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Portable out-of-hospital electrocardiography: A review of current technologies

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Abstract

Background: Availability of portable and home-based electrocardiography (ECG) is an important medical innovation, which has a potential to transform medical care. We performed this review to understand the current state of out-of-hospital portable ECG technologies with respect to their scope, ease of use, data transmission capabilities, and diagnostic accuracy.

Methods: We conducted PubMed and Internet searches for "handheld" or "wearable" or "patch" electrocardiography devices to enlist available technologies. We also searched PubMed with names of individual devices to obtain additional citations. We classified available devices as a "single limb lead ECG recording devices" and chest-lead "ECG recording devices." If a device used more than three electrodes, it was defined as a conventional electrocardiography or Holter machine and was excluded from this review. Results: We identified a total of 15 devices. Overall, only six of these devices (five single lead and one chest lead) featured in published medical literature as identified from PubMed search. A total of 13 citations were available for the single limb lead ECG recording devices and 6 citations for the chest-lead ECG recording devices. Conclusions: Despite the increase in number of such devices, published biomedical literature regarding their diagnostic accuracy, reproducibility, or utility is scant.

KEYWORDS

arrhythmia, chest leads, electrocardiography (ECG), handheld devices, holter monitor

INTRODUCTION 1

Cardiovascular diseases (CVDs) are leading cause of mortality worldwide, accounting for 17.3 million deaths per year, a number that is expected to grow to more than 23.6 million by 2030.¹ Early recognition of cardiovascular manifestations such as angina, dyspnea, palpitations, and syncope is emphasized, and patients with such symptom need to visit their doctors for evaluation. Performing electrocardiography (ECG), a modality that can detect lifethreatening conditions (such as ventricular or atrial arrhythmias, or ischemic changes in the ST segment), is used in healthcare facilities for initial assessment of such symptoms. ECG is useful as in

the presence of acute chest pain as ST-segment elevation suggests myocardial ischemia in more than 90% instances, ² and ST depression in more than 60% instances.³ In addition, ECG changes also suggest abnormalities in cardiac chambers, serum electrolyte levels, and certain drug toxicities. ⁴ Evaluation of cardiac rhythm for extended periods of time is rewarding for detection of arrhythmias. The diagnostic yield is increased by 15% to 39% by a 24hour recording. 5

Innovations in sensor technologies have made it possible to record electric impulses from heart in the absence of conventional ECG machines. Many such technologies are wearable and can record cardiac impulses for extended periods of time. This advancement has a

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potential to enhance utility of this technique in out-of-hospital settings such as within households, endurance trainings, sports training, and public places. It is also possible to immediately transmit obtained waveforms for expert interpretation, in addition to already available computerized reports. ^{6,7} Many such sensors are wearable, small in size, and can be used to monitor rhythms and waveforms over weeks or months. ⁸ Many handheld ECG devices give only limited information as compared to conventional 12-lead ECGs. Hence, concerns about their accuracy and reliability need to be examined. As information obtained by ECG invariably needs to be interpreted along with clinical inputs, it is debated if out-of-hospital use will really be beneficial. More visits to a hospital because of a false-positive test, and missed opportunities because of false negatives will always be a concern as this technology expands.

We performed this review to understand the current state of out-of-hospital electrocardiography technologies with respect to diagnostic accuracy and utility. Diagnostic accuracy of the devices is represented in Table 1 and utility (pros and cons) in Table 2. To distinguish this technology from conventional electrocardiography that could have been performed in an out-of-hospital setting, we focused only on portable, handheld, or wearable devices.

2 | METHODS

We used multiple overlapping data sources for this review. We performed PubMed and Internet searches for "handheld" or "wearable" or "patch" electrocardiography devices to enlist available technologies. We also searched PubMed with names of individual devices to obtain additional citations. We sought to include only those devices that were commercially available. Information about many devices was available only from the manufacturer, and for others from manufacturer and the PubMed citations. We classified available devices as a "single limb lead ECG recording devices" if they used fingers or thumb of both hands for capture. These devices typically used a touch sensation of fingers, thumb, wrist, or palm to capture electrical signals. Devices that could capture two or more ECG leads used sensors placed on the chest wall. These were classified as chest-lead "ECG recording devices." The sensors may have been embedded in a wearable patch, belt, or a card were so identified. We used the term electrode for a device that used wires to transmit the electric signal from the chest wall to the sensing device, as in conventional electrocardiography. If a device used more than three electrodes, it was defined as either a conventional electrocardiography or Holter machine and was excluded from this review. We also excluded devices that only analyzed the regularity of the pulse, without evaluating electrocardiograph.

3 | RESULTS

We identified a total of 15 devices, 12 of these were single limb lead ECG recording devices and remaining 3 were chest-lead ECG

recording devices. Overall, only six of these devices (five single lead and one chest lead) featured in published medical literature as identified from PubMed search (Table 1). A total of 13 citations were available for the single limb lead ECG recording devices and 6 citations for the chest-lead ECG recording devices. The devices that have been evaluated for their accuracy, reproducibility, or utility are described in the following sections. Pros and cons of each device are described in Table 2. Figure 1 and 2 represent the single-lead and multiple-lead ECG devices, respectively.

3.1 | Single-lead ECG recording devices

3.1.1 | Alivecor kardia

Alivecor is a smartphone ECG device that consists of phone case, which attaches to the compatible smartphone or tablet and has electrodes to transmit ECG rhythms to the smartphone. It displays ECG trace and also has a feature of enhanced filter that provides smooth ECG tracing. Alivecor Kardia is currently approved for purchase and use in over 25 countries (Australia, Bangladesh, United States, UK, India, Pakistan, Netherlands, Germany, Hong Kong, Chile, Switzerland, Norway, Spain, Jamaica, Poland, France, etc.). Its utility has been demonstrated in detection of atrial fibrillation in four studies and for detection of a prolonged QT interval in one study. In a study by Lau and colleagues,9 the sensitivity of the device for detection of atrial fibrillation was 98% and specificity of 97%. Similar accuracy estimates were obtained in a study by Lowers and colleagues (sensitivity of 98.5% and specificity of 91.4%).¹⁰ The prevalence of atrial fibrillation in these two studies was 35.7% and 6.7%, respectively. In another large study by Pak-Hei Chan ¹¹ where the prevalence of atrial fibrillation was low (2.7%), the sensitivity of the device was only 71.4%. The utility of the device was demonstrated in a community-based setting for detection of atrial fibrillation ¹² and for detection of QT interval. ¹³

3.1.2 Omron heartscan

It is a portable, compact, cordless, user-friendly ECG device with finger and chest electrodes and a high-resolution screen that displays the ECG waveform but it lacks a rechargeable battery. Its utility has been shown in detection of atrial fibrillation in 5 studies. In a study by Weisel J et al¹⁴ the sensitivity for detection of atrial fibrillation was low, that is, 30%, and specificity was high, that is, 97%. However, a study by Marazzi G et al¹⁵ demonstrated 100% sensitivity, 92% specificity, and 95% accuracy in detection of atrial fibrillation. Kearley K et al¹⁶ showed similar results in a large study among elderly age group (sensitivity-98.7% and specificity-76.2%). A study by de Asmundis C et al¹⁷ revealed significantly higher detection of symptom-related arrhythmias with Omron HeartScan compared with Holter monitor (P < .01). In a study by Gerrit Kaleschke et al¹⁸ diagnostic yield of Omron HeartScan in detection of atrial fibrillation was sensitivity 99% and specificity 96%.

		val					so c	Atrial	ves
Outcome		Prevalence of atrial fibrillation-35.8% Atrial fibrillation was defined as absent P wave and RR inte irregularity on ECG Sensitivity-98% (89%-100%) Specificity-97% (93%-99%) Accuracy-97% (94%-99%)	Prevalence of AF-2.76% Sensitivity-71.4% (51%-87%) Specificity-99.4% (50%-91%) PPV-76.9% (56%-91%) NPV-99.2% (98%-100%)	Prevalence of AF-6.7% Sensitivity-98.5% (92%-100%) Specificity-91.4% (89%-93%)	Alivecor is accurate in measuring QTc interval ($P < .01$)	Prevalence of AF-15% Sensitivity-30% (15.4% to 49.1%) Specificity-97% (92.5% to 99.2%)	Prevalence of AF-7.9% Atrial fibrillation was defined as the absence of distinct P w an absolutely irregular RR interval, and an atrial cycle lengl <200 ms on ECG. Sensitivity-98.7 (93.2 to 100) Specificity-76.2 (73.3 to 78.9) +LR-4.15 (3.69 to 4.67) -LR-0.017 (0.0024 to 0.12) PPV-26.3 (21.3 to 31.7) NPV-99.9 (99.2 to 100)	Detection of arrhythmias by of HeartScan was better when compared with Holter monitor (P < .01) Arrhythmias were defined as PACs, PVCs, Sinus tachycardia tachycardia	Prevalence of AF-9.34% Atrial fibrillation was defined as the absence of distinct P w and irregular RR interval Sensitivity-100% Specificity-92% Accuracy-95%
Sample size		109	1013	1000	119	199	1000	625	503
Study population			Patients with hypertension, with diabetes mellitus, and/or aged ≥65 y were recruited.	Pharmacy customers aged \ge 65 y (mean 76 \pm 7 y; 44% male) were screened.	Healthy volunteers and hospitalized patients in sinus rhythm on dofetilide or sotalol	Age ≥50 y without a pacemaker or defibrillator.	Ambulatory patients age 75 y and older	Patients with paroxysmal palpitations and dizziness suggestive of arrhythmias	Hypertensive patients
Study		Lau et al ⁹	Pak-Hei Chan et al ¹¹	Lowres N et al ¹⁰	Garabelli P et al ¹³	Weisel J et al ¹⁴	Kearley K et al ¹⁶	De Asmundis C et al ¹⁷	Marazzi G et al ¹⁵
Device	ad ECG device	Alivecor kardia				Omron HeartScan			
Sno	Single-le	с і				N			

Outcome	Diagnostic yield of Omron HeartScan in comparison with 12-lead ECG. Normal ECG (sensitivity 91% and specificity 95%), Atrial fibrillation (sensitivity 99% and specificity 96%), T-wave abnormalities (sensitivity 70% and specificity 75%) AV nodal block (sensitivity 79% and specificity 99%).	Zenicor ECG measured heart rate, QRS duration, and PR interval accurately but P-wave detection was not statistically significant. Atrial fibrillation was defined as irregularly irregular RR interval Sensitivity of 96% Specificity of 92%	Three-fourth of patients had recurrent episodes, and about 90% had episode in first 4 wk Arrhythmias were defined as PAC or PVC, AVNRT, paroxysmal atrial fibrillation, or atrial flutter.	In comparison with 24-h Holter ECG monitoring, E100 event recorders showed higher efficacy for detecting arrhythmias Arrhythmias included junctional arrhythmias, AVNRT, extrasystolic arrhythmias, atrial fibrillation, WPW syndrome, ventricular tachycardia, sinus tachycardia, and complete AV block.		ZioPatch detected greater arrhythmia events compared to Holter monitor ($P < .001$) Arrhythmia events were defined as detection of any 1 of 6 arrhythmias, including supraventricular tachycardia (>4 beats), atrial fibrillation/flutter (>4 beats), pause >3 s, atrioventricular block (Mobitz type II or third-degree atrioventricular block), ventricular tachycardia (>4 beats), or polymorphic ventricular tachycardiar fibrillation	Mean wear time was 7.6 \pm 3.6 d Diagnostic yield of arrhythmia detection by ZioPatch was greater when taken for the entire wear duration compared with the first 48-h Holter monitor ($P < .0001$). Arrhythmias were defined as one of the following: atrial fibrillation, pause >3 s, second-degree Mobitz II or complete AV block, SVT, VT, and symptomatic bradycardia.	Mean monitoring period of 10.8 \pm 2.8 d Atrial fibrillation was defined as the absence of distinct P waves and irregular RR interval. During first 24 h, mean atrial fibrillation detection by Holter and
Sample size	508	226 100	55	24		146	26751	74
Study population	Patients who had clinical indication of 12-lead ECG recording were consecutively enrolled in the AFNET centers at Munich from July 2007 to February 2008	Children (patients) aged 0-17 y with or without congenital heart defects, pacemaker/ICDs, or arrhythmia Patients with known AF recruited from a cardiology outpatient clinic	Patients with palpitations less than a week	Patients with complaints of heart arrhythmias and no changes in routine ECG and 24-h Holter monitor		Patients referred for evaluation of arrhythmias	Data from the device manufacturer (iRhythm Technologies) for patients who had completed ZioPatch monitoring for clinical indications from January 1, 2011, to December 31, 2011.	Patients with paroxysmal AF referred for Holter monitoring for detection of arrhythmias
Study	Gerrit Kaleschke et al ¹⁸	Usadel L et al ²¹ Doliwa PS et al ²⁰	Schuchert A et al ²²	Rekhviashvilli A et al ¹⁹	3 device	Barrett PM et al ²⁴	Turakhia MP et al ²³	Rosenberg M et al ²⁵
Jevice		Zenicor ECG	Miniscope	teka e100	nore lead ECC	CioPatch		
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TABLE 1 (Continued)

(Continues)

TABLE 1 (Continued)

Outcome	ZioPatch was comparable ($P < .0001$) but there were additional arrhythmia events detected by ZioPatch because of longer wear duration.	The mean monitor wear time was 10.9 d About 15% of first paroxysmal atrial fibrillation episodes occurred after 48 h and thus were detected by ZioPatch only. Atrial fibrillation was defined as RR irregularity for more than 30 s	Diagnostic yield 63% Significant arrhythmias are defined as follows: ventricular tachycardia (VT) ≥4 beats, supraventricular tachycardia (SVT) ≥4 beats, atrial fibrillation, ≥3 s pause, 2nd-degree Mobitz II, 3rd- degree AV block, or symptomatic bradycardia.	The mean times to first detected and first symptom-triggered arrhythmias were 2.7 \pm 3.0 and 3.3 \pm 3.3 d, respectively.
Sample size		1171	174	3209
Study population		Patients who were monitored between January 2012 and June 2013 and whose indication for monitoring was TIA or stroke (data obtained from manufacturer of ZioPatch)	Discharged adult Emergency department patients with symptoms of arrhythmia	Children receiving ZioPatch for clinical indications from January 2011 to December 2013.
Study		Christie E.Tung et al ²⁷	Schreiber D et al ²⁶	Bolourchi M et al ²⁸
Device				
Sno				

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3.1.3 Reka health

The E100 is a small, round easily portable ECG recording device with thumb electrodes. It is capable of storing large number of ECG recordings, has a built-in rechargeable battery, has a cloud-based service but it does not display the ECG tracing. The utility of REKA Health has been demonstrated in 1 study.¹⁹

3.1.4 | Zenicor ECG

Zenicor ECG is a handheld finger sensor, recorder, and display device with transmission capability to a smartphone. It is capable of storing large number of ECG recordings, has a built-in rechargeable battery, has a cloud-based service but it does not display the ECG tracing. The utility of Zenicor ECG has been demonstrated in 2 studies. In a study by Doliwa PS et al²⁰ sensitivity and specificity for atrial fibrillation detection were 96% and 92%, respectively. In a study among children by Usadel et al²¹ Zenicor yielded 92% sensitivity in diagnosing supraventricular tachycardia plus 77% sensitivity and 92% specificity in identifying abnormal ECGs.

3.1.5 | Schiller miniscope

Schiller Miniscope MS-3 Mini-ECG is a pocket ECG recorder with chest contact sensor and optional 3-5 ECG leads. Schuchert A et al^{22} have demonstrated the utility of Miniscope.

3.2 | Multiple-lead ECG devices

3.2.1 | ZioPatch

The ZioPatch is a 14-day, ambulatory ECG monitoring adhesive patch applied over the left pectoral region of patient's chest. It is a 3-lead ECG device, water resistant, wireless patch that requires no battery charging. After wearing the patch for prescribed period of time, the data are analyzed from the ZioPatch.

The utility of ZioPatch has been demonstrated in various studies. In a large study by Turakhia MP et al^{23} it was found that compared with first 48 hours of monitoring, the overall diagnostic yield was greater when data from the entire ZioPatch wear duration were included for any arrhythmia (P < .0001) and for any symptomatic arrhythmia (P < .0001). In another study by Barrett PM et al²⁴ it was shown that adhesive patch monitor detected more arrhythmia events compared with the Holter monitor over the total wear time (P < .001), although the Holter monitor detected more events during the initial 24-h monitoring period (P = .013). Michael A Rosenberg et al²⁵ revealed that during first 24-hour period, atrial fibrillation burden on the 24-hour Holter and the ZioPatch device was comparable (P < .0001). Because of longer monitoring in ZioPatch, additional individuals were detected to have atrial fibrillation. Schreiber D ²⁶ and colleagues in their study found a diagnostic yield of 63.2% in detection of atrial fibrillation. A study by Christine E Tung et al²⁷ showed that about

TABLE 2 Pros and cons of all commercially available devices in this review

Sno	Name of Device	Pros	Cons
1	Kardia Mobile	 Displays ECG trace Easy to carry Filter that smoothens ECG tracing FDA approved 	There is necessity of android/iPhone with this device
2	Omron HeartScan (HCG 801)	 Comes with built-in both chest and finger electrodes, which makes it more user-friendly 	A stand-alone gadgetNo built-in rechargeable battery
3	REKA E100	 Recording and storage device Can store more than 1,000 records Built-in rechargeable battery Cloud-based analysis service (paid) FDA approved 	 Does not display ECG recordings Available only by prescription from physician
4	Zenicore EKG	Recording and storage deviceCloud-based analysis service	Does not display ECG tracings
5	Miniscope M3	Displays ECG traceOptional 3-5 ECG leads	
6	AfibAlert	Small in sizeTwo finger recording deviceFDA approved	Does not display ECG recordingsNo built-in rechargeable battery
7	InstantCheck	Display of actual ECG recordStorage capabilityFDA approved	 Relatively short auto turnoff time No built-in rechargeable battery
8.	ReadMyHeart	Recording and storage deviceFDA approved	 Does not display ECG recordings No built-in rechargeable battery
9	Dimetek Micro Ambulatory ECG Recorder	 It can be used for quick recording as well as long Holter monitoring Can send ECG recordings as an Email attachment 	No built-in rechargeable battery
10	ECG check	 Low cost, simple Automatic beat to beat heart rate measurement	Can only be used with iPhoneNo built-in rechargeable battery
11	HeartCheck Pen	 Lighted Display screen It has cloud-based ECG interpretation service FDA approved 	No built-in rechargeable battery
12	PC80B color	Lighted color displayAllows for variable lengths of recordings	No built-in rechargeable battery
13	ZioPatch	 3-lead ECG device No battery charging, no electrode changes are necessary FDA approved	 Requires prolonged application by individuals to obtain true readings
14	Nuvant mobile cardiac telemetry	 3-lead ECG device, Wireless patch Automatically detects and transmits ECG to external lab	 Requires prolonged application by individuals to obtain true readings
15	CardioLeaf	 3-lead ECG device, wearable electrodes LED visual display, audio alert present Recorded data can be sent to cloud	

15% of first paroxysmal atrial fibrillation occurred after 48 hours, which will not be detected by conventional Holter monitor but can be detected by ZioPatch. The results in a large study among the pediatric age group 28 showed that the mean times to first detected and first symptom-triggered arrhythmias were 2.7 \pm 3.0 and 3.3 \pm 3.3 days, respectively.

4 | DISCUSSION

Of a total of 15 devices identified in our review, only 6 have been evaluated and published in biomedical literature. Despite a limited number of publications, sufficient literature exists to prove the concept and utility of such devices. There is a heterogeneity in terms of

SINGLE-LEAD ECG DEVICES





Aliyecor Kardja

Omron Heart Scan

REKA E100





Dimetek Microambulatory ECG recorder



Heart Check Pen



PC 80B color



Schiller Miniscope



Zenicor ECG

InstantCheck ECG

FIGURE 1 Single-lead electrocardiography (ECG) devices

MULTIPLE-LEAD ECG DEVICES



FIGURE 2 Multiple-lead electrocardiography (ECG) devices

available devices, and broadly these can be classified as single limb lead and multiple-lead devices. Single-lead devices maybe with or without a display of ECG and have a capability to detect abnormal rhythms. Multiple-lead devices use chest patch/electrodes and may have a utility to detect both abnormal rhythms and localization of ischemic abnormalities.

This innovation is encouraging as it can expand availability of a measurement to diverse settings ²⁹ such as primary care facilities (especially in low-health resource regions), health promotion industry (gymnasiums, sports clubs, physical activity promotion centers), and households (individuals at a higher risk of cardiovascular events). While we may still need to wait for the technology to become more robust, it is useful to reflect and debate potential pitfalls especially in settings where physician opinion is not immediately available.

In past years, many medical devices are now widely available beyond hospitals and clinics. Sphygmomanometers and glucometers are two such devices, which have enabled individuals to obtain selfmeasured blood pressure (SMBP) and self-measured blood glucose (SMBG) measurements. ³⁰ This expansion has undoubtedly led to improved awareness, detection, and control of hypertension and diabetes. Electrocardiography could be another such device that in coming years could expand to nonhospital settings, and it can be debated if this change will indeed be useful. While SMBP and SMBG both have simple numeric outputs, ECG is a waveform based on a complex analysis of rate, rhythm, and patterns of these waveforms. ³¹ While automated computerized interpretations of ECGs are available in hospitalbased devices, false-positives and need for a physician confirmation are invariably required. Further, a conventional ECG interpretation is made in light of symptoms and evaluation of multiple leads.

Single-lead devices have a potential utility among patients with a known episodic rhythm disorders such as atrial fibrillation, supraventricular, and ventricular tachycardia. While symptoms such as palpitations, dyspnea, or syncope are useful to screen these conditions, availability of home-based rhythm recognition devices can be useful in prioritizing visits to the emergency room. While prevalence of these episodic rhythm disturbances is low, early treatment has a high immediate impact in preventing mortality and morbidity. ³² This is in contrast to hypertension or diabetes, which are high-prevalence but low immediate impact situations. External auto-triggered loop recorder (ELR) is another option to screen patients with recurrence of syncope or palpitations. ³³

Chest pain is common life-threatening cardiovascular symptom that requires emergency care. While ECG is a mainstay in diagnostic algorithm of chest pain, a single ECG has limited sensitivity. Often serial ECGs with a cardiac biomarker study is required to make an accurate diagnosis. Utility of a single-lead ECG is highly questionable in this setting with a potential for false-negative test results. While false-positive result could cause more visits to the emergency room, a false-negative result is worse, as it may lead to potentially fatal missed diagnosis. Multiple-lead wearable devices are likely to be better than a single-lead device in this regard, but interpretation of the presence or absence of ischemia will still be uncertain as compared to a 12-lead ECG. In a recent study, clinic-based triage in acute coronary syndrome was better than ECG-based triage. ³⁴ Multiple chest-lead wearable devices however will have an unparalleled utility in diagnosis of stable angina, when individuals have chest pain or equivalent symptoms on exertion. There could be a potential to supplant exercise-electrocardiography in these situations.

5 | CONCLUSION

The number of available devices that can record and analyze electric signals emitting from the cardiac conduction system is on the rise. A

number of first-generation devices using a single lead to record cardiac rhythm have been manufactured, tested and are approved by regulatory agencies. These devices are best suited for a short-term rhythm analysis. Second generation devices that can record multiple leads are available as both wearable and nonwearable devices. Wearable devices are better suitable as ambulatory cardiac rhythm analysis devices and could be the future of Holter monitoring systems. Despite an explosion of such devices, published biomedical literature about their diagnostic accuracy, reproducibility, or utility is scant. The potential reasons for scant literature include early phase of development of such devices, regulatory environment not mandating robust studies prior to launch of such devices, devices being developed in engineering domain, and disconnect with biomedical research.

CONFLICT OF INTEREST

Authors declare no Conflict of Interests for this article.

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