Brief Report

Feasibility of a novel ECG electrode placement method in newborn infants

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Short Title: A novel ECG placement method

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Abstract

Background:

International newborn resuscitation guidelines recommend electrocardiogram (ECG) heart rate (HR) monitoring at birth. We evaluated the application time of pre-set ECG electrodes fixed to a polyethene patch allowing adhesive-free attachment to the wet skin of the newborn chest.

Objectives:

Using a three-electrode pre-set ECG patch configuration, application success was calculated using video analysis and measured at three time points, the time to: 1) apply electrodes; 2) detect recognisable QRS complexes after application; and 3) display a HR after application.

Method:

A prospective observational study in two UK tertiary maternity units was undertaken with seventy-one newborns including twenty-three who required resuscitation.

Results:

The median (IQR) time for ECG patch application was 8 (6-10) seconds, detection of recognisable QRS complexes 8 (2-12) seconds and time to output HR was 23 (15-37) seconds.

Conclusion:

Pre-set ECG chest electrodes allow rapid HR information at birth without electrode detachment or compromising skin integrity.

Introduction

Accurate heart rate (HR) assessment is a crucial component of newborn resuscitation algorithms. Electrocardiograms (ECG) provide rapid continuous monitoring of HR during resuscitation [1] and international guidelines suggest their use in the delivery room [1,2]. Ideally, ECG must be quickly sited by healthcare professionals (HCPs) and subsequent electrode detachment avoided. Conventional ECG electrodes require individual placement following skin drying and can take 26s to site [3]. Polyethene bags are used for thermal care in newborn preterm infants, adhering to the skin through surface tension but allowing removal from delicate skin without causing shearing damage. These benefits could save HCP time and aid stabilisation with more reliable monitoring. We aimed to evaluate the application time of pre-set ECG electrodes integrated onto a polyethene chest patch for newborn infants.

Materials and Methods

This is a sub-analysis of a prospective observational study group from a larger delivery room trial, HeartLight [3].

Study Population

The study was conducted in two tertiary maternity centres at Nottingham University Hospitals. Infants >22 weeks gestation were eligible for inclusion if the clinical team were offering active management at birth. Sample size was determined by the aims of the HeartLight protocol.

Study Design

Prior to birth, ECG electrodes (SKINTACT, Leonhard Lang, Innsbruck, Austria) were attached to a 7 cm by 7 cm square patch of low-density polyethene wrap normally used for preterm thermoregulation (Supplementary Material 1). Three holes (diameter 1cm) were made in the patch to allow electrode contact with the skin via ECG conduction gel placed onto the electrodes to avoid adhesive attachment to the skin. The electrodes were connected to a Carescape Monitor B450 (General Electric Healthcare, Chicago, US) outputting HR data every 5 seconds.

Following birth, the infant was brought to the resuscitaire. Infants ≥32 weeks were dried except the chest area for patch placement, infants <32 weeks were placed wet into a plastic bag. Their heads were dried and a cap placed (HeartLight trial). The ECG patch was then applied on the chest (Supplementary Video 1) and a pulse oximeter (Carescape B450) attached on the right hand/wrist. A webcam recorded the study along with LabVIEW 2014 (National Instruments, Texas, US) collected real-time data.

Outcome measures

Three time points were calculated: 1) time to apply the patch once picked up; 2) time to detect recognisable QRS complexes after placement (Supplementary Material 2); and 3) time after placement until the ECG HR value output. If a piece of equipment (for example a stethoscope on the chest) delayed the placing the pre-set electrodes this time was subtracted from the deployment time. Success rate, a measure of device reliability, is defined as the percentage of time during which the patch, once attached to the infant, reports a HR. Data are presented as median (range and/or IQR).

Results

Population

Seventy-one newborns were recruited to the study, four were excluded: video obscured (one), HeartLight protocol deviation (two), loss of HR output data (one). This left sixty-seven newborns included in the analysis (Table 1).

Outcomes

The median times for ECG application was 8s (IQR 6-10s) (Figure 1) and a recognisable QRS to be displayed after application was 8s (IQR 2-12s), with all infants displaying a QRS signal by 46s. The median time for a HR value output from the monitor was 23s (IQR 15-37s). Within 1 minute of arrival on the resuscitaire, all infants had a recognisable QRS signal and 80% a HR value. There were no electrode detachments and HR output success rate was 95% (n=8907/8440 timepoints).

Fourteen (21%) newborns were <1500g had an application time of 11s (IQR 7-12s) and time to QRS signal of 4s (IQR 1-7s). Infants ≥1500g had an application time of 8s (IQR 6-9s) and time to QRS signal of 9s (IQR 3-14s). There were no issues removing the patch or any areas of skin damage.

Discussion

Utilising the natural surface tension properties of wet newborn skin, we found a simple, biocompatible low-density polyethene patch allowed quick and easy electrode attachment across a range of infants at birth without any detachments, providing rapid HR information. International guidance suggest the use of continuous ECG monitoring. Despite the many advantages ECG continuous monitoring provides, the attachment of each electrode can be time consuming, often requiring a dedicated individual to apply them, and they can easily detach especially with wet or vernix covered skin.

Application time of ECG electrodes at birth has previously been studied with ranges between 17.1s and 114s [2, 5-6]. This wide range may be accounted for by differing start times, for example time of birth rather than being placed on the resuscitaire or handling the electrodes, and the number of HCPs involved in the resuscitation. Application time in this study was 8s with a narrow range following placement by a single HCP. Previously, a similar approach placed a patch on the back using adhesive tape [7]. Following initial evaluation of back placement, we opted to use the chest to allow repositioning if needed and avoid any damage to fragile skin from adhesive. If incorrectly placed or with poor signal quality, back placement would be more difficult to readjust without disrupting resuscitation efforts. Our success rate was a HR output for 95% of the timepoints during the study without any electrode displacements demonstrating the excellent attachment technique.

Following application, the initial QRS signal was obtained in a median of 8s and by 46s for all 67 infants. There was more variability and delay with the displayed HR which is dependent on the type of monitor and algorithms used to analyse the signal. As such we did not have access to the raw data and so were unable to interrogate delays further. Katheria *et al.* reported in two studies obtaining a visible or audible ECG signal within 2s (1-4s) of application [3] and within 66s (± 20s) from being placed on the resuscitation bed [8], although in the later study the ECG signal quality could only be used for 40 of the 86 infants. Iglesias *et al.* reported an ECG HR at 26s after application [6] and Gulati *et al* reported HR values at 29s but with a 30% failure rate at 1 minute from time of arrival onto the resuscitation bed [7]. Our HR output failure rate was 20% at 1 minute but all infants had a QRS signal by 46s. Median time to QRS signal was 8s and as such, it may be more helpful to HCPs to be able to see the ECG trace on the monitor rather than just a displayed number obtained by the algorithm.

Previous delays in ECG HR display have been attributed to not drying the skin well enough and thick vernix preventing ECG sensor attachment [9]. Iglesias *et al* reported no data in the first 30 seconds after birth [6] and Gulati *et al* found that infants vigorous at birth took longer to pick up a signal because of movement artefacts [7]. In our study, it was quicker to deploy the patch in larger infants, possibly because they were not placed in a polyethene bag, but the time to QRS and HR acquisition was slightly longer than smaller infants. The amount of conductive gel may have varied which could contribute to differences in data acquisition. The placement of the leads was not modified for different infant sizes as we wanted to see if a single product could be used no matter what the size of the baby.

Limitations of the present study were the low number of vaginal births and no infants required chest compressions. It is not possible to establish if there are any potential differences between caesarean or vaginal deliveries as a larger number of infants would be required. It is unlikely the patch would interfere with chest compressions as plastic wraps are used for most preterm infants without reported problems although there could be signal interference with or without the patch. Ideally, comparison with standard electrode placement would be undertaken for comparison but this was not the focus of the main study and should form part of a future study.

Conclusion

Using a pre-set ECG electrode chest patch enables quick, continuous monitoring and avoids single electrode detachment or potential skin stripping injuries from adhesives. The patch allows rapid HR signal acquisition and reliable output reporting with no electrode detachements. This approach warrants further development and evaluation to understand if these benefits result in improved monitoring and stabilisation outcomes.

Statements

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Ethics

Approved by NHS Health Research Authority 15/YH/0522, HeartLight study Clinicaltrials.gov NCT02701920, 3/3/2016.

Consent to participate/publish

Informed parental consent obtained prior to infant enrollement.

Conflict of Interest Statement

SM and JCr (shareholders), JCa (shareholder and CEO), BHG and DS (shareholders and non-executive directors) of SurePulse Medical Ltd who are developing newborn vital sign devices.

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Author Contributions

CH: designed protocol, acquired, analysed and interpreted data, drafted manuscript. LS: protocol design, acquired data. SM, JCr, JCa and BHG: protocol development, data analysis. DS: designed protocol, interpreted data. All authors revised and approved the final manuscript.

Data Availability Statement

Available upon reasonable request by contacting the corresponding author.

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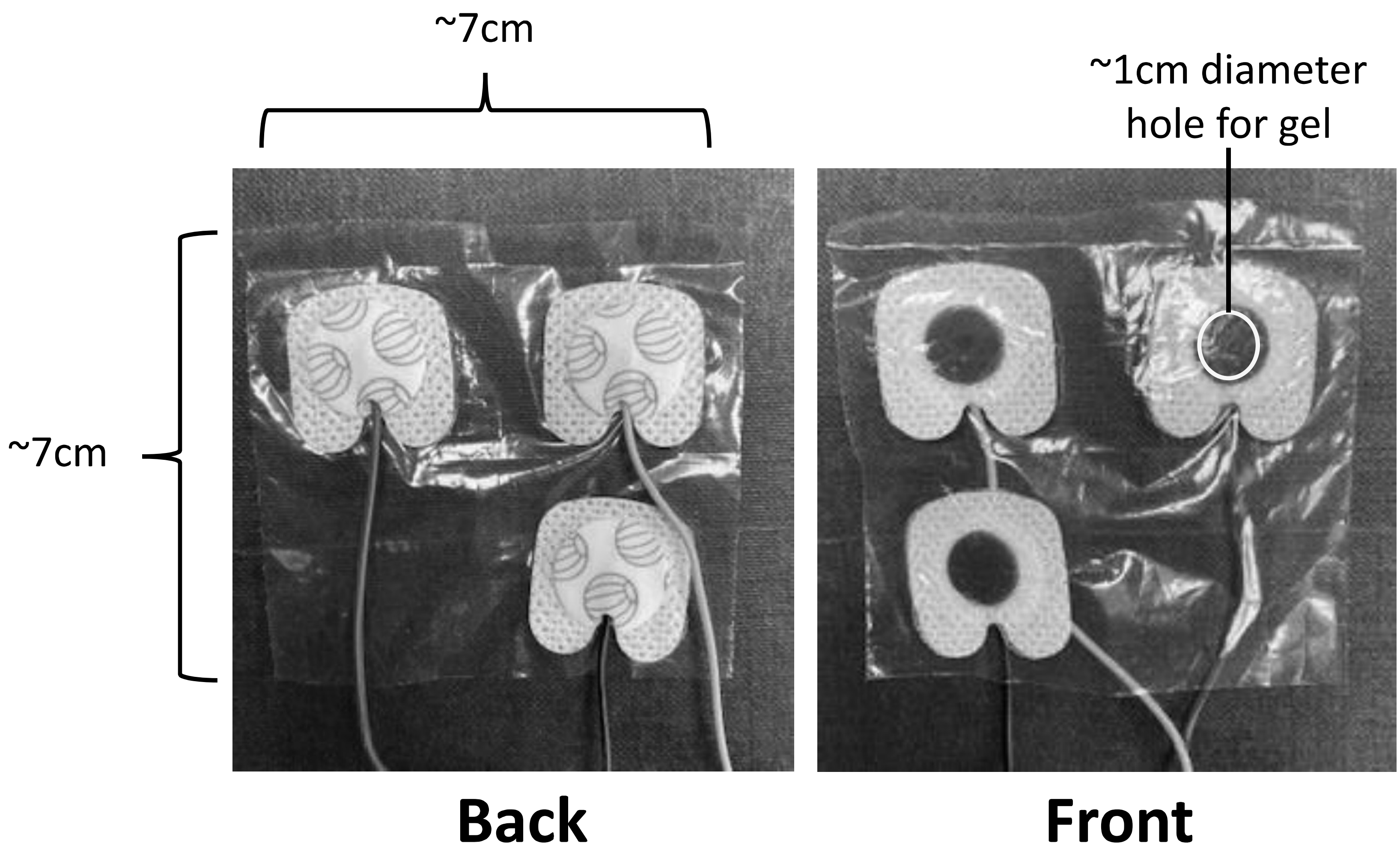
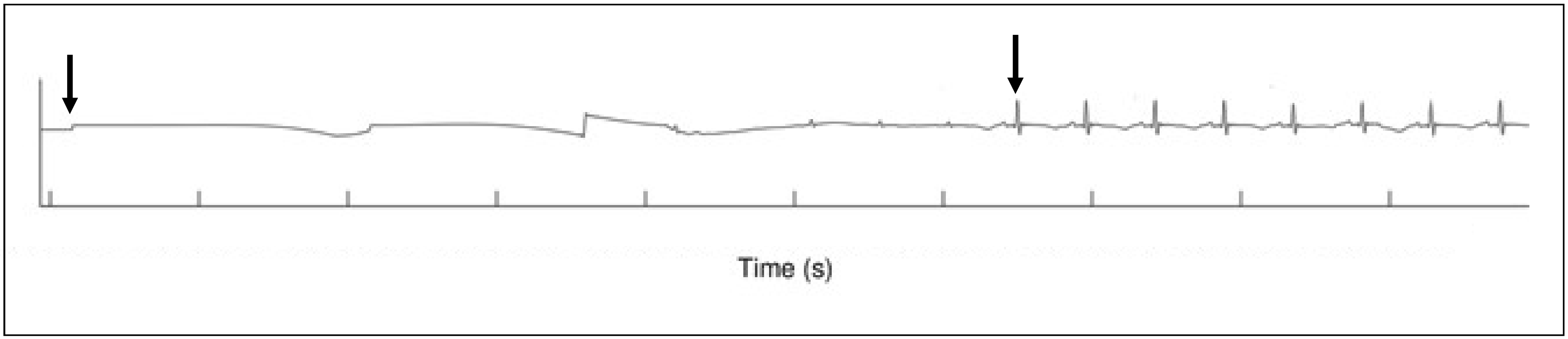
Figure Legends

Table 1. Characteristics of newborns included. Data are median (range) unless stated otherwise. Resuscitation refers to the need for at least positive pressure mask ventilation

Fig. 1. Violin plot of time taken to apply the ECG patch, obtain a QRS signal and output a heart rate (HR) on the Carescape B450 monitor in all 67 infants. Dashed line is the median value and dotted lines the IQR



Supplementary Material 1 Electrocardiogram (ECG) polyethene patch showing the back and front views



Supplementary Material 2: Electrocardiogram (ECG) trace showing application of patch (1st arrow) and when a recognisable QRS complex is first seen (2nd arrow) in seconds (s)

TABLES

Gestational group	<32 weeks (n=9)	32-36 weeks (n=38)	≥37 weeks (n=20)	All infants (n=67)
Gestation in weeks	28^{+5} (25^{+0}-31^{+2})	35^{+1} (32^{+2}-36^{+0})	39^{+0} (37^{+3}-42^{+0})	35^{+5} (25^{+0}-42^{+0})
Male (%)	6 (66)	15 (40)	7 (35)	28 (42)
Birthweight (kg)	1.16 (0.80-1.69)	2.25 (1.01-4.10)	3.38 (2.04-4.47)	2.44 (0.8-4.47)
Caesarean section (%)	8 (88)	29 (76)	20 (100)	57 (85)
Resuscitation needed (%)	7 (78)	14 (37)	2 (10)	23 (34)

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Resuscitation refers to the need for at least positive pressure mask ventilation.