Intelligence Cardiology', 'Artificial intelligence Coronary artery disease', 'Artificial intelligence Echocardiography'.

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