Journal of Electrocardiology 53 (2019) 89–94

Contents lists available at ScienceDirect

Journal of Electrocardiology

journal homepage: www.jecgonline.com

Home use of a compact, 12-lead ECG recording system for newborns

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ARTICLE INFO

Available online xxxx

Keywords:
ECG recorder
ECG electrodes
Newborn screening

ABSTRACT

Background: An easy-to-operate ECG recorder should be useful for newborn screening for heart conditions, by health care workers – or parents. We developed a one-piece electrode strip and a compact, 12-lead ECG recorder for newborns.
Method: We enrolled 2582 newborns in a trial to assess abilities of parents to record a 12-lead ECG on their infants (2–4 weeks-old). Newborns were randomized to recordings by parents (1290) or our staff (1292 controls). Educational backgrounds of parents varied, including 64% with no more than a high school diploma.
Results: For newborns randomized to parent recorded ECGs, 94% of parents completed a 10-minute recording. However, 42.6% asked for verbal help, and 12.7% needed physical help. ECG quality was the same for recordings by parents versus staff.
Conclusions: By use of a one-piece electrode strip and a compact recorder, 87% of parents recorded diagnostic quality ECGs on their newborn infants, with minimal assistance.

Introduction

Technical advances have led to ever smaller, robust, and reliable electrocardiographic (ECG) recorders, especially when compared to the original Einthoven string galvanometer invented in 1902 (reviewed in [1]). Development of the vacuum tube, transistor, and microchip each

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https://doi.org/10.1016/j.jelectrocard.2019.01.086
0022-0736/

led to smaller and more sensitive machines [2–6]. Electronic devices are now pocket-sized or wearable – like smartphones or watches. In the same way, 12-lead ECG recorders are also smaller, some weighing <2 oz. Examples of compact ECG recorders are: BIOX 1306 (Vasomedical, Inc.; Westbury, NY); CardioHolter ECG (Nasiff Associates, Inc.; Central Square, NY); EC-12RM (Labtech, Ltd.; Debrecen, Hungary); InvisionHeart ECG System (InvisionHeart, Inc.; Nashville, TN); IX-ECG12 (iWorx Systems, Inc.; Dover, NH); and QT ECG (QT Medical, Inc.; Torrance, CA).

Improvements in cutaneous electrodes also played a role in optimizing ECG recording [7]. Early electrode contacts used layers of gauze soaked in saline, and later pastes were applied [8]. Dry metal electrodes held in place with elastic straps or suction cups were also devised [9]. Ag/AgCl gel electrodes have become standard for ECG recording, but novel electrode materials continue to be pursued [10].

Recently, we developed a one-piece, pre-positioned multi-electrode strip for use on newborns [11]. The one-piece design enables recording an ECG in standard 12-lead format without connecting 10 separate wires, so lead placement is simpler and less error-prone. The purpose of this study was to evaluate whether this simplified 12-lead ECG recording system could be used by lay persons (parents) to record ECGs on challenging subjects – newborn infants. Here we report that a high percentage (87%) of parents were able to independently record a 10-minute ECG with the newborn system on their infants at home.

Material and methods

Newborn electrode strip and ECG recorder

The original design of the one-piece, pre-positioned electrode strip is described in [11]. The electrode strips used here were constructed from flexible printed circuit boards (FPCBs) sandwiched between non-woven fabric (top surface) and a thin layer of medical foam material with 3 M adhesive (on the undersurface for skin contact; Fig. 1). The adhesive underside of the strip has 7 Ag/AgCl hydrogel sensors as the 6 chest electrodes and the RL electrode (8 or 5 mm in diameter). Three coiled limb electrodes extend from the ends of the strip – 2 from the left end (for the LA and LL electrodes) and one from the right end (for the RA electrode). Each of these 3 wires is connected to an adhesive circle with an Ag/AgCl hydrogel sensor (10 mm in diameter). The adhesive strip and coiled limb electrodes are in one piece and ready for use out of the package.

The ECG recorder used in the study was a flat, square device weighing 30 g and measuring $50 \times 50 \times 10$ mm^3. The device snaps-on to the electrode strip via a plastic connector – without individual wires for the chest leads (Fig. 1C). The ECG sampling rate is 1000 Hz in 24-bit resolution. ECG data stored in the device memory (up to 2 h of recordings) can be transferred wirelessly to a smartphone or tablet computer or by wired USB. Battery life and charging times are 18 and 4 h, respectively.

Participants

Study coordinators recruited apparently healthy infants mainly from newborn nurseries at four hospitals in Southern California: St. Francis Medical Center (Lynwood); Harbor-UCLA Medical Center (Torrance); Providence Little Company of Mary Medical Center (Torrance); and Riverside County Regional Medical Center (Moreno Valley). Newborns were also recruited from the South Los Angeles Health Projects Women, Infants, and Children (WIC) center (SLAHP/WIC). Study coordinators approached potentially interested parents at these sites to identify eligible newborns. Pediatrics offices near Harbor-UCLA Medical Center referred additional participants.

Institutional review boards at the Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center (LA BioMed) and at participating hospitals approved all procedures and documents, before recruitment started. The study was registered at ClinicalTrials.gov (NCT02412709). Informed consent was obtained immediately before study procedures.

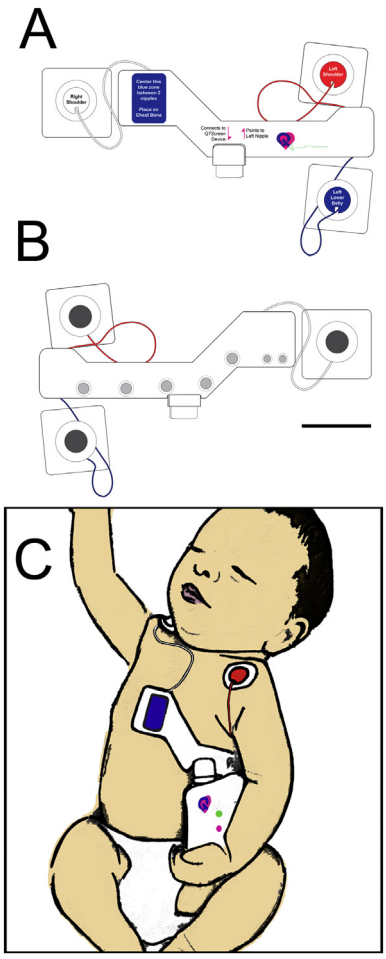

Fig. 1. Drawings of the one-piece ECG electrode strip, made of flexible printed circuit boards (FPCBs) sandwiched between non-woven fabric (top surface) and a thin layer of medical foam material with 3 M adhesive (on the undersurface, for skin contact). Three limb electrodes extend from the ends of the strip – 2 from the left end for the LA (red circle) and LL electrodes (blue circle), and one from the right end for the RA electrode (white circle). **A.** Top surface, showing the snap-on connector for the ECG recorder and instructions for placing the strip. **B.** Undersurface, showing 7 Ag/AgCl hydrogel sensors for the chest and RL electrodes (5 or 8 mm in diameter). Each of the 3 wires for the limb electrodes is connected to an adhesive circle with an Ag/AgCl hydrogel sensor (10 mm in diameter). Scale bar = 4 cm. **C.** A correctly placed electrode strip, with the ECG recorder attached and functioning. The infant pictured is 3 weeks old. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

Eligible infants were born at ≥36 weeks of gestation with a birth weight of 2.5 to 4.5 kg. They were 14–34 days old (2 to 4 weeks) at the time of starting study procedures. We excluded babies who were diagnosed with a congenital heart disease or had a skin condition, allergy, or chest deformity that could make ECG recording difficult or problematic, or if both parents were not competent in English or Spanish.

Randomization to parent-recorded or staff-recorded ECG groups

Newborns were assigned to parent- or staff-recorded ECG groups, to evaluate the effect of experience and training on ability to record an ECG by use of the newborn ECG system. We used a permuted block randomization scheme to assign participants to the groups (stratified by recruitment site; [12]). Block sizes were 2 or 4, with a balance between the 2 groups. The project biostatistician (XG) managed the randomization, by use of SAS (SAS Institute Inc., Cary, NC).

Baseline data

Study coordinators collected background data and medical histories immediately prior to ECG recordings at participant homes or in our study center at Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center (LA BioMed). Choice of location was determined by parent preference. Background data collected were: date of recording; date of birth; birth weight; sex; ethnicity; and data on the participating parent (contact information; language spoken; level of education; and sex). Inquiries on personal and family medical histories consisted of 2 questions: (1) Had the baby any episode of loss of consciousness or seizures? (2) Were there any sudden unexplained deaths, sudden infant death syndrome (SIDS) occurrences, or diagnoses of long QT syndrome among the parents or sibs? These questions pertained to a separate part of the study on newborn screening for long QT syndrome.

ECG recording

Participants had a standard 12-lead ECG recorded over 10 min (continuously recording from all 10 electrodes for 10 min, or 2 continuous recordings for 5 min each), by use of the newborn electrode strip and ECG device. Recordings were stored in device memory and later uploaded to a computer for viewing and interpretation.

Parent-recorded ECGs

Study coordinators offered parents step-by-step instructions for ECG recording (available in English and Spanish) in three formats: print (1-page, in color; see supplementary material); a video on a tablet computer (iPad); and an interactive slide show (also on an iPad). Briefly, instructions were: (1) place the infant in the supine position with the chest uncovered; (2) peel off the underside covering of the electrode strip to expose adhesives and hydrogel circles; (3) apply the electrode strip to the baby's chest, according to landmarks; (4) pull out and apply the RA, LA, and LL electrode circles to their appropriate positions; (5) plug the electrode strip into the recorder; (6) record the ECG; and (7) disconnect the recorder and remove the electrode strip after 10 min of recording, as indicated by a light on the recorder and a message on the iPad. No coaching by the study coordinator was provided.

Study coordinators provided the electrode strip, ECG recorder, and related materials, and then withdrew to observe the parents record the ECG without giving further instructions. Study coordinators observed each step of the procedure and noted the results on a checklist. Results noted at each step were independent of outcomes of other steps in the recording procedure. Parents were allowed to ask questions between steps, and make corrections before moving to the next step.

Study coordinators answered questions as if giving technical assistance by phone (verbal help). Assistance was considered "physical help" if the coordinator needed to examine the electrode strip or the recorder (e.g., following a "leads off" indicator). The result was counted as a staff-recorded ECG if the study coordinator applied the electrode strip, worked on the recorder, or took over the procedure from the parent.

Staff-recorded ECGs

A study coordinator recorded a 10-minute ECG for newborns in the staff-recorded ECG group.

Statistical analyses

We compared ECG recordings obtained from the newborn device and electrode strip to those from a conventional machine with 10 individually placed electrodes (Midmark IQecg). Recordings were reviewed by a pediatric cardiologist (NH). Statistical analyses of ECG intervals, axes, and amplitudes were by paired Student's *t*-tests.

Results and discussion

The study was a randomized, controlled trial to assess parents' abilities to record ECGs on their newborn babies (2 to 4 weeks of age), by use of the one-piece electrode strip and the compact ECG recorder. The trial enrolled 2582 newborns – with 1290 originally randomized to the parent-recorded ECG group, and 1292 randomized to the staff-recorded ECG group. Within the parent-recorded ECG group, 93.1% of parents (1201/1290) were able to record an ECG for 10 min. But 42.6% needed verbal help, and 12.7% needed physical help. By these data, we conclude that 87% of the parents were able to record an ECG following simple printed or video instructions – with limited help simulating remote (telephone) assistance (see below for details). ECGs recorded with the one-piece electrode strip and newborn device were essentially equivalent to ECGs from a current digital ECG device. There were no adverse effects reported by the parents. Specifically, there were no reports of skin reactions related to the electrode strip.

Participant characteristics (Tables 1 and 2)

Participant characteristics were similar for the parent-recorded and staff-recorded groups, including sex of the newborn, primary language, education level of the participating parent, and ethnic background (Table 1). Parent reports of ethnic background were: 83.1% white (2146/2582); 12.6% black (326/2582); 1.7% Asian (44/2582); 0.89% Native Hawaiian or other Pacific Islander (23/2582); 0.23% American Indian or Alaska Native (6/2582); and 1.4% with more than one race (37/2582). A large majority identified themselves as Hispanic or Latino (84.5%, or 2183/2582). In the study, 70.2% (1814/2582) of participants reported that English was their primary language, followed by Spanish (29.7%, or 766/2582). Most parents had no more than a high school education (64.1%, or 1656/2582).

Newborns in both groups had similar histories of seizures, occurrences of loss of consciousness, and family histories of sudden unexplained death or SIDS (Table 2A). Parent experiences with ECG recording were also similar – either watching ECGs being recorded on others or having ECGs themselves.

Parent performance in ECG recording

>98% of the parents reported that the test was easy to perform, after the ECG was complete (similar for the parent- and staff-recorded groups; Table 2B). Similar proportions of parents reported that they would ask their doctor to order such a test, if they were to have another baby.

Approximately 5% of the parents needed the staff member to record the ECG or complete the recording (Table 3). Among those parents, the main reasons were: (1) the parent did not feel comfortable placing the electrodes on the baby and therefore did not want to try (and did not open the package of the electrode strip – 61 parents), or tried and quickly gave up; (2) the parent could not read or understand the instructions (1% or less); or (3) the parent had technical difficulties, such as repeatedly attaching the electrode strip in the wrong position (1% or less).

Among participants randomized to parent recorded ECGs, 1219 completed a 10-minute ECG recording (1219/1290, or 94%). However, 42.6% of the parents asked for verbal help, and 12.7% needed physical help. Examples of physical help included: troubleshooting for a "leads off" indicator (e.g., pressing more firmly on electrode patches to ensure contact or slight adjustment of positions of limb electrodes by 1–2 cm); connecting the electrode strip to the recorder; pointing to the power button; and removing electrode patches from the baby after completion of an ECG recording.

Taking into account the percentage of parents who needed physical help to complete the ECG recordings, the overall rate of successful

Table 1
Participant characteristics for the parent-recorded and staff-recorded ECG groups.

		ECG recorded by		
		Parent	Staff	All
Number of newborns enrolled		1290	1292	2582
A. Sex, language, and education				
Sex of the newborn (%)	F	678 (52.56)	681 (52.71)	1359 (52.63)
	M	612 (47.44)	611 (47.29)	1223 (47.37)
Sex of the participating parent	F	1209 (93.72)	1233 (95.43)	2442 (94.58)
	M	81 (6.28)	59(4.57)	140 (5.42)
Primary language of the participating parent (%)	English	911 (70.62)	904 (69.97)	1815 (70.29)
	Spanish	379 (29.38)	388 (30.03)	767 (29.71)
	Not given	13 (1.01)	12 (0.93)	25 (0.97)
Education level of the participating parent (%)	<High school	354 (27.44)	315 (24.38)	669 (25.91)
	High school diploma	480 (37.21)	507 (39.24)	987 (38.23)
	Some college	273 (21.16)	279 (21.59)	552 (21.38)
	Associate degree	39 (3.02)	47 (3.64)	86 (3.33)
	Bachelor's degree	94 (7.29)	88 (6.81)	182 (7.05)
	Graduate school	18 (1.40)	20 (1.55)	38 (1.47)
	Professional school	15 (1.16)	20 (1.55)	35 (1.35)
	Other	4 (0.31)	4 (0.31)	8 (0.31)
B. Ethnicity				
Hispanic or Latino	Asian	5	5	10
	Native Hawaiian/Pacific Islander	4	2	6
	Black or African American	32	31	63
	American Indian or Alaska Native	1	1	2
	White	1055	1041	2096
	>1 race	3	3	6
Not Hispanic or Latino	Asian	25	9	34
	Native Hawaiian/Pacific Islander	9	8	17
	Black or African American	114	149	263
	American Indian or Alaska Native	1	3	4
	White	29	21	50
	>1 race	12	19	31

completion of procedures in the parent-recorded group was 87.3%. The mean total time needed for parents to complete the procedures was 23.7 ± 6.9 min (median 22.9), compared to 22.7 ± 2.8 min for the staff (median 23.3). There was no difference in ECG quality between recordings by parents versus staff.

ECG quality (Fig. 2)

A total of 2543 newborns had at least one diagnostic quality ECG successfully recorded. From the first 1491 newborns with ECGs by the electrode strip and newborn device (746 by parents, 745 by staff), 27 recordings had too much artifact and noise (27/1491 = 1.8%), so the ECG could not be used for accurate measurement of intervals. Among the next 1052 newborns, only 10 needed a repeat ECG (10/1052 = 0.95%). All repeat recordings were readable. There was no difference in occurrences of unreadable ECGs between the parent and staff recordings. Most of the artifacts and noise were due to movement of the babies, and some were related to ambient electromagnetic interference. There was no occurrence of device failure. Fig. 2 shows an example of a 10-second ECG recording.

Table 2
Parent responses to questions.

Question	Participant group					
	Parent-recorded ECG			Staff-recorded ECG		
	Yes (%)	No (%)	– (%)	Yes (%)	No (%)	– (%)
A. Asked before ECG recording						
Has your baby had any loss of consciousness or seizure episodes?	3 (0.23)	1284 (99.54)	3 (0.23)	7 (0.54)	1281 (99.15)	4 (0.31)
Have there been occurrences of sudden unexplained death, sudden infant death syndrome (SIDS), or long QT syndrome in your family?	6 (0.47)	1282 (99.38)	2 (0.15)	13 (1.01)	1275 (98.68)	4 (0.31)
Have you ever had an ECG performed on yourself?	300 (23.26)	988 (76.59)	2 (0.15)	306 (23.68)	981 (75.93)	5 (0.39)
Have you ever watched an ECG being performed?	422 (32.71)	866 (67.13)	2 (0.16)	439 (33.98)	846 (65.48)	7 (0.54)
B. Asked after ECG recording						
Did you find the ECG test on your baby easy to do?	1271 (98.53)	15 (1.16)	4 (0.31)	1274 (98.60)	9 (0.70)	9 (0.70)
If you were to have another baby, would you consider requesting the ECG test from your doctor?	1272 (98.60)	11 (0.85)	7 (0.55)	1268 (98.14)	11 (0.85)	13 (1.01)
C. Asked during a follow-up phone call						
Were the results of the ECG test useful?	1170 (90.70)	1 (0.08)	119 (9.2)	1144 (88.68)	3 (0.23)	145 (11.09)

"—" indicates missing data, or the parent did not respond.

Table 3
Parent performance with the newborn ECG recording system (among 1290 parents enrolled).

A. At the sequential steps of ECG recording			
Did the parent…	Yes	No	—
… open the package of the electrode strip?	1210 (93.80)	19 (1.47)	61 (4.73)
… correctly place the ECG strip, with…	1197 (92.79)	29 (2.25)	64 (4.96)
… the strip along the nipple line?	1196 (92.71)	30 (2.30)	64 (4.99)
… the blue rectangle over the sternum?	1198 (92.87)	28 (2.32)	64 (4.81)
… the white circle on the R shoulder?	1188 (92.09)	37 (2.87)	65 (5.04)
… the red circle on the L shoulder?	1194 (92.56)	31 (2.40)	65 (5.04)
… the blue circle on the L lower abdomen?	1188 (92.09)	38 (2.95)	64 (4.96)
… connect the recorder to the electrode strip?	1190 (92.25)	36 (2.79)	64 (4.96)
… find the power button?	1163 (90.16)	61 (4.72)	66 (5.12)
… record an ECG for 10 min?	1201 (93.10)	22 (1.71)	67 (5.19)
… detach the recorder?	1198 (92.87)	27 (2.10)	65 (5.03)
… remove the ECG strip?	1194 (92.56)	26 (2.03)	70 (5.41)
B. During the overall process of ECG recording			
Did the parent…	Yes	No	—
… correctly place the ECG electrode strip?	1192 (92.40)	28 (2.17)	70 (5.43)
… require verbal help?	550 (42.64)	676 (52.40)	64 (4.96)
… require physical help?	164 (12.71)	1061 (82.25)	65 (5.04)
… need the ECG to be recorded by the staff?	71 (5.50)	1203 (93.26)	16 (1.24)
… complete the visit?	1264 (97.98)	8 (0.62)	18 (1.40)

"—" indicates parents who preferred not to record the ECG or: required the staff member to place the electrode strip, touch the recorder, or complete the recording (or data were missing). A total of 70 parents randomized to the parent recording group preferred not to start or complete the recording (and asked for the ECG to done by a staff member). One parent withdrew from the study before starting the ECG (and did not desire a recording by a staff member).

Eighteen participants consented (out of the 63 infants who had ECGs in our study office, rather than at home) to an additional ECG with the Midmark IQecg digital ECG recorder (and 10 individually placed electrodes), to assess for differences in recordings with the one-piece electrode strip and newborn device. However, the ECG reader was not blinded to the type of recording device used, because the Midmark IQecg uses proprietary software for ECG reviews and measurements.

There were no differences in the PR intervals, QRS durations, QTc intervals, and axes, for the neonatal versus the conventional ECG recorder (Table 4). There were statistical differences in R amplitudes in V1 and S amplitudes in V1, but the small differences did not have clinical significance. One baby had borderline QTc prolongation on both ECGs (464 and 455 ms). One baby had right ventricular hypertrophy (RVH) on the conventional recorder, and possible RVH with the newborn system.

Fig. 2. Example of a standard 10-second ECG tracing recorded with the newborn electrode strip and device.

Table 4
Comparison of ECG measurements between the newborn and conventional recorders (18 participants).

Measurement	Newborn	Conventional	*P*-value
Heart rate, bpm	151	152	0.87
PR interval, ms	112	111	0.89
QRS duration, ms	44	52	0.12
QTc interval, ms	416	413	0.61
P-wave axis, degrees	76	69	0.20
QRS axis, degrees	114	121	0.18
T-wave axis, degrees	67	63	0.81
R amplitude in V1, mV	1.27	1.02	0.03
R amplitude in V6, mV	0.47	0.45	0.79
S amplitude in V1, mV	0.64	0.47	0.03
S amplitude in V6, mV	0.34	0.31	0.60

The conventional recorder was a Midmark IQecg digital ECG recorder with 10 individually placed electrodes. Paired Student's *t*-tests were used for statistical comparisons.

Another baby had possible RVH on both recordings. No other differences were noted in the clinical interpretations for the two ECG systems.

ECGs on each baby were also examined side-by-side for comparison. For the question, "Which ECG system has better quality ECG signals?" the rater reported that the newborn recorder was better in 11, the conventional recorder was better in 3, and the two systems were similar in 4. For the question, "Do the two ECGs look different?" Sixteen of 18 paired recordings showed no difference, and 2 showed more motion artifacts on the conventional recording.

Limitations

A larger sample size may be needed to establish that the newborn ECG system is equivalent (or better) than conventional recorders in detecting congenital heart conditions, such as long QT syndrome. The newborn ECG system has the advantage of longer recording times (e.g., 10 min in this study), compared to conventional recording. Nevertheless, the newborn ECG system is mainly designed for recording standard ECGs, rather than long term monitoring and automatic arrhythmia recognition. Also, the one-piece electrode strips are not reusable.

Conclusions

With a one-piece electrode strip and compact recorder, 87% of parents were able to record a high quality, standard 12-lead ECG on their newborn infant. ECG intervals and axes were essentially the same as those obtained with a conventional ECG recorder. The newborn recorder may be suitable for screening for heart conditions by health care workers or parents. Applications in other ages are also feasible, with larger electrode strips.

Acknowledgements and role of the funding source

This work was supported by the National Institutes of Health (grant 5R42HL112435-04 to QT Medical, Inc.).

QT Medical, Inc., was involved in the study design and collection of data. However, QT Medical, Inc., had no involvement in the analysis and interpretation of the data, the drafting of the article, or the decision to submit the article for publication.

Fig. 1 was prepared by Michelle M. Lin.

Declaration of interest

Ruey-Kang Chang is Founder and CEO of QT Medical, which manufactured the ECG recording device and electrode strip used in the study. There are no other known conflicts of interest associated with this publication and all other authors.

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